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## VOLUME 3

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## 10.0 References

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Pages 5 through 79 have been removed.

# APPENDIX 1

# Endeavor I 48 Month Report

# THE CLINICAL EVALUATION OF THE MEDTRONIC AVE* ABT-578 COATED DRIVER CORONARY STENT§ IN *DE NOVO* NATIVE CORONARY ARTERY LESIONS

## The ENDEAVOR I Study
## Clinical Study Report (Index Procedure through 1,440 Days)

| | |
|---|---|
| Sponsor: | Medtronic Vascular, Inc.<br>Santa Rosa, CA |
| Principal Investigator: | A/Prof. Ian Meredith<br>Melbourne, Australia |
| Data Coordinating Center: | HCRI (Harvard Clinical Research Institute)<br>Boston, MA |
| QCA Core Laboratory: | Brigham and Women's Angiographic Core Laboratory<br>Boston, MA |
| ECG Core Laboratory: | ECG and Arrhythmia Core Laboratory<br>HCRI (Harvard Clinical Research Institute)<br>Boston, MA |
| IVUS Core Laboratory: | Stanford University Cardiovascular Core Analysis Lab<br>Stanford, CA |
| Report Prepared By: | HCRI (Harvard Clinical Research Institute)<br>Boston, MA |
| Date: | June 7, 2007 |
| Version: | 1.0 FINAL |

This report has undergone a quality control process at HCRI.

*Medtronic AVE is now Medtronic Vascular, Inc.
§Endeavor Zotarolimus-Eluting Coronary Stent System

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## Section I: Structured Abstract

**Title**: The Clinical Evaluation of the Medtronic AVE ABT-578 Coated Driver Coronary Stent in *De Novo* Native Coronary Artery Lesions.

**Clinical Sites:** Eight (8) study sites in Australia and New Zealand participated in this study.

**Purpose:** To demonstrate the safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System for the treatment of single *de novo* lesions in native coronary arteries.

**Design:** This was a prospective, multi-centre, non-randomized, single-arm study that enrolled 100 subjects with symptomatic ischaemic heart disease attributable to native coronary artery stenoses that were amenable to treatment by percutaneous stenting. Study subjects with multiple vessel disease were allowed but only a single lesion per subject could be treated in this trial. The target lesion was required to be *de novo*, non-restenotic and in a native coronary artery. The patient was not to have undergone any coronary interventional treatment (including PTCA) to any coronary vessel within the 30 days prior to enrollment into this study. Additionally, no planned or "staged" coronary intervention could be performed on an enrolled patient until 30 days post-index procedure. An emergent intervention of any kind was allowed at any time.

**Enrollment:** 100 subjects with symptomatic ischaemic heart disease due to stenotic lesions of native coronary arteries with reference vessel diameters between 3.0 mm and 3.5 mm that were amenable to percutaneous treatment with stenting were enrolled in this study.

**Methods:** Baseline clinical and angiographic data were collected on standardized case report forms by clinical study personnel at the study sites. An independent Angiographic Core Laboratory and an independent IVUS Core Laboratory analyzed all baseline and follow-up angiograms and IVUS images. Angiographic Films were qualified at follow-up based on the qualification scheme in Appendix A. Specifically, the lower and upper windows for qualifying QCA for 4-month follow-up were 90 and 180 days, respectively; for 12-month follow-up they were 270 days and 480 days, respectively. Clinical follow-up for all subjects was performed at 30 days (telephone contact), 4 months (angiographic and IVUS measurements), 9 months (telephone contact), 12 months (angiographic and IVUS measurements), and at 2, 3 and 4 years (telephone contact) and will have a telephone contact at 5 years from the date of procedure.

The primary safety endpoint of this study was Major Adverse Cardiac Events (MACE) at 30 days. MACE was defined as the incidence of the combined clinical endpoints: death, myocardial infarction, emergent cardiac surgery, or clinically-driven repeat target lesion revascularization as determined by the Clinical Events Committee (CEC). The primary efficacy endpoint was the angiographic late lumen loss at 4 months, defined as the difference between the post-index procedure minimal lumen diameter (MLD) and the 4-month follow-up angiography MLD. The secondary endpoints for this study were: 1) Target vessel failure (TVF) defined as a composite of cardiac death, MI (Q wave and non-Q wave), or target vessel revascularization at 9 months; 2) Target lesion revascularization (TLR) rate, defined as the incidence of clinically driven repeat revascularization of the target lesion at 9 months; 3) Late lumen loss at 12 months as measured by angiographic data; and 4) Neointimal hyperplastic volume at 4 and 12 months as measured by

IVUS. The patient baseline demographics and clinical characteristics for this study and the potentially relevant predisposing disease factors analyzed were as follows: 1) age, 2) gender, 3) smoking history, 4) diabetes mellitus, 5) hypertension, 6) hyperlipidemia, 7) prior coronary artery bypass graft surgery (CABG), 8) prior myocardial infarction, 9) Canadian Cardiovascular Society (CCS) Angina class III or IV, 10) number of diseased, native, major epicardial coronary arteries, 11) ejection fraction. An independent Clinical Events Committee adjudicated all major clinical endpoints. All endpoints were analyzed on intent-to-treat and per-protocol bases. The intent-to-treat subset is the primary analytical subset. The per-protocol analytical subset is the secondary analytical subset. Patients [redacted] and [redacted] had evidence of a pre-procedure acute myocardial infarction within 72 hours of the intended treatment and were therefore excluded from the per-protocol analysis.[1]

**Results:** The principal effectiveness and safety results for the Endeavor Zotarolimus-Eluting Coronary Stent System are presented in Table 1a. The primary safety endpoint of the trial, incidence of major adverse cardiac events (MACE) at 30 days, was 1% (1/100). In-hospital incidence of MACE was 0%. At both 270 and 360 days, the incidence of MACE was 2% (2/100 and 2/99, respectively). At 720 days post-procedure, the incidence of MACE was 3.0% (3/99). The cumulative incidence of MACE at Day 1080 was 6.1% (6/98) and 7.2% (7/97) at 1440 days. The Kaplan-Meier estimate of freedom from MACE at 1440 days was 92.9%. The cumulative incidence of TVF at 1440 days was 5.2% (5/97). The Kaplan-Meier estimate of freedom from TVF at 1440 days was 94.9%. The Kaplan-Meier estimates are based on the full enrollment of 100 patients. Patients with follow-up less than 48 months are censored at time of dropout (and at time of death for all non-death endpoints).

The primary efficacy endpoint of the trial was late loss at 4 months. Of the one hundred (100) patients, ninety-eight returned for protocol specified angiography at 4 months and had qualified films for the 4-month analysis. Late lumen loss as measured in-segment (defined as the difference between the in-segment MLD at the post-index procedure and the in-segment MLD at follow up) was 0.22 ± 0.43 mm (98) and late lumen loss as measured in-stent (defined as the difference between the in-stent MLD at the post-index procedure and the in-stent MLD at follow-up) was 0.32 ± 0.37 mm (98). Of the ninety-eight (98) patients with qualified angiographic films, 3.1% (3/98) had binary angiographic restenosis (defined as ≥50% diameter stenosis by quantitative angiographic analysis).

Ninety-two patients returned for protocol specified angiography at 12 months and had qualified films for the 12-month analysis. Of the ninety-two qualified patients, 5.4% (5/92) had binary angiographic restenosis (defined as ≥50% diameter stenosis by quantitative angiographic analysis). Late lumen loss as measured in-segment was 0.43 ± 0.44 mm (92) and late lumen loss as measured in-stent was 0.58 ± 0.44 mm (92).

Eight (8/100, 8%) patients had at least two Endeavor stents implanted during the index procedure. Five patients (5/100, 5%) experienced a post-index procedure dissection. Of these five patients, one ([redacted] had two stents implanted.

[1] The pre-procedural CK and CK-MB laboratory results were not available until after the patients were enrolled into the trial. Patient [redacted] was enrolled on the basis of negative pre-procedural Troponin.

**Conclusions:** The acute clinical results demonstrate 100.0% (100/100) lesion, device, procedure and device-specific procedure success rates with MACE rates of 1.0% (1/100) at 30 days and 7.2% (7/97) at 48 months post-index procedure. The survival estimate free from the secondary endpoint TVF at 9 months post-index procedure was 98.0%. The survival estimate free from the endpoint of TVF at 48 months post-index procedure was 94.9%. The cumulative incidence of TVF at 48 months was 5.2% (5/97). The survival estimate free from TLR at 48 months post-index procedure was 96.9%, and the cumulative incidence of TLR at 48 months was 3.1% (3/97). Four-month angiographic late loss was $0.22 \pm 0.43$ in-segment and $0.32 \pm 0.37$ in-stent. Twelve-month angiographic late loss was $0.43 \pm 0.44$ in-segment and $0.58 \pm 0.44$ in-stent for the 92 evaluable patients.

## Table 1a. Principal Effectiveness and Safety Results (ITT)

| Effectiveness Measures | ENDEAVOR I (N=100 Patients) |
|---|---|
| Lesion Success | 100.0% (100/100) |
| Procedure Success | 100.0% (100/100) |
| Device Success | 100.0% (100/100) |
| Device-Specific Procedure Success | 100.0% (100/100) |
| Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.84±0.35 (100) |
| Range (min,max) | (2.12,3.67) |
| Post-Procedure In-Stent Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 5.37±7.51 (100) |
| Range (min,max) | (-17.28,25.48) |
| Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.52±0.42 (100) |
| Range (min,max) | (1.35,3.51) |
| Post-Procedure In-Segment Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 16.54±8.40 (100) |
| Range (min,max) | (3.79,42.25) |
| Four-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.52±0.44 (98) |
| Range (min,max) | (0.84,3.33) |
| Four-Month Follow-up In-Stent Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 14.40±13.10 (98) |
| Range (min,max) | (-8.84,78.73) |
| Four-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.29±0.46 (98) |
| Range (min,max) | (0.84,3.27) |
| Four-Month Follow-up In-Segment Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 22.36±12.08 (98) |
| Range (min,max) | (2.65,78.73) |
| Four-Month Late Loss In-Stent (mm) | |
| Mean±SD (n) | 0.32±0.37 (98) |
| Range (min,max) | (-0.63,2.41) |
| Four-Month Late Loss In-Segment (mm) | |
| Mean±SD (n) | 0.22±0.43 (98) |
| Range (min,max) | (-0.91,2.41) |
| Four-Month In-Stent Binary Restenosis | 2.0% (2/98) |
| Four-Month In-Segment Binary Restenosis | 3.1% (3/98) |
| Twelve-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.26±0.49 (92) |
| Range (min,max) | (0.73,3.33) |
| Twelve-Month Follow-up In-Stent Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 21.75±15.35 (92) |
| Range (min,max) | (-7.62,78.73) |
| Twelve-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.08±0.47 (92) |
| Range (min,max) | (0.73,3.21) |
| Twelve-Month Follow-up In-Segment Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 28.00±13.41 (92) |
| Range (min,max) | (6.80,78.73) |
| Twelve-Month Late Loss In-Stent (mm) | |
| Mean±SD (n) | 0.58±0.44 (92) |
| Range (min,max) | (-0.63,2.41) |
| Twelve-Month Late Loss In-Segment (mm) | |
| Mean±SD (n) | 0.43±0.44 (92) |
| Range (min,max) | (-0.64,2.41) |
| Twelve-Month In-Stent Binary Restenosis | 4.3% (4/92) |
| Twelve-Month In-Segment Binary Restenosis | 5.4% (5/92) |

N = The maximum number of eligible patients, n = The number of patients with evaluable data.
Denominators indicate the total number of patients with available data for related parameter.

## Table 1a. Principal Effectiveness and Safety Results (ITT) (Continued)

| Safety Measures (30 Days) | ENDEAVOR I (N=100 Patients) |
|---|---|
| In-Hospital MACE | 0.0% (0/100) |
| Out-of-Hospital MACE to 30 Days | 1.0% (1/100) |
| MACE to 30 Days | 1.0% (1/100) |
| Death | 0.0% (0/100) |
| Vascular Complications | 2.0% (2/100) |
| Early Stent Thrombosis | 1.0% (1/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Perforation | 0.0% (0/100) |
| Target Vessel Revascularization | 1.0% (1/100) |
| Target Lesion Revascularization | 1.0% (1/100) |
| Target Vessel Failure | 1.0% (1/100) |

| Safety Measures (270 Days) | ENDEAVOR I (N=100 Patients) |
|---|---|
| Out-of-Hospital MACE to 270 Days | 2.0% (2/100) |
| MACE to 270 Days | 2.0% (2/100) |
| Death | 0.0% (0/100) |
| Vascular Complications | 3.0% (3/100) |
| Early Stent Thrombosis | 1.0% (1/100) |
| Late Thrombosis | 0.0% (0/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Perforation | 0.0% (0/100) |
| Target Vessel Revascularization | 2.0% (2/100) |
| Target Lesion Revascularization | 2.0% (2/100) |
| Target Vessel Failure | 2.0% (2/100) |

| Safety Measures (360 Days) | ENDEAVOR I (N=100 Patients) |
|---|---|
| Out-of-Hospital MACE to 360 Days | 2.0% (2/99) |
| MACE to 360 Days | 2.0% (2/99) |
| Death | 0.0% (0/99) |
| Vascular Complications | 3.0% (3/99) |
| Early Stent Thrombosis | 1.0% (1/99) |
| Late Thrombosis | 0.0% (0/99) |
| Cerebrovascular Accident (CVA) | 0.0% (0/99) |
| Perforation | 0.0% (0/99) |
| Target Vessel Revascularization | 2.0% (2/99) |
| Target Lesion Revascularization | 2.0% (2/99) |
| Target Vessel Failure | 2.0% (2/99) |

## Table 1a. Principal Effectiveness and Safety Results (ITT) (Continued)

| Safety Measures (720 Days) | ENDEAVOR I (N=100 Patients) |
|---|---|
| Out-of-Hospital MACE to 720 Days | 3.0% (3/99) |
| MACE to 720 Days | 3.0% (3/99) |
| Death | 1.0% (1/99) |
| Vascular Complications | 3.0% (3/99) |
| Early Stent Thrombosis | 1.0% (1/99) |
| Late Thrombosis | 0.0% (0/99) |
| Cerebrovascular Accident (CVA) | 1.0% (1/99) |
| Perforation | 0.0% (0/99) |
| Target Vessel Revascularization | 4.0% (4/99) |
| Target Lesion Revascularization | 2.0% (2/99) |
| Target Vessel Failure | 4.0% (4/99) |

| Safety Measures (1080 Days) | ENDEAVOR I (N=100 Patients) |
|---|---|
| Out-of-Hospital MACE to 1080 Days | 6.1% (6/98) |
| MACE to 1080 Days | 6.1% (6/98) |
| Death | 3.1% (3/98) |
| Vascular Complications | 3.1% (3/98) |
| Early Stent Thrombosis | 1.0% (1/98) |
| Late Thrombosis | 0.0% (0/98) |
| Cerebrovascular Accident (CVA) | 1.0% (1/98) |
| Perforation | 0.0% (0/98) |
| Target Vessel Revascularization | 5.1% (5/98) |
| Target Lesion Revascularization | 3.1% (3/98) |
| Target Vessel Failure | 5.1% (5/98) |

| Safety Measures (1440 Days) | ENDEAVOR I (N=100 Patients) |
|---|---|
| Out-of-Hospital MACE to 1440 Days | 7.2% (7/97) |
| MACE to 1440 Days | 7.2% (7/97) |
| Death | 4.1% (4/97) |
| Vascular Complications | 3.1% (3/97) |
| Early Stent Thrombosis | 1.0% (1/97) |
| Late Thrombosis | 0.0% (0/97) |
| Cerebrovascular Accident (CVA) | 1.0% (1/97) |
| Perforation | 0.0% (0/97) |
| Target Vessel Revascularization | 5.2% (5/97) |
| Target Lesion Revascularization | 3.1% (3/97) |
| Target Vessel Failure | 5.2% (5/97) |

| Kaplan-Meier Estimate | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE-Free at 1440 days | 92.9% |
| TLR-Free at 1440 days | 96.9% |
| TVR-Free at 1440 days | 94.9% |
| TVF-Free at 1440 days | 94.9% |

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Denominators indicate the total number of patients with available data for related parameter.

## Table 1b. Principal Effectiveness and Safety Results (PP)

| Effectiveness Measures | ENDEAVOR I (N=98 Patients) |
|---|---|
| Lesion Success | 100.0% (98/98) |
| Procedure Success | 100.0% (98/98) |
| Device Success | 100.0% (98/98) |
| Device-Specific Procedure Success | 100.0% (98/98) |
| Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.84±0.35 (98) |
| Range (min,max) | (2.12,3.67) |
| Post-Procedure In-Stent Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 5.41±7.56 (98) |
| Range (min,max) | (-17.28,25.48) |
| Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.53±0.42 (98) |
| Range (min,max) | (1.35,3.51) |
| Post-Procedure In-Segment Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 16.37±8.23 (98) |
| Range (min,max) | (3.79,42.25) |
| Four-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.52±0.44 (96) |
| Range (min,max) | (0.84,3.33) |
| Four-Month Follow-up In-Stent Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 14.55±13.19 (96) |
| Range (min,max) | (-8.84,78.73) |
| Four-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.29±0.45 (96) |
| Range (min,max) | (0.84,3.27) |
| Four-Month Follow-up In-Segment Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 22.55±12.12 (96) |
| Range (min,max) | (2.65,78.73) |
| Four-Month Late Loss In-Stent (mm) | |
| Mean±SD (n) | 0.33±0.37 (96) |
| Range (min,max) | (-0.63,2.41) |
| Four-Month Late Loss In-Segment (mm) | |
| Mean±SD (n) | 0.24±0.41 (96) |
| Range (min,max) | (-0.47,2.41) |
| Four-Month In-Stent Binary Restenosis | 2.1% (2/96) |
| Four-Month In-Segment Binary Restenosis | 3.1% (3/96) |
| Twelve-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.25±0.49 (90) |
| Range (min,max) | (0.73,3.33) |
| Twelve-Month Follow-up In-Stent Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 22.09±15.26 (90) |
| Range (min,max) | (-7.62,78.73) |
| Twelve-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm) | |
| Mean±SD (n) | 2.08±0.46 (90) |
| Range (min,max) | (0.73,3.21) |
| Twelve-Month Follow-up In-Segment Percent Diameter Stenosis (% DS) | |
| Mean±SD (n) | 28.30±13.39 (90) |
| Range (min,max) | (6.80,78.73) |
| Twelve-Month Late Loss In-Stent (mm) | |
| Mean±SD (n) | 0.59±0.44 (90) |
| Range (min,max) | (-0.63,2.41) |
| Twelve-Month Late Loss In-Segment (mm) | |
| Mean±SD (n) | 0.45±0.43 (90) |
| Range (min,max) | (-0.49,2.41) |
| Twelve-Month In-Stent Binary Restenosis | 4.4% (4/90) |
| Twelve-Month In-Segment Binary Restenosis | 5.6% (5/90) |

N = The maximum number of eligible patients, n = The number of patients with evaluable data.
Denominators indicate the total number of patients with available data for related parameter.

## Table 1b. Principal Effectiveness and Safety Results (PP) (Continued)

| Safety Measures (30 Days) | ENDEAVOR I (N=98 Patients) |
|---|---|
| In-Hospital MACE | 0.0% (0/98) |
| Out-of-Hospital MACE to 30 Days | 1.0% (1/98) |
| MACE to 30 Days | 1.0% (1/98) |
| Death | 0.0% (0/98) |
| Vascular Complications | 2.0% (2/98) |
| Early Stent Thrombosis | 1.0% (1/98) |
| Cerebrovascular Accident (CVA) | 0.0% (0/98) |
| Perforation | 0.0% (0/98) |
| Target Vessel Revascularization | 1.0% (1/98) |
| Target Lesion Revascularization | 1.0% (1/98) |
| Target Vessel Failure | 1.0% (1/98) |

| Safety Measures (270 Days) | ENDEAVOR I (N=98 Patients) |
|---|---|
| Out-of-Hospital MACE to 270 Days | 2.0% (2/98) |
| MACE to 270 Days | 2.0% (2/98) |
| Death | 0.0% (0/98) |
| Vascular Complications | 3.1% (3/98) |
| Early Stent Thrombosis | 1.0% (1/98) |
| Late Thrombosis | 0.0% (0/98) |
| Cerebrovascular Accident (CVA) | 0.0% (0/98) |
| Perforation | 0.0% (0/98) |
| Target Vessel Revascularization | 2.0% (2/98) |
| Target Lesion Revascularization | 2.0% (2/98) |
| Target Vessel Failure | 2.0% (2/98) |

| Safety Measures (360 Days) | ENDEAVOR I (N=98 Patients) |
|---|---|
| Out-of-Hospital MACE to 360 Days | 2.1% (2/97) |
| MACE to 360 Days | 2.1% (2/97) |
| Death | 0.0% (0/97) |
| Vascular Complications | 3.1% (3/97) |
| Early Stent Thrombosis | 1.0% (1/97) |
| Late Thrombosis | 0.0% (0/97) |
| Cerebrovascular Accident (CVA) | 0.0% (0/97) |
| Perforation | 0.0% (0/97) |
| Target Vessel Revascularization | 2.1% (2/97) |
| Target Lesion Revascularization | 2.1% (2/97) |
| Target Vessel Failure | 2.1% (2/97) |

## Table 1b. Principal Effectiveness and Safety Results (PP) (Continued)

| Safety Measures (720 Days) | ENDEAVOR I (N=98 Patients) |
|---|---|
| Out-of-Hospital MACE to 720 Days | 3.1% (3/97) |
| MACE to 720 Days | 3.1% (3/97) |
| Death | 1.0% (1/97) |
| Vascular Complications | 3.1% (3/97) |
| Early Stent Thrombosis | 1.0% (1/97) |
| Late Thrombosis | 0.0% (0/97) |
| Cerebrovascular Accident (CVA) | 1.0% (1/97) |
| Perforation | 0.0% (0/97) |
| Target Vessel Revascularization | 4.1% (4/97) |
| Target Lesion Revascularization | 2.1% (2/97) |
| Target Vessel Failure | 4.1% (4/97) |

| Safety Measures (1080 Days) | ENDEAVOR I (N=98 Patients) |
|---|---|
| Out-of-Hospital MACE to 1080 Days | 6.3% (6/96) |
| MACE to 1080 Days | 6.3% (6/96) |
| Death | 3.1% (3/96) |
| Vascular Complications | 3.1% (3/96) |
| Early Stent Thrombosis | 1.0% (1/96) |
| Late Thrombosis | 0.0% (0/96) |
| Cerebrovascular Accident (CVA) | 1.0% (1/96) |
| Perforation | 0.0% (0/96) |
| Target Vessel Revascularization | 5.2% (5/96) |
| Target Lesion Revascularization | 3.1% (3/96) |
| Target Vessel Failure | 5.2% (5/96) |

| Safety Measures (1440 Days) | ENDEAVOR I (N=98 Patients) |
|---|---|
| Out-of-Hospital MACE to 1440 Days | 7.4% (7/95) |
| MACE to 1440 Days | 7.4% (7/95) |
| Death | 4.2% (4/95) |
| Vascular Complications | 3.2% (3/95) |
| Early Stent Thrombosis | 1.1% (1/95) |
| Late Thrombosis | 0.0% (0/95) |
| Cerebrovascular Accident (CVA) | 1.1% (1/95) |
| Perforation | 0.0% (0/95) |
| Target Vessel Revascularization | 5.3% (5/95) |
| Target Lesion Revascularization | 3.2% (3/95) |
| Target Vessel Failure | 5.3% (5/95) |

| Kaplan-Meier Estimate | ENDEAVOR I (N=98 Patients) |
|---|---|
| MACE-Free at 1440 days | 92.8% |
| TLR-Free at 1440 days | 96.9% |
| TVR-Free at 1440 days | 94.8% |
| TVF-Free at 1440 days | 94.8% |

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Denominators indicate the total number of patients with available data for related parameter.

## Section II. Detailed Summary

### A. Definitions

ABRUPT CLOSURE

*Abrupt Closure.* Defined as the occurrence of new (during the index procedure) severely reduced flow (TIMI grade 0-1) within the target vessel that persisted and required rescue by stenting or other treatment, or resulted in myocardial infarction or death. Abrupt closure requires proven association with a mechanical dissection of the treatment site or instrumented vessel, coronary thrombus, or severe spasm. Abrupt closure does not connote "no reflow" (due to microvascular flow limitation), in which the epicardial artery is patent but had reduced flow. Abrupt closure also does not connote transient closure with reduced flow in which the index treatment application does reverse the closure.

*Subabrupt Closure.* Defined as abrupt closure that occurred after the index procedure is completed (and the subject left the catheterization laboratory) and before the 14-day follow-up endpoint.

*Threatened Abrupt Closure.* Defined as a grade B dissection and ≥50% diameter stenosis or any dissection of grade C or higher.

ACUTE GAIN

Defined as the immediate dimensional change in minimal luminal diameter (in mm) that occurred after the final post dilatation as compared to the minimal luminal diameter at baseline and measured by quantitative coronary angiography from the average of 2 orthogonal views.

ACUTE SUCCESS[2]

*Device Success:* Attainment of <50% in-stent residual stenosis of the target lesion using only the assigned device.

*Lesion Success:* Attainment of <50% in-stent residual stenosis of the target lesion using any percutaneous method.

*Procedure Success:* Attainment of <50% in-stent residual stenosis of the target lesion and no in-hospital MACE.

*Device-Specific Procedure Success*[3]*:* Device success and no in-hospital MACE.

BLEEDING COMPLICATIONS

Defined as a procedure related hemorrhagic event that requires a transfusion or surgical repair. These may include a hematoma requiring treatment, retroperitoneal bleed.

[2] All analyses to determine acute success measures were conducted utilizing *in-stent* residual stenosis values. When in-stent % residual stenosis was not available, in-lesion % residual stenosis was used to complete the analysis.
[3] Device-Specific Procedure Success is utilized to account for procedural successes/failures that are related to the implanted device.

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION (CCS)

*Class I* Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.

*Class II* Slight limitation of ordinary activity. Angina upon walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the first hours after awakening. Angina if walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

*Class III* Marked limitations of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.

*Class IV* Inability to carry on any physical activity without discomfort. Angina syndrome may be present at rest.

*DE NOVO* LESION

Defined as a native coronary artery lesion not previously treated.

DEATH

Divided into 2 categories:

*Cardiac death* is defined as death due to any of the following:

1. Acute myocardial infarction.
2. Cardiac perforation/pericardial tamponade.
3. Arrhythmia or conduction abnormality.
4. Stroke within 30 days of the procedure or stroke suspected of being related to the procedure.
5. Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery.
6. Any death in which a cardiac cause cannot be excluded.

*Non-cardiac death* is defined as a death not due to cardiac causes (as defined above).

DEVICE SUCCESS

Attainment of <50% residual stenosis of the target lesion using only the assigned device.

DEVICE RELATED ADVERSE EVENT

Any adverse event for which a causal relationship between the device and the event is at least a reasonable possibility.

DISSECTION, NHLBI (National Heart, Lung, and Blood Institute) CLASSIFICATION

*Type A* Small radiolucent area within the lumen of the vessel disappearing with the passage of the contrast material.

*Type B* Appearance of contrast medium parallel to the lumen of the vessel disappearing within a few cardiac cycles.

*Type C* Dissection protruding outside the lumen of the vessel persisting after passage of the contrast material.

*Type D* Spiral shaped filling defect with or without delayed run-off of the contrast material in the antegrade flow.

*Type E* Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen.

*Type F* Filling defect accompanied by total coronary occlusion.

DISTAL EMBOLIZATION

Defined as a new abrupt cut off or filling defect distal to the treated lesion.

EMERGENT BYPASS SURGERY

Defined as coronary bypass surgery performed on an urgent or emergent basis for severe vessel dissection or closure, or treatment failure resulting in new ischemia.

IN-LESION MEASUREMENT

Defined as the measurements either within the stented segment or within 5 mm proximal or distal to the stent edges.

IN-STENT MEASUREMENT

Defined as the measurements within the stented segment.

LESION CLASS (American College of Cardiology/American Heart Association Class)

*Type A Lesions:* Minimally complex, discrete (length <10 mm), concentric, readily accessible, non angulated segment (<45°), smooth contour, little or no calcification, less than totally occlusive, not ostial in location, no major side branch involvement, and an absence of thrombus.

*Type B Lesions:* Moderately complex, tubular (length 10 to 20 mm), eccentric, moderate tortuosity of proximal segment, moderately angulated segment (>45°, <90°), irregular contour, moderate or heavy calcification, total occlusions <3 months old, ostial in location, bifurcation lesions requiring double guidewires, and some thrombus present.

*Type C Lesions:* Severely complex, diffuse (length >2 cm), excessive tortuosity of proximal segment, extremely angulated segments >90°, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

LESION SUCCESS

Attainment of <50% residual stenosis of the target lesion using any percutaneous method.

MAJOR ADVERSE CARDIAC EVENTS (MACE)

Defined as death, MI[4] (Q wave and non-Q wave), emergent bypass surgery, or target lesion revascularization (repeat PTCA or CABG).

[4] Myocardial infarction that has been adjudicated by the Clinical Events Committee as being clearly related to a non-target vessel will not be considered a MACE.

MINIMAL LUMINAL DIAMETER (MLD)

Defined as the mean minimum lumen diameter derived from two orthogonal views (by the quantitative coronary angiography laboratory).

MYOCARDIAL INFARCTION

A positive diagnosis of myocardial infarction is made when one of the following criteria is met:

1. Q wave MI: (QMI) will require one of the following criteria:
   1.1. Chest pain or other acute symptoms consistent with myocardial ischemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data.
   1.2. New pathologic Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data the CEC may adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data.
2. Non-Q Wave MI (NQWMI): for this trial NQWMI will be defined as elevated CK $\geq$2X the upper laboratory normal with the presence of elevated CK-MB (any amount above the institution's upper limit of normal) in the absence of new pathological Q waves.

NO REFLOW

Defined as a sustained or transient reduction in antegrade flow that is not associated with an obstructive lesion at the treatment site.

PERFORATION

Perforations will be classified as follows:

*Angiographic perforation:* perforation detected by the clinical site or the core laboratory at any point during the procedure.

*Clinical perforation:* perforation requiring additional treatment (including efforts to seal the perforation or pericardial drainage), or resulting in significant pericardial effusion, abrupt closure, myocardial infarction, or death.

*Pericardial haemorrhage/tamponade*: perforation resulting in cardiac tamponade.

PROCEDURE SUCCESS

Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.

RECURRENT MI

Any myocardial infarction that occurs after the index procedure.

RESTENOTIC LESION

Defined as a lesion in a vessel segment that has undergone prior percutaneous treatment without a stent placement.

REFERENCE VESSEL DIAMETER (RVD)

Defined as the average of normal segments within 10 mm proximal and distal to the target lesion from 2 orthogonal views using QCA.

STENT THROMBOSIS

Defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischemia (chest pain and ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency. Late Stent Thrombosis is reported according to the following criteria[5]:

*Definite Late Stent Thrombosis*. Myocardial Infarction >30 days after index and attributable to the target vessel, angiographic documentation (site reported or by QCA) of thrombus or total occlusion at the target site, and freedom from interim revascularization of the target vessel.

*Possible Late Stent Thrombosis*. Myocardial Infarction >30 days after index and attributable to the target vessel, no identifiable culprit lesion elsewhere, freedom from interim revascularization of the target lesion, and freedom from interim bypass grafting of the target vessel.

STUDY DEVIATION

An incident where the investigator or site personnel did not conduct the study according to the investigational plan, protocol or the investigator agreement.

*Major deviation:* Any deviation from subject inclusion and exclusion criteria or subject informed consent procedures.

*Minor deviation:* Deviation from a protocol requirement such as incomplete/inadequate subject testing procedures, non-compliance with medication regimens, follow-ups performed outside specified time windows, etc.

STROKE

Defined as sudden onset of vertigo, numbness, dysphasia, weakness, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain such as haemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists >24 hours.

TARGET LESION REVASCULARIZATION (TLR)

Defined as any clinically-driven repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel.

Clinically-driven revascularizations are those in which the subject has a positive functional study, ischemic ECG changes at rest in a distribution consistent with the target vessel, or ischemic symptoms. Revascularization of a target lesion with an in-lesion diameter stenosis ≥70% (by QCA) in the absence of the above-mentioned ischemic signs or symptoms is also

[5] Medtronic utilizes stent thrombosis definitions that are consistent with the Harvard Clinical Research Institute Clinical Events Committee's standard definitions.

considered clinically-driven. In the absence of QCA data for relevant follow-up angiograms, the clinical need for revascularization is adjudicated using the presence or absence of ischemic signs and symptoms.

Non-clinically driven repeat target lesion revascularizations are those in which the subject undergoes a non-emergent revascularization for a diameter stenosis <50% (by QCA). Non-emergent repeat target lesion revascularization for a diameter stenosis <70% (by QCA) in subjects without either a positive functional study or angina are also considered non-clinically driven.

TARGET VESSEL FAILURE (TVF)

Defined as target vessel revascularization (defined below), recurrent Q or Non Q-Wave myocardial infarction, or cardiac death that could not be clearly attributed to a vessel other than the target vessel.

Target vessel failure is a more conservative and broader category and includes any target vessel revascularization as well as any recurrent MI or any cardiac death that cannot be clearly attributed to a non-target vessel. Target vessel failure, thus, includes any revascularization or adverse endpoint due to renarrowing of any portion of the target vessel, and assumes that the entire vessel is vulnerable to late failures because of guide catheter or guide wire trauma or progression of disease remote from the treatment site.

Target vessel failure will be reported when:

1. Recurrent MI occurs in territory not clearly other than that of the target vessel.
2. Cardiac death not clearly due to a non-target vessel endpoint.
3. Target vessel revascularization is determined.

TARGET VESSEL REVASCULARIZATION (TVR)

Defined as any clinically driven (as defined for TLR) repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel.

TIMI CLASSIFICATION

*TIMI 0* No perfusion.

*TIMI 1* Penetration with minimal perfusion. Contrast fails to opacify the entire bed distal to the stenosis for the duration of the cine run.

*TIMI 2* Partial perfusion. Contrast opacifies the entire coronary bed distal to the stenosis. However, the rate of entry and/or clearance is slower in the coronary bed distal to the obstruction than in comparable areas not perfused by the dilated vessel.

*TIMI 3* Complete perfusion. Filling and clearance of contrast equally rapid in the coronary bed distal to stenosis as in other coronary beds.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

Defined as any serious adverse effect on health or safety or any life-threatening problem or death that is caused by or associated with an investigational device. The effect must have not been previously identified in nature, severity or degree of incidence in the investigational plan. Other serious problems associated with the device that affect the rights or welfare of study subjects may also be considered UADEs.

VASCULAR COMPLICATIONS

Vascular complications may include the following:

1. Pseudoaneurysm
2. Arteriovenous fistula
3. Peripheral ischemia/nerve injury
4. Vascular event requiring transfusion or surgical repair

## B. Study Design

This was a prospective, multi-centre, non-randomized, single-arm study that enrolled 100 subjects with symptomatic ischaemic heart disease attributable to native coronary artery stenoses that were amenable to treatment by percutaneous stenting.

Study subjects may have had multiple vessel disease but only a single lesion per subject was treated in this trial. The target lesion must have been *de novo*, non-restenotic and in a native coronary artery. Clinical follow-up for all subjects was performed at 30 days (telephone contact), 4 months (angiographic and IVUS measurements), 9 months (telephone contact), 12 months (angiographic and IVUS measurements), and at 2 and 3 years (telephone contact). In addition, subjects will have a yearly telephone contact up to 5 years from the date of procedure. Angiographic and IVUS measurements were also collected at 12 months post-index procedure.

### Selection of Subjects

This trial included 100 subjects with *de novo* native coronary artery lesions who agreed to participate in the study.

### Subject Selection Criteria

Ninety-seven subjects for this study met all of the following Inclusion/Exclusion criteria. Two subjects didn't meet the fifth exclusion criterion (evidence of an acute myocardial infarction within 72 hours of the intended treatment) because the laboratory data came in late. In these two cases, the site used the Troponin level to enroll the patients. One female subject of childbearing potential had a positive pregnancy test.

**Inclusion Criteria:** Candidates were included in the study only if all the following conditions were met except as described above:

1. The subject was ≥18 years of age.
2. The subject was an acceptable candidate for PTCA, stenting, and emergent CABG surgery.
3. The subject had clinical evidence of ischaemic heart disease or a positive functional study.
4. The target lesion / vessel met the following criteria:
   a) The target lesion was a single *de novo* lesion that was not previously treated with any interventional procedure. Only one lesion was treated per subject.
   b) The target vessel was a native coronary artery with a stenosis of ≥50% and <100%.
   c) The target lesion was ≤15 mm in length.
   d) The target vessel reference diameter was ≥3.0 mm and ≤3.5 mm. (Measurements were made by careful visual estimate, on-line quantitative coronary angiography, or intravascular ultrasound.)
5. Female subjects of childbearing potential had a negative pregnancy test within seven (7) days before the procedure.
6. The subject or the subject's legal representative was informed of the nature of the study and agreed to its provisions and provided written informed consent as approved by the Human Research Ethics Committee of the respective clinical site.
7. The subject and the treating physician agreed that the subject would return for all

required post-index procedure follow-up visits.

**Exclusion Criteria:** Candidates were excluded from the study if any of the following conditions were present:

1. A documented left ventricular ejection fraction <30%.
2. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine, clopidogrel, cobalt, nickel, chromium, molybdenum, or a sensitivity to contrast media, which could not be adequately pre-medicated.
3. History of an allergic reaction or significant sensitivity to drugs similar to ABT-578 (rapamycin or analogue).
4. A platelet count <100,000 cells/mm³ or >700,000 cells/mm³, or a WBC <3,000 cells/mm³.
5. Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes ≥2X the upper laboratory normal with the presence of a CK-MB elevated above the Institution's upper limit of normal).
6. Creatinine >170 micromol/L.
7. A previous coronary interventional procedure of any kind within the 30 days prior to the procedure.
8. The subject required planned interventional treatment of either the target or any non-target vessel within 30 days post-index procedure.
9. The target lesion required treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc.).
10. Previous stenting anywhere in the target vessel.
11. The target vessel had evidence of thrombus or was excessively tortuous (2 bends >90° to reach the target lesion).
12. The target lesion had any of the following characteristics:
    a) Lesion location was aorto-ostial, an unprotected left main lesion, or within 5 mm of the origin of the LAD, LCX, or RCA.
    b) Involved a side branch >2.0 mm in diameter.
    c) Was at or distal to a 45º bend in the vessel.
    d) Was moderately to severely calcified.
13. Unprotected left main coronary artery disease (an obstruction greater than 50% in the left main coronary artery).
14. History of a stroke or transient ischaemic attack within the prior 6 months.
15. Active peptic ulcer or upper GI bleeding within the prior 6 months.
16. The subject had a history of bleeding diathesis or coagulopathy or would refuse blood transfusions.
17. Concurrent medical condition with a life expectancy of less than 12 months.
18. Any previous or planned treatment with anti-restenotic therapies including, but not limited to, drug-eluting stents and brachytherapy.
19. Currently participating in any investigational drug or another device study, per NHMRC guideline.

**Subject Screening**

All subjects admitted for potential percutaneous revascularization of the native coronary arteries were screened for study eligibility. A member of the Institution's research team assigned to the Medtronic Vascular Driver Drug Eluting Stent Trial reviewed the subject's medical history to screen for study eligibility. A screening log was provided to study sites to maintain a cumulative log of all the screened subjects. This screening log was completed and faxed to Medtronic Vascular and HCRI on a weekly basis.

**Informed Consent**

All potential subjects consented prior to the index procedure. Once the Investigator had determined the subject's eligibility for the study, the background of the proposed study and the benefits and risks of the procedures and study were explained to the subject. The subject (or the subject's legal representative) signed the institution's Human Research Ethics Committee (HREC) approved informed consent prior to participation. Failure to provide informed consent rendered the subject ineligible for the study.

**Enrollment**

All subjects who met eligibility requirements were asked to participate. Subjects were considered enrolled into the study after it had been determined that the subject and the target lesion met all of the inclusion and exclusion criteria, signed informed consent had been obtained, and the study device was introduced into the guide catheter. Once enrolled, the inclusion/exclusion criteria sheet was faxed to HCRI and Medtronic Vascular within 24 hours of treatment for confirmation.

**Subject Withdrawal**

Following the introduction into the guide catheter of the intended device, all subjects were required to complete clinical, IVUS, and angiographic follow-up. Subjects were exempt from follow-up only if they withdraw their consent. A study subject that had been withdrawn from the study was not replaced.

## Schedule of Treatments and Assessments

| Index Hospitalization | | | | Follow-up | | | |
|---|---|---|---|---|---|---|---|
| Event | Screen | Procedure | Post-index procedure | 30 Day | 4 Month | 9 Month | 12 months – 5 years |
| Type of Contact | | | | Telephone | Angiography IVUS | Telephone | 12 months – Angiography IVUS 2 years- 5 years - Telephone |
| Informed Consent Signed | X | | | | | | |
| Inclusion/Exclusion Criteria | X | | | | | | |
| Medical and Cardiac History | X | | | | | | |
| Angina Status | X | | X | X | X | X | X |
| Pregnancy test | X [1,3] | | | | | | |
| Liver Function test | X[3] | | | | | | |
| CBC with differential[2], platelet count & serum urea, creatinine, electrolytes | X [3] | | X [4, 8] | | | | |
| 12-Lead Electrocardiogram | X [3] | | X [4] | | | | |
| CK & CK-MB | X [5] | | X [6] | | | | |
| ACT Measurements | | X | | | | | |
| Medication Regimen[7] | X | X | X | X | | | |
| Adverse Event Monitoring | | | X | X | X | X | X |
| Angiography (QCA) | X | X | | | X | | X |
| IVUS | | X | | | X | | X |

1. For women of childbearing potential only.
2. If WBC was within normal limits, a differential was not required.
3. Within 7 days prior to procedure.
4. Within 24 hours post-index procedure or at discharge, which ever came first.
5. Within 72 hours prior to procedure.
6. Within 6-8, 12-16, and 18-24 hour post-index procedure or prior to hospital discharge, which ever came first.
7. It was expected that clopidogrel be used, unless the patient was allergic or sensitive to this medication. For patients unable to take clopidogrel, or at the discretion of the physician, ticlopidine was used.
8. CBC with differential was not drawn post-index procedure.

## C. Objectives

### Primary Objective

The primary objective of this study was to evaluate the safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System in *de novo* lesions of native coronary arteries.

The primary safety endpoint was:

- Major adverse cardiac events (MACE) defined as death, MI (Q wave and non-Q wave), emergent bypass surgery, or target lesion revascularization (repeat PTCA or CABG) at 30 days.

The primary efficacy endpoint was:

- Late loss at 4 months as measured by QCA, defined as the difference between the post-index procedure minimal lumen diameter (MLD) and the follow-up angiography MLD.

### Secondary Objectives

The secondary objectives of this trial were to assess the medium and long-term safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System using the following clinical, IVUS and angiographic endpoints:

- Target vessel failure (TVF) at 9 months
- Clinically-driven target lesion revascularization (TLR) at 9 months
- Late loss at 12 months as measured by QCA
- Neointimal hyperplastic volume immediately post stent implantation, at 4 and 12 months as measured by IVUS

Additionally, assessment by IVUS of the cross sectional area, and three dimensional volume, of the external elastic membrane, lumen, plaque, media and stent immediately post-stent implantation and at 4 and 12 months was performed. These measurements were performed within the stent and at the proximal and distal margins (5 mm) of the stent. Other IVUS data such as qualitative patterns of late loss and malapposition were reported. Assessment for complications such as vessel aneurysm formation and in-stent thrombosis was also performed at 4- and 12-month IVUS follow-up.

In-stent and in-segment analyses were performed by QCA and IVUS. Such analyses included, but were not limited to, the angiographic and IVUS trial endpoints and the additional IVUS assessments as outlined above.

- "In-stent" was defined as the segment of vessel covered by the stent.
- "In-segment" was defined as the segment of vessel encompassing 5 mm proximal to the stent, the stented segment, and 5 mm distal to the stent.

### Additional Parameters

**<u>Angiography and Ultrasound</u>**

Diagnostic angiography was performed immediately prior to enrollment, immediately post-stent implantation, at 4 and 12 months post-index procedure. Quantitative coronary angiography (QCA) acquisition procedures were followed as outlined in the Angiographic Core Laboratory

guidelines. All coronary angiograms (both scheduled and non-scheduled) were submitted to the Angiographic Core Laboratory for quantitative and qualitative analysis. Intravascular ultrasound (IVUS) was performed immediately post-stent implantation, at the 4- and 12-month follow-up for all patients. Guidelines provided by the IVUS Core Laboratory were followed to acquire images for quantitative and qualitative analysis.

The following additional parameters were presented.

**Angiography:**

1) Baseline (pre-procedure), post-index procedure, 4- and 12-month minimal lumen diameter (MLD) by QCA.
2) Angiographic late loss at 4 and 12 months, defined as the absolute difference of the minimum lumen diameter (MLD) between the immediate post-index procedure result and the 4- and 12-month follow-up angiography result by QCA.
3) Acute gain, defined as the absolute difference of the minimum lumen diameter (MLD) between baseline (pre-procedure) and the immediate post-index procedure result by QCA.
4) Late loss index at 4 and 12 months, defined as the ratio of late loss by QCA at 4 and 12 months to acute gain by QCA.
5) Absolute difference in minimal lumen diameter (MLD) between baseline (pre-procedure) and 4- and 12-month follow-up by QCA.
6) Device success, defined as attainment of <50% residual diameter stenosis (by QCA) of the target lesion using only the assigned device.
7) Lesion success, defined as the attainment of <50% residual diameter stenosis (by QCA) of the target lesion using any percutaneous method.
8) Procedure success, defined as the attainment of <50% residual diameter stenosis (by QCA) of the target lesion and no in-hospital MACE.

**Ultrasound:**

1) External elastic membrane area and volume immediately post-stent implantation and 4 and 12 month follow-up by IVUS.
2) Stent area and volume immediately post-stent implantation and at 4 and 12 month follow-up by IVUS.
3) Lumen area and volume immediately post-stent implantation and at 4 and 12 month and follow-up by IVUS.
4) Plaque and media area and volume immediately post-stent implantation and at 4 and 12 month follow-up by IVUS.
5) Neointimal hyperplastic volume immediately post-stent implantation and at 4 and 12 months as measured by IVUS.

These measurements (where applicable) were performed at the proximal (5 mm) and distal margins (5 mm) of the stent as well as in-stent.

**Safety Parameters**

**MACE, TVF, TVR:** The clinical study endpoints of MACE, TVF and TLR were endpoints of this study and are discussed above.

**Adverse Events**

All adverse events were recorded on case report forms starting at the point of enrollment and continuing through the post-index procedure and follow-up periods.

**Unanticipated Adverse Device Effects**

Unanticipated Adverse Device Effects were defined as any serious adverse effect on health or safety or any life-threatening problem or death that was caused by or associated with an investigational device. The effect must not have been previously identified in nature, severity or degree of incidence in the investigational plan. Other serious problems associated with the device that affects the rights or welfare of study subjects may also have been considered UADEs.

**D. Study Phases and Procedures**

**Pre-Procedure (Screening) Phase**

The pre-procedure phase was the period prior to implantation of the investigational device. Subjects were evaluated against the inclusion and exclusion criteria. Investigators obtained written informed consent prior to the performance of any study-specific procedures.

**Procedural Phase**

The procedural phase began after the diagnostic angiogram. The procedural phase included the study stent implantation, collection of ACTs, final angiograms, and IVUS images. The procedural phase ended when the vascular sheath was removed.

**Post-Index Procedure Phase**

The post-index procedure phase was the 24-hour period immediately following implantation of the investigational device. At this time subjects had blood samples collected for the purpose of evaluating CK and CK-MB and also underwent a 12-lead ECG immediately following the procedure and immediately prior to discharge (or 16-24 hours following treatment, whichever occurred first). Information regarding concomitant medications and adverse events was recorded on the appropriate case report form.

**Discharge Phase**

Prior to discharge, subjects had blood samples collected and ECGs performed. Information regarding concomitant medications and adverse events was recorded on the appropriate case report form.

**Follow-up Phase**

Follow-up contacts and procedures were performed at the following time points:

30 days ±2 days (telephone)
4 months ± 7 days
9 months ± 7 days (telephone)

12 months ± 30 days
2 years ± 7 days
3 years ± 7 days
4 years ± 7 days

A total of 98 subjects returned at 4 months (± 7 days) to undergo angiography with IVUS pullback and 1 patient underwent angiography but no IVUS pullback. A total of 92 enrolled study subjects had angiographic follow-up at 12 months, and a total of 87 subjects had IVUS follow-up at 12-months post-index procedure. Information regarding adverse events was recorded on the appropriate case report form.

**Prior to Procedure**

**Clinical Laboratory Procedures**
For all subjects, an electrocardiogram, CBC, urea, creatinine, electrolytes, liver function tests and in addition, a pregnancy test (ßHCG subunit) for women of childbearing potential were obtained within seven days of the procedure. A creatine kinase (CK) enzyme and creatine kinase myocardial-band (CK-MB) isoenzyme test was obtained within 72 hours of the procedure. A baseline activated clotting time (ACT) was determined following arterial access. ACT and subsequent heparin dosing was recorded throughout the procedure. Documentation of a final ACT level, before leaving the catheterization laboratory was also performed. All ACTs were recorded in the medical record for source documentation purposes.

**Antiplatelet / Anticoagulation Regimen**
All subjects received aspirin (at least 300-325 mg daily) and clopidogrel (300 mg loading dose 6 hours prior to procedure when possible or 300 mg at procedure) prior to coronary stent implantation. If the subject was currently taking clopidogrel, the patient continued with 75 mg daily. The ACT was monitored and recorded on source documentation during the procedure and adjusted to keep the subject's ACT ≥250 sec., or 200-250 sec. if a glycoprotein IIb/IIIa receptor blocker was administered.

## Summary of Concomitant Medical Therapy

| Medication | Pre-Procedure | During Catheterization | Post-Index Procedure | Follow-up |
|---|---|---|---|---|
| IV Heparin | PRN | To maintain elevated ACT per site's standard practice | PRN | No |
| Intracoronary Nitroglycerin | No | 100 – 200 mcg prior to baseline and post intervention angiograms | No | No |
| Aspirin | 300-325 mg QD | No | 300-325 mg QD | 300-325 mg QD for 12 weeks, then ≥100 mg per physician discretion |
| Clopidogrel | 300 mg po 6 hours prior to procedure, or 300 mg po at procedure (if not given prior to procedure)<br><br>Note: If subject currently taking clopidogrel, continue 75 mg QD | | 75 mg po QD | 75 mg po QD for 12 weeks |

## Procedure

### Preparation, Angiography and Intravascular Ultrasound

Using standard procedures for balloon angioplasty, an introducer sheath of at least 6 French was introduced using the standard approach. After catheter introduction, heparin with or without a glycoprotein IIb/IIIa receptor blocker was administered and supplemented as needed to maintain anticoagulation throughout the procedure.

ACT and subsequent heparin dosing were recorded throughout the procedure. Documentation of a final ACT level, before leaving the catheterization laboratory, was left to the investigator's discretion. All ACTs were recorded in the medical record for source documentation purposes.

Following intracoronary injection of GTN, baseline angiography of the vessel was performed in at least two near-orthogonal views that showed the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.

### Lesion/Vessel Pre-treatment

The target lesion was pre-treated with standard percutaneous transluminal balloon angioplasty. This study's protocol did not allow for direct stenting. In general, a predilatation ratio of ≤1:1 between the balloon and the vessel was required. The use of other approved therapy (DCA, Laser, Rotational Atherectomy, etc.) was not allowed.

### Stenting Procedure

The stenting procedure was performed according to the Instructions for Use. No more than one study stent could have been used to treat the lesion. The only exceptions were due to a bailout procedure or insufficient lesion coverage. Operators were strongly encouraged to perform IVUS-guided, "optimal" stenting. Post dilatation was performed at the operator's discretion.

The guiding catheter used during the stent procedure was required to have a minimum internal diameter of 0.064 inches, while the guide wire diameter was required to be no larger than 0.014 inches.

At procedure completion, intracoronary injection of GTN was administered. Final angiography of the vessel was performed in the two near-orthogonal views that were taken at baseline, showing the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter. Finally, intravascular ultrasound (IVUS) with automated pullback was performed.

### Bailout Procedures

If the subject experienced a major dissection or an occlusive complication manifested as decreased target vessel flow, chest pain or ischaemic ECG changes which did not respond to repeat balloon inflations or intracoronary vasodilators (GTN, verapamil, diltiazem, nitroprusside), other bailout procedures were performed which included further stenting. If the subject required additional stents, a Medtronic Vascular Endeavor Zotarolimus-Eluting Coronary Stent System was used. If in the operator's opinion an alternative stent was required for best subject care, any currently approved non drug-eluting stent may have been used.

## Post-Index Procedure

### Subject Management

Immediately following the procedure, heparin was discontinued and the ACT was monitored in accordance with hospital protocol. Vascular sheaths were removed according to usual hospital practice. Approved vascular closure devices were used at the discretion of the investigator in accordance with the manufacturer's directions.

### Antiplatelet / Anticoagulation Regimen

All subjects received aspirin 300-325 mg for 12 weeks followed by at least 100 mg daily indefinitely per the physician's discretion, and clopidogrel 75 mg daily for at least 12 weeks.

### Clinical and Laboratory Procedures

An ECG was performed within 16-24 hours post-index procedure or prior to discharge (whichever occurred first). A 12-lead ECG was required to document any suspicious cardiac ischaemic episode.

CK and CK-MB was measured post-index procedure between:

- 6-8 hours,
- 12-16 hours, and
- 20-24 hours

If total CK values were within normal ranges, CK-MB measurements were performed per hospital standards. It was strongly encouraged however, that CK-MB measurements were obtained with every total CK drawn, even if CK values were within normal limits.

Every effort was made to obtain cardiac enzyme values within the specified time ranges, to help determine the presence or absence of myocardial infarction post-index procedure. Results of all cardiac enzyme tests, even tests performed outside the time range, were documented on the case report forms.

If any CK elevation was noted post-index procedure, CK and CK-MB measurements were performed every 8 hours for 24 hours, starting from when the first elevation was noted, and recorded on the appropriate case report form.

If a subject was discharged prior to 20 hours, the 20-24 hour blood draw was omitted. Every effort was made to obtain a blood sample prior to hospital discharge. Apart from CK measurements, blood was drawn for urea and electrolytes at 20-24 hours, or immediately prior to discharge.

## Follow-up Procedures

Follow-up procedures for this trial included:

1. Blood draws according to hospital standard or medication regimen.
2. Documentation of referring physicians, including general practitioners as well as cardiologists, family members, and neighbours. Any planned long absences from the area was recorded to facilitate continued ability to contact a study subject.

**Summary of Follow-up Procedures**

| Contact Period | Type of follow-up required |
|---|---|
| 30 days ± 2 days | Telephone Assessment |
| 4 months ± 7 days | Clinical, angiographic & IVUS follow-up for ALL subjects |
| 9 months ± 7 days | Telephone Assessment |
| 12 months ± 30 days | Clinical, angiographic & IVUS follow-up for ALL subjects |
| 2 years ± 7 days | Telephone Assessment |
| 3 years ± 7 days | Telephone Assessment |
| 4 years ± 7 days | Telephone Assessment |
| 5 years ± 7 days | Telephone Assessment |

**Angiographic and IVUS Follow-up**

Subjects enrolled in the registry underwent repeat angiography and IVUS at approximately 4 and 12 months after the index procedure.

All elective angiograms performed during the follow-up period were preceded by a physician evaluation during which the physician indicated whether or not the subject's clinical status warranted revascularization. All films were sent to the angiographic core laboratory for review. IVUS with automated pullback was also performed, and all images were sent to the IVUS Core Laboratory.

If repeat angiography was performed any time after the first month (≥30 days) and it demonstrated restenosis of the target vessel in association with objective evidence of recurrent ischaemia, that angiogram was analyzed as the follow-up angiogram, and the subjects were not required to undergo additional repeat angiography. IVUS with automated pullback was also performed, and all images were sent to the IVUS Core Laboratory.

In some cases, recurrent ischaemia may have developed less than 30 days after successful stent placement. If angiography demonstrated a significant stenosis or sub-acute thrombotic occlusion, the subject was considered an acute failure, and was continued to be included in the follow-up analysis that measures angiographic restenosis, and IVUS parameters. In this situation, recurrent ischaemia was attributed to sub-abrupt closure, rather than restenosis. If such subjects did not undergo a repeat percutaneous or surgical intervention, they were required to return for the follow-up angiograms and IVUS at approximately 4 and 12 months.

## E. Clinical Events

### Adverse Events

An adverse event was any undesirable experience (sign, symptom, illness, abnormal laboratory value, or other medical event) occurring in a subject that could be associated with the investigational product(s) that appeared or worsened during a clinical study. Significant device failure may have constituted an adverse event if an undesirable experience occurred.

Adverse events information was collected throughout the study. Adverse events were recorded on the case report forms by the Investigator or other appropriate site personnel. Event, date of onset, severity, duration, and relationship to device were recorded on the appropriate case report form.

### Serious Adverse Events and Death

The Investigator decided whether each event met the definition of a "serious" adverse event. The regulatory definition of a serious adverse event was an event that was fatal or life threatening, resulted in persistent or significant disability, required intervention to prevent permanent impairment/damage, or an event that resulted in congenital anomaly, malignancy, hospital admission or prolongation of hospitalization. The primary study endpoint, which included death, myocardial infarction (Q wave or non-Q wave), and revascularization, was considered serious by this definition.

Any serious adverse event or subject death that occurred during the follow-up period, regardless of cause, was reported to the Sponsor and HCRI within one working day after the investigator first learned of the event.

### Unanticipated Adverse Device Effects

An Unanticipated Adverse Device Effect (UADE) was defined as any serious adverse effect on health or safety or any life-threatening problem or death that was caused by or associated with an investigational device. The effect must have not been previously identified in nature, severity or degree of incidence in the investigational plan. Other serious problems associated with the device that effect the rights or welfare of study subjects have also been considered UADEs.

The occurrence of expected adverse events was reported using the appropriate case report form.

UADEs were reported to the sponsor, HREC and HCRI within one working day after the investigator first learned of the effect.

### Device Failures, Malfunctions and Near Incidents

All device failures, malfunctions and near incidents were documented and reported. In case of a device failure, malfunction or near incident related to the investigational device, the device was returned to Medtronic Vascular for analysis.

> **Device Failure:** A device had failed if it was used in accordance with the Instructions for Use, but did not perform according to Instructions for Use and negatively impacted the treatment.

**Device Malfunction:** A device malfunction was an unexpected change to the device that was contradictory to the Instructions for Use and may or may not have affected device performance.

**Near Incident:** Malfunction or deterioration in the characteristics and/or performance of the device which might have led to death or serious deterioration in health; incident occurred and was such that if it occurred again, it might have lead to death or serious deterioration in health.

**Device Misuse:** A misused device (one that was used by the investigator in a manner that was contradictory to the Instructions for Use) was not considered a malfunction.

All device failures and malfunctions were adjudicated by the independent Clinical Events Committee.

## F. Statistical Methods of Analysis

The main objective of this study was to demonstrate the acute safety of the Endeavor Zotarolimus-Eluting Coronary Stent System while gathering preliminary information on mid- and long-term safety and efficacy of the device. Consequently, the trial was designed to minimize the number of subjects exposed to the device while still providing enough information for a preliminary indication of safety and feasibility. Analyses were generated to assure investigators that a sample size of 100 subjects would be sufficient to provide reasonable confidence in the estimates of safety and efficacy generated by this study.

Data collected in this study were documented using summary tables. Demographic and background characteristics, safety and efficacy data were summarized. Descriptive statistics were provided. The statistics for continuous variables included mean, standard deviation, minimum, maximum, and sample size. Categorical variables were described with counts and percentages. Percentages were rounded to one decimal place. Computations for all results were performed using SAS Version 6.12 or higher computer software package.

### Analysis and Reporting of Results

All clinically relevant baseline and follow-up variables were tabulated. Means, standard deviations and ranges were reported for continuous variables, and percentages were reported for categorical variables. In addition, where appropriate, cumulative frequency distribution plots of angiographic and IVUS variables were performed. Kaplan-Meier techniques were utilized to assess survival free of MACE, TVR, TVF and TLR.

### Analysis Populations

Intent to Treat (ITT): All patients enrolled in the study.

Per-Protocol (PP): The following table highlights the conditions that need to be met for PP:

| Condition | ENDEAVOR I Criteria | ENDEAVOR I Patients |
|---|---|---|
| De-registered | During index | None |

| Condition | ENDEAVOR I Criteria | ENDEAVOR I Patients |
|---|---|---|
| | procedure:<br>1. Did not receive any device<br>2. Received assigned study device, and another type of DES | |
| The target lesion is a single de novo lesion that has not been previously treated with any interventional procedure. Only one lesion may be treated per subject. | Inclusion 4a | None |
| Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes 2X the upper laboratory normal with the presence of a CK – MB elevated above the Institution's upper limit of normal). | Exclusion 5 | |
| The target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc). | Exclusion 9 | None |
| Previous stenting anywhere in the target vessel. | Exclusion 10 | None |
| Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.[Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.] | Exclusion 20 | None |

IVUS Analysis Set: All patients enrolled in the study who had IVUS performed immediately post-stent procedure and at the 4- and 12-month follow-up.

Angiography Analysis Set: For each time point (baseline, post-index procedure, 4- and 12-month) the analysis set included all subjects enrolled in the study who had the angiogram required for the analysis at that time point (any subject with an angiogram within 30 days of the scheduled angiogram was included in the analysis at that time point). If an analysis involved more than one time point, subjects must have had all required angiograms in order to be included in the analysis.

## Section III. Tables and Figures

### Table 2a. Number of Patients Treated by Investigator - All Enrolled Subjects

| Site | Clinical Site | Principal Investigator | Number |
|---|---|---|---|
| 233 | Monash Medical Centre | Ian Meredith, MD | 14 |
| 234 | St. Vincent's Public Hospital, Melbourne | Rob Whitbourn, MD | 20 |
| 235 (A) | Mercy Hospital | John Ormiston, MD | 15 |
| 235 (B) | Green Lane Hospital | John Ormiston, MD | 17 |
| 237 | Dunedin Hospital | Patrick Kay, MD | 16 |
| 238 | St. Vincent's Public Hospital, Sydney | David Muller, MD | 12 |
| 239 | Eastern Heart Clinic | Mark Pitney, MD | 1 |
| 240 | Prince Charles Hospital | Con Aroney, MD | 2 |
| 241 | Royal Prince Alfred Hospital | Mark Adams, MD | 3 |
| **Total** | | | **100** |

Note: Site 235 is listed here as 2 locations, but has one Principal Investigator.

## Table 2b. Clinical Follow-Up Data Compliance (ITT)*

| Site | Index | 30-Day Contact | 9-Month Contact | 12-Month Contact | 2-Year Contact | 3-Year Contact | 4-Year Contact |
|---|---|---|---|---|---|---|---|
| 233 | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 92.86% (13/14) | 92.86% (13/14) | 92.31% (12/13) |
| 234 | 100.0% (20/20) | 100.0% (20/20) | 100.0% (20/20) | 100.0% (20/20) | 100.0% (19/19) | 100.0% (19/19) | 100.0% (19/19) |
| 235 | 100.0% (32/32) | 100.0% (32/32) | 100.0% (32/32) | 100.0% (32/32) | 100.0% (32/32) | 100.0% (31/31) | 100.0% (31/31) |
| 237 | 100.0% (16/16) | 100.0% (16/16) | 93.75% (15/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (15/15) | 100.0% (15/15) |
| 238 | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 91.67% (11/12) | 91.67% (11/12) | 91.67% (11/12) | 91.67% (11/12) |
| 239 | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) |
| 240 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 241 | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 66.67% (2/3) | 66.67% (2/3) |
| Total | 100.0% (100/100) | 100.0% (100/100) | 99.00% (99/100) | 99.00% (99/100) | 97.98% (97/99) | 96.91% (94/97) | 96.88% (93/96) |

* Clinical Follow-Up Data Compliance utilizes to last documented visit date to determine data compliance.

Patients who died or withdrew consent will be excluded from eligible for FU for the time points when they died/withdrew consent and forward.

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## Table 2c. Angiographic/IVUS Follow-Up Data Compliance (ITT)*

| Site | Baseline QCA | 4-Month QCA | 12-Month QCA | Baseline IVUS | 4-Month IVUS | 12-Month IVUS |
|---|---|---|---|---|---|---|
| 233 | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 92.86% (13/14) | 92.86% (13/14) | 92.86% (13/14) |
| 234 | 100.0% (20/20) | 100.0% (20/20) | 95.00% (19/20) | 100.0% (20/20) | 100.0% (20/20) | 90.00% (18/20) |
| 235 | 100.0% (32/32) | 100.0% (32/32) | 93.75% (30/32) | 96.88% (31/32) | 100.0% (32/32) | 90.63% (29/32) |
| 237 | 100.0% (16/16) | 100.0% (16/16) | 93.75% (15/16) | 93.75% (15/16) | 93.75% (15/16) | 93.75% (15/16) |
| 238 | 100.0% (12/12) | 91.67% (11/12) | 75.00% (9/12) | 83.33% (10/12) | 91.67% (11/12) | 66.67% (8/12) |
| 239 | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) |
| 240 | 100.0% (2/2) | 100.0% (2/2) | 50.00% (1/2) | 100.0% (2/2) | 100.0% (2/2) | 0.00% (0/2) |
| 241 | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) |
| Total | 100.0% (100/100) | 99.00% (99/100) | 92.00% (92/100) | 95.00% (95/100) | 97.00% (97/100) | 87.00% (87/100) |

* Angiographic/IVUS Follow-Up Data Compliance utilizes completed and qualified media to determine data compliance (see appendix for qualification algorithms).

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## Table 3. Major Adverse Events In-Hospital (ITT)

| In-Hospital Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 0.0% (0/100) |
| Death | 0.0% (0/100) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.0% (0/100) |
| Q Wave MI | 0.0% (0/100) |
| Non-Q Wave MI | 0.0% (0/100) |
| Emergent CABG | 0.0% (0/100) |
| Target Lesion Revascularization | 0.0% (0/100) |
| TL-CABG | 0.0% (0/100) |
| TL-PTCA | 0.0% (0/100) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/100) |
| TV/non-TL-CABG | 0.0% (0/100) |
| TV/non-TL-PTCA | 0.0% (0/100) |
| Target Vessel Revascularization | 0.0% (0/100) |
| Target Vessel Failure | 0.0% (0/100) |
| Perforation | 0.0% (0/100) |
| Early Stent Thrombosis | 0.0% (0/100) |
| Late Stent Thrombosis | 0.0% (0/100) |
| Vascular Complications | 1.0% (1/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Major Bleeding | 1.0% (1/100) |

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N = The maximum number of eligible patients.

## Table 4a. Major Adverse Events Out-of-Hospital to 30 Days (ITT)

| Out-of-Hospital Complications to 30 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 1.0% (1/100) |
| Death | 0.0% (0/100) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/100) |
| Q Wave MI | 0.0% (0/100) |
| Non-Q Wave MI | 1.0% (1/100) |
| Emergent CABG | 0.0% (0/100) |
| Target Lesion Revascularization | 1.0% (1/100) |
| TL-CABG | 1.0% (1/100) |
| TL-PTCA | 1.0% (1/100) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/100) |
| TV/non-TL-CABG | 0.0% (0/100) |
| TV/non-TL-PTCA | 0.0% (0/100) |
| Target Vessel Revascularization | 1.0% (1/100) |
| Target Vessel Failure | 1.0% (1/100) |
| Perforation | 0.0% (0/100) |
| Early Stent Thrombosis | 1.0% (1/100) |
| Late Stent Thrombosis | 0.0% (0/100) |
| Vascular Complications | 1.0% (1/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Major Bleeding | 1.0% (1/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 28 days post index procedure or an event through 30 days.

## Table 4b. Major Adverse Events Out-of-Hospital to 270 Days (ITT)

| Out-of-Hospital Complications to 270 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.0% (2/100) |
| Death | 0.0% (0/100) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/100) |
| Q Wave MI | 0.0% (0/100) |
| Non-Q Wave MI | 1.0% (1/100) |
| Emergent CABG | 0.0% (0/100) |
| Target Lesion Revascularization | 2.0% (2/100) |
| TL-CABG | 1.0% (1/100) |
| TL-PTCA | 2.0% (2/100) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/100) |
| TV/non-TL-CABG | 0.0% (0/100) |
| TV/non-TL-PTCA | 0.0% (0/100) |
| Target Vessel Revascularization | 2.0% (2/100) |
| Target Vessel Failure | 2.0% (2/100) |
| Perforation | 0.0% (0/100) |
| Early Stent Thrombosis | 1.0% (1/100) |
| Late Stent Thrombosis | 0.0% (0/100) |
| Vascular Complications | 2.0% (2/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Major Bleeding | 1.0% (1/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 263 days post index procedure or an event through 270 days.

## Table 4c. Major Adverse Events Out-of-Hospital to 360 Days (ITT)

| Out-of-Hospital Complications to 360 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.0% (2/99) |
| Death | 0.0% (0/99) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/99) |
| Q Wave MI | 0.0% (0/99) |
| Non-Q Wave MI | 1.0% (1/99) |
| Emergent CABG | 0.0% (0/99) |
| Target Lesion Revascularization | 2.0% (2/99) |
| TL-CABG | 1.0% (1/99) |
| TL-PTCA | 2.0% (2/99) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/99) |
| TV/non-TL-CABG | 0.0% (0/99) |
| TV/non-TL-PTCA | 0.0% (0/99) |
| Target Vessel Revascularization | 2.0% (2/99) |
| Target Vessel Failure | 2.0% (2/99) |
| Perforation | 0.0% (0/99) |
| Early Stent Thrombosis | 1.0% (1/99) |
| Late Stent Thrombosis | 0.0% (0/99) |
| Vascular Complications | 2.0% (2/99) |
| Cerebrovascular Accident (CVA) | 0.0% (0/99) |
| Major Bleeding | 1.0% (1/99) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

## Table 4d. Major Adverse Events Out-of-Hospital to 720 Days (ITT)

| Out-of-Hospital Complications to 720 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 3.0% (3/99) |
| Death | 1.0% (1/99) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/99) |
| Q Wave MI | 0.0% (0/99) |
| Non-Q Wave MI | 1.0% (1/99) |
| Emergent CABG | 0.0% (0/99) |
| Target Lesion Revascularization | 2.0% (2/99) |
| TL-CABG | 1.0% (1/99) |
| TL-PTCA | 2.0% (2/99) |
| Target Vessel Revascularization not involving the Target Lesion | 2.0% (2/99) |
| TV/non-TL-CABG | 1.0% (1/99) |
| TV/non-TL-PTCA | 1.0% (1/99) |
| Target Vessel Revascularization | 4.0% (4/99) |
| Target Vessel Failure | 4.0% (4/99) |
| Perforation | 0.0% (0/99) |
| Early Stent Thrombosis | 1.0% (1/99) |
| Late Stent Thrombosis | 0.0% (0/99) |
| Vascular Complications | 2.0% (2/99) |
| Cerebrovascular Accident (CVA) | 1.0% (1/99) |
| Major Bleeding | 1.0% (1/99) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 713 days post index procedure or an event through 720 days.

## Table 4e. Major Adverse Events Out-of-Hospital to 1080 Days (ITT)

| Out-of-Hospital Complications to 1080 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 6.1% (6/98) |
| Death | 3.1% (3/98) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/98) |
| Q Wave MI | 0.0% (0/98) |
| Non-Q Wave MI | 1.0% (1/98) |
| Emergent CABG | 0.0% (0/98) |
| Target Lesion Revascularization | 3.1% (3/98) |
| TL-CABG | 1.0% (1/98) |
| TL-PTCA | 3.1% (3/98) |
| Target Vessel Revascularization not involving the Target Lesion | 2.0% (2/98) |
| TV/non-TL-CABG | 1.0% (1/98) |
| TV/non-TL-PTCA | 1.0% (1/98) |
| Target Vessel Revascularization | 5.1% (5/98) |
| Target Vessel Failure | 5.1% (5/98) |
| Perforation | 0.0% (0/98) |
| Early Stent Thrombosis | 1.0% (1/98) |
| Late Stent Thrombosis | 0.0% (0/98) |
| Vascular Complications | 2.0% (2/98) |
| Cerebrovascular Accident (CVA) | 1.0% (1/98) |
| Major Bleeding | 1.0% (1/98) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 1073 days post index procedure or an event through 1080 days.

## Table 4f. Major Adverse Events Out-of-Hospital to 1440 Days (ITT)

| Out-of-Hospital Complications to 1440 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 7.2% (7/97) |
| Death | 4.1% (4/97) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/97) |
| Q Wave MI | 0.0% (0/97) |
| Non-Q Wave MI | 1.0% (1/97) |
| Emergent CABG | 0.0% (0/97) |
| Target Lesion Revascularization | 3.1% (3/97) |
| TL-CABG | 1.0% (1/97) |
| TL-PTCA | 3.1% (3/97) |
| Target Vessel Revascularization not involving the Target Lesion | 2.1% (2/97) |
| TV/non-TL-CABG | 1.0% (1/97) |
| TV/non-TL-PTCA | 1.0% (1/97) |
| Target Vessel Revascularization | 5.2% (5/97) |
| Target Vessel Failure | 5.2% (5/97) |
| Perforation | 0.0% (0/97) |
| Early Stent Thrombosis | 1.0% (1/97) |
| Late Stent Thrombosis | 0.0% (0/97) |
| Vascular Complications | 2.1% (2/97) |
| Cerebrovascular Accident (CVA) | 1.0% (1/97) |
| Major Bleeding | 1.0% (1/97) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 1433 days post index procedure or an event through 1440 days.

## Table 5a. Combined Major Adverse Events to 30 Days (ITT)

| Combined Complications to 30 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 1.0% (1/100) |
| Death | 0.0% (0/100) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/100) |
| Q Wave MI | 0.0% (0/100) |
| Non-Q Wave MI | 1.0% (1/100) |
| Emergent CABG | 0.0% (0/100) |
| Target Lesion Revascularization | 1.0% (1/100) |
| TL-CABG | 1.0% (1/100) |
| TL-PTCA | 1.0% (1/100) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/100) |
| TV/non-TL-CABG | 0.0% (0/100) |
| TV/non-TL-PTCA | 0.0% (0/100) |
| Target Vessel Revascularization | 1.0% (1/100) |
| Target Vessel Failure | 1.0% (1/100) |
| Perforation | 0.0% (0/100) |
| Early Stent Thrombosis | 1.0% (1/100) |
| Late Stent Thrombosis | 0.0% (0/100) |
| Vascular Complications | 2.0% (2/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Major Bleeding | 2.0% (2/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 28 days post index procedure or an event through 30 days.

## Table 5b. Combined Major Adverse Events to 270 Days (ITT)

| Combined Complications to 270 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.0% (2/100) |
| Death | 0.0% (0/100) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/100) |
| Q Wave MI | 0.0% (0/100) |
| Non-Q Wave MI | 1.0% (1/100) |
| Emergent CABG | 0.0% (0/100) |
| Target Lesion Revascularization | 2.0% (2/100) |
| TL-CABG | 1.0% (1/100) |
| TL-PTCA | 2.0% (2/100) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/100) |
| TV/non-TL-CABG | 0.0% (0/100) |
| TV/non-TL-PTCA | 0.0% (0/100) |
| Target Vessel Revascularization | 2.0% (2/100) |
| Target Vessel Failure | 2.0% (2/100) |
| Perforation | 0.0% (0/100) |
| Early Stent Thrombosis | 1.0% (1/100) |
| Late Stent Thrombosis | 0.0% (0/100) |
| Vascular Complications | 3.0% (3/100) |
| Cerebrovascular Accident (CVA) | 0.0% (0/100) |
| Major Bleeding | 2.0% (2/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 263 days post index procedure or an event through 270 days.

## Table 5c. Combined Major Adverse Events to 360 Days (ITT)

| Combined Complications to 360 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.0% (2/99) |
| Death | 0.0% (0/99) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/99) |
| Q Wave MI | 0.0% (0/99) |
| Non-Q Wave MI | 1.0% (1/99) |
| Emergent CABG | 0.0% (0/99) |
| Target Lesion Revascularization | 2.0% (2/99) |
| TL-CABG | 1.0% (1/99) |
| TL-PTCA | 2.0% (2/99) |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/99) |
| TV/non-TL-CABG | 0.0% (0/99) |
| TV/non-TL-PTCA | 0.0% (0/99) |
| Target Vessel Revascularization | 2.0% (2/99) |
| Target Vessel Failure | 2.0% (2/99) |
| Perforation | 0.0% (0/99) |
| Early Stent Thrombosis | 1.0% (1/99) |
| Late Stent Thrombosis | 0.0% (0/99) |
| Vascular Complications | 3.0% (3/99) |
| Cerebrovascular Accident (CVA) | 0.0% (0/99) |
| Major Bleeding | 2.0% (2/99) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

## Table 5d. Combined Major Adverse Events to 720 Days (ITT)

| Combined Complications to 720 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 3.0% (3/99) |
| Death | 1.0% (1/99) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/99) |
| Q Wave MI | 0.0% (0/99) |
| Non-Q Wave MI | 1.0% (1/99) |
| Emergent CABG | 0.0% (0/99) |
| Target Lesion Revascularization | 2.0% (2/99) |
| TL-CABG | 1.0% (1/99) |
| TL-PTCA | 2.0% (2/99) |
| Target Vessel Revascularization not involving the Target Lesion | 2.0% (2/99) |
| TV/non-TL-CABG | 1.0% (1/99) |
| TV/non-TL-PTCA | 1.0% (1/99) |
| Target Vessel Revascularization | 4.0% (4/99) |
| Target Vessel Failure | 4.0% (4/99) |
| Perforation | 0.0% (0/99) |
| Early Stent Thrombosis | 1.0% (1/99) |
| Late Stent Thrombosis | 0.0% (0/99) |
| Vascular Complications | 3.0% (3/99) |
| Cerebrovascular Accident (CVA) | 1.0% (1/99) |
| Major Bleeding | 2.0% (2/99) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 713 days post index procedure or an event through 720 days.

## Table 5e. Combined Major Adverse Events to 1080 Days (ITT)

| Combined Complications to 1080 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 6.1% (6/98) |
| Death | 3.1% (3/98) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/98) |
| Q Wave MI | 0.0% (0/98) |
| Non-Q Wave MI | 1.0% (1/98) |
| Emergent CABG | 0.0% (0/98) |
| Target Lesion Revascularization | 3.1% (3/98) |
| TL-CABG | 1.0% (1/98) |
| TL-PTCA | 3.1% (3/98) |
| Target Vessel Revascularization not involving the Target Lesion | 2.0% (2/98) |
| TV/non-TL-CABG | 1.0% (1/98) |
| TV/non-TL-PTCA | 1.0% (1/98) |
| Target Vessel Revascularization | 5.1% (5/98) |
| Target Vessel Failure | 5.1% (5/98) |
| Perforation | 0.0% (0/98) |
| Early Stent Thrombosis | 1.0% (1/98) |
| Late Stent Thrombosis | 0.0% (0/98) |
| Vascular Complications | 3.1% (3/98) |
| Cerebrovascular Accident (CVA) | 1.0% (1/98) |
| Major Bleeding | 2.0% (2/98) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 1073 days post index procedure or an event through 1080 days.

## Table 5f. Combined Major Adverse Events to 1440 Days (ITT)

| Combined Complications to 1440 Days | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 7.2% (7/97) |
| Death | 4.1% (4/97) |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 1.0% (1/97) |
| Q Wave MI | 0.0% (0/97) |
| Non-Q Wave MI | 1.0% (1/97) |
| Emergent CABG | 0.0% (0/97) |
| Target Lesion Revascularization | 3.1% (3/97) |
| TL-CABG | 1.0% (1/97) |
| TL-PTCA | 3.1% (3/97) |
| Target Vessel Revascularization not involving the Target Lesion | 2.1% (2/97) |
| TV/non-TL-CABG | 1.0% (1/97) |
| TV/non-TL-PTCA | 1.0% (1/97) |
| Target Vessel Revascularization | 5.2% (5/97) |
| Target Vessel Failure | 5.2% (5/97) |
| Perforation | 0.0% (0/97) |
| Early Stent Thrombosis | 1.0% (1/97) |
| Late Stent Thrombosis | 0.0% (0/97) |
| Vascular Complications | 3.1% (3/97) |
| Cerebrovascular Accident (CVA) | 1.0% (1/97) |
| Major Bleeding | 2.1% (2/97) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 1433 days post index procedure or an event through 1440 days.

## Table 6a. Hierarchical Major Adverse Events to 30 Days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 1.0% (1/100) |
| Death | 0.0% (0/100) |
| Non-fatal Q Wave MI | 0.0% (0/100) |
| Non-fatal Non-Q Wave MI without Q Wave MI | 1.0% (1/100) |
| Emergent CABG without Death or MI | 0.0% (0/100) |
| TL-CABG without Death or MI | 0.0% (0/100) |
| TL-PTCA without Death, MI, or TL-CABG | 0.0% (0/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 28 days post index procedure or an event through 30 days.

## Table 6b. Hierarchical Major Adverse Events to 270 Days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 2.0% (2/100) |
| Death | 0.0% (0/100) |
| Non-fatal Q Wave MI | 0.0% (0/100) |
| Non-fatal Non-Q Wave MI without Q Wave MI | 1.0% (1/100) |
| Emergent CABG without Death or MI | 0.0% (0/100) |
| TL-CABG without Death or MI | 0.0% (0/100) |
| TL-PTCA without Death, MI, or TL-CABG | 1.0% (1/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 263 days post index procedure or an event through 270 days.

## Table 6c. Hierarchical Major Adverse Events to 360 Days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 2.0% (2/99) |
| Death | 0.0% (0/99) |
| Non-fatal Q Wave MI | 0.0% (0/99) |
| Non-fatal Non-Q Wave MI without Q Wave MI | 1.0% (1/99) |
| Emergent CABG without Death or MI | 0.0% (0/99) |
| TL-CABG without Death or MI | 0.0% (0/99) |
| TL-PTCA without Death, MI, or TL-CABG | 1.0% (1/99) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

## Table 6d. Hierarchical Major Adverse Events to 720 Days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 3.0% (3/99) |
| Death | 1.0% (1/99) |
| Non-fatal Q Wave MI | 0.0% (0/99) |
| Non-fatal Non-Q Wave MI without Q Wave MI | 1.0% (1/99) |
| Emergent CABG without Death or MI | 0.0% (0/99) |
| TL-CABG without Death or MI | 0.0% (0/99) |
| TL-PTCA without Death, MI, or TL-CABG | 1.0% (1/99) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 713 days post index procedure or an event through 720 days.

## Table 6e. Hierarchical Major Adverse Events to 1080 Days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 6.1% (6/98) |
| Death | 3.1% (3/98) |
| Non-fatal Q Wave MI | 0.0% (0/98) |
| Non-fatal Non-Q Wave MI without Q Wave MI | 1.0% (1/98) |
| Emergent CABG without Death or MI | 0.0% (0/98) |
| TL-CABG without Death or MI | 0.0% (0/98) |
| TL-PTCA without Death, MI, or TL-CABG | 2.0% (2/98) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 1073 days post index procedure or an event through 1080 days.

## Table 6f. Hierarchical Major Adverse Events to 1440 Days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 7.2% (7/97) |
| Death | 4.1% (4/97) |
| Non-fatal Q Wave MI | 0.0% (0/97) |
| Non-fatal Non-Q Wave MI without Q Wave MI | 1.0% (1/97) |
| Emergent CABG without Death or MI | 0.0% (0/97) |
| TL-CABG without Death or MI | 0.0% (0/97) |
| TL-PTCA without Death, MI, or TL-CABG | 2.1% (2/97) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with information beyond 1433 days post index procedure or an event through 1440 days.

## Table 7a. Adverse Events (to 1440 Days)

| Adverse Events (to 1440 Days) | ENDEAVOR I (N= 100 Patients) |
|---|---|
| *TOTAL* | *88.0% (88/100)* |
| *BLOOD AND LYMPHATIC SYSTEM DISORDERS* | *4(4.0%)* |
| ANAEMIA NOS | 3(3.0%) |
| MACROCYTIC ANAEMIA NOS | 1(1.0%) |
| NEUTROPENIA | 1(1.0%) |
| THROMBOCYTOPENIA | 1(1.0%) |
| *CARDIAC DISORDERS* | *62(62.0%)* |
| ANGINA PECTORIS | 52(52.0%) |
| ARRHYTHMIA NOS | 2(2.0%) |
| ATRIAL FIBRILLATION | 5(5.0%) |
| ATRIOVENTRICULAR BLOCK COMPLETE | 1(1.0%) |
| ATRIOVENTRICULAR BLOCK FIRST DEGREE | 1(1.0%) |
| ATRIOVENTRICULAR BLOCK NOS | 2(2.0%) |
| BRADYCARDIA NOS | 12(12.0%) |
| CARDIAC FAILURE CONGESTIVE | 1(1.0%) |
| CORONARY ARTERY DISSECTION | 2(2.0%) |
| CORONARY ARTERY STENOSIS | 4(4.0%) |
| MYOCARDIAL INFARCTION | 3(3.0%) |
| NODAL ARRHYTHMIA | 1(1.0%) |
| PALPITATIONS | 4(4.0%) |
| SINUS ARREST | 1(1.0%) |
| SUPRAVENTRICULAR TACHYCARDIA | 1(1.0%) |
| *EAR AND LABYRINTH DISORDERS* | *3(3.0%)* |
| LABYRINTHITIS NOS | 2(2.0%) |
| VERTIGO | 1(1.0%) |
| *EYE DISORDERS* | *1(1.0%)* |
| CATARACT | 1(1.0%) |
| GLAUCOMA NOS | 1(1.0%) |
| *GASTROINTESTINAL DISORDERS* | *30(30.0%)* |
| ABDOMINAL DISCOMFORT | 1(1.0%) |
| ABDOMINAL PAIN NOS | 3(3.0%) |
| ABDOMINAL PAIN UPPER | 2(2.0%) |
| COLITIS ULCERATIVE | 1(1.0%) |
| CONSTIPATION | 3(3.0%) |
| DIARRHOEA NOS | 3(3.0%) |
| DYSPEPSIA | 2(2.0%) |
| GASTROINTESTINAL DISORDER NOS | 1(1.0%) |
| GASTROINTESTINAL HAEMORRHAGE NOS | 1(1.0%) |
| GASTROOESOPHAGEAL REFLUX DISEASE | 2(2.0%) |
| GINGIVAL BLEEDING | 3(3.0%) |
| MOUTH ULCERATION | 1(1.0%) |
| NAUSEA | 12(12.0%) |
| PEPTIC ULCER | 1(1.0%) |
| RETROPERITONEAL HAEMORRHAGE | 1(1.0%) |
| TONGUE HAEMATOMA | 1(1.0%) |
| TOOTHACHE | 1(1.0%) |
| VOMITING NOS | 5(5.0%) |
| *GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS* | *41(41.0%)* |
| ADVERSE DRUG REACTION NOS | 1(1.0%) |
| CHEST DISCOMFORT | 1(1.0%) |
| CHEST PAIN | 17(17.0%) |
| CHEST TIGHTNESS | 1(1.0%) |
| DEATH NOS | 1(1.0%) |
| FALL | 2(2.0%) |
| FEELING COLD | 1(1.0%) |

## Table 7a. Adverse Events (to 1440 Days) (Continued)

| Adverse Events (to 1440 Days) | ENDEAVOR I (N= 100 Patients) |
|---|---|
| INJECTION SITE BRUISING | 6(6.0%) |
| INJECTION SITE HAEMORRHAGE | 15(15.0%) |
| INJECTION SITE MASS | 1(1.0%) |
| INJECTION SITE OEDEMA | 1(1.0%) |
| INJECTION SITE PAIN | 10(10.0%) |
| INJECTION SITE RASH | 1(1.0%) |
| OEDEMA PERIPHERAL | 1(1.0%) |
| PAIN NOS | 2(2.0%) |
| PYREXIA | 2(2.0%) |
| RIGORS | 2(2.0%) |
| *HEPATOBILIARY DISORDERS* | *2(2.0%)* |
| CHOLECYSTITIS NOS | 1(1.0%) |
| JAUNDICE NOS | 1(1.0%) |
| *IMMUNE SYSTEM DISORDERS* | *1(1.0%)* |
| ANAPHYLACTIC REACTION | 1(1.0%) |
| *INFECTIONS AND INFESTATIONS* | *12(12.0%)* |
| BRONCHITIS NOS | 1(1.0%) |
| FUNGAL RASH NOS | 1(1.0%) |
| GIARDIASIS | 1(1.0%) |
| INFLUENZA | 1(1.0%) |
| LOWER RESPIRATORY TRACT INFECTION NOS | 5(5.0%) |
| PNEUMONIA NOS | 2(2.0%) |
| PYELONEPHRITIS NOS | 1(1.0%) |
| TOOTH ABSCESS | 1(1.0%) |
| TOOTH INFECTION | 1(1.0%) |
| UPPER RESPIRATORY TRACT INFECTION NOS | 1(1.0%) |
| *INJURY, POISONING AND PROCEDURAL COMPLICATIONS* | *9(9.0%)* |
| CORONARY ARTERY RESTENOSIS | 3(3.0%) |
| FOOT FRACTURE | 1(1.0%) |
| LIMB INJURY NOS | 1(1.0%) |
| POST PROCEDURAL PAIN | 1(1.0%) |
| RADIUS FRACTURE | 1(1.0%) |
| ROAD TRAFFIC ACCIDENT | 1(1.0%) |
| STENT OCCLUSION | 1(1.0%) |
| *INVESTIGATIONS* | *23(23.0%)* |
| ARTHROSCOPY | 1(1.0%) |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | 1(1.0%) |
| BLOOD CREATINE PHOSPHOKINASE MB INCREASED | 1(1.0%) |
| BLOOD CREATININE INCREASED | 1(1.0%) |
| BLOOD GLUCOSE FLUCTUATION | 1(1.0%) |
| BLOOD PRESSURE DECREASED | 5(5.0%) |
| BLOOD PRESSURE INCREASED | 3(3.0%) |
| CARDIAC TROPONIN INCREASED | 1(1.0%) |
| CAROTID BRUIT | 1(1.0%) |
| ELECTROCARDIOGRAM ST SEGMENT ELEVATION | 7(7.0%) |
| HEART RATE INCREASED | 1(1.0%) |
| HEART RATE IRREGULAR | 1(1.0%) |
| LIVER FUNCTION TESTS NOS ABNORMAL | 1(1.0%) |
| WEIGHT DECREASED | 1(1.0%) |
| WEIGHT INCREASED | 1(1.0%) |
| WHITE BLOOD CELL COUNT INCREASED | 1(1.0%) |
| *METABOLISM AND NUTRITION DISORDERS* | *3(3.0%)* |
| DIABETES MELLITUS NON INSULIN DEPENDENT | 1(1.0%) |
| DIABETES MELLITUS NOS | 1(1.0%) |
| HYPONATRAEMIA | 1(1.0%) |

## Table 7a. Adverse Events (to 1440 Days) (Continued)

| Adverse Events (to 1440 Days) | ENDEAVOR I (N= 100 Patients) |
|---|---|
| *MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS* | *24(24.0%)* |
| ARTHRALGIA | 4(4.0%) |
| BACK PAIN | 10(10.0%) |
| FACIAL PAIN | 1(1.0%) |
| FIBROMYALGIA | 1(1.0%) |
| LOCALISED OSTEOARTHRITIS | 1(1.0%) |
| MUSCLE ATROPHY | 1(1.0%) |
| MUSCLE CRAMPS | 2(2.0%) |
| MUSCLE SPASMS | 1(1.0%) |
| MUSCLE TIGHTNESS | 1(1.0%) |
| MYALGIA | 1(1.0%) |
| NECK PAIN | 1(1.0%) |
| PAIN IN LIMB | 5(5.0%) |
| POLYMYALGIA RHEUMATICA | 1(1.0%) |
| RELAPSING POLYCHONDRITIS | 1(1.0%) |
| *NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)* | *4(4.0%)* |
| LUNG ADENOCARCINOMA NOS | 1(1.0%) |
| LUNG CANCER STAGE UNSPECIFIED (EXCL METASTATIC TUMOURS TO LUNG) | 1(1.0%) |
| LUNG CANCER STAGE UNSPECIFIED EXCL METASTATIC TUMOURS TO LUNG | 1(1.0%) |
| LUNG NEOPLASM NOS | 1(1.0%) |
| MALIGNANT MELANOMA STAGE IV | 1(1.0%) |
| PROSTATE CANCER NOS | 1(1.0%) |
| *NERVOUS SYSTEM DISORDERS* | *29(29.0%)* |
| CEREBROVASCULAR ACCIDENT | 2(2.0%) |
| CONVULSIONS NOS | 1(1.0%) |
| DIZZINESS | 10(10.0%) |
| HEADACHE NOS | 7(7.0%) |
| LOSS OF CONSCIOUSNESS | 1(1.0%) |
| MEMORY IMPAIRMENT | 1(1.0%) |
| OBSTRUCTIVE SLEEP APNOEA SYNDROME | 1(1.0%) |
| PARAESTHESIA | 2(2.0%) |
| PARKINSON S DISEASE NOS | 1(1.0%) |
| SLEEP APNOEA SYNDROME | 1(1.0%) |
| SYNCOPE | 2(2.0%) |
| TEMPORAL ARTERITIS | 1(1.0%) |
| TREMOR | 1(1.0%) |
| VASOVAGAL ATTACK | 6(6.0%) |
| *PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS* | *1(1.0%)* |
| ABORTION SPONTANEOUS NOS | 1(1.0%) |
| *PSYCHIATRIC DISORDERS* | *3(3.0%)* |
| DEPRESSION | 1(1.0%) |
| DISORIENTATION | 1(1.0%) |
| INSOMNIA | 1(1.0%) |
| *RENAL AND URINARY DISORDERS* | *7(7.0%)* |
| DYSURIA | 1(1.0%) |
| HAEMATURIA | 3(3.0%) |
| RENAL COLIC | 1(1.0%) |
| RENAL VEIN OCCLUSION | 1(1.0%) |
| URINARY RETENTION | 2(2.0%) |
| URINE FLOW DECREASED | 1(1.0%) |
| *REPRODUCTIVE SYSTEM AND BREAST DISORDERS* | *5(5.0%)* |
| BREAST MASS NOS | 1(1.0%) |
| EPIDIDYMO ORCHITIS NOS | 1(1.0%) |
| HYDROCELE | 1(1.0%) |
| PROSTATOMEGALY | 1(1.0%) |

## Table 7a. Adverse Events (to 1440 Days) (Continued)

| Adverse Events (to 1440 Days) | ENDEAVOR I (N= 100 Patients) |
|---|---|
| SCROTAL SEBACEOUS CYSTS | 1(1.0%) |
| *RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS* | *23(23.0%)* |
| ASTHMA NOS | 1(1.0%) |
| COUGH | 2(2.0%) |
| DYSPNOEA EXACERBATED | 4(4.0%) |
| DYSPNOEA NOS | 16(16.0%) |
| EMPHYSEMA | 1(1.0%) |
| EPISTAXIS | 1(1.0%) |
| *SKIN AND SUBCUTANEOUS TISSUE DISORDERS* | *10(10.0%)* |
| ANGIONEUROTIC OEDEMA | 1(1.0%) |
| CONTUSION | 7(7.0%) |
| RASH NOS | 1(1.0%) |
| SWEATING INCREASED | 1(1.0%) |
| *SURGICAL AND MEDICAL PROCEDURES* | *12(12.0%)* |
| CHOLECYSTECTOMY | 1(1.0%) |
| CORONARY ARTERY SURGERY | 1(1.0%) |
| CORONARY REVASCULARISATION | 4(4.0%) |
| HIP ARTHROPLASTY | 3(3.0%) |
| HOSPITALISATION | 3(3.0%) |
| SEPTOPLASTY | 1(1.0%) |
| TOOTH EXTRACTION NOS | 1(1.0%) |
| TRANSURETHRAL PROSTATECTOMY | 3(3.0%) |
| *VASCULAR DISORDERS* | *32(32.0%)* |
| AORTIC ANEURYSM | 1(1.0%) |
| AORTIC STENOSIS | 1(1.0%) |
| CIRCULATORY COLLAPSE | 2(2.0%) |
| HAEMATOMA NOS | 16(16.0%) |
| HAEMORRHAGE NOS | 1(1.0%) |
| HYPERTENSION NOS | 8(8.0%) |
| HYPERTENSIVE ENCEPHALOPATHY | 1(1.0%) |
| HYPOTENSION NOS | 7(7.0%) |
| ORTHOSTATIC HYPOTENSION | 3(3.0%) |
| PERIPHERAL COLDNESS | 1(1.0%) |
| VASCULAR PSEUDOANEURYSM | 1(1.0%) |

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* Of note, patient 235-016 experienced two adverse events of lung adenocarcinoma and lung neoplasm.
NOS - Not Otherwise Specified.
NOTE: AEs missing event dates are included in this listing.
N = The maximum number of eligible patients, n = The number of patients with evaluable data.
Denominators indicate the total number of patients with available data for related parameters.
This table is stratified via System Organ Class and Preferred Term using MedDRA Version 5.0.

## Table 7b. Adverse Events by Site (to 1440 Days)

| Site | ENDEAVOR I |
|---|---|
| 233 | 11.5% (66/573) |
| 234 | 21.1% (121/573) |
| 235 | 19.5% (112/573) |
| 237 | 22.7% (130/573) |
| 238 | 19.5% (112/573) |
| 239 | 0.5% (3/573) |
| 240 | 3.7% (21/573) |
| 241 | 1.4% (8/573) |

Denominator indicates the total number of Adverse Events

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## Table 8a. Serious Adverse Events (to 1440 Days)

| Serious Adverse Events (to 1440 Days) | ENDEAVOR I (N= 100 Patients) |
|---|---|
| *TOTAL* | *51.0% (51/100)* |
| *CARDIAC DISORDERS* | *22(22.0%)* |
| ANGINA PECTORIS | 14(14.0%) |
| ARRHYTHMIA NOS | 1(1.0%) |
| ATRIAL FIBRILLATION | 2(2.0%) |
| ATRIOVENTRICULAR BLOCK COMPLETE | 1(1.0%) |
| BRADYCARDIA NOS | 3(3.0%) |
| CORONARY ARTERY DISSECTION | 1(1.0%) |
| CORONARY ARTERY OCCLUSION | 1(1.0%) |
| CORONARY ARTERY STENOSIS | 2(2.0%) |
| CORONARY ARTERY THROMBOSIS | 1(1.0%) |
| EXTRASYSTOLES NOS | 1(1.0%) |
| MYOCARDIAL INFARCTION | 3(3.0%) |
| PALPITATIONS | 1(1.0%) |
| SINUS BRADYCARDIA | 1(1.0%) |
| VENTRICULAR FIBRILLATION | 1(1.0%) |
| VENTRICULAR TACHYCARDIA | 1(1.0%) |
| *EAR AND LABYRINTH DISORDERS* | *1(1.0%)* |
| LABYRINTHITIS NOS | 1(1.0%) |
| *EYE DISORDERS* | *1(1.0%)* |
| CATARACT | 1(1.0%) |
| GLAUCOMA NOS | 1(1.0%) |
| *GASTROINTESTINAL DISORDERS* | *4(4.0%)* |
| ABDOMINAL PAIN NOS | 1(1.0%) |
| APPENDIX DISORDER NOS | 1(1.0%) |
| RECTAL HAEMORRHAGE | 1(1.0%) |
| RETROPERITONEAL HAEMORRHAGE | 1(1.0%) |
| *GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS* | *14(14.0%)* |
| CHEST PAIN | 8(8.0%) |
| DEATH NOS | 1(1.0%) |
| FALL | 1(1.0%) |
| GENERAL PHYSICAL HEALTH DETERIORATION | 1(1.0%) |
| INJECTION SITE HAEMORRHAGE | 1(1.0%) |
| MALAISE | 1(1.0%) |
| PAIN NOS | 1(1.0%) |
| *HEPATOBILIARY DISORDERS* | *2(2.0%)* |
| CHOLECYSTITIS ACUTE NOS | 1(1.0%) |
| CHOLECYSTITIS CHRONIC NOS | 1(1.0%) |
| JAUNDICE NOS | 1(1.0%) |
| *INFECTIONS AND INFESTATIONS* | *5(5.0%)* |
| LOWER RESPIRATORY TRACT INFECTION NOS | 1(1.0%) |
| PNEUMONIA NOS | 2(2.0%) |
| PYELONEPHRITIS NOS | 1(1.0%) |
| RESPIRATORY TRACT INFECTION NOS | 1(1.0%) |
| UPPER RESPIRATORY TRACT INFECTION NOS | 1(1.0%) |
| *INJURY, POISONING AND PROCEDURAL COMPLICATIONS* | *3(3.0%)* |
| RADIUS FRACTURE | 1(1.0%) |
| STENT OCCLUSION | 2(2.0%) |
| *INVESTIGATIONS* | *1(1.0%)* |
| ARTHROSCOPY | 1(1.0%) |
| CAROTID BRUIT | 1(1.0%) |
| *MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS* | *3(3.0%)* |
| BACK PAIN | 1(1.0%) |

## Table 8a. Serious Adverse Events (to 1440 Days) (Continued)

| Serious Adverse Events (to 1440 Days) | ENDEAVOR I (N= 100 Patients) |
|---|---|
| CHEST WALL PAIN | 1(1.0%) |
| LOCALISED OSTEOARTHRITIS | 1(1.0%) |
| *NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)* | *5(5.0%)* |
| BLADDER CANCER NOS | 1(1.0%) |
| BLADDER NEOPLASM NOS | 1(1.0%) |
| BRAIN NEOPLASM NOS | 1(1.0%) |
| LUNG CANCER STAGE UNSPECIFIED (EXCL METASTATIC TUMOURS TO LUNG) | 1(1.0%) |
| MALIGNANT MELANOMA | 1(1.0%) |
| MALIGNANT MELANOMA SITE/STAGE UNSPECIFIED | 1(1.0%) |
| *NERVOUS SYSTEM DISORDERS* | *3(3.0%)* |
| CAROTID ARTERY STENOSIS | 1(1.0%) |
| CEREBROVASCULAR ACCIDENT | 1(1.0%) |
| DIZZINESS | 1(1.0%) |
| *RENAL AND URINARY DISORDERS* | *4(4.0%)* |
| HAEMATURIA | 1(1.0%) |
| RENAL COLIC | 1(1.0%) |
| URINARY RETENTION | 2(2.0%) |
| *REPRODUCTIVE SYSTEM AND BREAST DISORDERS* | *2(2.0%)* |
| EPIDIDYMO-ORCHITIS NOS | 1(1.0%) |
| HYDROCELE | 1(1.0%) |
| *RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS* | *4(4.0%)* |
| DYSPNOEA EXACERBATED | 1(1.0%) |
| DYSPNOEA EXERTIONAL | 1(1.0%) |
| DYSPNOEA NOS | 1(1.0%) |
| NASAL OBSTRUCTION | 1(1.0%) |
| *SKIN AND SUBCUTANEOUS TISSUE DISORDERS* | *2(2.0%)* |
| ANGIONEUROTIC OEDEMA | 1(1.0%) |
| RASH GENERALISED | 1(1.0%) |
| *SURGICAL AND MEDICAL PROCEDURES* | *18(18.0%)* |
| CORONARY ARTERY SURGERY | 3(3.0%) |
| CORONARY REVASCULARISATION | 14(14.0%) |
| HEART VALVE REPLACEMENT NOS | 1(1.0%) |
| HIP ARTHROPLASTY | 2(2.0%) |
| *VASCULAR DISORDERS* | *7(7.0%)* |
| AORTIC STENOSIS | 1(1.0%) |
| CIRCULATORY COLLAPSE | 2(2.0%) |
| HYPERTENSION AGGRAVATED | 1(1.0%) |
| HYPERTENSIVE ENCEPHALOPATHY | 1(1.0%) |
| ORTHOSTATIC HYPOTENSION | 1(1.0%) |
| VASCULAR PSEUDOANEURYSM | 1(1.0%) |

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NOS - Not Otherwise Specified.
NOTE: SAEs missing event dates are included in this listing.
N = The maximum number of eligible patients, n = The number of patients with evaluable data.
Denominators indicate the total number of patients with available data for related parameters.
This table is stratified via System Organ Class and Preferred Term using MedDRA Version 5.0.

## Table 8b. Serious Adverse Events by Site (to 1440 Days)

| Site | ENDEAVOR I |
|---|---|
| 233 | 14.6% (19/130) |
| 234 | 14.6% (19/130) |
| 235 | 24.6% (32/130) |
| 237 | 31.5% (41/130) |
| 238 | 10.0% (13/130) |
| 240 | 4.6% (6/130) |

Denominator indicates the total number of Serious Adverse Events

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## Table 9. Site Reported Major Adverse Events to 1440 days (ITT)

| Complications | ENDEAVOR I (N=100 Patients) |
|---|---|
| MACE (Death, Emergent CABG, MI, TLR) | 10.0% (10/100) |
| Death | 4.0% (4/100) |
| Emergent CABG | 1.0% (1/100) |
| MI | 3.0% (3/100) |
| Q-Wave | 0.0% (0/100) |
| Non Q-Wave | 3.0% (3/100) |
| TLR | 3.0% (3/100) |
| TVR not involving the Target Lesions | 4.0% (4/100) |
| Major Bleeding Events | 0.0% (0/100) |
| Major Vascular Events | 0.0% (0/100) |

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N = the maximum number of eligible patients, Denominators indicate the total number of patients with available data for related parameter. Among the 10 MACEs that were reported by sites, 7 of them were adjudicated as MACE by the CEC. Some events are triggered for CEC adjudications by data other than site-reported MAEs.

## Table 10. Medication - Anti-coagulants Use

| Anti-coagulant | ENDEAVOR I (N=100 Patients) |
|---|---|
| **Pre-Procedure** | |
| Aspirin | 91.0% (91/100) |
| Clopidogrel | 90.0% (90/100) |
| Ticlopidine | 0.0% (0/100) |
| **During Procedure** | |
| Clopidogrel | 6.0% (6/100) |
| Ticlopidine | 0.0% (0/100) |
| **Post-Procedure** | |
| Aspirin | 86.0% (86/100) |
| Clopidogrel | 86.0% (86/100) |
| Ticlopidine | 0.0% (0/100) |
| Aspirin and Clopidogrel/Ticlopidine | 85.0% (85/100) |
| **At Discharge** | |
| Aspirin | 100.0% (100/100) |
| Clopidogrel | 100.0% (100/100) |
| Ticlopidine | 0.0% (0/100) |
| IIb/IIIa Inhibitors | 0.0% (0/100) |
| Aspirin and Clopidogrel/Ticlopidine | 100.0% (100/100) |
| **At 30-Days** | |
| Aspirin | 100.0% (100/100) |
| Clopidogrel | 99.0% (99/100) |
| Ticlopidine | 1.0% (1/97) |
| Aspirin and Clopidogrel/Ticlopidine | 99.0% (99/100) |
| **At 4-Month** | |
| Aspirin | 98.0% (98/100) |
| Clopidogrel | 92.0% (92/100) |
| Ticlopidine | 1.0% (1/100) |
| Aspirin and Clopidogrel/Ticlopidine | 90.0% (90/100) |
| **At 9-Month** | |
| Aspirin | 96.0% (95/99) |
| Clopidogrel | 14.0% (14/100) |
| Ticlopidine | 0.0% (0/100) |
| Aspirin and Clopidogrel/Ticlopidine | 13.0% (13/100) |
| **At 12-Month** | |
| Aspirin | 97.0% (96/99) |
| Clopidogrel | 14.1% (14/99) |
| Ticlopidine | 0.0% (0/99) |
| Aspirin and Clopidogrel/Ticlopidine | 13.1% (13/99) |
| **At 2-Years** | |
| Aspirin | 94.8% (92/97) |
| Clopidogrel | 11.5% (11/96) |
| Ticlopidine | 0.0% (0/95) |
| Aspirin and Clopidogrel/Ticlopidine | 9.3% (9/97) |
| **At 3-Years** | |
| Aspirin | 94.7% (89/94) |
| Clopidogrel | 7.4% (7/94) |
| Ticlopidine | 0.0% (0/94) |
| Aspirin and Clopidogrel/Ticlopidine | 5.3% (5/95) |
| **At 4-Years** | |
| Aspirin | 95.7% (88/92) |
| Clopidogrel | 11.8% (11/93) |
| Ticlopidine | 1.1% (1/93) |
| Aspirin and Clopidogrel/Ticlopidine | 9.7% (9/93) |

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N = The maximum number of eligible patients, n = The number of patients with evaluable data.
Denominators indicate the total number of patients with available data for related parameter.

## Figure 1. Survival Free from MACE at 1440 Days (ITT)

| MACE | 0 | 180 | 360 | 540 | 720 | 900 | 1080 | 1260 | 1440 |
|---|---|---|---|---|---|---|---|---|---|
| # Entered | 100 | 100 | 98 | 97 | 96 | 96 | 94 | 92 | 92 |
| # Censored | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 |
| # Incomplete | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| # Events | 0 | 2 | 0 | 1 | 0 | 1 | 2 | 0 | 1 |
| % Survived | 100.0% | 98.0% | 98.0% | 97.0% | 97.0% | 96.0% | 93.9% | 93.9% | 92.9% |
| SE | 0.0% | 1.4% | 1.4% | 1.7% | 1.7% | 2.0% | 2.4% | 2.4% | 2.6% |
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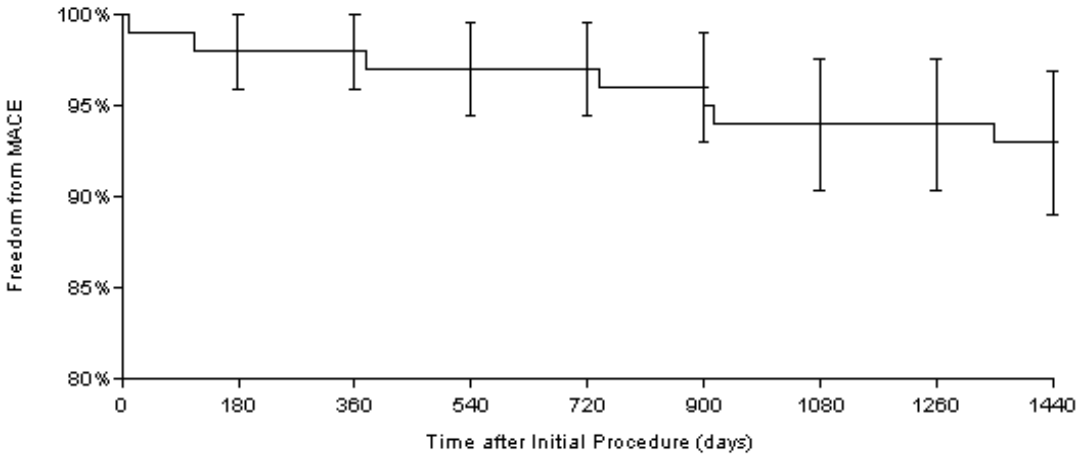

**Figure 2. Survival Free from Target Lesion Revascularization Event at 1440 Days (ITT)**

| TLR | 0 | 180 | 360 | 540 | 720 | 900 | 1080 | 1260 | 1440 |
|---|---|---|---|---|---|---|---|---|---|
| # Entered | 100 | 100 | 97 | 96 | 95 | 95 | 93 | 91 | 91 |
| # Censored | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 1 |
| # Incomplete | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 1 |
| # Events | 0 | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| % Survived | 100.0% | 98.0% | 98.0% | 98.0% | 98.0% | 98.0% | 96.9% | 96.9% | 96.9% |
| SE | 0.0% | 1.4% | 1.4% | 1.4% | 1.4% | 1.4% | 1.8% | 1.8% | 1.8% |
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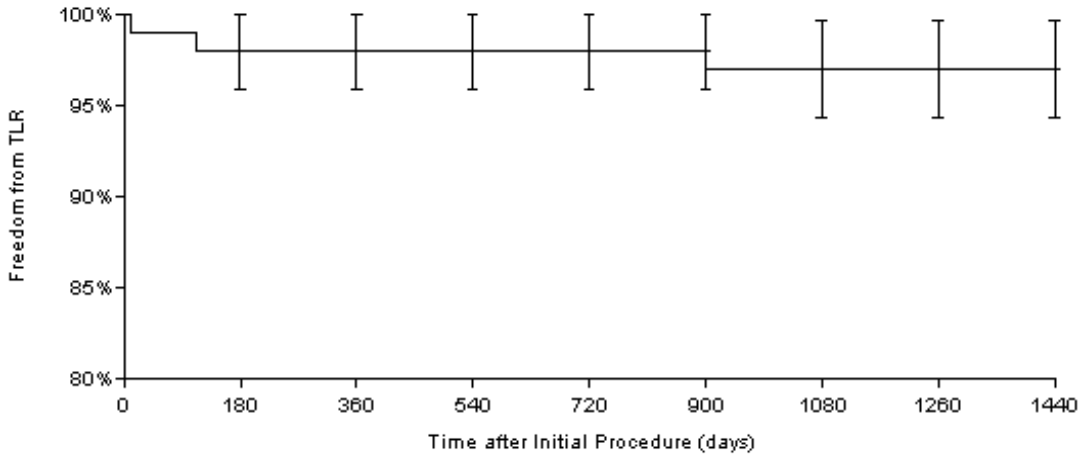

**Figure 3. Survival Free from Target Vessel Failure Event at 1440 Days (ITT)**

| TVF | 0 | 180 | 360 | 540 | 720 | 900 | 1080 | 1260 | 1440 |
|---|---|---|---|---|---|---|---|---|---|
| # Entered | 100 | 100 | 98 | 97 | 94 | 94 | 92 | 90 | 90 |
| # Censored | 0 | 0 | 1 | 1 | 0 | 2 | 1 | 0 | 2 |
| # Incomplete | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| # Events | 0 | 2 | 0 | 2 | 0 | 0 | 1 | 0 | 0 |
| % Survived | 100.0% | 98.0% | 98.0% | 96.0% | 96.0% | 96.0% | 94.9% | 94.9% | 94.9% |
| SE | 0.0% | 1.4% | 1.4% | 2.0% | 2.0% | 2.0% | 2.3% | 2.3% | 2.3% |
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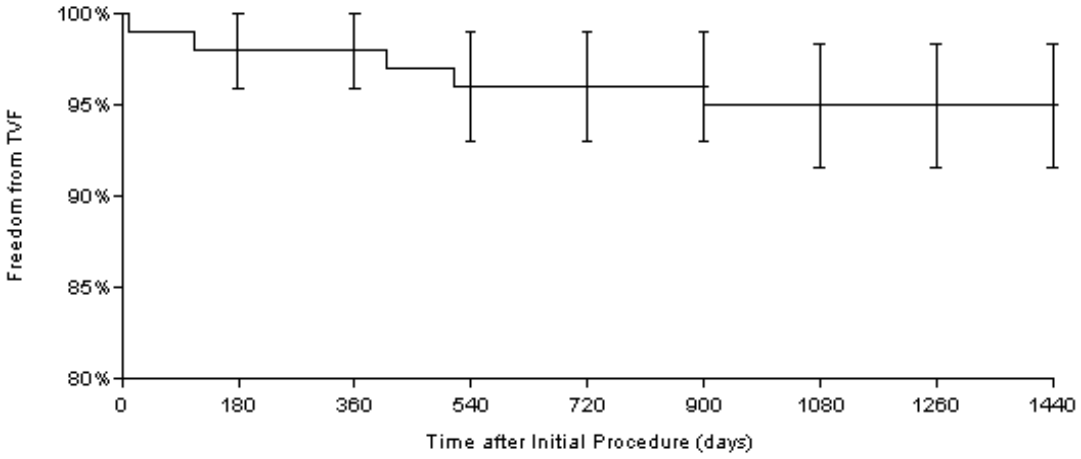

**Figure 4. Survival Free from Target Vessel Revascularization Event at 1440 Days (ITT)**

| TVR | 0 | 180 | 360 | 540 | 720 | 900 | 1080 | 1260 | 1440 |
|---|---|---|---|---|---|---|---|---|---|
| # Entered | 100 | 100 | 98 | 97 | 94 | 94 | 92 | 90 | 90 |
| # Censored | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 |
| # Incomplete | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 1 |
| # Events | 0 | 2 | 0 | 2 | 0 | 0 | 1 | 0 | 0 |
| % Survived | 100.0% | 98.0% | 98.0% | 96.0% | 96.0% | 96.0% | 94.9% | 94.9% | 94.9% |
| SE | 0.0% | 1.4% | 1.4% | 2.0% | 2.0% | 2.0% | 2.3% | 2.3% | 2.3% |
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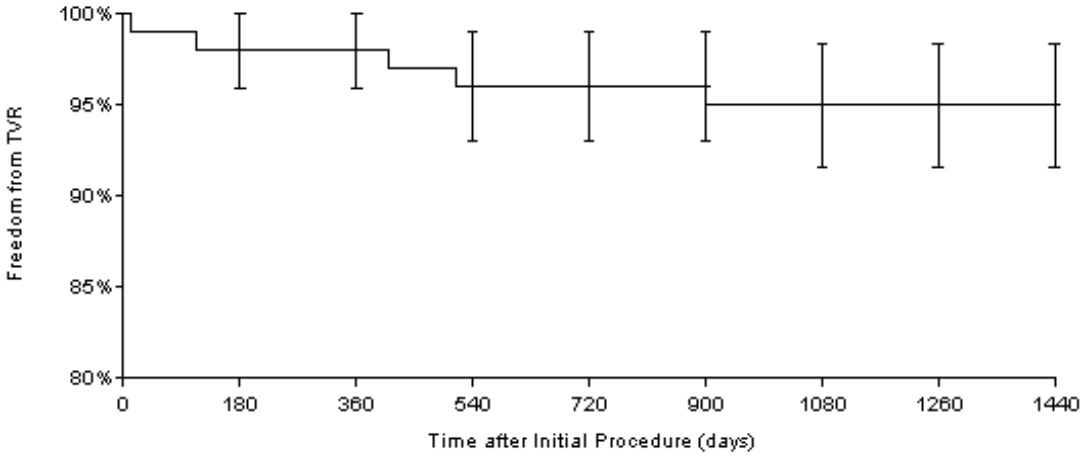

## Table 11. Summary of Device Performance

| Malfunction Description | ENDEAVOR I |
|---|---|
| **Any delivery issue** | **0** |
| Never delivered | 0 |
| Delivery malfunction, subsequent success[1] | 0 |
| Delivery malfunction after initial success | 0 |
| **Other Performance Issues** | **1** |
| Stent compression | 1 |
| **Outcome if Treatment Never Delivered** | **0** |
| Proximal Deployment | 0 |
| Embolization | 0 |
| Dislodgement | 0 |
| Misplacement | 0 |
| **Treatment** | **0** |
| PTCA only | 0 |
| Use of other devices outside assigned strategy | 0 |

[1] At least one device deployed but not successfully.

**Table 12. Narrative Summaries of Device Performance Narratives**

| | Case Summary |
|---|---|
| | **Device Performance–Stent Compression** |
| | The patient is a 58 year-old man with a history of current smoking, dyslipidemia and a MI in 1/2003 who presented with CCS Class IV angina and a positive functional ischaemia study. On 2/24/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by successful delivery of the Medtronic AVE Driver Coronary Stent system in the mid RCA. Post-treatment IVUS was performed and two pullbacks were done; one with the wire in place and one with the wire withdrawn. Following the ultrasound examination, the operator encountered difficulty withdrawing the IVUS catheter. Further angiography revealed a "compression" or "concertinaing" of the stent distally. It was presumed that the IVUS catheter had caught on the distal end of the stent. Additional balloon inflations were performed using 2 mm, 2.5 mm and 3.5 mm balloons. A second Driver stent was then delivered to the distal part of the lesion and across the primary stent and, overlapping the stent, was deployed at 16 atm. An attempt to perform additional IVUS examination was abandoned after difficulty was again encountered trying to pass the catheter across the stents. The procedure was terminated. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis, no dissection and TIMI 3 flow with comment "the first stent deformed after IVUS." The post-index procedure course was uncomplicated and the patient was discharged on 2/25/2003 on ASA and clopidogrel. |

## Table 13. Narrative Summaries of Major Adverse Events

The narratives presented below are sorted by patient ID in the hierarchical order of MACE (Cardiac Death, Non-Cardiac Death, Q wave MI, Non-Q wave MI, Emergent CABG, Target Lesion Revascularization). All deaths regardless of time from procedure are reported.

Cerebrovascular Accidents have also been narrated for this study; these narratives are presented at the end of this section.

| Site | Patient | Summary |
|---|---|---|
| | | **Non-cardiac Death 1351 days post-procedure**<br>The patient was a 66 year old man with a history of MI on 01/22/2003 and dyslipidemia who presented with MI. On 03/03/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by successful delivery of one ENDEAVOR DES in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the mid LAD with a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and he was discharged on 03/04/2003 on ASA and clopidogrel. The site reported the patient was diagnosed with lung cancer in December 2005. He underwent chemotherapy and had two hospitalizations in June and October 2006 related to the cancer. The site reported the patient was referred for palliative care in June 2006 and died at home on 11/13/2006. The official cause of death was reported as lung carcinoma and the categorical cause of death was non-cardiac. No autopsy was performed. |
| | | **Non-cardiac Death 379 days post-procedure**<br>The patient was a 68 year-old man with a history of current smoking who presented with unstable angina, CCS Class unknown. On 03/27/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by successful delivery of one ENDEAVOR DES in the mid LAD. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/28/2003 on ASA and clopidogrel. On 10/14/2003 the patient was diagnosed with a brain tumor and on 10/20/2003 he underwent a craniotomy with excision of the tumor and was discharged on 10/24/2003. The patient was rehospitalized on 03/07/2004 after collapsing. A narrative indicates the patient was transferred to the Palliative Care Unit on 03/21/2004 for general deterioration of his condition relating to the pre-existing brain tumor and he expired on 04/09/2004. The Death Certificate reported metastatic melanoma as the cause of death. |

**Summary**

**Non-cardiac Death 916 days post-procedure**

The patient was a 45 year old man with a history of current smoking, diabetes, dyslipidemia, hypertension and a MI on 03/13/2003 who presented with MI and a positive functional ischemia study. On 03/21/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by successful delivery of one ENDEAVOR DES in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and he was discharged on 03/22/2003 on ASA and clopidogrel. The site reported the patient died on 09/22/2005 and noted that no autopsy was performed. The Death Certificate listed the cause of death as metastatic adenocarcinoma.

**Non-cardiac Death 740 days post-procedure**

The patient was a 52 year-old man with a history of dyslipidemia, hypertension, CAD in a 1st degree relative, previous PTCA of a non-target vessel and a MI on 09/13/2002 who presented with CCS Class II stable angina and a positive functional ischemia study. On 03/03/2003 he underwent the index procedure with pre-treatment balloon angioplasty and severe spasm was noted at the site of stenosis according to the Cardiac Catheterization Report. This was treated with prolonged balloon inflation, which resulted in a distal grade C dissection. One ENDEAVOR DES was successfully delivered to the distal CX and a second study stent was placed proximal to and overlapping the first study stent. The stent was post-dilated and IVUS was performed. The Angiographic Core Lab reported a 5% final residual in-lesion stenosis with no dissection and TIMI 3 flow. During suturing of the access site, the patient experienced a vasovagal “sinus arrest” and sinus bradycardia which was treated successfully with atropine and IV fluids and he was discharged on 03/04/2003 on ASA and clopidogrel. On 02/14/2005 the patient was rehospitalized and diagnosed with “invasive carcinoma” of the bladder and esophageal cancer with stricture. He was discharged on 02/17/2005 with medication to control his symptoms. On 02/24/2005 the patient was urgently admitted for abnormal liver function tests, jaundice, and vomiting. The site reported the patient's condition deteriorated and he subsequently died on 03/12/2005 at 17:45. No autopsy was performed and the site reported the official cause of death was small cell carcinoma of the bladder.

| Site | Patient | Summary |
|---|---|---|
| | | **Non-Q wave MI, Subacute Closure/Stent Thrombosis 10 days post-procedure, Target Lesion Revascularization–PTCA 11 days post-procedure, Target Lesion Revascularization–CABG 17 days post-procedure**<br>The patient is a 48 year-old man with a history of hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 03/31/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by successful delivery of the ENDEAVOR DES System in the mid RCA. The stent was post-dilated. During IVUS pullback imaging, the patient complained of chest pain. The site reported ST changes and a drop in the patient's heart rate. This episode resolved after treatment with nitroglycerin, morphine, naloxone and oxygen. The Angiographic Core Lab reported a 12% final residual stenosis with a grade B dissection with staining, no thrombus and TIMI 3 flow. There was no enzymatic evidence of MI. The ECG Core Lab reported a new sinus arrhythmia, no major new ST-T abnormalities and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 04/01/2003 on ASA and clopidogrel. The patient presented by ambulance to an outlying hospital on 04/07/2003 at 1:30 pm with severe chest pain. He was treated with morphine while enroute. A CK level drawn on 04/07/2003 at 2 pm was 67 with no CKMB measured. A second CK drawn at 5:40 pm was 91 (nl 174, ratio <1). The CKMB was not measured. No further CK or CKMB levels were reported between 04/07/2003 - 04/09/2003. The troponin level reportedly peaked at 8.3 (nl 0.5, ratio 16.6). On 04/09/2003 the troponin level decreased to 2.9 (nl 0.5, ratio 5.8). On 04/10/2003 the patient experienced recurrent chest pain. The troponin level increased to 7.5 (nl 0.5, ratio 15) with a CK of 195 (nl 174, ratio 1.1). On 04/10/2003, while still experiencing chest pain, the patient was transferred to the enrolling hospital for further management. The patient arrived at the enrolling hospital with site reported ST-T abnormalities noted on the ECG. He was treated with IV Streptokinase and on 04/11/2003 underwent emergent repeat angiography with administration of abciximab. Repeat angiography revealed a site reported subtotal occlusion “below stent with thrombus in RCA.” The cardiac catheterization report noted balloon angioplasty was performed with no change in flow secondary to heavy thrombus. He returned to the cath lab later on 04/11/2003 for further angiography. The site reported a subtotal occlusion of the RCA, a spastic vessel with a thrombus at the distal end of stent reported on the cardiac catheterization report. The Angiographic Core Lab analyzed the repeat angiography performed on 04/11/2003 and reported a 57% in-stent renarrowing with no thrombus and TIMI 1 flow. Intravenous heparin and tirofiban infused over the weekend. On 04/12/2003 the CK peaked at 543 (nl 190, ratio 2.9) with a non-concurrent peak CKMB of 49.5 (nl 9.3, ratio 5.3) on 04/11/2003. The ECG Core Lab reviewed ECG tracings from 04/07/2003 to 04/11/2003 and reported new major persistent inferoposterior ST elevations and no new Q waves and noted that the tracing was inadequate with severe artifact and with left arm and left leg leads interchanged on 04/11/2003 at 00:25. Repeat angiography on 04/15/2003 revealed site reported a subtotal occlusion below the stent with “probable long spiral off end of stent (dissection with thrombus).” The Angiographic Core Lab reported a 67% in-stent renarrowing with no thrombus and TIMI 1 flow. The decision was made to proceed with CABG surgery which was scheduled for within the week. Heparin, tirofiban and clopidogrel were discontinued. On 04/17/2003 the patient underwent CABG surgery of the R-PDA, the mid LAD and the 1st OM. The CEC requested a re-read of the 04/11/2003 angiography and the revised Angiographic Core Lab report noted no thrombus and it withdrew the comment “attempted TVR” and added “no target vessel revascularization attempted.” |

| Site | Patient | Summary |
|---|---|---|
| | | **Target Vessel Revascularization–CABG 515 days post-procedure**<br>The patient is a 64 year old man with a history of current smoking, dyslipidemia, and hypertension who presented with CCS Class I unstable angina. On 02/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS, and the successful delivery of one ENDEAVOR DES in the mid LAD. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/18/2003 on ASA and clopidogrel. Protocol re-study on 02/16/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 33% in-lesion restenosis reported by the Angiographic Core Lab. In a narrative the site reported a "patent" mid LAD stent and an 80% ostial lesion. The patient was placed on a waiting list for bypass surgery. On 07/16/2004 he underwent elective off-pump CABG surgery with a LIMA to the proximal LAD and was discharged on 07/20/2004. |
| | | **Target Lesion Revascularization–PTCA 112 days post-procedure**<br>The patient is a 74 year-old man with a history of dyslipidemia, hypertension, premature CAD in a first degree relative, a percutaneous revascularization in the target vessel, and a MI in November 1995 who presented with CCS Class I stable angina. On 04/01/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by successful delivery of one ENDEAVOR DES in the proximal RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/02/2003 on ASA and clopidogrel. On 07/20/2003 the patient was rehospitalized at an outlying hospital with a site reported non-Q wave MI. The CK peaked at 102 (nl 220, ratio <1) and the CKMB was not measured. The cardiac catheterization report indicated the patient had a significant troponin rise and inferolateral ECG changes. The peak troponin T reported was 0.16 (nl 0.03, ratio 5.3). The ECG Core Lab reported new major intermittent inferolateral ST depressions, inferior anterolateral/apical T wave inversions, and no new Q waves. After review of the findings the CEC ruled the event did not meet the criteria for the Protocol's definition for MI. Repeat angiography on 07/22/2003 for recurrent angina without a functional ischemia study revealed a 79% in-stent restenosis reported by the Angiographic Core Lab. The patient underwent successful balloon angioplasty and placement of an Express2™ stent in the proximal RCA |

| | Summary |
|---|---|
| | **Target Lesion Revascularization–PTCA 901 and 1294 days post-procedure**<br>The patient is a 60 year-old woman with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class III unstable angina. On 02/20/2003 she underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by successful delivery of one ENDEAVOR DES in the mid LAD. A second study stent was placed proximal to and overlapping the first stent for a site reported bailout. The stent was post-dilated. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/21/2003 on ASA and clopidogrel. On 08/05/2005 patient was rehospitalized for chest pain and shortness of breath. A Discharge Report noted that repeated troponin levels were negative and there were no ECG changes. Repeat angiography on 08/09/2005 for recurrent clinical symptoms and without a positive functional ischemia study revealed a 69% proliferative in-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with cutting balloon angioplasty of the mid LAD. Repeat angiography on 09/06/2006 for recurrent clinical symptoms and without a positive functional ischemia study revealed a 66% proliferative in-stent restenosis reported by the Angiographic Core Lab with the notation in-stent and distal edge in-stent restenosis, target lesion revascularization. The site reported a 99% stenosis of the target lesion. The patient underwent repeat revascularization with a drug eluting stent placed in the mid LAD. |
| | **Target Vessel Revascularization–PTCA 409 days post-procedure**<br>The patient is a 72 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class II unstable angina and a positive functional ischemia study. On 03/28/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by successful delivery of one ENDEAVOR DES in the proximal LAD. The stent was post-dilated. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/30/2003 on ASA and clopidogrel. On 05/10/2004 the patient was rehospitalized for “ongoing” left sided chest pain. Repeat angiography on 05/10/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 27% in-lesion restenosis reported by the Angiographic Core Lab with the notation “PCI for mid LAD lesion, remote target vessel revascularization, study stent patent.” The patient underwent repeat revascularization with balloon angioplasty and placement of a Taxus™ stent in the mid LAD. |

| Site | Patient | Summary |
|---|---|---|
| | | **CVA 452 days post-procedure**<br>The patient is a 70 year-old man with a history of dyslipidemia and a MI on 03/29/2003 who presented with MI and a positive functional ischemia study. On 04/07/2003 he underwent the index procedure pre-treatment balloon angioplasty, IVUS, and the successful delivery of one ENDEAVOR DES in the mid RCA. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/08/2003 on ASA and clopidogrel. On 07/02/2004 the patient complained of a gradual onset of a parietal, vertex and frontal headache. On 07/05/2004 blurred vision developed and he consulted with an optometrist who documented left homonymous hemianopia according to a narrative. The site reported the patient was still taking ASA. On 07/07/2004 the patient was transferred to the investigational institution and a CT showed a "wedge-shaped hypodense lesion" in the right occipital region which was consistent with a cerebral infarction and he was diagnosed with a non-hemorrhagic CVA and was discharged on 07/09/2004. The visual symptoms subsided and subsequently resolved after a few weeks. |

## Listing 1. Detailed Patient Listing

**Listing 1. Detailed Patient Listing (Continued)**

# Appendix A: Methods for Qualifying Angiograms

**Ascertainment of Qualifying Angiograms**

1. Identify patients in the angiographic subset.
2. Identify experimental lesions in the angiographic subset; discard non-experimental lesions:
    a. Compare post and pre films to see if the CASS numbers match;
    b. Compare the FU with baseline. If any CASS numbers do not match, then issue query and await resolution.
3. Reconcile duplicate QCA readings or inappropriate QCA readings (e.g., follow-up reads on baseline CRF's). The angiographic core laboratory will receive queries regarding duplicate or inappropriate QCA readings. Once the readings are reconciled, the duplicate or inappropriate readings will be discarded.
4. Perform all analyses as lesion-based, NOT patient or vessel-based.
5. Exemptions from Angiographic F/U:
    a. Intent to Treat analyses:
        i. Peri-procedural CABG (within 14 days);
        ii. Death before F/U QCA due in the absence of a qualifying angiogram.
    b. Per-protocol analyses:
        i. Patients who withdraw consent for further follow-up, including angiograms;
        ii. Lesion never successfully treated with assigned device strategy.
6. Define the upper window that will be acceptable for qualifying angiograms:
    a. One Hundred Eighty (180) days for 4-month follow-up;
    b. Four Hundred Eighty (480) days for 12-month follow-up.
7. All QCA ≤ 14 days post-procedure and instances of subacute closure will not be included for analysis of restenosis.
8. All QCA after any TVR (clinically indicated or NOT) that occurs >14 days post-procedure are censored; TVR changes natural history of the lesion. TVRs occurring within the first 14 days post-procedure should NOT be used for excluding subsequent QCA's (unless it's a CABG, which exempts the patient).
9. Define a date cut-off as the earliest acceptable date for qualifying angiograms:
    a. Ninety (90) days for 4-month follow-up and Two Hundred Seventy (270) days for 12-month follow-up.
    b. If QCA between days 15-90 days for 4-month follow-up or between 15-270 days for 12-month follow-up and in-segment QCADS ≥70%, angiogram qualifies as restenosis.
    c. If QCA between days 15-90 days for 4-month follow-up or between 15-270 days for 12-month follow-up and in-segment QCADS <50% and NO clinically-driven TLR occurred within a reasonable time window (vide infra), the angiogram is censored.
    d. If QCA between days 15-90 days for 4-month follow-up or between 15-270 days for 12-month follow-up and in-segment QCADS <50% but is associated with a TLR that the CEC has deemed clinically-driven (despite the fact that the QCADS <50%), then this angiogram should be considered *qualified* and should NOT be censored. This lesion will have undergone a clinically-driven TLR in the absence of angiographic restenosis.
    e. If QCA between days 15-90 days for 4-month follow-up or 15-270 days for 12-month follow-up and in-segment QCADS 50-69.9% and a TVR (clinically indicated or NOT) occurs within a reasonable time window (e.g., 30 days after the QCA), the angiogram qualifies as restenosis.
    f. If QCA between days 15-90 days for 4-month follow-up or 15-270 days for 12-month follow-up and QCADS 50-69.9% and NO TVR occurs within a reasonable time window, the angiogram is censored.
10. In case of multiple qualifying angiograms, first take the one associated with TVR and/or TLR, whichever occurs first, then use the one closest to the follow up date, and then take the latest one (to allow for vessel remodeling).
11. If a QCA has an in-lesion diameter stenosis which qualifies (e.g., in-lesion DS 53% with TVR at day 60), then the entire angiogram should qualify, even if the in-stent diameter stenosis <50%.
12. If the in-lesion MLD is 0 (total occlusion) upstream (proximal to) the experimental stent, then the in-stent MLD should be set to zero. The two situations where in-stent MLD is not zero even if in-lesion MLD is zero are in cases where no stent was deployed during the index procedure or where the total occlusion is distal to the stent (in which case the in-stent MLD should be available and >0).

# APPENDIX 2

# Endeavor II 36 Month Report

## (Listing 1. Detailed Patient Listing was Provided Electronically to FDA)

# A Randomized Controlled Trial to Evaluate the Safety and Efficacy of the Medtronic AVE* ABT-578 Eluting DRIVER Coronary Stent[§] in *De Novo* Native Coronary Artery Lesions

## The ENDEAVOR II Study
## Clinical Study Report (Index Procedure through 1080 Days)

| | |
|---|---|
| Sponsor: | Medtronic Vascular, Inc.<br>Santa Rosa, CA518 |
| | Medtronic Bakken Research Center<br>The Netherlands |
| Investigators: | Dr. J. Fajadet<br>France |
| | Dr. W. Wijns<br>Belgium |
| Data Coordinating Center: | HCRI (Harvard Clinical Research Institute)<br>Boston, MA |
| QCA Core Laboratory: | Brigham and Women's Angiographic Core Laboratory<br>Boston, MA |
| ECG Core Laboratory: | ECG and Arrhythmia Core Laboratory<br>HCRI (Harvard Clinical Research Institute)<br>Boston, MA |
| IVUS Core Laboratory: | Stanford University Cardiovascular Core Analysis Lab<br>Stanford, CA |
| Report Prepared By: | HCRI (Harvard Clinical Research Institute)<br>Boston, MA |
| Date: | August 29, 2007 |
| Version: | 1.1 FINAL |

This report has undergone a quality control process at HCRI.

*Medtronic AVE is now Medtronic Vascular, Inc.
[§]Endeavor Zotarolimus-Eluting Coronary Stent System

# Table of Contents

## Section I. Structured Abstract

**Title:** A Randomized Controlled Trial to Evaluate the Safety and Efficacy of the Medtronic AVE ABT-578 Eluting DRIVER Coronary Stent in *De Novo* Native Coronary Artery Lesions.

**Design:** A prospective, multi-center, double-blind, two-arm randomized controlled trial to evaluate the safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System in subjects with *de novo* lesions of the native coronary arteries.

**Purpose:** To demonstrate the safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System coated with 10 µg/mm ABT-578 compared to the Driver Stent for the treatment of single *de novo* lesions in native coronary arteries 2.25-3.5 mm in diameter.

**Clinical Sites:** Seventy-two (72) study sites in Asia, Australia, Europe, Israel and New Zealand enrolled subjects into this trial.

**Enrollment:** One thousand one hundred and ninety-seven (1,197)[1] subjects with symptomatic ischaemic heart disease due to stenotic lesions of native coronary arteries with reference vessel diameters ≥2.25 mm and ≤3.5 mm and lesion lengths of ≥14 mm and ≤27 mm that were amenable to percutaneous treatment with stenting were enrolled in this trial. Subjects were randomized in a double-blind fashion (1:1 randomization) to one of two treatments: Driver Bare Metal Stent (Driver) or Endeavor Zotarolimus-Eluting Coronary Stent System (Endeavor).

**Methods:** Baseline clinical and angiographic data were collected on standardized case report forms by clinical study personnel at the study sites. Clinical follow-up for all subjects was performed at 30 days and at 270 days post-index procedure. Telephone follow-up occurred at 6-, 12-, 24- and 36-months and will occur annually thereafter out to 5 years. An independent Angiographic Core Laboratory and an independent IVUS Core Laboratory analyzed all baseline angiograms and IVUS images. Follow-up angiography was scheduled at 8 months for the first 600 consecutively enrolled patients. Angiographic films were qualified at follow-up based on the qualification scheme in Appendix B. IVUS evaluation occurred at 8 months post-index procedure as a sub-study at selected sites for 328 of the 600 angiographic follow-up patients. Additionally, blood sampling for up to 120 patients (for pharmacokinetic [PK] analysis as a sub-study at selected sites) was conducted by an independent third party prior to procedure and at 0.25 hr, 0.5 hr, 1 hr, 2 hr, 4 hr, 6 hr, 12 hr, 24 hr (or discharge, whichever came first) and at 7, 14 and 30 days post-index procedure. Clinical hematology and chemistry evaluation occurred at 24 hours, 30 days, and 270 days post-index procedure.

The primary endpoint for this trial was the target vessel failure (TVF) rate, defined as a composite of target vessel revascularization (TVR), recurrent Q wave or non-Q wave myocardial infarction (MI), or cardiac death that could not be clearly attributed to a vessel other than the target vessel at 270 days post index procedure.

[1] Four (4) of the 1,197 patients were randomized but did not undergo a procedure; the clinical study personnel did not collect data on these four (4) patients [redacted]). Thus, this report represents data on 1,193 patients.

The secondary endpoints for this trial included: MACE defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (TLR) at 30 days and 6, 9, 12, 24, and 36 months, and annually thereafter out to 5 years; lesion success is defined as attainment of <50% residual stenosis of the target lesion using any percutaneous method; device success is defined as attainment of <50% residual stenosis of the target lesion using only the assigned device; procedure success is defined as attainment of <50% residual stenosis of the target lesion and no in-hospital MACE; device-specific procedure success is defined as device success and no in-hospital MACE; late loss at 8 months as measured by QCA, is defined as the difference between the post-index procedure minimal lumen diameter (MLD) and the follow-up MLD; angiographic in-stent and in-segment binary restenosis rate (≥50% diameter stenosis) at 8 months post-index procedure; in-stent and in-segment minimum lumen diameter (MLD) at 8 months post-index procedure; neointimal hyperplastic volume at 8 months as measured by intravascular ultrasound (IVUS); TLR at 270 days post-index procedure; TVR at 270 days post-index procedure; pharmacokinetic assessment in a subset of subjects; and safety and tolerance.

**Demographics:** Of the 1,197 enrolled patients, treatment was attempted on 1,193. Baseline demographics and clinical characteristics showed a mean age of 61.58 years for patients in the Endeavor arm and 61.89 years for patients in the Driver arm (p=0.616). The Endeavor group had 77.2% (461/597) male enrollment and the Driver group had 75.3% (449/596) male enrollment (p=0.455). In the Endeavor arm, 21.7% (129/595) of patients had prior percutaneous coronary revascularization compared to 18.0% (107/594) of subjects in Driver (p=0.127). In the Endeavor group, 18.2% (108/595) of patients had a history of diabetes mellitus compared to 22.2% (132/595) of patients in the Driver group (p=0.096).

**Results:** The cumulative incidence of the primary endpoint of TVF at 270 days for Endeavor was 7.9% (47/592) and for Driver it was 15.1% (89/591) (p<0.001). The cumulative incidence of TLR at 270 days post-index procedure for Endeavor was 4.6% (27/592); for Driver it was 11.8% (70/591) (p<0.001).

In-hospital incidence of MACE was 2.5% (15/597) for patients in the Endeavor group and 2.9% (17/596) for patients in the Driver group. Incidence of MACE at 270 days was 7.3% (43/592) for patients in the Endeavor arm and 14.4% (85/591) for patients in the Driver arm (p<0.001).

The three year safety results were based on 96.6% (1156/1197) of patients with event data through 1080 days post-procedure or follow-up information beyond 1050 days post-procedure. At 1080 days, the cumulative incidence of MACE for the Endeavor patients was 12.0% (69/577) compared to the Driver patients which was 20.7% (120/579) (p<0.001). The Kaplan-Meier estimate of freedom from MACE at 1080 days for Endeavor patients was 88.3%; for Driver patients it was 79.6%. The Kaplan-Meier estimates of survival rates free from TLR and TVF at 1080 days was 92.8% and 87.4%, respectively for Endeavor and 85.4% and 78.9%, respectively for Driver. The treatment comparison p-values were <0.001 (log-rank test).

**Discussion of Results:**

This analysis of the ENDEAVOR II study reports 36-month results for the multi-center randomized comparison of the Endeavor Zotarolimus-Eluting Coronary Stent System coated with 10 μg/mm ABT-578 compared with the Driver Bare Metal Stent for the treatment of single *de novo* lesions in native coronary arteries 2.25-3.5 mm in diameter. The results include a summary of baseline patient and lesion characteristics, procedural device performance, acute angiographic outcomes, 30-day Major Adverse Cardiac Events (MACE), 8-month angiographic and intravascular ultrasound (IVUS) results on selected patient subsets, and clinical follow-up to 36 months. Analyses are conducted for the primary endpoint of 9-month target vessel failure (TVF, defined as cardiac death, MI, or clinically-driven repeat revascularization of the target vessel) and secondary endpoints of device success (attainment of <50% diameter stenosis using only the assigned device), MACE (any death, MI, emergent cardiac bypass surgery, or target lesion revascularization) through 36 months, procedure success (attainment of <50% diameter stenosis using any method without in-hospital MACE), 8-month angiographic late loss (difference between minimum lumen diameter immediately post-procedure and at 8 months follow-up as measured by the angiographic core laboratory) within the stent (in-stent) or stented segment (in-segment, stent plus 5 mm proximal and distal to the stent), 8-month in-stent and in-segment binary angiographic restenosis (BAR, ≥50% diameter stenosis), target lesion revascularization (TLR, defined as adjudicated clinically-driven repeat revascularization of the stented segment), and target vessel revascularization (TVR, defined as adjudicated clinically-driven repeat revascularization of the target lesion or any segment of the epicardial vessel containing the target lesion or its intervening sidebranches) through 36 months.

**Baseline patient and lesion characteristics:**

Baseline patient characteristics are shown in Table 3. Randomized patients had a mean age of 61.7 years, 24% were women, 20% had diabetes, 36% had multivessel coronary artery disease, and the mean left ventricular ejection fraction was 61%. Baseline lesion characteristics and quantitative angiographic data are shown in Tables 4 and 6. The ACC/AHA lesion classification was B2 or C for 79% of lesions. The mean reference diameter was 2.75 ± 0.48 mm and the mean lesion length was 14.21 ± 5.64 mm. There were no statistically significant differences between the randomized groups for any of the baseline clinical or lesion characteristics. These baseline characteristics are representative of moderate risk for development of restenosis and 9-month clinical events. Compared with the published SIRIUS[2] and TAXUS IV[3] studies the proportion of patients with diabetes is slightly less (24% in TAXUS IV and 26% in SIRIUS), and reference diameter (2.76 mm in TAXUS IV and 2.81 mm in SIRIUS) and lesion length are about the same (13.4 mm and 14.4 mm in TAXUS IV and SIRIUS, respectively).

[2] Moses, JW; Leon, MB; Popma, JJ; Fitzgerald, PJ; Holmes, DR; O'Shaughnessy, C; Caputo, RP; Kereiakes, DJ; Williams, DO; Teirstein, PS, Jaeger, JL; Kuntz, RD. Sirolimus-Eluting Stents versus Standard Stents in Patients with Stenosis in a Native Coronary Artery. The New England Journal of Medicine 2003; 349:1315-1323.

[3] Stone, GW; Ellis, SG; Cox, DA; Hermiller, J; O'Shaughnessy, C; Mann, JT; Turco, M; Caputo, R; Bergin, P; Greenberg, J; Popma, JJ; Russell, ME. A Polymer-Based, Paclitaxel-Eluting Stent in Patients with Coronary Artery Disease. The New England Journal of Medicine 2004; 350:221-331.

**Acute procedural results and device performance:**

Device success was achieved in nearly 99% of patients in each group. In-hospital MACE occurred in 2.5% (15/597) of patients in the Endeavor arm and 2.9% (17/596) of patients in the Driver arm, yielding acute procedure success of 97.3% and 97.1%, respectively. The acute quantitative angiographic results are shown in Table 6. The final angiographic results showed overall post-procedure mean in-stent percent diameter stenosis of 6.04 ± 10.43% and mean in-segment percent diameter stenosis of 20.39 ± 10.26%. There were no acute angiographic result differences between groups.

**Thirty-day MACE and early stent thrombosis:**

By 30 days, MACE had occurred in 2.9% (17/596) of patients in the Endeavor arm and 3.7% (22/594) of patients in the Driver arm. These rates are not significantly different and are consistent with other contemporary stent trials. Review of the individual safety components demonstrates early stent thrombosis occurred in 0.8% of patients (0.5% Endeavor vs. 1.2% Driver, p=NS). Of the seven (7) Q wave MIs in the overall population, five (5) were associated with stent thrombosis. Early repeat revascularization was infrequent and nearly identical in both groups, and the 30-day non-Q wave MI rate (2.5% in the overall population; 2.3% in the Endeavor group vs. 2.7% in the Driver group) was similar to contemporary stent trials without a statistical difference between groups.

**Eight-month follow-up angiographic and IVUS results:**

Of the 1,197 randomized patients, 600 (298 Endeavor and 302 Driver) were prospectively enrolled in a routine angiographic follow-up subset. Qualifying follow-up angiography was available for 529 (88.2%) patients (88.6% in the Endeavor arm and 87.7% in the Driver arm) and is reported in Tables 6 and 8. The angiographic in-stent late loss was significantly lower for Endeavor (0.62 ± 0.46 vs 1.03 ± 0.59 mm, $p<0.001$). This translated into significantly lower in-stent (9.5% vs. 33.2%, $p<0.001$) and in-segment (13.3% vs. 34.7%, $p<0.001$) BAR. Of note, there was no significant increase in proximal or distal edge late loss or BAR for Endeavor.

**Nine-month clinical outcomes:**

Nine-month clinical follow-up was available for 1,183 (98.8%) patients. The primary endpoint of 9-month TVF was significantly lower for Endeavor (7.9% vs. 15.1%, $p<0.001$). The Kaplan-Meier (KM) estimates of TVF were 7.9% vs. 15.0%. TLR occurred in 4.6% vs. 11.8%, $p<0.001$ (KM estimate 4.6% vs. 11.9%) and TVR occurred in 5.6% vs. 12.5%, $p<0.001$ (KM estimate 5.6% vs. 12.5%). The overall rate of 9-month MACE was 7.3% vs. 14.4%, $p<0.001$ (KM estimate 7.2% vs. 14.3%).

**Twelve-month clinical outcomes:**

Twelve-month clinical follow-up was available for 1,179 (98.5%) patients. The rate of 12-month TVF was significantly lower for Endeavor (10.0% vs. 16.6%, p<0.001). The KM estimates of TVF rates were 10.0% vs. 16.5%. TLR occurred in 5.9% vs. 13.1%, p<0.001 (KM estimates 6.0% vs. 13.2%) and TVR occurred in 7.5% vs. 14.1%, p<0.001 (KM estimates 7.5 % vs. 14.1%). The overall rate of 12-month MACE was 8.8% vs. 15.6%, p<0.001 (KM estimates 8.8% vs. 15.5%).

**Twenty-four month clinical outcomes:**

Twenty-four month clinical follow-up was available for 1,173 (98.0%) patients. The rate of 24-month TVF was significantly lower for Endeavor (11.1% vs. 19.8%, p<0.001) (KM estimates 11.0% vs. 19.7%). TLR occurred in 6.5% vs. 14.2%, p<0.001 (KM estimates 6.5% vs. 14.3%) and TVR occurred in 8.3% vs. 16.4%, p<0.001 (KM estimates 8.3 % vs. 16.4%). The overall rate of 24-month MACE was 9.9% vs. 18.1%, p<0.001 (KM estimates 9.8% vs. 17.9%).

**Thirty-six month clinical outcomes:**

Thirty-six month clinical follow-up was available for 1,156 (96.6%) patients. The rate of 36-month TVF was significantly lower for Endeavor (12.8% vs. 21.4%, p<0.001) (KM estimates 12.6% vs. 21.1%). TLR occurred in 7.3% vs. 14.7%, p<0.001 (KM estimates 7.2% vs. 14.6%) and TVR occurred in 9.5% vs. 17.6%, p<0.001 (KM estimates 9.4 % vs. 17.4%). The overall rate of 36-month MACE was 12.0% vs. 20.7%, p<0.001 (KM estimates 11.7% vs. 20.4%).

**Summary:**

(1) The Endeavor Zotarolimus-Eluting Coronary Stent System demonstrates safety based on the following:
   A. Device success is nearly 100% and compares favorably with the Driver bare metal stent.
   B. The 30-day MACE rate is low and similar to the rate in the Driver bare metal stent.
   C. The long term MACE rates are significantly favorable to the Endeavor stent.
   D. There was no evidence of increased early or late stent thrombosis in the Endeavor stent compared with the Driver bare metal stent.

(2) The Endeavor Zotarolimus-Eluting Coronary Stent System demonstrated efficacy with significantly lower rate of the primary clinical endpoint of TVF, sustained in long term follow-up.

(3) The secondary angiographic efficacy endpoints of late loss and BAR (in-stent and in-segment) were significantly lower for the Endeavor Zotarolimus-Eluting Coronary Stent System.

(4) The secondary clinical efficacy endpoints of TLR and TVR were significantly lower for the Endeavor Zotarolimus-Eluting Coronary Stent System and remain significantly lower in long term follow-up.

**Conclusion:** Based on acute procedural results, 8-month angiographic, and 9-month and long-term clinical follow-up the Endeavor Zotarolimus-Eluting Coronary Stent System has demonstrated similar safety and superior efficacy compared with the Driver bare metal stent.

**Hypothesis Tests:**

Primary Endpoint

The primary endpoint evaluated in this study was target vessel failure (TVF), defined as the composite of cardiac death, recurrent myocardial infarction, or target vessel revascularization at 270 days post-index procedure. The null hypothesis for this study was that the Endeavor Zotarolimus-Eluting Coronary Stent System had a primary endpoint rate equal to that of the control (Driver bare metal stent). The alternative hypothesis was that the Endeavor Zotarolimus-Eluting Coronary Stent System had a primary endpoint rate not equal to the control stent. Specifically, the null and alternative hypotheses were

$$H_o: \pi_{DE} = \pi_{CS}$$
$$H_a: \pi_{DE} \neq \pi_{CS}$$

where $\pi_{DE}$ was the primary endpoint rate estimate for the Endeavor Zotarolimus-Eluting Coronary Stent System and $\pi_{CS}$ was the primary endpoint rate estimate for the control (Driver bare metal).

The results were as follows:

- The 270-day target vessel failure rate of the subjects treated with the control strategy ($\pi_{CS}$) was observed to be 15.1% (89/591).
- The 270-day target vessel failure rate of the subjects treated with the Endeavor Zotarolimus-Eluting Coronary Stent System ($\pi_{DE}$) was 7.9% (47/592).

The p-value for the two-sided significance test was <0.001 using the Fisher's Exact test, therefore rejecting the null hypothesis. This fact and the fact that the observed 270-day TVF rates were less for Endeavor Zotarolimus-Eluting Coronary Stent System than for the control group signified that the Endeavor Zotarolimus-Eluting Coronary Stent System was *superior* compared to the control strategy with respect to 270-day TVF.

Site/Region Poolability

To account for the pooling of results across geographic regions, the following analyses were performed (See Appendix Table 1 for Region Listing).

*Assessment of Region Differences in Baseline Characteristics*

The baseline demographics of diabetes and major coronary stenosis, and lesion characteristics of lesion length, reference vessel diameter (RVD), in-segment minimum lumen diameter (MLD) and location of left anterior descending (LAD) were tabulated for each region. Specifically, descriptive statistics (sample size, mean, median, standard deviation, minimum, maximum) are presented for continuous variables and counts and percentages are presented for categorical variables (Appendix Table 2a).

Assessment of differences in baseline characteristics across regions was performed using one-way analysis of variance for continuous parameters and the logistic regression for categorical parameters. The Appendix Table 2b summarizes p-values for these tests.

Baseline demographic and lesion characteristics were then tabulated for each geographic region and treatment (Appendix Table 3a). Within each treatment, assessment of differences in baseline characteristics across regions was performed using one-way analysis of variance for continuous parameters and the logistic regression for categorical parameters. The Appendix Table 3b summarizes p-values for these tests.

From the Appendix Table 2b and Table 3b, it is evident that for all the baseline characteristics identified above, there are significant differences across the sites in baseline characteristics. However, this does not prevent sites from being pooled for analysis if the treatment effect on 270-day TVF is similar across regions. To assess if this similarity exists, rates of 270-day TVF are presented by geographic region and treatment group (Appendix Table 5 and Table 7). For most regions, the Driver 270-day TVF rate was higher than the Endeavor 270-day TVF rate. A formal assessment of the treatment-by-region interaction was carried out using logistic regression, with a resulting non-significant p-value of 0.9987. This regression model included terms for region, treatment and treatment-by-region interaction. This non-significant interaction result supports the similarity of treatment effect on 270-day TVF across the regions.

*Supportive Analysis on 270-day TVF (Primary Endpoint)*

Stepwise logistic regression, using a 0.10 level of entry and 0.10 level of stay, was conducted to find the subset of the baseline characteristics related to 270-day TVF (Appendix Table 4). This was performed for both treatments combined. The subset of characteristics related to 270-day TVF (hereafter referred to as *baseline predictors*) were then used as covariates in comparing treatments on 270-day TVF as discussed below, using logistic regression. Region was included as a candidate for entry in these stepwise logistic models; treatment was included as a candidate for entry in the model for both treatment groups combined.

Significant baseline predictors entering the stepwise model were treatment group, post-procedure MLD, number of total stents implanted, ACC/AHA lesion morphology class, pre-procedure thrombus. Region and diabetes did not enter as candidates for entry into the stepwise model. However, for completeness, a treatment comparison on 270-day TVF was carried out first using logistic regression *adjusting for geographic region only*, yielding a treatment comparison p-value of <0.001. The Hosmer-Lemeshow Goodness of Fit test p-

value was 0.936 and the c-statistic was 0.681 indicating good calibration but poor discriminatory ability of the logistic regression model. The treatment comparison on 270-day TVF was then carried out using logistic regression adjusting for geographic region and the set of baseline predictors found to be significantly related to 270-day TVF above, yielding a significant p-value of <0.001. The Hosmer-Lemeshow Goodness of Fit test p-value was 0.916 and the c-statistic was 0.733 indicating good calibration but below average discriminatory ability of the logistic regression model (Appendix Table 6). Both logistic models support the efficacy of Endeavor over the control strategy.

Secondary Endpoint Analysis

The endpoint evaluated was the angiographic Late Loss at 8 months as determined by core lab measurement of the difference between the MLD after follow-up and post stent implantation. The objective was to prove that with respect to this endpoint the Endeavor Zotarolimus-Eluting Coronary Stent System performed better than the control Driver bare metal stent. The null-hypothesis tested was that the mean Late Loss at 8 months in patients treated with the Endeavor Zotarolimus-Eluting Coronary Stent System was equal to the mean Late Loss at 8 months in patients treated with the control Driver bare metal. The alternative hypothesis was that the mean Late Loss at 8 months in patients treated with the drug-eluting stent was not equal to that in patients treated with the control stent. Specifically, the null and alternative hypotheses were

$$\text{Ho}: \ \mu_{CS} = \mu_{DE}$$
$$\text{Ha}: \ \mu_{CS} \neq \mu_{DE}$$

where $\mu_{DE}$ was the mean Late Loss at 8 months for the Endeavor Zotarolimus-Eluting Coronary Stent System and $\mu_{CS}$ was the mean Late Loss at 8 months for the control Driver bare metal stent. The results were as follows:

- The mean Late Loss at 8 months in the Endeavor Zotarolimus-Eluting Coronary Stent System arm was 0.62 mm±0.46 mm in-stent and 0.36 mm±0.46 mm in-segment (N=264).
- The mean Late Loss at 8 months in the control arm was 1.03 mm±0.59 mm in-stent and 0.72 mm±0.61 mm in-segment (N=263).

The p-value for the T-test was <0.001, therefore rejecting the null hypothesis. This p-value and the above Late Loss means signify that the Endeavor Zotarolimus-Eluting Coronary Stent System is *superior* compared to the control strategy with regard to Late Loss at 8 months.

## Table 1a. Principal Effectiveness and Safety Result (ITT)

| Effectiveness Measures | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Lesion Success | 99.7% (587/589) | 100.0% (590/590) | 99.8% (1177/1179) | -0.3% [-0.8%,0.1%] | 0.249 |
| Device Success | 98.8% (585/592) | 99.2% (586/591) | 99.0% (1171/1183) | -0.3% [-1.5%,0.8%] | 0.773 |
| Procedure Success | 97.3% (573/589) | 97.1% (573/590) | 97.2% (1146/1179) | 0.2% [-1.7%,2.0%] | 1.000 |
| Device-Specific Procedure Success | 96.5% (571/592) | 96.4% (570/591) | 96.4% (1141/1183) | 0.0% [-2.1%,2.1%] | 1.000 |
| Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 2.59±0.43 (588) | 2.61±0.44 (589) | 2.60±0.43 (1177) | -0.02 [-0.07,0.03] | 0.436 |
| Range (min,max) | (0.00,3.78) | (1.44,4.00) | (0.00,4.00) | | |
| Post-Procedure In-Stent Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 6.04±10.43 (588) | 6.23±10.03 (589) | 6.13±10.23 (1177) | -0.18 [-1.36,0.99] | 0.757 |
| Range (min,max) | (-29.89,100.00) | (-39.63,33.75) | (-39.63,100.00) | | |
| Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 2.21±0.49 (589) | 2.24±0.49 (590) | 2.23±0.49 (1179) | -0.03 [-0.09,0.03] | 0.302 |
| Range (min,max) | (0.00,3.72) | (0.90,3.89) | (0.00,3.89) | | |
| Post-Procedure In-Segment Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 20.39±10.26 (589) | 20.11±9.38 (590) | 20.25±9.83 (1179) | 0.28 [-0.84,1.41] | 0.622 |
| Range (min,max) | (-6.91,100.00) | (-1.94,56.78) | (-6.91,100.00) | | |
| Eight-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 1.99±0.56 (264) | 1.62±0.70 (265) | 1.80±0.66 (529) | 0.37 [0.26,0.48] | <0.001 |
| Range (min,max) | (0.00,3.31) | (0.00,3.05) | (0.00,3.31) | | |
| Eight-Month Follow-up In-Stent Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 27.91±17.30 (264) | 42.24±21.73 (265) | 35.09±20.89 (529) | -14.33 [-17.68,-10.97] | <0.001 |
| Range (min,max) | (-3.86,100.00) | (0.10,100.00) | (-3.86,100.00) | | |
| Eight-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 1.86±0.55 (264) | 1.56±0.67 (265) | 1.71±0.63 (529) | 0.30 [0.19,0.40] | <0.001 |
| Range (min,max) | (0.00,3.34) | (0.00,2.88) | (0.00,3.34) | | |
| Eight-Month Follow-up In-Segment Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 32.67±16.27 (264) | 44.33±20.45 (265) | 38.51±19.37 (529) | -11.66 [-14.82,-8.50] | <0.001 |
| Range (min,max) | (1.04,100.00) | (8.49,100.00) | (1.04,100.00) | | |
| Eight-Month Late Loss In-Stent (mm) | | | | | |
| Mean±SD (n) | 0.62±0.46 (264) | 1.03±0.59 (263) | 0.82±0.56 (527) | -0.41 [-0.50,-0.32] | <0.001 |
| Range (min,max) | (-0.37,2.50) | (-0.07,2.78) | (-0.37,2.78) | | |
| Eight-Month Late Loss In-Segment (mm) | | | | | |
| Mean±SD (n) | 0.36±0.46 (264) | 0.72±0.61 (263) | 0.54±0.57 (527) | -0.36 [-0.45,-0.27] | <0.001 |
| Range (min,max) | (-1.06,2.24) | (-0.40,2.78) | (-1.06,2.78) | | |
| Eight-Month In-Stent Binary Restenosis | 9.5% (25/264) | 33.2% (88/265) | 21.4% (113/529) | -23.7% [-30.4%,-17.1%] | <0.001 |
| Eight-Month In-Segment Binary Restenosis | 13.3% (35/264) | 34.7% (92/265) | 24.0% (127/529) | -21.5% [-28.5%,-14.4%] | <0.001 |

## Table 1a. Principal Effectiveness and Safety Result (ITT) (Continued)

| Safety Measures (30 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| In-Hospital MACE | 2.5% (15/597) | 2.9% (17/596) | 2.7% (32/1193) | -0.3% [-2.2%,1.5%] | 0.725 |
| Out-of-Hospital MACE to 30 Days | 0.3% (2/596) | 0.8% (5/594) | 0.6% (7/1190) | -0.5% [-1.4%,0.4%] | 0.287 |
| MACE to 30 Days | 2.9% (17/596) | 3.7% (22/594) | 3.3% (39/1190) | -0.9% [-2.9%,1.2%] | 0.421 |
| Death | 0.2% (1/596) | 0.0% (0/594) | 0.1% (1/1190) | 0.2% [-0.2%,0.5%] | 1.000 |
| Vascular Complications | 0.3% (2/596) | 1.2% (7/594) | 0.8% (9/1190) | -0.8% [-1.8%,0.1%] | 0.108 |
| Early Stent Thrombosis | 0.5% (3/596) | 1.2% (7/594) | 0.8% (10/1190) | -0.7% [-1.7%,0.4%] | 0.224 |
| Cerebrovascular Accident (CVA) | 0.0% (0/596) | 0.2% (1/594) | 0.1% (1/1190) | -0.2% [-0.5%,0.2%] | 0.499 |
| Perforation | 0.5% (3/596) | 0.3% (2/594) | 0.4% (5/1190) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 1.2% (7/596) | 1.2% (7/594) | 1.2% (14/1190) | -0.0% [-1.2%,1.2%] | 1.000 |
| Target Lesion Revascularization | 0.8% (5/596) | 1.2% (7/594) | 1.0% (12/1190) | -0.3% [-1.5%,0.8%] | 0.579 |
| Target Vessel Failure | 3.2% (19/596) | 3.7% (22/594) | 3.4% (41/1190) | -0.5% [-2.6%,1.6%] | 0.638 |

| Safety Measures (180 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 180 Days | 2.0% (12/593) | 6.4% (38/593) | 4.2% (50/1186) | -4.4% [-6.7%,-2.1%] | <0.001 |
| MACE to 180 Days | 4.6% (27/593) | 8.9% (53/593) | 6.7% (80/1186) | -4.4% [-7.2%,-1.5%] | 0.004 |
| Death | 0.5% (3/593) | 0.5% (3/593) | 0.5% (6/1186) | 0.0% [--,--] | 1.000 |
| Vascular Complications | 0.5% (3/593) | 1.2% (7/593) | 0.8% (10/1186) | -0.7% [-1.7%,0.4%] | 0.342 |
| Early Stent Thrombosis | 0.5% (3/593) | 1.2% (7/593) | 0.8% (10/1186) | -0.7% [-1.7%,0.4%] | 0.342 |
| Late Stent Thrombosis | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.0% (0/593) | 0.3% (2/593) | 0.2% (2/1186) | -0.3% [-0.8%,0.1%] | 0.500 |
| Perforation | 0.5% (3/593) | 0.3% (2/593) | 0.4% (5/1186) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 2.7% (16/593) | 6.2% (37/593) | 4.5% (53/1186) | -3.5% [-5.9%,-1.2%] | 0.005 |
| Target Lesion Revascularization | 2.2% (13/593) | 6.2% (37/593) | 4.2% (50/1186) | -4.0% [-6.3%,-1.8%] | <0.001 |
| Target Vessel Failure | 4.9% (29/593) | 8.9% (53/593) | 6.9% (82/1186) | -4.0% [-6.9%,-1.2%] | 0.008 |

| Safety Measures (270 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 270 Days | 4.9% (29/592) | 12.0% (71/591) | 8.5% (100/1183) | -7.1% [-10.3%,-4.0%] | <0.001 |
| MACE to 270 Days | 7.3% (43/592) | 14.4% (85/591) | 10.8% (128/1183) | -7.1% [-10.6%,-3.6%] | <0.001 |
| Death | 1.2% (7/592) | 0.5% (3/591) | 0.8% (10/1183) | 0.7% [-0.4%,1.7%] | 0.342 |
| Vascular Complications | 0.5% (3/592) | 1.2% (7/591) | 0.8% (10/1183) | -0.7% [-1.7%,0.4%] | 0.224 |
| Early Stent Thrombosis | 0.5% (3/592) | 1.2% (7/591) | 0.8% (10/1183) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.2% (1/592) | 0.5% (3/591) | 0.3% (4/1183) | -0.3% [-1.0%,0.3%] | 0.374 |
| Perforation | 0.5% (3/592) | 0.3% (2/591) | 0.4% (5/1183) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 5.6% (33/592) | 12.5% (74/591) | 9.0% (107/1183) | -6.9% [-10.2%,-3.7%] | <0.001 |
| Target Lesion Revascularization | 4.6% (27/592) | 11.8% (70/591) | 8.2% (97/1183) | -7.3% [-10.4%,-4.2%] | <0.001 |
| Target Vessel Failure | 7.9% (47/592) | 15.1% (89/591) | 11.5% (136/1183) | -7.1% [-10.7%,-3.5%] | <0.001 |

## Table 1a. Principal Effectiveness and Safety Result (ITT) (Continued)

| Safety Measures (360 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 360 Days | 6.4% (38/590) | 13.2% (78/589) | 9.8% (116/1179) | -6.8% [-10.2%,-3.4%] | <0.001 |
| MACE to 360 Days | 8.8% (52/590) | 15.6% (92/589) | 12.2% (144/1179) | -6.8% [-10.5%,-3.1%] | <0.001 |
| Death | 1.4% (8/590) | 0.7% (4/589) | 1.0% (12/1179) | 0.7% [-0.5%,1.8%] | 0.385 |
| Vascular Complications | 0.5% (3/590) | 1.2% (7/589) | 0.8% (10/1179) | -0.7% [-1.7%,0.4%] | 0.224 |
| Early Stent Thrombosis | 0.5% (3/590) | 1.2% (7/589) | 0.8% (10/1179) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.3% (2/590) | 0.5% (3/589) | 0.4% (5/1179) | -0.2% [-0.9%,0.6%] | 0.687 |
| Perforation | 0.5% (3/590) | 0.3% (2/589) | 0.4% (5/1179) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 7.5% (44/590) | 14.1% (83/589) | 10.8% (127/1179) | -6.6% [-10.2%,-3.1%] | <0.001 |
| Target Lesion Revascularization | 5.9% (35/590) | 13.1% (77/589) | 9.5% (112/1179) | -7.1% [-10.5%,-3.8%] | <0.001 |
| Target Vessel Failure | 10.0% (59/590) | 16.6% (98/589) | 13.3% (157/1179) | -6.6% [-10.5%,-2.8%] | <0.001 |

| Safety Measures (720 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 720 Days | 7.5% (44/587) | 15.7% (92/586) | 11.6% (136/1173) | -8.2% [-11.8%,-4.6%] | <0.001 |
| MACE to 720 Days | 9.9% (58/587) | 18.1% (106/586) | 14.0% (164/1173) | -8.2% [-12.2%,-4.3%] | <0.001 |
| Death | 2.0% (12/587) | 2.2% (13/586) | 2.1% (25/1173) | -0.2% [-1.8%,1.5%] | 0.843 |
| Vascular Complications | 0.5% (3/587) | 1.2% (7/586) | 0.9% (10/1173) | -0.7% [-1.7%,0.4%] | 0.224 |
| Early Stent Thrombosis | 0.5% (3/587) | 1.2% (7/586) | 0.9% (10/1173) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.7% (4/587) | 0.5% (3/586) | 0.6% (7/1173) | 0.2% [-0.7%,1.1%] | 1.000 |
| Perforation | 0.5% (3/587) | 0.3% (2/586) | 0.4% (5/1173) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 8.3% (49/587) | 16.4% (96/586) | 12.4% (145/1173) | -8.0% [-11.8%,-4.3%] | <0.001 |
| Target Lesion Revascularization | 6.5% (38/587) | 14.2% (83/586) | 10.3% (121/1173) | -7.7% [-11.1%,-4.2%] | <0.001 |
| Target Vessel Failure | 11.1% (65/587) | 19.8% (116/586) | 15.4% (181/1173) | -8.7% [-12.8%,-4.6%] | <0.001 |

| Safety Measures (1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 1080 Days | 9.5% (55/577) | 18.7% (108/579) | 14.1% (163/1156) | -9.1% [-13.1%,-5.1%] | <0.001 |
| MACE to 1080 Days | 12.0% (69/577) | 20.7% (120/579) | 16.3% (189/1156) | -8.8% [-13.0%,-4.5%] | <0.001 |
| Death | 3.3% (19/577) | 4.5% (26/579) | 3.9% (45/1156) | -1.2% [-3.4%,1.0%] | 0.362 |
| Vascular Complications | 0.5% (3/577) | 1.2% (7/579) | 0.9% (10/1156) | -0.7% [-1.8%,0.4%] | 0.342 |
| Early Stent Thrombosis | 0.5% (3/577) | 1.2% (7/579) | 0.9% (10/1156) | -0.7% [-1.8%,0.4%] | 0.342 |
| Late Stent Thrombosis | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 1.0% (6/577) | 1.2% (7/579) | 1.1% (13/1156) | -0.2% [-1.4%,1.0%] | 1.000 |
| Perforation | 0.5% (3/577) | 0.3% (2/579) | 0.4% (5/1156) | 0.2% [-0.6%,0.9%] | 0.686 |
| Target Vessel Revascularization | 9.5% (55/577) | 17.6% (102/579) | 13.6% (157/1156) | -8.1% [-12.0%,-4.2%] | <0.001 |
| Target Lesion Revascularization | 7.3% (42/577) | 14.7% (85/579) | 11.0% (127/1156) | -7.4% [-11.0%,-3.8%] | <0.001 |
| Target Vessel Failure | 12.8% (74/577) | 21.4% (124/579) | 17.1% (198/1156) | -8.6% [-12.9%,-4.3%] | <0.001 |

## Table 1a. Principal Effectiveness and Safety Result (ITT) (Continued)

| Kaplan-Meier Estimate | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | P-value |
|---|---|---|---|---|
| MACE-Free at 1080 days | 88.3% | 79.6% | 83.9% | <0.001 |
| TLR-Free at 1080 days | 92.8% | 85.4% | 89.1% | <0.001 |
| TVR-Free at 1080 days | 90.6% | 82.6% | 86.6% | <0.001 |
| TVF-Free at 1080 days | 87.4% | 78.9% | 83.2% | <0.001 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Table 1b. Principal Effectiveness and Safety Result (PP)

| Effectiveness Measures | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Lesion Success | 99.8% (575/576) | 100.0% (570/570) | 99.9% (1145/1146) | -0.2% [-0.5%,0.2%] | 1.000 |
| Device Success | 99.8% (575/576) | 99.8% (569/570) | 99.8% (1144/1146) | 0.0% [-0.5%,0.5%] | 1.000 |
| Procedure Success | 97.4% (561/576) | 97.0% (553/570) | 97.2% (1114/1146) | 0.4% [-1.5%,2.3%] | 0.723 |
| Device-Specific Procedure Success | 97.4% (561/576) | 97.0% (553/570) | 97.2% (1114/1146) | 0.4% [-1.5%,2.3%] | 0.723 |
| Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 2.59±0.43 (576) | 2.61±0.43 (570) | 2.60±0.43 (1146) | -0.02 [-0.07,0.03] | 0.373 |
| Range (min,max) | (0.00,3.78) | (1.44,4.00) | (0.00,4.00) | | |
| Post-Procedure In-Stent Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 6.09±10.47 (576) | 6.19±10.08 (570) | 6.14±10.27 (1146) | -0.10 [-1.29,1.09] | 0.868 |
| Range (min,max) | (-29.89,100.00) | (-39.63,33.75) | (-39.63,100.00) | | |
| Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 2.22±0.49 (576) | 2.24±0.49 (570) | 2.23±0.49 (1146) | -0.03 [-0.08,0.03] | 0.376 |
| Range (min,max) | (0.00,3.72) | (0.90,3.89) | (0.00,3.89) | | |
| Post-Procedure In-Segment Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 20.29±9.95 (576) | 20.18±9.39 (570) | 20.24±9.67 (1146) | 0.11 [-1.01,1.23] | 0.851 |
| Range (min,max) | (-6.91,100.00) | (-1.94,56.78) | (-6.91,100.00) | | |
| Eight-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 1.99±0.56 (258) | 1.62±0.70 (256) | 1.80±0.66 (514) | 0.37 [0.26,0.48] | <0.001 |
| Range (min,max) | (0.00,3.31) | (0.00,3.05) | (0.00,3.31) | | |
| Eight-Month Follow-up In-Stent Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 27.76±17.26 (258) | 42.29±21.83 (256) | 35.00±20.95 (514) | -14.53 [-17.94,-11.12] | <0.001 |
| Range (min,max) | (-3.86,100.00) | (0.10,100.00) | (-3.86,100.00) | | |
| Eight-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm) | | | | | |
| Mean±SD (n) | 1.87±0.55 (258) | 1.56±0.67 (256) | 1.71±0.63 (514) | 0.30 [0.20,0.41] | <0.001 |
| Range (min,max) | (0.00,3.34) | (0.00,2.88) | (0.00,3.34) | | |
| Eight-Month Follow-up In-Segment Percent Diameter Stenosis (% DS) | | | | | |
| Mean±SD (n) | 32.52±16.18 (258) | 44.37±20.52 (256) | 38.42±19.38 (514) | -11.86 [-15.06,-8.65] | <0.001 |
| Range (min,max) | (1.04,100.00) | (8.49,100.00) | (1.04,100.00) | | |
| Eight-Month Late Loss In-Stent (mm) | | | | | |
| Mean±SD (n) | 0.62±0.46 (258) | 1.03±0.59 (254) | 0.82±0.57 (512) | -0.42 [-0.51,-0.33] | <0.001 |
| Range (min,max) | (-0.37,2.50) | (-0.07,2.78) | (-0.37,2.78) | | |
| Eight-Month Late Loss In-Segment (mm) | | | | | |
| Mean±SD (n) | 0.35±0.46 (258) | 0.72±0.62 (254) | 0.53±0.57 (512) | -0.37 [-0.46,-0.27] | <0.001 |
| Range (min,max) | (-1.06,2.24) | (-0.40,2.78) | (-1.06,2.78) | | |
| Eight-Month In-Stent Binary Restenosis | 9.3% (24/258) | 33.6% (86/256) | 21.4% (110/514) | -24.3% [-31.1%,-17.5%] | <0.001 |
| Eight-Month In-Segment Binary Restenosis | 12.8% (33/258) | 35.2% (90/256) | 23.9% (123/514) | -22.4% [-29.5%,-15.2%] | <0.001 |

## Table 1b. Principal Effectiveness and Safety Result (PP) (Continued)

| Safety Measures (30 Days) | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| In-Hospital MACE | 2.6% (15/581) | 3.0% (17/575) | 2.8% (32/1156) | -0.4% [-2.3%,1.5%] | 0.723 |
| Out-of-Hospital MACE to 30 Days | 0.2% (1/580) | 0.7% (4/573) | 0.4% (5/1153) | -0.5% [-1.3%,0.2%] | 0.215 |
| MACE to 30 Days | 2.8% (16/580) | 3.7% (21/573) | 3.2% (37/1153) | -0.9% [-2.9%,1.1%] | 0.408 |
| Death | 0.2% (1/580) | 0.0% (0/573) | 0.1% (1/1153) | 0.2% [-0.2%,0.5%] | 1.000 |
| Vascular Complications | 0.3% (2/580) | 1.0% (6/573) | 0.7% (8/1153) | -0.7% [-1.7%,0.3%] | 0.176 |
| Early Stent Thrombosis | 0.5% (3/580) | 1.0% (6/573) | 0.8% (9/1153) | -0.5% [-1.5%,0.5%] | 0.339 |
| Cerebrovascular Accident (CVA) | 0.0% (0/580) | 0.2% (1/573) | 0.1% (1/1153) | -0.2% [-0.5%,0.2%] | 0.497 |
| Perforation | 0.5% (3/580) | 0.3% (2/573) | 0.4% (5/1153) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 1.0% (6/580) | 1.0% (6/573) | 1.0% (12/1153) | -0.0% [-1.2%,1.2%] | 1.000 |
| Target Lesion Revascularization | 0.7% (4/580) | 1.0% (6/573) | 0.9% (10/1153) | -0.4% [-1.4%,0.7%] | 0.545 |
| Target Vessel Failure | 3.1% (18/580) | 3.7% (21/573) | 3.4% (39/1153) | -0.6% [-2.6%,1.5%] | 0.628 |

| Safety Measures (180 Days) | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 180 Days | 1.9% (11/577) | 6.5% (37/572) | 4.2% (48/1149) | -4.6% [-6.9%,-2.3%] | <0.001 |
| MACE to 180 Days | 4.5% (26/577) | 9.1% (52/572) | 6.8% (78/1149) | -4.6% [-7.5%,-1.7%] | 0.002 |
| Death | 0.5% (3/577) | 0.5% (3/572) | 0.5% (6/1149) | -0.0% [-0.8%,0.8%] | 1.000 |
| Vascular Complications | 0.5% (3/577) | 1.0% (6/572) | 0.8% (9/1149) | -0.5% [-1.5%,0.5%] | 0.340 |
| Early Stent Thrombosis | 0.5% (3/577) | 1.0% (6/572) | 0.8% (9/1149) | -0.5% [-1.5%,0.5%] | 0.340 |
| Late Stent Thrombosis | 0.0% (0/577) | 0.0% (0/572) | 0.0% (0/1149) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.0% (0/577) | 0.3% (2/572) | 0.2% (2/1149) | -0.3% [-0.8%,0.1%] | 0.248 |
| Perforation | 0.5% (3/577) | 0.3% (2/572) | 0.4% (5/1149) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 2.6% (15/577) | 6.3% (36/572) | 4.4% (51/1149) | -3.7% [-6.1%,-1.3%] | 0.002 |
| Target Lesion Revascularization | 2.1% (12/577) | 6.3% (36/572) | 4.2% (48/1149) | -4.2% [-6.5%,-1.9%] | <0.001 |
| Target Vessel Failure | 4.9% (28/577) | 9.1% (52/572) | 7.0% (80/1149) | -4.2% [-7.2%,-1.3%] | 0.005 |

| Safety Measures (270 Days) | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 270 Days | 4.7% (27/576) | 11.9% (68/570) | 8.3% (95/1146) | -7.2% [-10.4%,-4.1%] | <0.001 |
| MACE to 270 Days | 7.1% (41/576) | 14.4% (82/570) | 10.7% (123/1146) | -7.3% [-10.8%,-3.7%] | <0.001 |
| Death | 1.2% (7/576) | 0.5% (3/570) | 0.9% (10/1146) | 0.7% [-0.4%,1.8%] | 0.342 |
| Vascular Complications | 0.5% (3/576) | 1.1% (6/570) | 0.8% (9/1146) | -0.5% [-1.6%,0.5%] | 0.339 |
| Early Stent Thrombosis | 0.5% (3/576) | 1.1% (6/570) | 0.8% (9/1146) | -0.5% [-1.6%,0.5%] | 0.339 |
| Late Stent Thrombosis | 0.0% (0/576) | 0.0% (0/570) | 0.0% (0/1146) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.2% (1/576) | 0.5% (3/570) | 0.3% (4/1146) | -0.4% [-1.0%,0.3%] | 0.372 |
| Perforation | 0.5% (3/576) | 0.4% (2/570) | 0.4% (5/1146) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 5.4% (31/576) | 12.5% (71/570) | 8.9% (102/1146) | -7.1% [-10.4%,-3.8%] | <0.001 |
| Target Lesion Revascularization | 4.3% (25/576) | 11.8% (67/570) | 8.0% (92/1146) | -7.4% [-10.5%,-4.3%] | <0.001 |
| Target Vessel Failure | 7.8% (45/576) | 15.1% (86/570) | 11.4% (131/1146) | -7.3% [-10.9%,-3.6%] | <0.001 |

## Table 1b. Principal Effectiveness and Safety Result (PP) (Continued)

| Safety Measures (360 Days) | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 360 Days | 6.3% (36/574) | 13.2% (75/568) | 9.7% (111/1142) | -6.9% [-10.4%,-3.5%] | <0.001 |
| MACE to 360 Days | 8.7% (50/574) | 15.7% (89/568) | 12.2% (139/1142) | -7.0% [-10.7%,-3.2%] | <0.001 |
| Death | 1.4% (8/574) | 0.7% (4/568) | 1.1% (12/1142) | 0.7% [-0.5%,1.9%] | 0.385 |
| Vascular Complications | 0.5% (3/574) | 1.1% (6/568) | 0.8% (9/1142) | -0.5% [-1.6%,0.5%] | 0.339 |
| Early Stent Thrombosis | 0.5% (3/574) | 1.1% (6/568) | 0.8% (9/1142) | -0.5% [-1.6%,0.5%] | 0.339 |
| Late Stent Thrombosis | 0.0% (0/574) | 0.0% (0/568) | 0.0% (0/1142) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.3% (2/574) | 0.5% (3/568) | 0.4% (5/1142) | -0.2% [-0.9%,0.6%] | 0.685 |
| Perforation | 0.5% (3/574) | 0.4% (2/568) | 0.4% (5/1142) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 7.3% (42/574) | 14.1% (80/568) | 10.7% (122/1142) | -6.8% [-10.3%,-3.2%] | <0.001 |
| Target Lesion Revascularization | 5.7% (33/574) | 13.0% (74/568) | 9.4% (107/1142) | -7.3% [-10.6%,-3.9%] | <0.001 |
| Target Vessel Failure | 9.9% (57/574) | 16.7% (95/568) | 13.3% (152/1142) | -6.8% [-10.7%,-2.9%] | <0.001 |

| Safety Measures (720 Days) | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 720 Days | 7.3% (42/572) | 15.6% (88/565) | 11.4% (130/1137) | -8.2% [-11.9%,-4.6%] | <0.001 |
| MACE to 720 Days | 9.8% (56/572) | 18.1% (102/565) | 13.9% (158/1137) | -8.3% [-12.3%,-4.3%] | <0.001 |
| Death | 2.1% (12/572) | 2.3% (13/565) | 2.2% (25/1137) | -0.2% [-1.9%,1.5%] | 0.842 |
| Vascular Complications | 0.5% (3/572) | 1.1% (6/565) | 0.8% (9/1137) | -0.5% [-1.6%,0.5%] | 0.339 |
| Early Stent Thrombosis | 0.5% (3/572) | 1.1% (6/565) | 0.8% (9/1137) | -0.5% [-1.6%,0.5%] | 0.339 |
| Late Stent Thrombosis | 0.0% (0/572) | 0.0% (0/565) | 0.0% (0/1137) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 0.7% (4/572) | 0.5% (3/565) | 0.6% (7/1137) | 0.2% [-0.7%,1.1%] | 1.000 |
| Perforation | 0.5% (3/572) | 0.4% (2/565) | 0.4% (5/1137) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization | 8.2% (47/572) | 16.3% (92/565) | 12.2% (139/1137) | -8.1% [-11.9%,-4.3%] | <0.001 |
| Target Lesion Revascularization | 6.3% (36/572) | 14.0% (79/565) | 10.1% (115/1137) | -7.7% [-11.2%,-4.2%] | <0.001 |
| Target Vessel Failure | 11.0% (63/572) | 19.8% (112/565) | 15.4% (175/1137) | -8.8% [-13.0%,-4.6%] | <0.001 |

| Safety Measures (1080 Days) | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Out-of-Hospital MACE to 1080 Days | 9.3% (52/562) | 18.6% (104/558) | 13.9% (156/1120) | -9.4% [-13.4%,-5.4%] | <0.001 |
| MACE to 1080 Days | 11.7% (66/562) | 20.8% (116/558) | 16.3% (182/1120) | -9.0% [-13.3%,-4.8%] | <0.001 |
| Death | 3.0% (17/562) | 4.7% (26/558) | 3.8% (43/1120) | -1.6% [-3.9%,0.6%] | 0.165 |
| Vascular Complications | 0.5% (3/562) | 1.1% (6/558) | 0.8% (9/1120) | -0.5% [-1.6%,0.5%] | 0.340 |
| Early Stent Thrombosis | 0.5% (3/562) | 1.1% (6/558) | 0.8% (9/1120) | -0.5% [-1.6%,0.5%] | 0.340 |
| Late Stent Thrombosis | 0.0% (0/562) | 0.0% (0/558) | 0.0% (0/1120) | 0.0% [--,--] | -- |
| Cerebrovascular Accident (CVA) | 1.1% (6/562) | 1.3% (7/558) | 1.2% (13/1120) | -0.2% [-1.4%,1.1%] | 0.789 |
| Perforation | 0.5% (3/562) | 0.4% (2/558) | 0.4% (5/1120) | 0.2% [-0.6%,1.0%] | 1.000 |
| Target Vessel Revascularization | 9.4% (53/562) | 17.6% (98/558) | 13.5% (151/1120) | -8.1% [-12.1%,-4.2%] | <0.001 |
| Target Lesion Revascularization | 7.1% (40/562) | 14.5% (81/558) | 10.8% (121/1120) | -7.4% [-11.0%,-3.8%] | <0.001 |
| Target Vessel Failure | 12.8% (72/562) | 21.5% (120/558) | 17.1% (192/1120) | -8.7% [-13.1%,-4.3%] | <0.001 |

## Table 1b. Principal Effectiveness and Safety Result (PP) (Continued)

| Kaplan-Meier Estimate | Endeavor (N=581 patients) | Driver (N=575 patients) | All Patients (N=1156 Patients) | P-value |
|---|---|---|---|---|
| MACE-Free at 1080 days | 88.5% | 79.6% | 84.1% | <0.001 |
| TLR-Free at 1080 days | 92.9% | 85.6% | 89.3% | <0.001 |
| TVR-Free at 1080 days | 90.7% | 82.7% | 86.7% | <0.001 |
| TVF-Free at 1080 days | 87.4% | 78.9% | 83.2% | <0.001 |

N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Section II. Detailed Summary

### A. Definitions

ABRUPT CLOSURE

*Abrupt Closure.* Defined as the occurrence of new (during the index procedure) severely reduced flow (TIMI grade 0-1) within the target vessel that persisted and required rescue by stenting or other treatment, or resulted in myocardial infarction or death. Abrupt closure requires proven association with a mechanical dissection of the treatment site or instrumented vessel, coronary thrombus, or severe spasm. Abrupt closure does not connote "no reflow" (due to microvascular flow limitation), in which the epicardial artery is patent but had reduced flow. Abrupt closure also does not connote transient closure with reduced flow in which the index treatment application does reverse the closure.

*Subabrupt Closure.* Defined as abrupt closure that occurred after the index procedure is completed (and the subject left the catheterization laboratory) and before the 14-day follow-up endpoint.

*Threatened Abrupt Closure.* Defined as a grade B dissection and ≥50% diameter stenosis or any dissection of grade C or higher.

ACUTE GAIN

Defined as the immediate dimensional change in minimal luminal diameter (in mm) that occurred after the final post dilatation as compared to the minimal luminal diameter at baseline and measured by quantitative coronary angiography from the average of 2 orthogonal views.

ACUTE SUCCESS[4]

*Device Success:* Attainment of <50% residual stenosis of the target lesion using only the assigned device.

*Lesion Success:* Attainment of <50% residual stenosis of the target lesion using any percutaneous method.

*Procedure Success:* Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.

*Device-Specific Procedure Success*[5]*:* Device success and no in-hospital MACE.

BLEEDING COMPLICATIONS

Defined as a procedure related hemorrhagic event that requires a transfusion or surgical repair. These may include a hematoma requiring treatment, retroperitoneal bleed.

[4] All analyses to determine acute success measures were conducted utilizing *in-stent* residual stenosis values. When in-stent % residual stenosis was not available, in-lesion % residual stenosis was used to complete the analysis.
[5] Device-Specific Procedure Success is utilized to account for procedural successes/failures that are related to the implanted device.

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION (CCS)

*Class I* Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.

*Class II* Slight limitation of ordinary activity. Angina upon walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the first hours after awakening. Angina if walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

*Class III* Marked limitations of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.

*Class IV* Inability to carry on any physical activity without discomfort. Angina syndrome may be present at rest.

CBC (COMPLETE BLOOD COUNT)

Includes:

Hematocrit (HCT)
Hemoglobin (HB)
Platelet count
Red blood cell (RBC) count
White Blood Cell (WBC)
White Blood Cell (WBC) Differential

CHEMISTRY PANEL

Includes:

| | |
|---|---|
| Alanine aminotransferase* | Glucose |
| Alkaline phosphatase | Chloride |
| Aspartate aminotransferase** | HDL |
| Calcium | LDL |
| Cholesterol (total) | Potassium |
| Creatinine | Sodium |
| Creatinine kinase | Triglycerides |
| Gamma glutamyl transferase | Urea nitrogen |

* Also called serum glutamic pyruvic transaminase (SGPT)
** Also called serum glutamic oxaloacetic transaminase (SGOT)

*DE NOVO* LESION

Defined as a native coronary artery lesion not previously treated.

DEATH

Divided into 2 categories:

*Cardiac death* is defined as death due to any of the following:

1. Acute myocardial infarction.
2. Cardiac perforation/pericardial tamponade.

3. Arrhythmia or conduction abnormality.
4. Stroke within 30 days of the procedure or stroke suspected of being related to the procedure.
5. Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery.
6. Any death in which a cardiac cause cannot be excluded.

*Non-cardiac death* is defined as a death not due to cardiac causes (as defined above).

DEVICE RELATED ADVERSE EVENT

Any adverse event for which a causal relationship between the device and the event is at least a reasonable possibility.

DEVICE SUCCESS

Attainment of <50% residual stenosis of the target lesion using only the assigned device.

DEVICE-SPECIFIC PROCEDURE SUCCESS

Device success and no in-hospital MACE

DISSECTION, NHLBI (National Heart, Lung, and Blood Institute) CLASSIFICATION

*Type A* Small radiolucent area within the lumen of the vessel disappearing with the passage of the contrast material.

*Type B* Appearance of contrast medium parallel to the lumen of the vessel disappearing within a few cardiac cycles.

*Type C* Dissection protruding outside the lumen of the vessel persisting after passage of the contrast material.

*Type D* Spiral shaped filling defect with or without delayed run-off of the contrast material in the antegrade flow.

*Type E* Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen.

*Type F* Filling defect accompanied by total coronary occlusion.

DISTAL EMBOLIZATION

Defined as a new abrupt cut-off or filling defect distal to the treated lesion.

EMERGENT BYPASS SURGERY

Defined as coronary bypass surgery performed on an urgent or emergent basis for severe vessel dissection or closure, or treatment failure resulting in new ischaemia.

IN-LESION MEASUREMENT (ALSO IN-SEGMENT MEASUREMENT)

Defined as the measurements either within the stented segment or within 5 mm proximal or distal to the stent edges.

IN-STENT MEASUREMENT

Defined as the measurements within the stented segment.

LESION CLASS (American College of Cardiology/American Heart Association Class)

*Type A Lesions:* Minimally complex, discrete (length <10 mm), concentric, readily accessible, non angulated segment (<45°), smooth contour, little or no calcification, less than totally occlusive, not ostial in location, no major side branch involvement, and an absence of thrombus.

*Type B Lesions:* Moderately complex, tubular (length 10 to 20 mm), eccentric, moderate tortuosity of proximal segment, moderately angulated segment (>45°, <90°), irregular contour, moderate or heavy calcification, total occlusions <3 months old, ostial in location, bifurcation lesions requiring double guidewires, and some thrombus present.

*Type C Lesions:* Severely complex, diffuse (length >2 cm), excessive tortuosity of proximal segment, extremely angulated segments >90°, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions**.**

LESION SUCCESS

Attainment of <50% residual stenosis of the target lesion using any percutaneous method.

MAJOR ADVERSE CARDIAC EVENTS (MACE)

Defined as death, MI[6] (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (repeat PTCA or CABG).

MINIMAL LUMINAL DIAMETER (MLD)

Defined as the mean minimum lumen diameter derived from two orthogonal views (by the quantitative coronary angiography laboratory).

MYOCARDIAL INFARCTION

A positive diagnosis of myocardial infarction is made when one of the following criteria is met:

1. **Q wave MI (QMI):** will require one of the following criteria:
   1.1. Chest pain or other acute symptoms consistent with myocardial ischaemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data.
   1.2. New pathologic Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data the CEC may adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data.
2. **Non-Q wave MI (NQWMI):** for this trial NQWMI will be defined as elevated CK ≥2X the upper laboratory normal with the presence of elevated CK-MB (any amount above the institution's upper limit of normal) in the absence of new pathological Q waves.

[6] Myocardial infarction that has been adjudicated by the Clinical Events Committee as being clearly related to a non-target vessel will not be considered a MACE.

NO REFLOW

Defined as a sustained or transient reduction in antegrade flow that is not associated with an obstructive lesion at the treatment site.

PERFORATION

Perforations will be classified as follows:

*Angiographic perforation*: perforation detected by the clinical site or the core laboratory at any point during the procedure.

*Clinical perforation*: perforation requiring additional treatment (including efforts to seal the perforation or pericardial drainage), or resulting in significant pericardial effusion, abrupt closure, myocardial infarction, or death.

*Pericardial haemorrhage/tamponade*: perforation resulting in cardiac tamponade.

PROCEDURE SUCCESS

Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.

RECURRENT MI

Any myocardial infarction that occurs after the index procedure.

REFERENCE VESSEL DIAMETER (RVD)

Defined as the average of normal segments within 10 mm proximal and distal to the target lesion from 2 orthogonal views using QCA.

RESOURCES

Defined as hospital and physician resources associated with treatment that are paid by government or private insurers.

RESTENOTIC LESION

Defined as a lesion in a vessel segment that has undergone prior percutaneous treatment without a stent placement.

STENT THROMBOSIS

Defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically-driven angiographic restudy for documented ischaemia (chest pain and ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency. Late Stent Thrombosis is reported according to the following criteria[7]:

*Definite Late Stent Thrombosis*. Myocardial Infarction >30 days after index and attributable to the target vessel, angiographic documentation (site reported or by QCA) of thrombus or total occlusion at the target site, and freedom from interim revascularization of the target vessel.

[7] Medtronic utilizes stent thrombosis definitions that are consistent with the Harvard Clinical Research Institute Clinical Events Committee's standard definitions.

*Possible Late Stent Thrombosis*. Myocardial Infarction >30 days after index and attributable to the target vessel, no identifiable culprit lesion elsewhere, freedom from interim revascularization of the target lesion, and freedom from interim bypass grafting of the target vessel.

STROKE

Defined as sudden onset of vertigo, numbness, dysphasia, weakness, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain such as haemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists >24 hours.

STUDY DEVIATION

An incident where the investigator or site personnel did not conduct the study according to the investigational plan, protocol or the investigator agreement.

*Major deviation*: Any deviation from subject inclusion and exclusion criteria or subject informed consent procedures.

*Minor deviation*: Deviation from a protocol requirement such as incomplete/inadequate subject testing procedures, non-compliance with medication regimens, follow-ups performed outside specified time windows, etc.

TARGET LESION REVASCULARIZATION (TLR)

Defined as any clinically-driven repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel.

Clinically-driven revascularizations are those in which the subject has a positive functional study, ischaemic ECG changes at rest in a distribution consistent with the target vessel, or ischaemic symptoms. Revascularization of a target lesion with an in-segment diameter stenosis ≥70% (by QCA) in the absence of the above-mentioned ischaemic signs or symptoms is also considered clinically-driven. In the absence of QCA data for relevant follow-up angiograms, the clinical need for revascularization is adjudicated using the presence or absence of ischaemic signs and symptoms.

Non-clinically-driven repeat target lesion revascularizations are those in which the subject undergoes a non-emergent revascularization for a diameter stenosis <50% (by QCA). Non-emergent repeat target lesion revascularization for a diameter stenosis <70% (by QCA) in subjects without either a positive functional study or angina are also considered non-clinically-driven.

TARGET VESSEL FAILURE (TVF)

Defined as target vessel revascularization (defined below), recurrent Q or non-Q wave myocardial infarction, or cardiac death that could not be clearly attributed to a vessel other than the target vessel.

Target vessel failure is a more conservative and broader category and includes any target vessel revascularization as well as any recurrent MI or any cardiac death that cannot be clearly attributed to a non-target vessel. Target vessel failure, thus, includes any revascularization or adverse endpoint due to renarrowing of any portion of the target vessel,

and assumes that the entire vessel is vulnerable to late failures because of guide catheter or guidewire trauma or progression of disease remote from the treatment site.

Target vessel failure will be reported when:

1. Recurrent MI occurs in territory not clearly other than that of the target vessel.
2. Cardiac death not clearly due to a non-target vessel event.
3. Target vessel revascularization is determined.

TARGET VESSEL REVASCULARIZATION (TVR)

Defined as any clinically-driven (as defined for TLR) repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel.

TIMI FLOW CLASSIFICATION

*TIMI 0* No perfusion.

*TIMI 1* Penetration with minimal perfusion. Contrast fails to opacify the entire bed distal to the stenosis for the duration of the cine run.

*TIMI 2* Partial perfusion. Contrast opacifies the entire coronary bed distal to the stenosis. However, the rate of entry and/or clearance is slower in the coronary bed distal to the obstruction than in comparable areas not perfused by the dilated vessel.

*TIMI 3* Complete perfusion. Filling and clearance of contrast equally rapid in the coronary bed distal to stenosis as in other coronary beds.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

Defined as any serious adverse effect on health or safety or any life-threatening problem or death that is caused by or associated with an investigational device. The effect must have not been previously identified in nature, severity or degree of incidence in the investigational plan. Other serious problems associated with the device that affects the rights or welfare of study subjects may also be considered UADEs.

VASCULAR COMPLICATIONS

Vascular complications may include the following:

1. Pseudoaneurysm
2. Arteriovenous fistula
3. Peripheral ischaemia/nerve injury
4. Vascular event requiring transfusion or surgical repair

## B. Study Design

This was a prospective, multi-center, randomized, double-blind, two-arm study that enrolled 1,197 subjects with symptomatic ischaemic heart disease attributable to stenotic lesions of the native coronary arteries that were amenable to treatment by percutaneous stenting.

Study subjects may have had multiple vessel disease but only a single lesion per subject was allowed for this trial. The target lesion must have been *de novo* and in a native coronary artery.

Clinical follow-up for all subjects was performed at 30 and 270 days. Telephone follow-up for all patients was performed at 6, 12 and 24 months and annually thereafter out to 5 years post-index procedure.

The first 600 consecutive study subjects that enrolled were scheduled to have angiographic follow-up at 8 months post-index procedure.

A sub-study with IVUS evaluation at pre-selected sites was performed at baseline and at 8 months post-index procedure. These subjects were drawn from the angiographic cohort. It was estimated that approximately 300 patients were to have an IVUS evaluation at baseline.

Up to 120 subjects were scheduled to have blood samples taken for PK analysis as a sub-study at selected sites. This analysis was conducted by an independent third party.

### Selection of Subjects

This trial includes 1,197 subjects with *de novo* native coronary artery lesions who agreed to participate in the study. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data were collected on these patients. Seventy-eight (78) patients did not meet the eligibility criteria.

### Subject Selection Criteria

**Inclusion Criteria**:
**Note: Subjects could only be included in the study once.**

1. The subject was ≥18 years of age (or minimum age dictated by local regulations).
2. The subject was an acceptable candidate for PTCA, stenting, and emergent CABG.
3. The subject had clinical evidence of ischaemic heart disease or a positive functional study.
4. The subject had single vessel disease or had multi-vessel disease with only moderate stenosis (max 50-60% or total occlusion (100%) for which no interventions were planned at the time of study inclusion).
5. The target lesion / vessel must have met the following criteria:
   a. The target lesion was a single *de novo* lesion that had not been previously treated with any interventional procedure. Only one lesion may have been treated per

subject.
   b. The target vessel was a native coronary artery with a stenosis of ≥50% and <100%.
   c. The target lesion was ≥14 mm and ≤27 mm in length.
   d. The target vessel reference diameter was ≥2.25 mm and ≤3.5 mm. (Measurements were made by careful visual estimate, on-line quantitative coronary angiography, or intravascular ultrasound.)
6. Female subjects of childbearing potential had a negative pregnancy test within seven (7) days before the procedure.
7. The subject or the subject's legal representative had been informed of the nature of the study and agreed to its provisions and provided written informed consent as approved by the Institutional Review Board/Ethics Committee of the respective clinical site.
8. The subject and the treating physician agreed that the subject would comply with all required post-index procedure follow-up.

**Exclusion Criteria:**

1. A documented left ventricular ejection fraction <30%.
2. A known hypersensitivity or contraindication to aspirin, heparin, clopidogrel, cobalt, nickel, chromium, or a sensitivity to contrast media, which could not have been adequately pre-medicated.
3. Had a history of an allergic reaction or significant sensitivity or received drugs similar to/or synergistic to ABT-578 (rapamycin, tacrolimus, sirolimus, CCI-779 or other analogues).
4. A platelet count <100,000 cells/mm³ or >700,000 cells/mm³, or a WBC <3,000 cells/mm³.
5. Had evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes ≥2X the upper laboratory normal with the presence of a CK-MB elevated above the Institution's upper limit of normal).
6. Creatinine >2.0 mg/dl.
7. A previous coronary interventional procedure of any kind within the 30 days prior to the procedure.
8. The subject required planned interventional treatment of either the target or any non-target vessel within 30 days post-index procedure.
9. The target lesion required treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc.).
10. Had previous stenting anywhere in the target vessel.
11. The target vessel had evidence of thrombus or was excessively tortuous (2 bends >90° to reach the target lesion).
12. Had significant (>50%) stenosis proximal or distal to the target lesion that may have required revascularization or impede run off.
13. Target lesion located in native vessel distally to anastomosis with vein graft or LIMA.
14. The target lesion had any of the following characteristics:
    a. Lesion location was aorto-ostial, an unprotected left main lesion, or within 5 mm of the origin of the LAD, LCX, or RCA.

b. Involved a side branch >2.0 mm in diameter.
c. Was at or distal to a 45º bend in the vessel.
d. Was severely calcified.

15. Had an unprotected left main coronary artery disease (an obstruction greater than 50% in the left main coronary artery).
16. Had a history of a stroke or transient ischaemic attack within the prior 6 months.
17. Had an active peptic ulcer or upper GI bleeding within the prior 6 months.
18. The subject had a history of bleeding diathesis or coagulopathy or would have refused blood transfusions.
19. Had a concurrent medical condition with a life expectancy of less than 12 months.
20. Had any previous or planned treatment with anti-restenotic therapies including, but not limited to, drug-eluting stents and brachytherapy.
21. Was currently participating in an investigational drug or another device study that had not completed the primary endpoint or that clinically interfered with the current study endpoints. [Note: Trials requiring extended follow-up for products that were investigational, but had since become commercially available, were not considered investigational trials.]

## Baseline and Screening

### Subject Screening

All patients admitted for potential percutaneous revascularization of the native coronary arteries were screened for study eligibility. A member of the Institution's research team assigned to the Medtronic Vascular Endeavor Zotarolimus-Eluting Coronary Stent System reviewed the subject's medical and cardiac history to screen for study eligibility. A screening log was provided to study sites to maintain a cumulative log of all the screened subjects. This screening log was completed and faxed to Quintiles (the Study Monitor) on a weekly basis.

### Informed Consent

All potential subjects were consented **prior** to performing any study related procedures. Once the Investigator had determined the subject's eligibility for the study, the background of the proposed study and the benefits and risks of the procedures and study were explained to the subject. The subject (or the subject's legal representative) signed the site's Ethics Committee approved informed consent prior to participation. Failure to provide informed consent rendered the subject ineligible for the study.

### Subject Withdrawal

Following the introduction into the guide catheter of the intended device, all living subjects were required to complete all assigned follow-ups, including angiography, IVUS and/or PK sampling if applicable. Subjects were exempt from follow-up only if they withdrew their consent. A study subject that had been withdrawn from the study was not replaced.

## Clinical Laboratory Procedures and Tests

Performed for all subjects prior to the procedure to guarantee eligibility (see Schedule of Treatments and Assessments):

1. *Within seven days of the procedure*, a 12-lead electrocardiogram, CBC, chemistry panel, and in addition, a pregnancy test (ßHCG subunit) for women of childbearing potential were obtained.
2. *Within 72 hours of the procedure,* a creatine kinase (CK) enzyme and creatine kinase myocardial-band (CK-MB) isoenzyme test was obtained. In addition, CRP (C - reactive protein) levels in selected sites with the ability to measure quantitative CRP levels were obtained. Troponin measurements may have been made in addition to CK. Centers that had the capability were strongly encouraged to measure Troponin levels.
3. *Following arterial access*, a baseline activated clotting time (ACT) was determined. ACT and subsequent heparin dosing was recorded throughout the procedure. Documentation of a final ACT level, before leaving the catheterization laboratory was also performed. All ACTs were recorded in the medical record for source documentation purposes.

**Enrollment**

All subjects who met eligibility requirements were asked to participate. Subjects were considered enrolled into the study after:

1. Signed *informed consent* had been obtained,
2. The subject and the target lesion met all of the *inclusion and exclusion criteria*,
3. The study device was introduced into the guide catheter.

The subject enrollment and device tracking CRFs were faxed to Quintiles within 24 hours of enrollment.

**Randomization**

Randomization occurred prior to any percutaneous treatment to the target lesion. Eligible subjects were randomized in a double-blind fashion to one of the two treatments (1:1 randomization):

1. Driver
   OR
2. Endeavor

Randomization was accomplished at each site using an Interactive Voice Randomization System (IVRS). Randomization was administered on a per site basis. Subjects were randomized to one of the two treatment arms, labeled respectively Treatment A and Treatment B. Neither the investigator nor the patient knew which stent was implanted.

**Data Safety Monitoring Board (DSMB)**

The Data Safety Monitoring Board (DSMB) was composed of five members (four physicians from the fields of cardiology and interventional cardiology and one bio-statistician), who were not directly involved in the conduct of the trial. The DSMB reviewed the study on a periodic basis.

Based on the safety data, the DSMB could have recommended that the Executive Committee modify or stop the trial. All final decisions, however, regarding trial modifications, rested with the Executive Committee. No formal statistical rules for stopping the trial were defined.

**Clinical Events Committee**

The Clinical Events Committee was made up of interventional and non-interventional cardiologists who were not participants in the study. The Clinical Events Committee was charged with the development of specific criteria used for the categorization of clinical events and clinical endpoints in the trial.

At the onset of the trial, the Clinical Events Committee established explicit rules outlining the minimum amount of data required, and the algorithm followed in order to classify a clinical event. All members of the Clinical Events Committee were blinded to the tabulated primary results and treatment groups of the trial.

Once the specific criteria for clinical events and endpoints were established by the Clinical Events Committee, the Harvard Clinical Research Institute (HCRI) was responsible for categorizing all clinical events when all necessary data were available.

## Schedule of Treatments and Assessments

| INDEX HOSPITALIZATION | | | | FOLLOW-UP | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Event** | **Screen** | **Procedure** | **Post-Index Procedure** | **7 Day** | **14 Day** | **30 Day** | **6 Month** | **8 Month** | **9 Month** | **12 months-5 years** |
| Type of Contact | | | | | | Office visit | Telephone | Angio[7]/ IVUS[8,] | Office visit | Telephone |
| Informed Consent Signed | X | | | | | | | | | |
| Inclusion/Exclusion Criteria | X | | | | | | | | | |
| Medical and Cardiac History | X | | | | | | | | | |
| Angina Status | X | | X | | | X | X | X | X | X |
| Pregnancy test | X [1,2] | | | | | | | | | |
| CBC with differential, platelet count Chemistry Panel [11] | X [2] | | X [3] | | | X | | | X | |
| PK Sample | X[9] | | X [9] | X [9] | X [9] | X [9] | | | | |
| CRP | X [8] | | X [8] | | | | | | | |
| CK & CK-MB | X [4] | | X [5] | | | | | | | |
| Troponin | X [10] | | X [10] | | | | | | | |
| 12-Lead Electrocardiogram | X [4] | | X [3] | | | | | | | |
| ACT Measurements[12] | | X | | | | | | | | |
| Medication Regimen [6] | X | X | X | | | X | X | | X | X |
| Adverse Event Monitoring | | | X | X | X | X | X | X | X | X (SAE) |
| Angiography (QCA) | X | X | | | | | | X [7] | | |
| IVUS | | X [8] | | | | | | X [8] | | |

1. For women of childbearing potential only.
2. Within 7 days prior to procedure.
3. Within 24 hours post-index procedure or at discharge, which ever came first.
4. Within 72 hours prior to procedure.
5. Within 6-8, 12-16, and 20-24 hours post-index procedure or prior to hospital discharge, whichever came first.
6. It was expected that clopidogrel was used, unless the patient was allergic or sensitive to this medication. For patients unable to take clopidogrel, or at the discretion of the physician, ticlopidine was used.
7. A subset including the first 600 consecutive study subjects enrolled had angiographic follow-up at 8 months.
8. Selected clinical sites only.
9. Up to 120 subjects had blood samples taken prior to procedure and at 0.25hr, 0.5hr, 1hr, 2hr, 4hr, 6hr, 12hr, 24hr (or discharge, whichever came first) and at 7, 14 and 30 days post-index procedure for pharmacokinetic (PK) analysis as a sub-study at selected sites.
10. Optional – Measurement was recommended if the lab had the capability.
11. Please see complete list in definitions section.
12. Optional – per hospital practice.

## C. Objectives

### Primary Objective

The primary objective of this study was to demonstrate the safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System coated with 10 μg/mm ABT-578 compared to the Driver bare metal stent for the treatment of single *de novo* lesions in native coronary arteries 2.25-3.5 mm in diameter.

The primary endpoint was Target Vessel Failure (TVF) rate defined as a composite of target vessel revascularization, recurrent Q wave or Non-Q wave myocardial infarction, or cardiac death that could not be clearly attributed to a vessel other than the target vessel at 270 days post index procedure.

### Secondary Objectives

The secondary objectives of this trial were to assess the medium- and long-term safety and efficacy of the Endeavor when compared to the Driver bare metal stent using the following endpoints:

- Device Success defined as attainment of <50% residual stenosis of the target lesion using only the assigned device.
- Lesion Success defined as attainment of <50% residual stenosis of the target lesion using any percutaneous method.
- Procedure Success defined as attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.
- Major Cardiac Adverse Events (MACE) defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (TLR) at 30 days and 6, 9, and 12 months and annually thereafter out to 5 years.
- Late loss at 8 months as measured by QCA, defined as the difference between the post-index procedure minimal lumen diameter (MLD) and the follow-up angiography MLD.
- Angiographic in-stent and in-segment binary restenosis rate (≥50% diameter stenosis) at 8 months post-index procedure.
- In-stent and in-segment minimum lumen diameter (MLD) at 8 months post-index procedure.
- Neointimal hyperplastic volume at 8 months as measured by intravascular ultrasound (IVUS).
- Target Lesion Revascularization (TLR) at 270 days post-index procedure.
- Target Vessel Revascularization (TVR) at 270 days post-index procedure.
- Pharmacokinetic assessment in a subset of subjects.
- Safety and tolerance.

## D. Study Phases and Procedures

### Procedure

### Preparation, Angiography and Intravascular Ultrasound

1. Using standard procedures for balloon angioplasty, an introducer sheath of at least 6 French was introduced using the standard approach.
2. The guiding catheter used during the stent procedure was to have had a minimum internal diameter of 0.064″ and the guidewire diameter should not have been larger than 0.014″.
3. After catheter introduction, heparin with or without a glycoprotein IIb/IIIa receptor blocker was administered and supplemented as needed to maintain anticoagulation throughout the procedure.
4. Following intracoronary injection of GTN, baseline angiography of the vessel was performed in at least two near-orthogonal views that showed the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.
5. Intravascular ultrasound (IVUS) with automated pullback was then performed in the selected IVUS sub-study sites.

### Lesion/Vessel Pre-treatment

The target lesion was to have been pre-treated with standard percutaneous transluminal balloon angioplasty. The protocol did not allow for direct stenting.

Predilatation was to have been performed with a balloon with a diameter at least 0.5 mm smaller than the stent to create a channel through the lesion to facilitate the crossing of the stent in order to avoid damage to the coating. Also, a balloon length was to have been selected matching the lesion length to avoid dilatation of the vessel wall adjacent to the stent. The length of the predilatation balloon was to have been shorter than the stent that was intended to be implanted.

The use of other approved therapy (DCA, Laser, Rotational Atherectomy, etc.) was not allowed.

### Stenting Procedure

The stenting procedure was performed according to the Instructions for Use. Care was taken to select the stent package from the correctly labeled treatment arm (A or B) as designated by randomization.

No more than one study stent was to have been used to treat the lesion. The only exception was insufficient lesion coverage or a bailout procedure.

The delivery system was advanced over the guidewire until the ends of the stent, identified by the balloon markers, bracketed the target lesion. Stent position was confirmed by angiography.

A stent was to have been selected long enough to cover the lesion completely. If more than one stent was needed to cover the lesion completely, it was recommended to overlap the stents 1-2 mm. The 8 or 9 mm stent was only to be used as a secondary stent to cover dissection post stent deployment, or if the primary stent failed to cover the lesion completely.

No more than 30 mm of total study stent length was to be used per patient. If additional stents were required, a Driver stent should have been used.

Stent deployment was to have been performed by careful visual assessment of stent expansion and apposition guided by on-line QCA measurement of the Minimal Lumen Diameter (MLD) function. The aim was to reach a diameter stenosis <10% with avoidance of proximal or distal dissections.

After stent deployment, the delivery balloon was deflated and the delivery catheter was carefully withdrawn on negative pressure with the guidewire remaining across the lesion.

At procedure completion, an intracoronary injection of GTN was to have been administered and final angiography of the vessel performed in the two near-orthogonal views that were taken at baseline, showing the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.

**AVAILABLE STENT DIAMETERS AND LENGTHS**

| Diameters (mm) | Lengths (mm) | | | | |
|---|---|---|---|---|---|
| | 8.0* | 9.0* | 18.0 | 24.0 | 30.0 |
| 2.25 | ✓ | | ✓ | ✓ | ✓ |
| 2.50 | ✓ | | ✓ | ✓ | ✓ |
| 3.0 | | ✓ | ✓ | ✓ | ✓ |
| 3.5 | | ✓ | ✓ | ✓ | ✓ |

*To be used as a secondary stent only (in cases of insufficient lesion coverage or bailout).

## IVUS Evaluation

At selected sites, an intravascular ultrasound (IVUS) evaluation was to have been performed after the stent implantation was considered optimal by careful visual assessment and / or by on-line QCA measurement of the MLD-function. A system with automated pullback was to have been used. It was up to the investigator's discretion whether the stent implantation was IVUS guided or IVUS was only for documentary purposes. Among the 328 patients who were enrolled in the IVUS patient set, 297 patients had evaluable baseline films and 247 patients had evaluable 8-month follow-up films.

**Bailout Procedures**

If the subject experienced a major dissection or an occlusive complication manifested as decreased target vessel flow, chest pain or ischaemic ECG changes which did not respond to repeat balloon inflations or intracoronary vasodilators (GTN, verapamil, diltiazem, nitroprusside), other bailout procedures performed which might have included further stenting. If the subject required additional stents, a study stent from the same treatment group (A or B) was to have been used. If it was considered appropriate by the operator, a study stent with a length of 8 or 9 mm (depending on diameter) was to have been used in this instance. Please note that the total length of stent used (treatment A or B) should not have exceeded 30 mm. If additional stenting was required beyond total length of 30 mm, then a Driver stent was to have been used. Among the 90 patients who received total length of stent >30 mm, 44 patients received subsequent Driver stents.

**Treatment Failures**

Failure to implant the Endeavor Zotarolimus-Eluting Coronary Stent System at the intended target lesion was to have been recorded on the CRF as a treatment failure. In the event of a failure to implant the stent, the investigator had the choice to treat the target lesion with an approved device. The investigator must have returned any damaged or unused stents to Medtronic Vascular, Inc.

**Post-Index Procedure**

**Subject Management**

Immediately following the procedure:

1. Heparin was to have been discontinued.
2. ACT was to have been monitored in accordance with hospital protocol.
3. Vascular sheaths were to have been removed according to usual hospital practice.
4. Approved vascular closure devices may have been used at the discretion of the investigator in accordance with the manufacturer's directions.

**Anti-platelet / Anticoagulation Regimen**

All subjects were to have received at least 75 mg aspirin daily indefinitely and clopidogrel 75 mg daily for at least 12 weeks.

**Clinical and Laboratory Procedures**

An ECG was to have been performed within 24 hours post-index procedure or prior to discharge (whichever occurred first). A 12-lead ECG was required to document any suspicious cardiac ischaemic episode.

CK and CK-MB were measured post-index procedure between:

- 6-8 hours,
- 12-16 hours, and
- 20-24 hours (or discharge whichever came first).

If total CK values were within normal ranges, CK-MB measurements may not have been performed per hospital standards. It was strongly encouraged however that CK-MB measurements were obtained with every total CK drawn, even if CK values were within normal limits.

Every effort was to have been made to obtain cardiac enzyme values within the specified time ranges, to help determine the presence or absence of myocardial infarction post-index procedure. Results of all cardiac enzyme tests, even tests performed outside the time range, were documented on the case report forms.

If any CK elevation was noted post-index procedure, CK and CK-MB measurements were to have been continued to be performed every 8 hours for 24 hours, starting from when the first elevation was noted, and recorded on the appropriate case report form.

If a patient was discharged prior to 20 hours, the 20-24 hour blood draw may have been omitted. Every effort was to have been made to obtain a blood sample prior to hospital discharge.

Troponin measurements could have been made in addition to CK. Centers that had the capability were strongly encouraged to measure Troponin levels. CRP levels were measured before and after the procedure by selected sites able to measure CRP quantitatively.

A complete blood count with differential, platelets and chemistry was performed on all patients within 24 hours post-index procedure or before discharge, whichever came first.

**Pharmacokinetic Sampling Sub-study**

Up to 120 subjects had blood samples taken pre-procedure and at 0.25 hr, 0.5 hr, 1 hr, 2 hr, 4 hr, 6 hr, 12 hr and 24 hr (or discharge, whichever came first) and at 7, 14 and 30 days post-index procedure for a sub-study PK analysis at selected sites.

**Concomitant Medical Therapy**

It was strongly recommended that all subjects received the medication regimen listed below. All medications administered were to have been recorded in the subject's medical record. All concomitant medications taken by the patient for 30 days post-index procedure were to have been reported on the study case report form. All anti-platelet and anti-coagulant medication taken throughout the study was to have been reported on the study case report form.

| | | |
|---|---|---|
| Prior to Procedure | IV Heparin | PRN |
| | Aspirin | At least 75 mg QD |
| | Clopidogrel[1, 2] | 300 mg loading dose (if patient not currently taking clopidogrel) |
| During Procedure | IV Heparin | To maintain ACT ≥250 sec., or 200-250 sec. if GP IIb/IIIa blocker is used |
| | Intracoronary Nitroglycerin | 100-200 μg *prior to baseline* and post intervention angiograms |
| Post-Index Procedure | IV Heparin | PRN |
| | Aspirin | At least 75 mg QD indefinitely |
| | Clopidogrel[1] | 75 mg po QD (for 12 weeks) |

1. It was expected that clopidogrel was used, unless the patient was allergic or sensitive to this medication. For patients unable to take clopidogrel, or at the discretion of the physician, ticlopidine was used. For patients on ticlopidine, CBCs were to be performed as per the drug labeling.
2. If the patient had been on clopidogrel for at least 48 hours prior to the procedure, the daily dose was continued and no additional loading dose given prior to the procedure.

**Follow-up Procedures**

Follow-up procedures for this trial included:

1. Blood draws according to hospital standard or medication regimen.
2. Documentation of referring physicians, including general practitioners as well as cardiologists, family members, and neighbors, for assistance in locating patient if lost to follow-up. Any planned long absences from the area were recorded to facilitate continued ability to contact a study subject.
3. In cases where the telephone contact at the required follow-up was not documented in the hospital file, the CRF may have served as a source document.
4. Subjects enrolled will be followed for five years after the index procedure.

   6-8 Hours, 12-16 Hours, 20-24 Hours Post-Index Procedure
   CK and CK-MB were to have been measured within the specific time ranges to help determine the presence or absence of myocardial infarction post-index procedure.

   An ECG was to have been performed within 24 hours post-index procedure or prior to discharge (whichever comes first).

   24 Hours post-index procedure or before discharge, whichever came first
   A complete blood count with differential, platelets and chemistry panel was to have been done on all patients.

   48 Hours post-index procedure or before discharge, whichever came first
   CRP (C-Reactive Protein) levels were collected in selected sites with the ability to measure quantitative CRP levels.

Thirty Days Post-Index Procedure (±5 days)
A clinic visit was scheduled at thirty days. The assessment consisted of angina status (according to the Canadian Cardiovascular Society Classification of angina), **all** adverse events, CBC with differential, platelets, chemistry panel, **all** concomitant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Six Months Post-Index Procedure (±14 days)
A telephone assessment was performed at six months. The assessment consisted of angina status (according to the Canadian Cardiovascular Society Classification of angina), **all** adverse events, concomitant anti-platelet/anti-coagulant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Eight Months Post-Index Procedure (±14 days)
A subset of the first 600 consecutively enrolled study subjects underwent an angiogram at eight months. Angiographies should have been performed in the same manner as described in Section 5.5 and appendix B in the protocol. Additionally, 328 angiographic subjects underwent IVUS at baseline and at eight months post-index procedure as a sub-study at selected sites.

Nine Months Post-Index Procedure (±14 days)
A clinic visit was scheduled at nine months post-index procedure and consisted of angina status assessment (according to the Canadian Cardiovascular Society Classification of angina), **all** adverse events, CBC with differential, platelets, chemistry panel concomitant anti-platelet/anti-coagulant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Twelve, Twenty-Four and Thirty-Six Months Post-Index Procedure (±30 days) and annually thereafter out to five years
A telephone assessment was performed at twelve, twenty-four and thirty-six months post-procedure and will be performed annually thereafter out to five years and consist(ed) of an assessment of angina status (according to the Canadian Cardiovascular Society Classification of angina); serious adverse events including major adverse cardiac events, concomitant anti-platelet/anti-coagulant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

5. Up to 120 subjects were to have had blood samples taken at 7, 14 and 30 days post-index procedure for a sub-study PK analysis at selected sites.

**Summary of Follow-Up Procedures**

| Contact Period | Type of follow-up required |
|---|---|
| 7 ± 2 days | PK Sample (sub-study) |
| 14 ± 3 days | PK Sample (sub-study) |
| 30 ± 5 days | Clinic Visit<br>CBC with differential, platelets, chemistry panel<br>PK Sample (sub-study) |
| 6 months ±14 days | Telephone Assessment |
| 8 months ±14 days | Angiographic follow-up for subset of first 600 consecutive patients<br>IVUS follow-up for subset of subjects |
| 270 days ±14 days | Clinic visit<br>CBC with differential, platelets, chemistry panel |
| 12 months ± 30 days, and annually thereafter out to 5 years. | Telephone Assessment |

## Angiographic Follow-up

All ELECTIVE angiograms performed during the 5-year follow-up period should have been preceded by a physician evaluation during which the physician indicated whether or not the subject's clinical status warranted revascularization. Angiograms, including unscheduled angiograms, were sent to the Angiographic Core Laboratory for review.

The first 600 consecutively enrolled study subjects underwent repeat angiography at approximately 8 months after the index procedure.

If repeat angiography was performed any time after the first month (≥30 days) and it demonstrated restenosis of the target vessel in association with objective evidence of recurrent ischaemia, that angiogram was analyzed as the follow-up angiogram, and the subjects were not required to undergo additional repeat angiography.

In some cases, recurrent ischaemia might have developed less than 30 days after successful stent placement. If angiography demonstrated a significant stenosis or sub-acute thrombotic occlusion of the target vessel, the subject was considered an acute failure, and continued to be included in the follow-up analysis that measures angiographic restenosis. In this situation, recurrent ischaemia was attributed to sub-abrupt closure, rather than restenosis. Even if subjects assigned to the angiographic follow-up cohort did undergo a repeat percutaneous intervention within 30 days, they were required to return for the follow-up angiogram at approximately 8 months.

As a general principle, clinically-driven angiograms performed within 5 months after the procedure were not considered follow-up angiograms unless a target lesion intervention was performed. Clinically-driven angiograms after 5 months post-index procedure may have

been considered as a follow-up angiogram and may not have to have been repeated at 8 months post-index procedure. Angiographic Films were qualified at follow-up based on the qualification scheme in Appendix B. .

**IVUS Follow-up**

Patients who were part of the IVUS sub-study at baseline underwent an IVUS evaluation during the follow-up angiography (at 8 months or earlier if a re-intervention was performed). The IVUS sites were notified and instructed to stop IVUS evaluation once the recruitment for the angiographic sub-study had been completed. However, these IVUS sites could have continued to enroll patients (without performing IVUS procedures).

## E. Clinical Events

### Adverse Events

An adverse event was any undesirable medical occurrence in a clinical study subject, whether it was considered to be related to the device or not, that includes a clinical sign, symptom, or condition and/or an observation of a near incident.

Adverse event information was collected throughout the study and documented in the subject's medical record. All adverse events occurring up to 270 days post-index procedure whether associated with the investigational product or not, were recorded on the case report forms by the Investigator or other appropriate site personnel.

Event, date of onset, severity, duration, and relationship to device were recorded on the appropriate case report form. Adverse events were followed until the event had subsided or, in case of permanent impairment, until the event stabilized and the overall clinical outcome had been ascertained.

After 270 days, only serious adverse events including major adverse cardiac events and device related adverse events were recorded on the case report forms.

#### Device Related Adverse Event

A device related adverse event was defined as any adverse event for which a causal relationship between the device and the event was at least a reasonable possibility, i.e., the relationship could not be excluded.

### Serious Adverse Events and Death

The Investigator decided whether each event met the definition of a "serious" adverse event. The regulatory definition of a serious adverse event was an event that was fatal or life threatening, resulted in persistent or significant disability, requires intervention to prevent permanent impairment/damage, or an event that resulted in congenital anomaly, malignancy, hospital admission or prolongation of hospitalization.

The primary study endpoint, which included death, myocardial infarction (Q wave or non-Q wave), and revascularization, would be considered serious by this definition.

Any serious adverse event or subject death occurring during the 5 year follow-up period, regardless of cause, must be reported to Medtronic within one working day after the investigator first learns of the event.

**Unanticipated Adverse Device Effects**

An Unanticipated Adverse Device Effect (UADE) was defined as any adverse effect on health or safety or any life-threatening problem or death that was caused by or associated with an investigational device. The effect must not have been previously identified in nature, severity or degree of incidence in the Investigational Plan, Investigator's Brochure or Instructions for Use. Other serious problems associated with the device that effect the rights or welfare of study subjects may have also been considered UADEs.

UADEs must have been reported to the sponsor and the IRB/EC (if required) within one working day after the investigator first learned of the effect.

**Device Failures, Malfunctions and Near Incidents**

All device failures, malfunctions and near incidents were documented and reported. In case of a device failure, malfunction or near incident related to the investigational device, the device was returned to Medtronic Vascular, Inc. for analysis.

**Device Failure:** A device had failed if it was used in accordance with the Instructions for Use, but did not perform according to Instructions for Use and negatively impacted the treatment.

**Device Malfunction:** A device malfunction was an unexpected change to the device that was contradictory to the Instructions for Use and did or did not affect device performance.

**Near Incident:** Malfunction or deterioration in the characteristics and/or performance of the device which might have led to death or serious deterioration in health; incident occurred and was such that if it occurred again, it might lead to death or serious deterioration in health.

**Device Misuse:** A misused device (one that was used by the investigator in a manner that was contradictory to the Instructions for Use) was not considered a malfunction.

## F. Statistical Methods of Analysis

This was a randomized, controlled, prospective, multi-center two-arm trial designed to assess the safety and effectiveness of the Endeavor Zotarolimus-Eluting Coronary Stent System compared to the Driver bare metal stent. The primary endpoint evaluated in this study was target vessel failure, defined as the composite of cardiac death, recurrent myocardial infarction, or target vessel revascularization at 270 days post-index procedure.

The study was conducted at 72 centers and enrolled 1,197 subjects.

### Primary Analysis Sample

The primary analysis sample was based on the principle of intention-to-treat. For this study, all subjects who met the study entry criteria, signed the written informed consent and were randomized to a treatment arm were counted in the primary analysis.

### Secondary Analysis Sample

The secondary analysis sample was based on the principle of per-protocol. The following table highlights the conditions that need to be met for PP.

| Condition | ENDEAVOR II Criteria | | | |
|---|---|---|---|---|
| | **Endeavor** | **Patients** | **Driver** | **Patients** |
| De-registered | During index procedure:<br>1. Did not receive any device<br>2. Received assigned study device, and another type of DES | | During index procedure:<br>1. Did not receive any device<br>2. Received assigned study device, and another type of DES | |
| Cross Over Implantation | Assigned Endeavor, but received Driver | | Assigned Driver, but received Endeavor | |
| The target lesion is a single de novo lesion that has not been previously treated with any interventional procedure. Only one lesion may be treated per subject. | Inclusion 5a | | Inclusion 5a | |
| Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes 2X the upper laboratory normal with the presence of a CK – MB elevated above the Institution's upper limit of normal). | Exclusion 5 | | Exclusion 5 | |

| Condition | ENDEAVOR II Criteria | | | |
|---|---|---|---|---|
| | Endeavor | Patients | Driver | |
| The target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc). | Exclusion 9 | None | Exclusion 9 | |
| Previous stenting anywhere in the target vessel. | Exclusion 10 | | Exclusion 10 | |
| Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.[Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.] | Exclusion 21 | | Exclusion 21 | |

## Endpoint Analysis and Reporting of Results

All statistical analyses were performed using SAS for Windows (version 6.12 or higher) or other widely accepted statistical or graphical software. Patient data listings and tabular and graphical presentations of results were provided.

All clinically relevant baseline variables were tabulated and compared between subjects assigned the Endeavor Zotarolimus-Eluting Coronary Stent System and control arm of the trial. Categorical variables were tested using appropriate contingency table analyses (exact or chi-square approximations), and continuous variables were tested using unpaired Student's t-test. Multivariable regression and multivariable survival analysis was utilized to examine alternative hypotheses, such as exploration of outcome determinants. Multi-variable testing used linear regression for continuous response variables and logistic regression for dichotomous response variables. The time-sensitive nature of any response variable was displayed by using a Kaplan-Meier plot, with differences between groups for such variables tested by log rank tests.

A statistical significance was declared if the two-sided P-value is $<0.05$.

Secondary endpoint testing and subgroup hypothesis testing was performed using identical statistical techniques as in the primary endpoint analysis.

## Section III. Tables and Figures

### Table 2a. Number of Patients Treated by Investigator - All Enrolled Subjects

| Site | Clinical Site | Location | Principal Investigator | Number of Patients Enrolled |
|---|---|---|---|---|
| 301 | Monash Medical Centre | Clayton, Australia | Ian Meredith MD | 13 |
| 302 | St. Vincent's Hospital | Fitzroy, Australia | Rob Whitebourn MD | 21 |
| 307 | Grantham Hospital | Hong Kong, China | On-Hing Kwok MD | 7 |
| 308 | Prince of Wales Hospital | Hong Kong, China | John Ormiston MD | 16 |
| 309 | National Heart Center/Singapore General Hospital | Singapore, Singapore | Charles Wah-Hak Chan | 20 |
| 310 | National University Hospital/The Heart Institute | Singapore, Singapore | Huay Cheem Tan | 7 |
| 313 | St. Vincent's Hospital | Darlinghurst, Australia | David Muller | 14 |
| 314 | Greenlane Hospital | Auckland, New Zealand | John Ormiston MD | 36 |
| 315 | Dunedin Hospital | Dunedin, New Zealand | Patrick Kay | 17 |
| 317 | Mercy Hospital | Auckland, New Zealand | John Ormiston MD | 2 |
| 401 | A.Z. Middelheim | Antwerp, Belgium | P.H.M.J Vermeersch | 12 |
| 402 | C.H.U. Sart | Liege, Belgium | V. Legrand | 1 |
| 403 | C.H.R de la Citadelle | Liege, Belgium | Jean Boland | 6 |
| 404 | Onze-Lieve Vrouw Ziekenhuis | Aalst, Belgium | W.C.Y Wijns | 16 |
| 405 | U.Z. Gasthuisberg | Leuven, Belgium | Christophe Dubois | 8 |
| 406 | Z.O.L Campus St-Jan | Genk, Belgium | Mathias Vrolix | 13 |
| 407 | Rigshopsital | Koebenhhavn, Denmark | Henning Kelbaek | 2 |
| 408 | Skejby Hospital | Aarhus, Denmark | Leif Thuesen | 11 |
| 409 | Hopital Bichat Claude Bernard | Paris, France | Jean-Michel Juliard | 5 |
| 410 | Centre Hospitalier prive Saint Martin | Caen, France | Pascal Richard | 5 |
| 411 | CHU de Caen | Caen, France | Gilles Grollier | 6 |
| 412 | Hopital Jean Minjoz | Besancon, France | Francois Schiele | 17 |
| 413 | Clinique Pasteur | Toulouse , France | Jean Fajadet | 10 |
| 414 | Clinique Saint Augustin | Bordeaux, France | Olivier Darremont | 13 |
| 417 | Hopital Cardiologique du Haut Leveque, CHU de Bordeaux | Pessac, France | Pierre Coste | 3 |
| 418 | CHU Rangueil | Toulouse, France | Didier Carrie | 10 |
| 419 | Hopital Laennec, CHU Nord | Nantes, France | Pierre-Dominiqu | 3 |
| 420 | Institut Hospitalier Jacques Cartier | Massy, France | Yves Louvard | 2 |
| 422 | Catharina Ziekenhuis | Eindhoven, Netherlands | J.J.R.M Bonnier | 28 |
| 423 | Leids Universitair Medisch Centrum | Leiden, Netherlands | J.W Jukema | 12 |
| 424 | Onze Lieve Vrouwe Gasthuis | Amsterdam, Netherlands | G.J Laarman | 66 |
| 425 | Stichting Sint Antonius Ziekenhuis | Nieuwegein, Netherlands | M.J Suttorp | 41 |
| 426 | Academisch Ziekenhuis Vrije | Amsterdam, Netherlands | C.C. de Cock | 8 |
| 428 | Hosp. de Santa Marta | Lisbon, Portugal | Jorge Quininha | 8 |

*(Table continued on next page.)*

## Table 2a. Number of Patients Treated by Investigator - All Enrolled Subjects (Continued)

| Site | Clinical Site | Location | Principal Investigator | Number of Patients Enrolled |
|---|---|---|---|---|
| 437 | Derriford Hospital | Plymouth, UK | Joseph Motwani | 14 |
| 438 | Freeman Hospital | Newcastle Upon Tyne, UK | Azfar Zaman | 7 |
| 439 | Glenfield Hospital | Leicester, UK | Anthony Gershlick | 2 |
| 440 | John Radcliffe Hospital | Headington, Oxford, UK | Adrian Banning | 2 |
| 441 | Royal Infirmary of Edinburgh | Edinburgh, UK | Neal Uren | 8 |
| 442 | Southampton General Hospital | Southampton, UK | Keith Dawkins | 2 |
| 444 | Hopital Lariboisiere | Paris, France | Patrick Henry | 5 |
| 501 | Allgemeines Krankenhaus d. Stadt | Wein, Austria | Dietmar Glogar | 15 |
| 502 | Universitaetsklinik Innsbruck | Innsbruck, Austria | Othmar Pachinger | 5 |
| 503 | Universitaetsklinikum | Kiel, Germany | Ruediger Simon | 16 |
| 504 | Allgemeines Krankenhaus St. Georg | Hamburg, Germany | Karl-Heinz Kuck | 54 |
| 505 | Herzzentrum Bad Krozingen | Bad Krozingen, Germany | Franz-Josef Neumann | 6 |
| 506 | Kerckhoff-Klinik | Bad Nauheim, Germany | Christian Hamm | 20 |
| 507 | Krankenhaus und Herzzentrum | Siegburg, Germany | Eberhard Grube | 32 |
| 508 | Krankenhaus der Barmherzigen Brueder | Trier, Germany | Karl-Eugen Hauptmann | 42 |
| 509 | Universitaet Aachen | Aachen, Germany | R. Hoffmann | 11 |
| 510 | St. Johannes Hospital | Dortmund, Germany | Hubertus Heuer | 32 |
| 511 | Herzzentrum Leipzig GmbH | Leipzig, Germany | Peter Sick | 16 |
| 512 | Universitaetskliniken des Saarlandes | Homburg, Germany | Benno Hennen | 29 |
| 513 | Universitaetsklinik Hamburg | Hamburg, Germany | Thomas Muenzel | 47 |
| 514 | Klinikum Benjamin Franklin Medizinische Klinik II | Berlin, Germany | Hans-Peter Schultheiss | 37 |
| 515 | Humboldt Universitaetsklinikum Charite Berlin | Berlin, Germany | Wolfgang Rutsch | 18 |
| 516 | University Hospital of Ioannina | Ioannina, Greece | L. Michalis | 11 |
| 517 | Rabin Medical Center | Petach Tikva, Israel | Ran Kornowski | 24 |
| 518 | Hadassah Medical Center- Ein Kerem | Jerusalem, Israel | Chaim Lotan | 18 |
| 519 | Carmel Medical Center | Haifa, Israel | Basil Lewis | 16 |
| 520 | Rambam Medical Center | Haifa, Israel | Refael Beyar | 15 |
| 531 | Klinika Kardiologii | Warszawa, Poland | Witold Ruzyllo | 33 |
| 532 | Szpital Specjalistyczny im. Jana Pawla II | Krakow, Poland | Piotr Pieniazek | 33 |
| 533 | I Klinika Kardiologii Slaskiej Akademii Medycznej | Katowice, Poland | Janusz Drzewiecki | 41 |
| 534 | Slaskie Centrum Chorob Serca | Zabrze, Poland | Andrzej Lekston | 19 |
| 537 | Hopitaux Universitaires de Geneve- HUG | Geneve, Switzerland | Edoardo Camenzind | 25 |
| 538 | Universitatsspital Zurich | Zurich, Switzerland | Franz Eberli | 9 |
| 539 | Herzzentrum Bodensee | Kreuzlingen, Switzerland | Micheal Pieper | 37 |
| 540 | Klinikum der Johann W. Goethe-Universitaet | Frankfurt, Germany | Andreas Zeiher | 27 |
| 541 | Rabin Medical Center | Petach Tikva, Israel | Ran Kornowski | 4 |
| 542 | Chaim Sheba Medical Center | Ramat Gan, Israel | Victor Guetta | 2 |
| 543 | Klinik Dr. Mueller | Muenchen, Germany | Sigmund Silber | 4 |
| | | | **Total** | **1197** |

## Table 2b. Clinical Follow-up Data Compliance (ITT)[8]

| Site | Index | 30-Day Contact | 6-Month Contact | 9-Month Contact | 12-Month Contact | 24-Month Contact | 36-Month Contact |
|---|---|---|---|---|---|---|---|
| 301 | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) |
| 302 | 100.0% (21/21) | 100.0% (21/21) | 100.0% (21/21) | 100.0% (21/21) | 95.24% (20/21) | 95.24% (20/21) | 95.24% (20/21) |
| 307 | 100.0% (7/7) | 100.0% (7/7) | 71.43% (5/7) | 85.71% (6/7) | 85.71% (6/7) | 85.71% (6/7) | 85.71% (6/7) |
| 308 | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) |
| 309 | 100.0% (20/20) | 100.0% (20/20) | 100.0% (20/20) | 100.0% (20/20) | 95.00% (19/20) | 95.00% (19/20) | 94.44% (17/18) |
| 310 | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (6/6) |
| 313 | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 92.86% (13/14) | 92.86% (13/14) | 92.86% (13/14) |
| 314 | 97.22% (35/36) | 97.22% (35/36) | 94.44% (34/36) | 94.44% (34/36) | 94.44% (34/36) | 94.44% (34/36) | 94.44% (34/36) |
| 315 | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 88.24% (15/17) |
| 317 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 401 | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 100.0% (11/11) | 91.67% (11/12) | 91.67% (11/12) |
| 402 | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) |
| 403 | 100.0% (6/6) | 100.0% (6/6) | 100.0% (5/5) | 83.33% (5/6) | 83.33% (5/6) | 83.33% (5/6) | 83.33% (5/6) |
| 404 | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) |
| 405 | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) |
| 406 | 100.0% (13/13) | 100.0% (13/13) | 76.92% (10/13) | 92.31% (12/13) | 84.62% (11/13) | 84.62% (11/13) | 84.62% (11/13) |
| 407 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 408 | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) |
| 409 | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) |
| 410 | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) | 100.0% (5/5) |
| 411 | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) |
| 412 | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) | 100.0% (17/17) |
| 413 | 90.00% (9/10) | 90.00% (9/10) | 90.00% (9/10) | 80.00% (8/10) | 80.00% (8/10) | 80.00% (8/10) | 80.00% (8/10) |
| 414 | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (13/13) | 100.0% (12/12) |
| 417 | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) |
| 418 | 100.0% (10/10) | 100.0% (10/10) | 100.0% (10/10) | 100.0% (10/10) | 100.0% (10/10) | 100.0% (10/10) | 90.00% (9/10) |
| 419 | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) | 100.0% (3/3) |
| 420 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 422 | 100.0% (28/28) | 96.43% (27/28) | 96.43% (27/28) | 96.43% (27/28) | 96.43% (27/28) | 96.43% (27/28) | 96.43% (27/28) |
| 423 | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 100.0% (12/12) | 91.67% (11/12) |
| 424 | 100.0% (66/66) | 100.0% (66/66) | 93.94% (62/66) | 96.97% (64/66) | 96.97% (64/66) | 96.97% (64/66) | 93.94% (62/66) |
| 425 | 100.0% (41/41) | 100.0% (41/41) | 97.56% (40/41) | 100.0% (41/41) | 100.0% (41/41) | 100.0% (41/41) | 97.50% (39/40) |
| 426 | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) |
| 428 | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) |
| 437 | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 100.0% (14/14) | 100.0% (13/13) | 92.31% (12/13) |

[8] Clinical Follow-Up Data Compliance utilizes to last documented visit date to determine data compliance.

## Table 2b. Clinical Follow-up Data Compliance (ITT) (Continued)

| Site | Index | 30-Day Contact | 6-Month Contact | 9-Month Contact | 12-Month Contact | 24-Month Contact | 36-Month Contact |
|---|---|---|---|---|---|---|---|
| 438 | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) | 100.0% (7/7) |
| 439 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 440 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 441 | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) | 100.0% (8/8) |
| 442 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 444 | 100.0% (5/5) | 100.0% (5/5) | 80.00% (4/5) | 80.00% (4/5) | 80.00% (4/5) | 80.00% (4/5) | 80.00% (4/5) |
| 501 | 100.0% (15/15) | 100.0% (15/15) | 100.0% (15/15) | 100.0% (15/15) | 93.33% (14/15) | 93.33% (14/15) | 93.33% (14/15) |
| 502 | 100.0% (5/5) | 80.00% (4/5) | 80.00% (4/5) | 100.0% (5/5) | 60.00% (3/5) | 80.00% (4/5) | 100.0% (5/5) |
| 503 | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 93.75% (15/16) | 93.75% (15/16) | 93.75% (15/16) |
| 504 | 100.0% (54/54) | 98.15% (53/54) | 98.15% (53/54) | 96.30% (52/54) | 94.44% (51/54) | 92.31% (48/52) | 85.19% (46/54) |
| 505 | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (6/6) | 100.0% (5/5) |
| 506 | 100.0% (20/20) | 100.0% (20/20) | 100.0% (20/20) | 100.0% (20/20) | 95.00% (19/20) | 100.0% (19/19) | 90.00% (18/20) |
| 507 | 96.88% (31/32) | 96.88% (31/32) | 93.75% (30/32) | 90.63% (29/32) | 87.50% (28/32) | 90.32% (28/31) | 84.38% (27/32) |
| 508 | 100.0% (42/42) | 100.0% (42/42) | 100.0% (42/42) | 100.0% (41/41) | 100.0% (41/41) | 95.12% (39/41) | 95.12% (39/41) |
| 509 | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) | 100.0% (11/11) | 90.91% (10/11) | 90.91% (10/11) | 90.91% (10/11) |
| 510 | 100.0% (32/32) | 100.0% (32/32) | 100.0% (32/32) | 100.0% (32/32) | 100.0% (32/32) | 96.77% (30/31) | 93.55% (29/31) |
| 511 | 100.0% (16/16) | 100.0% (16/16) | 93.75% (15/16) | 93.75% (15/16) | 93.75% (15/16) | 93.75% (15/16) | 92.86% (13/14) |
| 512 | 100.0% (29/29) | 100.0% (29/29) | 100.0% (29/29) | 96.55% (28/29) | 96.55% (28/29) | 93.10% (27/29) | 96.43% (27/28) |
| 513 | 100.0% (47/47) | 100.0% (47/47) | 97.87% (46/47) | 97.87% (46/47) | 97.87% (46/47) | 97.87% (46/47) | 91.30% (42/46) |
| 514 | 100.0% (37/37) | 83.78% (31/37) | 89.19% (33/37) | 86.49% (32/37) | 89.19% (33/37) | 81.08% (30/37) | 78.38% (29/37) |
| 515 | 100.0% (18/18) | 100.0% (18/18) | 100.0% (18/18) | 100.0% (18/18) | 100.0% (18/18) | 100.0% (17/17) | 94.44% (17/18) |
| 516 | 100.0% (11/11) | 90.91% (10/11) | 100.0% (11/11) | 100.0% (11/11) | 81.82% (9/11) | 81.82% (9/11) | 81.82% (9/11) |
| 517 | 100.0% (24/24) | 100.0% (24/24) | 100.0% (24/24) | 100.0% (24/24) | 100.0% (24/24) | 95.83% (23/24) | 95.83% (23/24) |
| 518 | 100.0% (18/18) | 94.44% (17/18) | 88.89% (16/18) | 88.89% (16/18) | 94.44% (17/18) | 88.89% (16/18) | 82.35% (14/17) |
| 519 | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 100.0% (16/16) | 93.75% (15/16) | 87.50% (14/16) | 87.50% (14/16) |
| 520 | 100.0% (15/15) | 100.0% (15/15) | 80.00% (12/15) | 100.0% (15/15) | 100.0% (15/15) | 100.0% (15/15) | 100.0% (14/14) |
| 531 | 100.0% (33/33) | 96.97% (32/33) | 100.0% (33/33) | 96.97% (32/33) | 93.75% (30/32) | 90.91% (30/33) | 90.91% (30/33) |
| 532 | 100.0% (33/33) | 100.0% (33/33) | 100.0% (33/33) | 100.0% (33/33) | 100.0% (33/33) | 100.0% (33/33) | 100.0% (33/33) |
| 533 | 97.56% (40/41) | 97.56% (40/41) | 97.56% (40/41) | 97.56% (40/41) | 97.56% (40/41) | 97.56% (40/41) | 97.56% (40/41) |
| 534 | 100.0% (19/19) | 78.95% (15/19) | 94.74% (18/19) | 94.74% (18/19) | 94.74% (18/19) | 94.74% (18/19) | 94.74% (18/19) |
| 537 | 100.0% (25/25) | 100.0% (25/25) | 92.00% (23/25) | 100.0% (25/25) | 96.00% (24/25) | 96.00% (24/25) | 96.00% (24/25) |
| 538 | 100.0% (9/9) | 100.0% (9/9) | 100.0% (9/9) | 87.50% (7/8) | 100.0% (8/8) | 77.78% (7/9) | 77.78% (7/9) |
| 539 | 100.0% (37/37) | 97.30% (36/37) | 100.0% (37/37) | 100.0% (37/37) | 100.0% (37/37) | 100.0% (37/37) | 100.0% (35/35) |
| 540 | 100.0% (27/27) | 100.0% (27/27) | 100.0% (27/27) | 100.0% (27/27) | 96.30% (26/27) | 96.30% (26/27) | 96.30% (26/27) |

## Table 2b. Clinical Follow-up Data Compliance (ITT) (Continued)

| Site | Index | 30-Day Contact | 6-Month Contact | 9-Month Contact | 12-Month Contact | 24-Month Contact | 36-Month Contact |
|---|---|---|---|---|---|---|---|
| 541 | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) |
| 542 | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) | 50.00% (1/2) | 50.00% (1/2) | 50.00% (1/2) |
| 543 | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) | 100.0% (4/4) |
| Total | 99.67% (1193/1197) | 98.25% (1176/1197) | 97.16% (1162/1196) | 97.49% (1165/1195) | 96.14% (1147/1193) | 95.12% (1131/1189) | 93.31% (1101/1180) |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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## Table 2c. Angiographic/IVUS Follow-up Data Compliance (ITT)[9]

| Site | Baseline QCA | 8-Month QCA | Baseline IVUS | 8-Month IVUS |
|---|---|---|---|---|
| 301 | 100.0% (13/13) | 90.91% (10/11) | 100.0% (9/9) | 88.89% (8/9) |
| 302 | 95.24% (20/21) | 87.50% (14/16) | 100.0% (5/5) | 80.00% (4/5) |
| 307 | 100.0% (7/7) | 71.43% (5/7) | | |
| 308 | 100.0% (16/16) | 90.91% (10/11) | | |
| 309 | 95.00% (19/20) | 100.0% (11/11) | | |
| 310 | 100.0% (7/7) | 100.0% (3/3) | | |
| 313 | 100.0% (14/14) | 90.00% (9/10) | 100.0% (9/9) | 88.89% (8/9) |
| 314 | 97.22% (35/36) | 91.30% (21/23) | 90.48% (19/21) | 85.71% (18/21) |
| 315 | 100.0% (17/17) | 100.0% (9/9) | 100.0% (8/8) | 100.0% (8/8) |
| 317 | 100.0% (2/2) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) |
| 401 | 100.0% (12/12) | 100.0% (10/10) | 87.50% (7/8) | 75.00% (6/8) |
| 402 | 100.0% (1/1) | | | |
| 403 | 100.0% (6/6) | 100.0% (2/2) | 100.0% (2/2) | 100.0% (2/2) |
| 404 | 100.0% (16/16) | 100.0% (12/12) | 83.33% (10/12) | 66.67% (8/12) |
| 405 | 87.50% (7/8) | 100.0% (2/2) | | |
| 406 | 100.0% (13/13) | 77.78% (7/9) | | |
| 407 | 100.0% (2/2) | 100.0% (2/2) | 0.00% (0/2) | 50.00% (1/2) |
| 408 | 100.0% (11/11) | 87.50% (7/8) | | |
| 409 | 100.0% (5/5) | | | |
| 410 | 100.0% (5/5) | | | |
| 411 | 100.0% (6/6) | 100.0% (1/1) | | |
| 412 | 88.24% (15/17) | 66.67% (2/3) | 100.0% (3/3) | 33.33% (1/3) |
| 413 | 90.00% (9/10) | 75.00% (3/4) | 100.0% (3/3) | 100.0% (3/3) |
| 414 | 100.0% (13/13) | 100.0% (1/1) | | |
| 417 | 100.0% (3/3) | | | |
| 418 | 100.0% (10/10) | 100.0% (3/3) | 100.0% (3/3) | 66.67% (2/3) |
| 419 | 66.67% (2/3) | | | |
| 420 | 100.0% (2/2) | | | |
| 422 | 100.0% (28/28) | 100.0% (13/13) | 75.00% (9/12) | 66.67% (8/12) |
| 423 | 100.0% (12/12) | 100.0% (6/6) | 100.0% (6/6) | 83.33% (5/6) |
| 424 | 100.0% (66/66) | 89.19% (33/37) | | |
| 425 | 100.0% (41/41) | 90.00% (18/20) | 100.0% (20/20) | 90.00% (18/20) |

[9] Angiographic Follow-Up Data Compliance utilizes all the films that were read by Angiographic Core Lab; IVUS Follow-up Data Compliance utilizes the non-missing reading from IVUS Core Lab.

## Table 2c. Angiographic/IVUS Follow-up Data Compliance (ITT) (Continued)

| Site | Baseline QCA | 8-Month QCA | Baseline IVUS | 8-Month IVUS |
|---|---|---|---|---|
| 426 | 100.0% (8/8) | 100.0% (8/8) | | |
| 428 | 100.0% (8/8) | 100.0% (3/3) | | |
| 437 | 100.0% (14/14) | | | |
| 438 | 100.0% (7/7) | | | |
| 439 | 100.0% (2/2) | | | |
| 440 | 100.0% (2/2) | 100.0% (1/1) | 100.0% (1/1) | 100.0% (1/1) |
| 441 | 100.0% (8/8) | | | |
| 442 | 100.0% (2/2) | | | |
| 444 | 100.0% (5/5) | 100.0% (1/1) | | |
| 501 | 100.0% (15/15) | 92.31% (12/13) | 100.0% (13/13) | 92.31% (12/13) |
| 502 | 100.0% (5/5) | 100.0% (5/5) | | |
| 503 | 100.0% (16/16) | 100.0% (12/12) | | |
| 504 | 96.30% (52/54) | 74.19% (23/31) | 95.24% (20/21) | 52.38% (11/21) |
| 505 | 100.0% (6/6) | 100.0% (1/1) | | |
| 506 | 100.0% (20/20) | 75.00% (12/16) | 100.0% (16/16) | 50.00% (8/16) |
| 507 | 96.88% (31/32) | 85.19% (23/27) | 92.31% (24/26) | 73.08% (19/26) |
| 508 | 100.0% (42/42) | 100.0% (24/24) | 95.65% (22/23) | 100.0% (23/23) |
| 509 | 90.91% (10/11) | 87.50% (7/8) | 85.71% (6/7) | 71.43% (5/7) |
| 510 | 100.0% (32/32) | 94.44% (17/18) | | |
| 511 | 100.0% (16/16) | 100.0% (5/5) | | |
| 512 | 100.0% (29/29) | 100.0% (12/12) | 22.22% (2/9) | 55.56% (5/9) |
| 513 | 97.87% (46/47) | 82.35% (28/34) | | |
| 514 | 100.0% (37/37) | 81.25% (13/16) | 93.75% (15/16) | 68.75% (11/16) |
| 515 | 100.0% (18/18) | 77.78% (7/9) | | |
| 516 | 100.0% (11/11) | 100.0% (4/4) | | |
| 517 | 100.0% (24/24) | 100.0% (2/2) | 0.00% (0/1) | 0.00% (0/1) |
| 518 | 100.0% (18/18) | 100.0% (3/3) | 66.67% (2/3) | 0.00% (0/3) |
| 519 | 100.0% (16/16) | 83.33% (5/6) | 100.0% (5/5) | 100.0% (5/5) |
| 520 | 100.0% (15/15) | 0.00% (0/1) | 100.0% (1/1) | 0.00% (0/1) |
| 531 | 96.97% (32/33) | 93.33% (14/15) | 85.71% (12/14) | 78.57% (11/14) |
| 532 | 100.0% (33/33) | 100.0% (17/17) | 100.0% (17/17) | 88.24% (15/17) |
| 533 | 97.56% (40/41) | 90.48% (19/21) | 100.0% (12/12) | 75.00% (9/12) |
| 534 | 100.0% (19/19) | 100.0% (6/6) | | |
| 537 | 100.0% (25/25) | 100.0% (9/9) | | |

## Table 2c. Angiographic/IVUS Follow-up Data Compliance (ITT) (Continued)

| Site | Baseline QCA | 8-Month QCA | Baseline IVUS | 8-Month IVUS |
|---|---|---|---|---|
| 538 | 100.0% (9/9) | 100.0% (3/3) | 100.0% (3/3) | 66.67% (2/3) |
| 539 | 100.0% (37/37) | 78.57% (11/14) | | |
| 540 | 100.0% (27/27) | 100.0% (19/19) | 75.00% (12/16) | 56.25% (9/16) |
| 541 | 100.0% (4/4) | | | |
| 542 | 50.00% (1/2) | | | |
| 543 | 100.0% (4/4) | | | |
| Total | 98.66% (1181/1197) | 90.32% (541/599) | 90.55% (297/328) | 75.30% (247/328) |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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## Table 3. Baseline Demographics and Clinical Characteristics (ITT)

| Patient Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Age (yrs) | | | | | |
| Mean±SD (n) | 61.58±10.53 (597) | 61.89±10.45 (596) | 61.73±10.48 (1193) | -0.30 [-1.50,0.89] | 0.616 |
| Range (min,max) | (30.00,87.00) | (28.00,90.00) | (28.00,90.00) | | |
| Number of Men | 77.2% (461/597) | 75.3% (449/596) | 76.3% (910/1193) | 1.9% [-2.9%,6.7%] | 0.455 |
| History of Smoking | 35.3% (207/587) | 35.2% (207/588) | 35.2% (414/1175) | 0.1% [-5.4%,5.5%] | 1.000 |
| Prior Percutaneous Coronary Revascularization | 21.7% (129/595) | 18.0% (107/594) | 19.8% (236/1189) | 3.7% [-0.9%,8.2%] | 0.127 |
| Hyperlipidemia Requiring Treatment | 80.5% (476/591) | 76.9% (455/592) | 78.7% (931/1183) | 3.7% [-1.0%,8.3%] | 0.136 |
| Diabetes Mellitus | 18.2% (108/595) | 22.2% (132/595) | 20.2% (240/1190) | -4.0% [-8.6%,0.5%] | 0.096 |
| Insulin Dependent Diabetes | 4.5% (27/594) | 7.4% (44/595) | 6.0% (71/1189) | -2.8% [-5.5%,-0.2%] | 0.050 |
| Hypertension Requiring Treatment | 63.4% (378/596) | 68.2% (403/591) | 65.8% (781/1187) | -4.8% [-10.2%,0.6%] | 0.087 |
| Prior MI | 39.7% (236/594) | 41.5% (247/595) | 40.6% (483/1189) | -1.8% [-7.4%,3.8%] | 0.555 |
| Premature CAD in First Degree Relative | 35.9% (192/535) | 30.8% (163/530) | 33.3% (355/1065) | 5.1% [-0.5%,10.8%] | 0.079 |
| Prior CABG | 4.7% (28/597) | 4.9% (29/596) | 4.8% (57/1193) | -0.2% [-2.6%,2.2%] | 0.893 |
| Revascularization for Angina or MI | 91.3% (545/597) | 91.1% (543/596) | 91.2% (1088/1193) | 0.2% [-3.0%,3.4%] | 0.919 |
| Worst One | | | | | 0.479 |
| Stable | 49.2% (268/545) | 50.8% (276/543) | 50.0% (544/1088) | | |
| Unstable | 33.2% (181/545) | 33.3% (181/543) | 33.3% (362/1088) | | |
| MI | 17.6% (96/545) | 15.8% (86/543) | 16.7% (182/1088) | | |
| CCS Class III or IV† | 54.4% (261/480) | 54.2% (262/483) | 54.3% (523/963) | 0.1% [-6.2%,6.4%] | 1.000 |
| Positive Stress Test | 53.1% (223/420) | 55.2% (214/388) | 54.1% (437/808) | -2.1% [-8.9%,4.8%] | 0.572 |
| Race | | | | | 0.589 |
| White | 94.1% (562/597) | 94.1% (561/596) | 94.1% (1123/1193) | | |
| Black | 0.0% (0/597) | 0.2% (1/596) | 0.1% (1/1193) | | |
| Hispanic | 0.2% (1/597) | 0.5% (3/596) | 0.3% (4/1193) | | |
| Asian | 4.5% (27/597) | 4.5% (27/596) | 4.5% (54/1193) | | |
| Other | 1.2% (7/597) | 0.7% (4/596) | 0.9% (11/1193) | | |
| Number of diseased, native, major epicardial coronary vessels (>50% Stenosed) | | | | | 0.639 |
| Single | 64.8% (387/597) | 62.9% (375/596) | 63.9% (762/1193) | | |
| Double | 23.5% (140/597) | 26.3% (157/596) | 24.9% (297/1193) | | |
| Triple | 11.7% (70/597) | 10.7% (64/596) | 11.2% (134/1193) | | |
| Ejection Fraction (%) | | | | | |
| Mean±SD (n) | 61.53±12.00 (455) | 60.82±11.85 (453) | 61.18±11.92 (908) | 0.72 [-0.84,2.27] | 0.367 |
| Range (min,max) | (30.00,94.00) | (28.00,91.00) | (28.00,94.00) | | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.
†CCS – Canadian Cardiovascular Society angina class.

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## Table 4. Baseline Lesion Characteristics (ITT)

| Lesion Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Vessel Location | | | | | 0.319 |
| LAD | 43.2% (255/590) | 47.5% (281/591) | 45.4% (536/1181) | | |
| LCX | 22.4% (132/590) | 21.2% (125/591) | 21.8% (257/1181) | | |
| RCA | 34.4% (203/590) | 31.3% (185/591) | 32.9% (388/1181) | | |
| LMCA | 0.0% (0/590) | 0.0% (0/591) | 0.0% (0/1181) | | |
| Lesion Location | | | | | 0.623 |
| Ostial | 3.1% (18/590) | 2.0% (12/591) | 2.5% (30/1181) | | |
| Proximal | 35.1% (207/590) | 35.7% (211/591) | 35.4% (418/1181) | | |
| Mid | 53.7% (317/590) | 55.2% (326/591) | 54.4% (643/1181) | | |
| Distal | 8.1% (48/590) | 7.1% (42/591) | 7.6% (90/1181) | | |
| Length | | | | | 0.174 |
| Discrete (< 10 mm) | 27.0% (157/582) | 23.6% (139/588) | 25.3% (296/1170) | | |
| Tubular (10–19.9 mm) | 59.1% (344/582) | 60.9% (358/588) | 60.0% (702/1170) | | |
| Diffuse (≥ 20 mm) | 13.9% (81/582) | 15.5% (91/588) | 14.7% (172/1170) | | |
| Eccentric | 73.6% (434/590) | 69.9% (413/591) | 71.7% (847/1181) | 3.7% [-1.5%,8.8%] | 0.175 |
| Bend | | | | | 0.727 |
| < 45 degrees | 79.2% (467/590) | 80.0% (473/591) | 79.6% (940/1181) | | |
| ≥ 45 degrees and < 90 degrees | 18.1% (107/590) | 17.1% (101/591) | 17.6% (208/1181) | | |
| ≥ 90 degrees | 2.7% (16/590) | 2.9% (17/591) | 2.8% (33/1181) | | |
| Thrombus | 2.4% (14/590) | 3.6% (21/591) | 3.0% (35/1181) | -1.2% [-3.1%,0.8%] | 0.303 |
| Tortuosity | | | | | 0.061 |
| None | 84.4% (498/590) | 88.2% (521/591) | 86.3% (1019/1181) | | |
| Moderate | 13.6% (80/590) | 10.3% (61/591) | 11.9% (141/1181) | | |
| Severe | 2.0% (12/590) | 1.5% (9/591) | 1.8% (21/1181) | | |
| Calcification | | | | | 0.096 |
| Mild | 76.3% (450/590) | 72.1% (426/591) | 74.2% (876/1181) | | |
| Moderate | 17.3% (102/590) | 20.0% (118/591) | 18.6% (220/1181) | | |
| Severe | 6.4% (38/590) | 8.0% (47/591) | 7.2% (85/1181) | | |
| Ulcerated | 6.8% (40/590) | 6.3% (37/591) | 6.5% (77/1181) | 0.5% [-2.3%,3.3%] | 0.725 |
| Aneurysm | 2.5% (15/590) | 3.7% (22/591) | 3.1% (37/1181) | -1.2% [-3.2%,0.8%] | 0.316 |
| Intimal Flap | 0.7% (4/590) | 1.4% (8/591) | 1.0% (12/1181) | -0.7% [-1.8%,0.5%] | 0.385 |
| TIMI Flow | | | | | 0.602 |
| 0 | 0.3% (2/588) | 0.2% (1/590) | 0.3% (3/1178) | | |
| 1 | 2.0% (12/588) | 1.5% (9/590) | 1.8% (21/1178) | | |
| 2 | 4.1% (24/588) | 4.1% (24/590) | 4.1% (48/1178) | | |
| 3 | 93.5% (550/588) | 94.2% (556/590) | 93.9% (1106/1178) | | |
| Total Occlusion | 2.4% (14/588) | 1.7% (10/590) | 2.0% (24/1178) | 0.7% [-0.9%,2.3%] | 0.419 |
| Branch Vessel Disease | 11.4% (67/590) | 8.1% (48/591) | 9.7% (115/1181) | 3.2% [-0.1%,6.6%] | 0.063 |
| Sidebranch Stenosis (%) | | | | | |
| Mean±SD (n) | 27.41±28.46 (235) | 24.36±27.09 (209) | 25.98±27.83 (444) | 3.05 [-2.14,8.25] | 0.249 |
| Range (min,max) | (0.00,95.00) | (0.00,90.00) | (0.00,95.00) | | |
| Modified ACC/AHA Lesion Class | | | | | 0.426 |
| A | 2.9% (17/590) | 4.1% (24/591) | 3.5% (41/1181) | | |
| B1 | 18.6% (110/590) | 16.9% (100/591) | 17.8% (210/1181) | | |
| B2 | 50.8% (300/590) | 54.7% (323/591) | 52.8% (623/1181) | | |
| C | 27.6% (163/590) | 24.4% (144/591) | 26.0% (307/1181) | | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value. All data assessed by the Angiographic Core Laboratory.

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## Table 5. Procedural Characteristics (ITT)

| Lesion Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Pre-Stent Balloon Angioplasty | | | | | |
| Nominal Diameter (mm) | | | | | |
| Mean±SD (n) | 2.54±0.37 (586) | 2.51±0.37 (590) | 2.52±0.37 (1176) | 0.03 [-0.02,0.07] | 0.216 |
| Range (min,max) | (1.50,3.50) | (1.50,4.05) | (1.50,4.05) | | |
| Maximum Pressure (atm) | | | | | |
| Mean±SD (n) | 10.88±3.01 (586) | 10.99±3.30 (589) | 10.93±3.16 (1175) | -0.11 [-0.47,0.25] | 0.547 |
| Range (min,max) | (4.00,20.00) | (5.00,25.00) | (4.00,25.00) | | |
| Stenting Procedure | | | | | |
| Maximum Pressure (atm) | | | | | |
| Mean±SD (n) | 13.67±2.84 (591) | 13.82±2.92 (591) | 13.75±2.88 (1182) | -0.16 [-0.48,0.17] | 0.354 |
| Range (min,max) | (8.00,24.00) | (7.00,30.00) | (7.00,30.00) | | |
| 1st Post-Stent Balloon Dilatation | | | | | |
| Nominal Diameter (mm) | | | | | |
| Mean±SD (n) | 3.28±0.50 (150) | 3.27±0.52 (159) | 3.27±0.51 (309) | 0.01 [-0.10,0.13] | 0.828 |
| Range (min,max) | (2.00,4.50) | (1.50,4.50) | (1.50,4.50) | | |
| Maximum Pressure (atm) | | | | | |
| Mean±SD (n) | 15.02±3.65 (150) | 15.36±3.79 (159) | 15.20±3.72 (309) | -0.34 [-1.18,0.49] | 0.416 |
| Range (min,max) | (3.00,26.00) | (2.00,24.00) | (2.00,26.00) | | |
| 2nd Post-Stent Balloon Dilatation | | | | | |
| Nominal Diameter (mm) | | | | | |
| Mean±SD (n) | 2.93±0.41 (20) | 3.09±0.35 (23) | 3.02±0.38 (43) | -0.17 [-0.40,0.06] | 0.147 |
| Range (min,max) | (2.50,3.50) | (2.50,4.00) | (2.50,4.00) | | |
| Maximum Pressure (atm) | | | | | |
| Mean±SD (n) | 16.55±3.94 (20) | 15.91±3.88 (23) | 16.21±3.88 (43) | 0.64 [-1.78,3.05] | 0.597 |
| Range (min,max) | (9.00,26.00) | (6.00,24.00) | (6.00,26.00) | | |
| Maximum Post Balloon Diameter (mm) | | | | | |
| Mean±SD (n) | 3.26±0.50 (158) | 3.26±0.52 (165) | 3.26±0.51 (323) | -0.00 [-0.12,0.11] | 0.941 |
| Range (min,max) | (2.00,4.50) | (1.50,4.50) | (1.50,4.50) | | |
| Maximum Post Balloon Pressure (atm) | | | | | |
| Mean±SD (n) | 15.12±3.62 (158) | 15.47±3.85 (165) | 15.30±3.74 (323) | -0.35 [-1.17,0.47] | 0.406 |
| Range (min,max) | (3.00,26.00) | (2.00,24.00) | (2.00,26.00) | | |
| GP IIb/IIIa Inhibitors | 13.2% (79/597) | 10.4% (62/594) | 11.8% (141/1191) | 2.8% [-0.9%,6.5%] | 0.151 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Table 6a. Quantitative Angiographic Analysis (ITT)

| Lesion Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **Pre-Procedure** | | | | | |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.73±0.48 (590) | 2.76±0.49 (591) | 2.75±0.48 (1181) | -0.03 [-0.08,0.03] | 0.325 |
| Range (min,max) | (1.61,4.51) | (1.64,4.23) | (1.61,4.51) | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 0.83±0.34 (590) | 0.84±0.35 (591) | 0.83±0.34 (1181) | -0.01 [-0.05,0.03] | 0.562 |
| Range (min,max) | (0.00,2.34) | (0.00,2.15) | (0.00,2.34) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 69.74±10.89 (590) | 69.58±11.00 (591) | 69.66±10.94 (1181) | 0.16 [-1.09,1.41] | 0.800 |
| Range (min,max) | (27.06,100.00) | (37.36,100.00) | (27.06,100.00) | | |
| Lesion Length (mm) | | | | | |
| Mean±SD (n) | 14.04±5.56 (582) | 14.38±5.73 (588) | 14.21±5.64 (1170) | -0.34 [-0.99,0.31] | 0.304 |
| Range (min,max) | (4.15,42.07) | (2.71,39.53) | (2.71,42.07) | | |
| **Post-Procedure** | | | | | |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.77±0.47 (589) | 2.80±0.50 (590) | 2.79±0.48 (1179) | -0.03 [-0.08,0.03] | 0.326 |
| Range (min,max) | (1.65,4.44) | (1.62,4.33) | (1.62,4.44) | | |
| In-Segment | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.21±0.49 (589) | 2.24±0.49 (590) | 2.23±0.49 (1179) | -0.03 [-0.09,0.03] | 0.302 |
| Range (min,max) | (0.00,3.72) | (0.90,3.89) | (0.00,3.89) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 20.39±10.26 (589) | 20.11±9.38 (590) | 20.25±9.83 (1179) | 0.28 [-0.84,1.41] | 0.622 |
| Range (min,max) | (-6.91,100.00) | (-1.94,56.78) | (-6.91,100.00) | | |
| Within the Stent | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.59±0.43 (588) | 2.61±0.44 (589) | 2.60±0.43 (1177) | -0.02 [-0.07,0.03] | 0.436 |
| Range (min,max) | (0.00,3.78) | (1.44,4.00) | (0.00,4.00) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.94±0.43 (588) | 2.95±0.43 (589) | 2.95±0.43 (1177) | -0.00 [-0.05,0.05] | 0.937 |
| Range (min,max) | (0.00,4.20) | (1.87,4.25) | (0.00,4.25) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 6.04±10.43 (588) | 6.23±10.03 (589) | 6.13±10.23 (1177) | -0.18 [-1.36,0.99] | 0.757 |
| Range (min,max) | (-29.89,100.00) | (-39.63,33.75) | (-39.63,100.00) | | |
| Proximal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.73±0.58 (566) | 2.74±0.59 (568) | 2.74±0.59 (1134) | -0.02 [-0.09,0.05] | 0.583 |
| Range (min,max) | (1.25,4.67) | (1.30,4.65) | (1.25,4.67) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.95±0.56 (566) | 2.96±0.57 (568) | 2.95±0.56 (1134) | -0.02 [-0.08,0.05] | 0.640 |
| Range (min,max) | (1.50,5.44) | (1.61,4.71) | (1.50,5.44) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 1.91±12.51 (566) | 1.90±12.05 (568) | 1.91±12.28 (1134) | 0.01 [-1.42,1.44] | 0.993 |
| Range (min,max) | (-40.04,57.84) | (-27.39,47.85) | (-40.04,57.84) | | |
| Distal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.34±0.53 (586) | 2.36±0.55 (589) | 2.35±0.54 (1175) | -0.02 [-0.09,0.04] | 0.449 |
| Range (min,max) | (1.02,4.70) | (0.94,4.13) | (0.94,4.70) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.56±0.52 (586) | 2.58±0.54 (589) | 2.57±0.53 (1175) | -0.02 [-0.08,0.04] | 0.460 |
| Range (min,max) | (1.21,4.83) | (1.22,4.22) | (1.21,4.83) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 15.95±11.27 (586) | 15.90±11.21 (589) | 15.93±11.23 (1175) | 0.05 [-1.24,1.34] | 0.939 |
| Range (min,max) | (-12.57,51.72) | (-16.99,51.63) | (-16.99,51.72) | | |

*(Footnotes on next page)*

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of angiographic patients in pre- and post-procedure, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the angiographic Core Laboratory.

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## Table 6a. Quantitative Angiographic Analysis (ITT) (Continued)

| Lesion Characteristic | Endeavor (N=298 patients) | Driver (N=302 patients) | All Patients (N=600 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **8 Month Follow-up** | | | | | |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.75±0.43 (264) | 2.78±0.47 (265) | 2.76±0.45 (529) | -0.03 [-0.11,0.05] | 0.449 |
| Range (min,max) | (1.69,3.90) | (1.47,4.10) | (1.47,4.10) | | |
| In-Segment | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 1.86±0.55 (264) | 1.56±0.67 (265) | 1.71±0.63 (529) | 0.30 [0.19,0.40] | <0.001 |
| Range (min,max) | (0.00,3.34) | (0.00,2.88) | (0.00,3.34) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 32.67±16.27 (264) | 44.33±20.45 (265) | 38.51±19.37 (529) | -11.66 [-14.82,-8.50] | <0.001 |
| Range (min,max) | (1.04,100.00) | (8.49,100.00) | (1.04,100.00) | | |
| Within the Stent | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 1.99±0.56 (264) | 1.62±0.70 (265) | 1.80±0.66 (529) | 0.37 [0.26,0.48] | <0.001 |
| Range (min,max) | (0.00,3.31) | (0.00,3.05) | (0.00,3.31) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.47±0.48 (264) | 2.20±0.64 (265) | 2.34±0.58 (529) | 0.27 [0.17,0.36] | <0.001 |
| Range (min,max) | (0.00,3.82) | (0.00,3.56) | (0.00,3.82) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 27.91±17.30 (264) | 42.24±21.73 (265) | 35.09±20.89 (529) | -14.33 [-17.68,-10.97] | <0.001 |
| Range (min,max) | (-3.86,100.00) | (0.10,100.00) | (-3.86,100.00) | | |
| Proximal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.53±0.62 (257) | 2.49±0.71 (254) | 2.51±0.67 (511) | 0.03 [-0.08,0.15] | 0.556 |
| Range (min,max) | (0.11,3.77) | (0.00,4.07) | (0.00,4.07) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.80±0.59 (257) | 2.79±0.69 (254) | 2.80±0.64 (511) | 0.01 [-0.10,0.12] | 0.892 |
| Range (min,max) | (0.11,4.17) | (0.00,4.37) | (0.00,4.37) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 8.31±17.33 (257) | 10.61±19.85 (254) | 9.45±18.64 (511) | -2.30 [-5.54,0.93] | 0.163 |
| Range (min,max) | (-31.99,95.05) | (-29.97,100.00) | (-31.99,100.00) | | |
| Distal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.28±0.54 (262) | 2.18±0.60 (262) | 2.23±0.58 (524) | 0.10 [0.00,0.20] | 0.042 |
| Range (min,max) | (0.08,3.87) | (0.00,3.53) | (0.00,3.87) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.50±0.51 (262) | 2.40±0.61 (262) | 2.45±0.57 (524) | 0.09 [-0.00,0.19] | 0.059 |
| Range (min,max) | (1.23,4.31) | (0.00,3.88) | (0.00,4.31) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 17.63±13.79 (262) | 22.15±16.16 (262) | 19.89±15.17 (524) | -4.52 [-7.09,-1.94] | <0.001 |
| Range (min,max) | (-18.97,95.51) | (-10.11,100.00) | (-18.97,100.00) | | |
| Binary Restenosis | | | | | |
| In-Segment | 13.3% (35/264) | 34.7% (92/265) | 24.0% (127/529) | -21.5% [-28.5%,-14.4%] | <0.001 |
| Within the Stent | 9.5% (25/264) | 33.2% (88/265) | 21.4% (113/529) | -23.7% [-30.4%,-17.1%] | <0.001 |
| Proximal Edge | 3.5% (9/257) | 4.3% (11/254) | 3.9% (20/511) | -0.8% [-4.2%,2.5%] | 0.656 |
| Distal Edge | 1.9% (5/262) | 5.3% (14/262) | 3.6% (19/524) | -3.4% [-6.6%,-0.2%] | 0.059 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of angiographic patients in 8-month follow-up, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the Angiographic Core Laboratory.

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## Table 6a. Quantitative Angiographic Analysis (ITT) (Continued)

| Lesion Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **Acute Gain (mm)** | | | | | |
| In-Segment | | | | | |
| Mean±SD (n) | 1.38±0.47 (589) | 1.40±0.47 (590) | 1.39±0.47 (1179) | -0.02 [-0.07,0.03] | 0.479 |
| Range (min,max) | (-1.04,2.93) | (0.04,3.22) | (-1.04,3.22) | | |
| Within the Stent | | | | | |
| Mean±SD (n) | 1.76±0.44 (588) | 1.77±0.45 (589) | 1.76±0.44 (1177) | -0.01 [-0.06,0.04] | 0.717 |
| Range (min,max) | (-1.04,3.15) | (0.44,3.25) | (-1.04,3.25) | | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of angiographic patients in pre- and post-procedure, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the Angiographic Core Laboratory.

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## Table 6a. Quantitative Angiographic Analysis (ITT) (Continued)

| Lesion Characteristic | Endeavor (N=298 patients) | Driver (N=302 patients) | All Patients (N=600 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **8 Month Late Loss (mm)** | | | | | |
| In-Segment | | | | | |
| Mean±SD (n) | 0.36±0.46 (264) | 0.72±0.61 (263) | 0.54±0.57 (527) | -0.36 [-0.45,-0.27] | <0.001 |
| Range (min,max) | (-1.06,2.24) | (-0.40,2.78) | (-1.06,2.78) | | |
| Within the Stent | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 0.62±0.46 (264) | 1.03±0.59 (263) | 0.82±0.56 (527) | -0.41 [-0.50,-0.32] | <0.001 |
| Range (min,max) | (-0.37,2.50) | (-0.07,2.78) | (-0.37,2.78) | | |
| Mean Diameter Late Loss | | | | | |
| Mean±SD (n) | 0.48±0.32 (264) | 0.78±0.47 (263) | 0.63±0.43 (527) | -0.30 [-0.36,-0.23] | <0.001 |
| Range (min,max) | (-0.31,1.52) | (-0.17,2.86) | (-0.31,2.86) | | |
| Within the Proximal Edge | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 0.21±0.45 (253) | 0.30±0.54 (251) | 0.25±0.50 (504) | -0.09 [-0.17,-0.00] | 0.049 |
| Range (min,max) | (-1.16,1.87) | (-0.93,2.64) | (-1.16,2.64) | | |
| Mean Diameter Late Loss | | | | | |
| Mean±SD (n) | 0.15±0.37 (253) | 0.20±0.47 (251) | 0.18±0.42 (504) | -0.06 [-0.13,0.01] | 0.116 |
| Range (min,max) | (-0.96,1.77) | (-1.11,2.71) | (-1.11,2.71) | | |
| Within the Distal Edge | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 0.06±0.38 (262) | 0.22±0.46 (260) | 0.14±0.43 (522) | -0.17 [-0.24,-0.09] | <0.001 |
| Range (min,max) | (-0.73,1.70) | (-0.86,2.15) | (-0.86,2.15) | | |
| Mean Diameter Late Loss | | | | | |
| Mean±SD (n) | 0.06±0.32 (262) | 0.21±0.42 (260) | 0.14±0.38 (522) | -0.15 [-0.22,-0.09] | <0.001 |
| Range (min,max) | (-0.63,1.02) | (-0.73,2.36) | (-0.73,2.36) | | |
| **Loss Index** | | | | | |
| In-Segment | | | | | |
| Arithmetic | | | | | |
| Mean±SD (n) | 0.24±0.38 (264) | 0.51±0.49 (263) | 0.38±0.46 (527) | -0.27 [-0.35,-0.20] | <0.001 |
| Range (min,max) | (-1.02,2.06) | (-0.92,3.59) | (-1.02,3.59) | | |
| Regression | | | | | |
| Coefficient ± SE | 0.29±0.06 | 0.35±0.07 | 0.34±0.05 | -0.06[-0.24,0.13] | |
| Within the Stent | | | | | |
| Arithmetic | | | | | |
| Mean±SD (n) | 0.35±0.27 (264) | 0.59±0.37 (263) | 0.47±0.35 (527) | -0.25 [-0.30,-0.19] | <0.001 |
| Range (min,max) | (-0.20,1.61) | (-0.06,2.60) | (-0.20,2.60) | | |
| Regression | | | | | |
| Coefficient ± SE | 0.25±0.06 | 0.14±0.08 | 0.21±0.05 | 0.12[-0.08,0.31] | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of angiographic patients in 8-month follow-up, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the Angiographic Core Laboratory.

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## Table 6b. Interpolated Angiographic Analysis (ITT)

| Lesion Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **Pre-Procedure** | | | | | |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.66±0.51 (590) | 2.68±0.53 (591) | 2.67±0.52 (1181) | -0.02 [-0.08,0.04] | 0.426 |
| Range (min,max) | (1.48,4.51) | (1.57,4.39) | (1.48,4.51) | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 0.83±0.34 (590) | 0.84±0.35 (591) | 0.83±0.34 (1181) | -0.01 [-0.05,0.03] | 0.562 |
| Range (min,max) | (0.00,2.34) | (0.00,2.15) | (0.00,2.34) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 68.73±11.22 (590) | 68.50±11.44 (591) | 68.61±11.33 (1181) | 0.24 [-1.06,1.53] | 0.720 |
| Range (min,max) | (25.59,100.00) | (26.05,100.00) | (25.59,100.00) | | |
| Lesion Length (mm) | | | | | |
| Mean±SD (n) | 14.04±5.56 (582) | 14.38±5.73 (588) | 14.21±5.64 (1170) | -0.34 [-0.99,0.31] | 0.304 |
| Range (min,max) | (4.15,42.07) | (2.71,39.53) | (2.71,42.07) | | |
| **Post-Procedure** | | | | | |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.77±0.47 (589) | 2.78±0.49 (590) | 2.77±0.48 (1179) | -0.01 [-0.07,0.04] | 0.699 |
| Range (min,max) | (1.65,4.57) | (1.52,4.41) | (1.52,4.57) | | |
| In-Segment | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.21±0.49 (589) | 2.24±0.49 (590) | 2.23±0.49 (1179) | -0.03 [-0.09,0.03] | 0.302 |
| Range (min,max) | (0.00,3.72) | (0.90,3.89) | (0.00,3.89) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 20.02±10.99 (589) | 19.26±10.18 (590) | 19.64±10.59 (1179) | 0.76 [-0.45,1.97] | 0.220 |
| Range (min,max) | (-0.13,100.00) | (-1.93,66.23) | (-1.93,100.00) | | |
| Within the Stent | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.59±0.43 (588) | 2.61±0.44 (589) | 2.60±0.43 (1177) | -0.02 [-0.07,0.03] | 0.436 |
| Range (min,max) | (0.00,3.78) | (1.44,4.00) | (0.00,4.00) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.94±0.43 (588) | 2.95±0.43 (589) | 2.95±0.43 (1177) | -0.00 [-0.05,0.05] | 0.937 |
| Range (min,max) | (0.00,4.20) | (1.87,4.25) | (0.00,4.25) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 5.72±10.56 (588) | 5.45±9.74 (589) | 5.58±10.15 (1177) | 0.27 [-0.89,1.44] | 0.643 |
| Range (min,max) | (-35.16,100.00) | (-39.63,41.78) | (-39.63,100.00) | | |
| Proximal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.73±0.58 (566) | 2.74±0.59 (568) | 2.74±0.59 (1134) | -0.02 [-0.09,0.05] | 0.583 |
| Range (min,max) | (1.25,4.67) | (1.30,4.65) | (1.25,4.67) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.95±0.56 (566) | 2.96±0.57 (568) | 2.95±0.56 (1134) | -0.02 [-0.08,0.05] | 0.640 |
| Range (min,max) | (1.50,5.44) | (1.61,4.71) | (1.50,5.44) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 0.85±17.93 (566) | 0.11±18.35 (568) | 0.48±18.14 (1134) | 0.74 [-1.37,2.86] | 0.490 |
| Range (min,max) | (-65.99,59.28) | (-63.92,46.39) | (-65.99,59.28) | | |
| Distal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.34±0.53 (586) | 2.36±0.55 (589) | 2.35±0.54 (1175) | -0.02 [-0.09,0.04] | 0.449 |
| Range (min,max) | (1.02,4.70) | (0.94,4.13) | (0.94,4.70) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.56±0.52 (586) | 2.58±0.54 (589) | 2.57±0.53 (1175) | -0.02 [-0.08,0.04] | 0.460 |
| Range (min,max) | (1.21,4.83) | (1.22,4.22) | (1.21,4.83) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 15.65±11.37 (586) | 15.10±11.53 (589) | 15.38±11.45 (1175) | 0.55 [-0.76,1.86] | 0.410 |
| Range (min,max) | (-9.98,51.11) | (-25.36,64.73) | (-25.36,64.73) | | |

*(Footnotes on next page)*

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of angiographic patients in pre- and post-procedure, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the angiographic Core Laboratory.

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## Table 6b. Interpolated Angiographic Analysis (ITT) (Continued)

| Lesion Characteristic | Endeavor (N=298 patients) | Driver (N=302 patients) | All Patients (N=600 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **8 Month Follow-up** | | | | | |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.59±0.46 (264) | 2.58±0.53 (265) | 2.59±0.50 (529) | 0.01 [-0.08,0.09] | 0.849 |
| Range (min,max) | (1.46,3.92) | (1.34,4.05) | (1.34,4.05) | | |
| In-Segment | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 1.86±0.55 (264) | 1.56±0.67 (265) | 1.71±0.63 (529) | 0.30 [0.19,0.40] | <0.001 |
| Range (min,max) | (0.00,3.34) | (0.00,2.88) | (0.00,3.34) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 28.24±17.03 (264) | 39.77±21.50 (265) | 34.01±20.22 (529) | -11.53 [-14.85,-8.22] | <0.001 |
| Range (min,max) | (0.46,100.00) | (2.43,100.00) | (0.46,100.00) | | |
| Within the Stent | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 1.99±0.56 (264) | 1.62±0.70 (265) | 1.80±0.66 (529) | 0.37 [0.26,0.48] | <0.001 |
| Range (min,max) | (0.00,3.31) | (0.00,3.05) | (0.00,3.31) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.47±0.48 (264) | 2.20±0.64 (265) | 2.34±0.58 (529) | 0.27 [0.17,0.36] | <0.001 |
| Range (min,max) | (0.00,3.82) | (0.00,3.56) | (0.00,3.82) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 23.16±18.18 (264) | 37.60±22.56 (265) | 30.39±21.71 (529) | -14.44 [-17.94,-10.94] | <0.001 |
| Range (min,max) | (-11.63,100.00) | (-5.89,100.00) | (-11.63,100.00) | | |
| Proximal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.53±0.62 (257) | 2.49±0.71 (254) | 2.51±0.67 (511) | 0.03 [-0.08,0.15] | 0.556 |
| Range (min,max) | (0.11,3.77) | (0.00,4.07) | (0.00,4.07) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.80±0.59 (257) | 2.79±0.69 (254) | 2.80±0.64 (511) | 0.01 [-0.10,0.12] | 0.892 |
| Range (min,max) | (0.11,4.17) | (0.00,4.37) | (0.00,4.37) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 1.79±20.54 (257) | 2.77±23.00 (254) | 2.28±21.78 (511) | -0.98 [-4.77,2.81] | 0.611 |
| Range (min,max) | (-67.58,95.21) | (-90.27,100.00) | (-90.27,100.00) | | |
| Distal Edge (mm) | | | | | |
| MLD (mm) | | | | | |
| Mean±SD (n) | 2.28±0.54 (262) | 2.18±0.60 (262) | 2.23±0.58 (524) | 0.10 [0.00,0.20] | 0.042 |
| Range (min,max) | (0.08,3.87) | (0.00,3.53) | (0.00,3.87) | | |
| Mean Diameter (mm) | | | | | |
| Mean±SD (n) | 2.50±0.51 (262) | 2.40±0.61 (262) | 2.45±0.57 (524) | 0.09 [-0.00,0.19] | 0.059 |
| Range (min,max) | (1.23,4.31) | (0.00,3.88) | (0.00,4.31) | | |
| % Stenosis | | | | | |
| Mean±SD (n) | 12.32±14.04 (262) | 15.62±17.19 (262) | 13.97±15.76 (524) | -3.30 [-5.99,-0.60] | 0.017 |
| Range (min,max) | (-55.87,94.50) | (-41.04,100.00) | (-55.87,100.00) | | |
| Binary Restenosis | | | | | |
| In-Segment | 11.4% (30/264) | 30.9% (82/265) | 21.2% (112/529) | -19.6% [-26.3%,-12.8%] | <0.001 |
| Within the Stent | 8.0% (21/264) | 29.1% (77/265) | 18.5% (98/529) | -21.1% [-27.5%,-14.7%] | <0.001 |
| Proximal Edge | 2.3% (6/257) | 2.8% (7/254) | 2.5% (13/511) | -0.4% [-3.2%,2.3%] | 0.787 |
| Distal Edge | 1.5% (4/262) | 3.1% (8/262) | 2.3% (12/524) | -1.5% [-4.1%,1.0%] | 0.382 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of angiographic patients in 8-month follow-up, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the Angiographic Core Laboratory.

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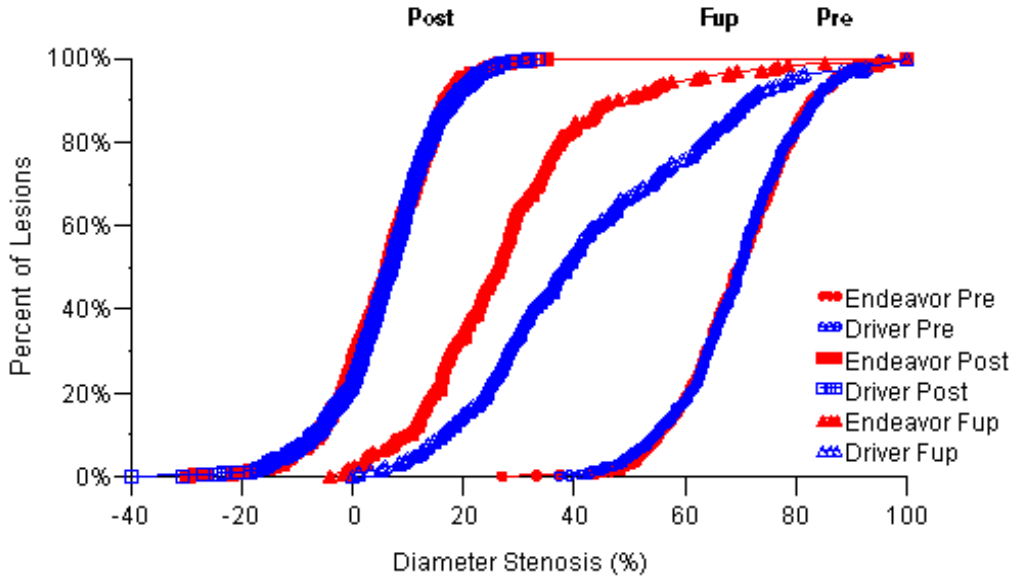
## Figure 1. Cumulative Frequency Distribution of In-Stent Percent Diameter Stenosis (ITT)

| All Lesion in Original Cohort with QCA data | | | | | |
|---|---|---|---|---|---|
| | Pre-Procedure | | | Post-Procedure In-Stent | |
| Measure | Endeavor (N=598 patients) | Driver (N=599 patients) | | Endeavor (N=598 patients) | Driver (N=599 patients) |
| Number | 590 | 591 | | 588 | 589 |
| Median | 69.8% | 70.0% | | 6.6% | 7.1% |
| Minimum | 27.1% | 37.4% | | -29.9% | -39.6% |
| Maximum | 100.0% | 100.0% | | 100.0% | 33.8% |
| Mean | 69.7% | 69.6% | | 6.0% | 6.2% |
| SD | 10.9% | 11.0% | | 10.4% | 10.0% |
| COV | 15.6% | 15.8% | | 172.6% | 161.2% |
| Diff [CI] | 0.2% [-1.1%,1.4%] | | | -0.2% [-1.4%,1.0%] | |

| All Lesions in Angiographic Follow-up Subset with QCA data | | | | | | |
|---|---|---|---|---|---|---|
| | Pre-Procedure | | Eight-Month Follow-up In-Stent | | Post-Procedure In-Stent | |
| Measure | Endeavor (N=298 patients) | Driver (N=302 patients) | Endeavor (N=298 patients) | Driver (N=302 patients) | Endeavor (N=298 patients) | Driver (N=302 patients) |
| Number | 294 | 298 | 264 | 265 | 294 | 297 |
| Median | 70.5% | 70.9% | 26.4% | 38.5% | 6.0% | 6.0% |
| Minimum | 33.3% | 37.4% | -3.9% | 0.1% | -29.9% | -39.6% |
| Maximum | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 31.3% |
| Mean | 70.5% | 70.4% | 27.9% | 42.2% | 5.3% | 5.5% |
| SD | 10.7% | 11.2% | 17.3% | 21.7% | 11.0% | 10.2% |
| COV | 15.1% | 15.9% | 62.0% | 51.4% | 207.2% | 185.7% |
| Diff [CI] | 0.1% [-1.7%,1.8%] | | -14.3% [-17.7%,-11.0%] | | -0.1% [-1.9%,1.6%] | |




*(Footnotes on next page)*

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

All data assessed by the Angiographic Core Laboratory.

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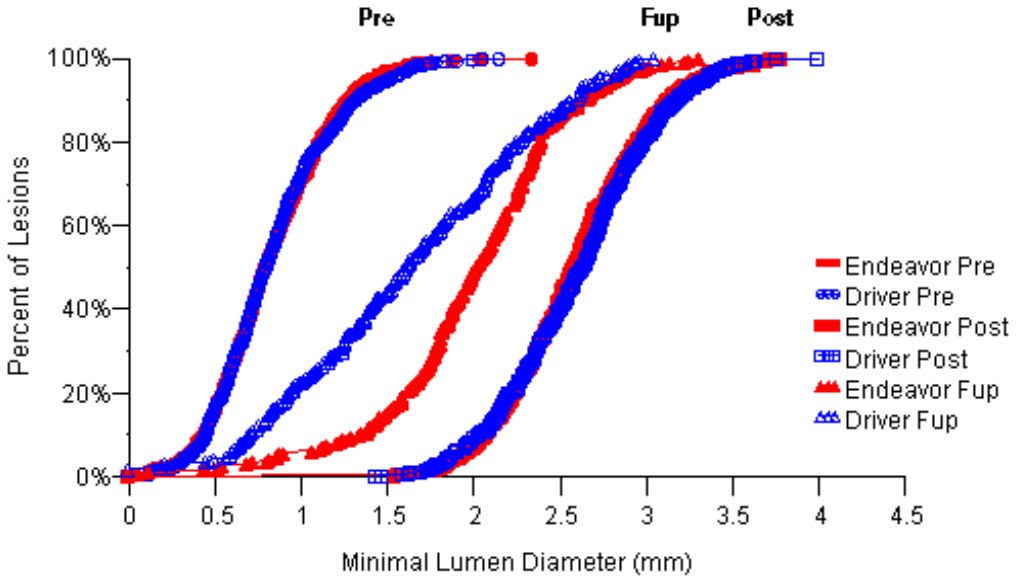
## Figure 2. Cumulative Frequency Distribution of In-Stent Minimum Lumen Diameter (ITT)

| All Lesion in Original Cohort with QCA data | | | | | |
|---|---|---|---|---|---|
| | Pre-Procedure | | | Post-Procedure In-Stent | |
| Measure | Endeavor (N=598 patients) | Driver (N=599 patients) | | Endeavor (N=598 patients) | Driver (N=599 patients) |
| Number | 590 | 591 | | 588 | 589 |
| Median | 0.79 | 0.80 | | 2.58 | 2.64 |
| Minimum | 0.00 | 0.00 | | 0.00 | 1.44 |
| Maximum | 2.34 | 2.15 | | 3.78 | 4.00 |
| Mean | 0.83 | 0.84 | | 2.59 | 2.61 |
| SD | 0.34 | 0.35 | | 0.43 | 0.44 |
| COV | 40.8% | 41.6% | | 16.5% | 16.7% |
| Diff [CI] | -0.01 [-0.05,0.03] | | | -0.02 [-0.07,0.03] | |

| All Lesions in Angiographic Follow-up Subset with QCA data | | | | | | |
|---|---|---|---|---|---|---|
| | Pre-Procedure | | Eight-Month Follow-up In-Stent | | Post-Procedure In-Stent | |
| Measure | Endeavor (N=298 patients) | Driver (N=302 patients) | Endeavor (N=298 patients) | Driver (N=302 patients) | Endeavor (N=298 patients) | Driver (N=302 patients) |
| Number | 294 | 298 | 264 | 265 | 294 | 297 |
| Median | 0.78 | 0.76 | 2.02 | 1.62 | 2.60 | 2.67 |
| Minimum | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 1.46 |
| Maximum | 1.88 | 2.15 | 3.31 | 3.05 | 3.78 | 3.75 |
| Mean | 0.81 | 0.82 | 1.99 | 1.62 | 2.61 | 2.65 |
| SD | 0.33 | 0.35 | 0.56 | 0.70 | 0.44 | 0.42 |
| COV | 40.7% | 42.6% | 28.1% | 43.2% | 16.9% | 15.8% |
| Diff [CI] | -0.01 [-0.06,0.05] | | 0.37 [0.26,0.48] | | -0.04 [-0.11,0.03] | |




*(Footnotes on next page)*

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

All data assessed by the Angiographic Core Laboratory.

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# Table 7. Acute Success (ITT)

| Success | Endeavor | Driver |
|---|---|---|
| Lesions Evaluable for Lesion Success | 589 | 590 |
| Patients Evaluable for Procedure Success | 589 | 590 |
| Lesions Evaluable for Device Success | 592 | 591 |
| Patients Evaluable for Device-Specific Procedure Success | 592 | 591 |

| Lesion | Endeavor | Driver | Difference | 95% CI |
|---|---|---|---|---|
| Success | 587 | 590 | | |
| % Successful | 99.7% | 100.0% | -0.3% | [-0.8%,0.1%] |
| Failure | 2 | 0 | | |
| % Failed | 0.3% | 0.0% | 0.3% | [-0.1%,0.8%] |

| Procedure | Endeavor | Driver | Difference | 95% CI |
|---|---|---|---|---|
| Success | 573 | 573 | | |
| % Successful | 97.3% | 97.1% | 0.2% | [-1.7%,2.0%] |
| Failure | 16 | 17 | | |
| % Failed | 2.7% | 2.9% | -0.2% | [-2.0%,1.7%] |

| Device | Endeavor | Driver | Difference | 95% CI |
|---|---|---|---|---|
| Success | 585 | 586 | | |
| % Successful | 98.8% | 99.2% | -0.3% | [-1.5%,0.8%] |
| Failure | 7 | 5 | | |
| % Failed | 1.2% | 0.8% | 0.3% | [-0.8%,1.5%] |

| Device-Specific Procedure Success | Endeavor | Driver | Difference | 95% CI |
|---|---|---|---|---|
| Success | 571 | 570 | | |
| % Successful | 96.5% | 96.4% | 0.0% | [-2.1%,2.1%] |
| Failure | 21 | 21 | | |
| % Failed | 3.5% | 3.6% | -0.0% | [-2.1%,2.1%] |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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# Table 8. Post-Procedure Morphology and Length of Stay (ITT)

| Patient Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Post-Procedure Hospital Length of Stay (days) | | | | | |
| Mean±SD (n) | 1.6±1.5 (597) | 1.9±2.8 (596) | 1.7±2.2 (1193) | -0.3 [-0.5,-0.0] | 0.040 |
| Range (min,max) | (0.0,11.0) | (0.0,43.0) | (0.0,43.0) | | |
| Median | 1.0 | 1.0 | 1.0 | | |
| Interquartile Range (25%,75%) | (1.0,2.0) | (1.0,2.0) | (1.0,2.0) | | |
| Diameter of stents implanted (per stent) | | | | | 0.600 |
| 2.25 mm | 2.4% (16/666) | 2.6% (17/661) | 2.5% (33/1327) | | |
| 2.50 mm | 15.9% (106/666) | 15.3% (101/661) | 15.6% (207/1327) | | |
| 2.75 mm | 0.2% (1/666) | 0.0% (0/661) | 0.1% (1/1327) | | |
| 3.00 mm | 46.2% (308/666) | 45.4% (300/661) | 45.8% (608/1327) | | |
| 3.50 mm | 35.3% (235/666) | 36.8% (243/661) | 36.0% (478/1327) | | |
| Pre-Stent Thrombus | 2.4% (14/590) | 3.6% (21/591) | 3.0% (35/1181) | -1.2% [-3.1%,0.8%] | 0.303 |
| Post-Procedure Thrombus | 0.5% (3/589) | 0.2% (1/590) | 0.3% (4/1179) | 0.3% [-0.3%,1.0%] | 0.374 |
| Post-Procedure Dissection | | | | | 0.269 |
| None | 98.6% (581/589) | 97.8% (577/590) | 98.2% (1158/1179) | | |
| Type A | 0.3% (2/589) | 0.3% (2/590) | 0.3% (4/1179) | | |
| Type B | 0.7% (4/589) | 1.0% (6/590) | 0.8% (10/1179) | | |
| Type C | 0.3% (2/589) | 0.5% (3/590) | 0.4% (5/1179) | | |
| Type D | 0.0% (0/589) | 0.2% (1/590) | 0.1% (1/1179) | | |
| Type E | 0.0% (0/589) | 0.2% (1/590) | 0.1% (1/1179) | | |
| Type F | 0.0% (0/589) | 0.0% (0/590) | 0.0% (0/1179) | | |
| Post-Procedure TIMI | | | | | 0.253 |
| 0 | 0.3% (2/588) | 0.0% (0/590) | 0.2% (2/1178) | | |
| 1 | 0.0% (0/588) | 0.0% (0/590) | 0.0% (0/1178) | | |
| 2 | 0.5% (3/588) | 0.3% (2/590) | 0.4% (5/1178) | | |
| 3 | 99.1% (583/588) | 99.7% (588/590) | 99.4% (1171/1178) | | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.

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## Table 9. Follow-up Morphology (ITT)

| Patient Characteristic | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **Eight-Month Follow-up** | | | | | |
| Thrombus | 0.8% (2/264) | 1.1% (3/265) | 0.9% (5/529) | -0.4% [-2.0%,1.3%] | 1.000 |
| TIMI Flow | | | | | 0.067 |
| 0 | 0.0% (0/264) | 1.5% (4/264) | 0.8% (4/528) | | |
| 1 | 1.1% (3/264) | 0.8% (2/264) | 0.9% (5/528) | | |
| 2 | 0.4% (1/264) | 1.9% (5/264) | 1.1% (6/528) | | |
| 3 | 98.5% (260/264) | 95.8% (253/264) | 97.2% (513/528) | | |
| Total Occlusion | 1.1% (3/264) | 2.3% (6/264) | 1.7% (9/528) | -1.1% [-3.3%,1.1%] | 0.504 |
| In-stent Restenosis Pattern | | | | | 0.004 |
| IA | 0.0% (0/35) | 0.0% (0/92) | 0.0% (0/127) | | |
| IB | 28.6% (10/35) | 5.4% (5/92) | 11.8% (15/127) | | |
| IC | 14.3% (5/35) | 12.0% (11/92) | 12.6% (16/127) | | |
| ID | 0.0% (0/35) | 1.1% (1/92) | 0.8% (1/127) | | |
| II | 34.3% (12/35) | 64.1% (59/92) | 55.9% (71/127) | | |
| III | 20.0% (7/35) | 12.0% (11/92) | 14.2% (18/127) | | |
| IV | 2.9% (1/35) | 5.4% (5/92) | 4.7% (6/127) | | |
| ISR Length (mm) | | | | | |
| Mean±SD (n) | 13.28±6.46 (35) | 17.91±7.88 (91) | 16.62±7.77 (126) | -4.63 [-7.59,-1.67] | 0.002 |
| Range (min,max) | (3.80,35.25) | (2.78,41.69) | (2.78,41.69) | | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.

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## Table 10. Major Adverse Events In-Hospital (ITT)

| In-Hospital Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.5% (15/597) | 2.9% (17/596) | 2.7% (32/1193) | -0.3% [-2.2%,1.5%] | 0.725 |
| Death | 0.2% (1/597) | 0.0% (0/596) | 0.1% (1/1193) | 0.2% [-0.2%,0.5%] | 1.000 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 2.5% (15/597) | 2.7% (16/596) | 2.6% (31/1193) | -0.2% [-2.0%,1.6%] | 0.858 |
| Q Wave MI | 0.2% (1/597) | 0.3% (2/596) | 0.3% (3/1193) | -0.2% [-0.7%,0.4%] | 0.624 |
| Non-Q Wave MI | 2.3% (14/597) | 2.3% (14/596) | 2.3% (28/1193) | -0.0% [-1.7%,1.7%] | 1.000 |
| Emergent CABG | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 0.5% (3/597) | 0.3% (2/596) | 0.4% (5/1193) | 0.2% [-0.6%,0.9%] | 1.000 |
| TL-CABG | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| TL-PTCA | 0.5% (3/597) | 0.3% (2/596) | 0.4% (5/1193) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Revascularization not involving the Target Lesion | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| TV/non-TL-CABG | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| TV/non-TL-PTCA | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| Target Vessel Revascularization | 0.5% (3/597) | 0.3% (2/596) | 0.4% (5/1193) | 0.2% [-0.6%,0.9%] | 1.000 |
| Target Vessel Failure | 2.5% (15/597) | 2.9% (17/596) | 2.7% (32/1193) | -0.3% [-2.2%,1.5%] | 0.725 |
| Perforation | 0.5% (3/597) | 0.3% (2/596) | 0.4% (5/1193) | 0.2% [-0.6%,0.9%] | 1.000 |
| Early Stent Thrombosis | 0.3% (2/597) | 0.3% (2/596) | 0.3% (4/1193) | -0.0% [-0.7%,0.7%] | 1.000 |
| Late Stent Thrombosis | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/597) | 1.0% (6/596) | 0.7% (8/1193) | -0.7% [-1.6%,0.3%] | 0.178 |
| Cerebrovascular Accident (CVA) | 0.0% (0/597) | 0.0% (0/596) | 0.0% (0/1193) | 0.0% [--,--] | -- |
| Major Bleeding | 1.0% (6/597) | 1.8% (11/596) | 1.4% (17/1193) | -0.8% [-2.2%,0.5%] | 0.234 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with available data for related parameter.

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## Table 11a. Major Adverse Events Out-of-Hospital to 30 Days (ITT)

| Out-of-Hospital Complications to 30 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 0.3% (2/596) | 0.8% (5/594) | 0.6% (7/1190) | -0.5% [-1.4%,0.4%] | 0.287 |
| Death | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.2% (1/596) | 0.8% (5/594) | 0.5% (6/1190) | -0.7% [-1.5%,0.1%] | 0.124 |
| Q Wave MI | 0.2% (1/596) | 0.5% (3/594) | 0.3% (4/1190) | -0.3% [-1.0%,0.3%] | 0.374 |
| Non-Q Wave MI | 0.0% (0/596) | 0.3% (2/594) | 0.2% (2/1190) | -0.3% [-0.8%,0.1%] | 0.249 |
| Emergent CABG | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 0.3% (2/596) | 0.8% (5/594) | 0.6% (7/1190) | -0.5% [-1.4%,0.4%] | 0.287 |
| TL-CABG | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| TL-PTCA | 0.3% (2/596) | 0.8% (5/594) | 0.6% (7/1190) | -0.5% [-1.4%,0.4%] | 0.287 |
| Target Vessel Revascularization not involving the Target Lesion | 0.3% (2/596) | 0.0% (0/594) | 0.2% (2/1190) | 0.3% [-0.1%,0.8%] | 0.500 |
| TV/non-TL-CABG | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| TV/non-TL-PTCA | 0.3% (2/596) | 0.0% (0/594) | 0.2% (2/1190) | 0.3% [-0.1%,0.8%] | 0.500 |
| Target Vessel Revascularization | 0.7% (4/596) | 0.8% (5/594) | 0.8% (9/1190) | -0.2% [-1.2%,0.8%] | 0.753 |
| Target Vessel Failure | 0.7% (4/596) | 0.8% (5/594) | 0.8% (9/1190) | -0.2% [-1.2%,0.8%] | 0.753 |
| Perforation | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| Early Stent Thrombosis | 0.2% (1/596) | 0.8% (5/594) | 0.5% (6/1190) | -0.7% [-1.5%,0.1%] | 0.124 |
| Late Stent Thrombosis | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| Vascular Complications | 0.2% (1/596) | 0.2% (1/594) | 0.2% (2/1190) | -0.0% [-0.5%,0.5%] | 1.000 |
| Cerebrovascular Accident (CVA) | 0.0% (0/596) | 0.2% (1/594) | 0.1% (1/1190) | -0.2% [-0.5%,0.2%] | 0.499 |
| Major Bleeding | 0.2% (1/596) | 0.3% (2/594) | 0.3% (3/1190) | -0.2% [-0.7%,0.4%] | 0.624 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

This table is based on evaluable patients – those with information beyond 25 days post-index procedure or an event through 30 days.

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## Table 11b. Major Adverse Events Out-of-Hospital to 180 Days (ITT)

| Out-of-Hospital Complications to 180 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.0% (12/593) | 6.4% (38/593) | 4.2% (50/1186) | -4.4% [-6.7%,-2.1%] | <0.001 |
| Death | 0.3% (2/593) | 0.5% (3/593) | 0.4% (5/1186) | -0.2% [-0.9%,0.6%] | 1.000 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.2% (1/593) | 1.0% (6/593) | 0.6% (7/1186) | -0.8% [-1.7%,0.0%] | 0.124 |
| Q Wave MI | 0.2% (1/593) | 0.5% (3/593) | 0.3% (4/1186) | -0.3% [-1.0%,0.3%] | 0.624 |
| Non-Q Wave MI | 0.0% (0/593) | 0.5% (3/593) | 0.3% (3/1186) | -0.5% [-1.1%,0.1%] | 0.249 |
| Emergent CABG | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 1.7% (10/593) | 5.9% (35/593) | 3.8% (45/1186) | -4.2% [-6.4%,-2.1%] | <0.001 |
| TL-CABG | 0.0% (0/593) | 0.2% (1/593) | 0.1% (1/1186) | -0.2% [-0.5%,0.2%] | 1.000 |
| TL-PTCA | 1.7% (10/593) | 5.7% (34/593) | 3.7% (44/1186) | -4.0% [-6.2%,-1.9%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 0.8% (5/593) | 0.7% (4/593) | 0.8% (9/1186) | 0.2% [-0.8%,1.2%] | 1.000 |
| TV/non-TL-CABG | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| TV/non-TL-PTCA | 0.8% (5/593) | 0.7% (4/593) | 0.8% (9/1186) | 0.2% [-0.8%,1.2%] | 1.000 |
| Target Vessel Revascularization | 2.2% (13/593) | 6.1% (36/593) | 4.1% (49/1186) | -3.9% [-6.1%,-1.6%] | 0.001 |
| Target Vessel Failure | 2.4% (14/593) | 6.6% (39/593) | 4.5% (53/1186) | -4.2% [-6.6%,-1.9%] | <0.001 |
| Perforation | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| Early Stent Thrombosis | 0.2% (1/593) | 0.8% (5/593) | 0.5% (6/1186) | -0.7% [-1.5%,0.1%] | 0.218 |
| Late Stent Thrombosis | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/593) | 0.2% (1/593) | 0.3% (3/1186) | 0.2% [-0.4%,0.7%] | 1.000 |
| Cerebrovascular Accident (CVA) | 0.0% (0/593) | 0.3% (2/593) | 0.2% (2/1186) | -0.3% [-0.8%,0.1%] | 0.500 |
| Major Bleeding | 0.3% (2/593) | 0.3% (2/593) | 0.3% (4/1186) | 0.0% [--,--] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

This table is based on evaluable patients – those with information beyond 166 days post-index procedure or an event through 180 days.

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## Table 11c. Major Adverse Events Out-of-Hospital to 270 Days (ITT)

| Out-of-Hospital Complications to 270 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 4.9% (29/592) | 12.0% (71/591) | 8.5% (100/1183) | -7.1% [-10.3%,-4.0%] | <0.001 |
| Death | 1.0% (6/592) | 0.5% (3/591) | 0.8% (9/1183) | 0.5% [-0.5%,1.5%] | 0.506 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.2% (1/592) | 1.2% (7/591) | 0.7% (8/1183) | -1.0% [-1.9%,-0.1%] | 0.038 |
| Q Wave MI | 0.2% (1/592) | 0.5% (3/591) | 0.3% (4/1183) | -0.3% [-1.0%,0.3%] | 0.374 |
| Non-Q Wave MI | 0.0% (0/592) | 0.7% (4/591) | 0.3% (4/1183) | -0.7% [-1.3%,-0.0%] | 0.062 |
| Emergent CABG | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 4.1% (24/592) | 11.5% (68/591) | 7.8% (92/1183) | -7.5% [-10.5%,-4.4%] | <0.001 |
| TL-CABG | 0.3% (2/592) | 0.5% (3/591) | 0.4% (5/1183) | -0.2% [-0.9%,0.6%] | 0.687 |
| TL-PTCA | 3.7% (22/592) | 11.0% (65/591) | 7.4% (87/1183) | -7.3% [-10.2%,-4.3%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 1.5% (9/592) | 2.2% (13/591) | 1.9% (22/1183) | -0.7% [-2.2%,0.9%] | 0.400 |
| TV/non-TL-CABG | 0.2% (1/592) | 0.0% (0/591) | 0.1% (1/1183) | 0.2% [-0.2%,0.5%] | 1.000 |
| TV/non-TL-PTCA | 1.4% (8/592) | 2.2% (13/591) | 1.8% (21/1183) | -0.8% [-2.4%,0.7%] | 0.282 |
| Target Vessel Revascularization | 5.1% (30/592) | 12.4% (73/591) | 8.7% (103/1183) | -7.3% [-10.5%,-4.1%] | <0.001 |
| Target Vessel Failure | 5.6% (33/592) | 12.9% (76/591) | 9.2% (109/1183) | -7.3% [-10.6%,-4.0%] | <0.001 |
| Perforation | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| Early Stent Thrombosis | 0.2% (1/592) | 0.8% (5/591) | 0.5% (6/1183) | -0.7% [-1.5%,0.1%] | 0.124 |
| Late Stent Thrombosis | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/592) | 0.2% (1/591) | 0.3% (3/1183) | 0.2% [-0.4%,0.7%] | 1.000 |
| Cerebrovascular Accident (CVA) | 0.2% (1/592) | 0.5% (3/591) | 0.3% (4/1183) | -0.3% [-1.0%,0.3%] | 0.374 |
| Major Bleeding | 0.3% (2/592) | 0.3% (2/591) | 0.3% (4/1183) | -0.0% [-0.7%,0.7%] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

This table is based on evaluable patients – those with information beyond 256 days post-index procedure or an event through 270 days.

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## Table 11d. Major Adverse Events Out-of-Hospital to 360 Days (ITT)

| Out-of-Hospital Complications to 360 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 6.4% (38/590) | 13.2% (78/589) | 9.8% (116/1179) | -6.8% [-10.2%,-3.4%] | <0.001 |
| Death | 1.2% (7/590) | 0.7% (4/589) | 0.9% (11/1179) | 0.5% [-0.6%,1.6%] | 0.547 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.2% (1/590) | 1.2% (7/589) | 0.7% (8/1179) | -1.0% [-2.0%,-0.1%] | 0.038 |
| Q Wave MI | 0.2% (1/590) | 0.5% (3/589) | 0.3% (4/1179) | -0.3% [-1.0%,0.3%] | 0.374 |
| Non-Q Wave MI | 0.0% (0/590) | 0.7% (4/589) | 0.3% (4/1179) | -0.7% [-1.3%,-0.0%] | 0.062 |
| Emergent CABG | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 5.4% (32/590) | 12.7% (75/589) | 9.1% (107/1179) | -7.3% [-10.6%,-4.1%] | <0.001 |
| TL-CABG | 0.3% (2/590) | 0.7% (4/589) | 0.5% (6/1179) | -0.3% [-1.2%,0.5%] | 0.452 |
| TL-PTCA | 5.1% (30/590) | 12.1% (71/589) | 8.6% (101/1179) | -7.0% [-10.1%,-3.8%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 2.0% (12/590) | 2.5% (15/589) | 2.3% (27/1179) | -0.5% [-2.2%,1.2%] | 0.567 |
| TV/non-TL-CABG | 0.2% (1/590) | 0.0% (0/589) | 0.1% (1/1179) | 0.2% [-0.2%,0.5%] | 1.000 |
| TV/non-TL-PTCA | 1.9% (11/590) | 2.5% (15/589) | 2.2% (26/1179) | -0.7% [-2.4%,1.0%] | 0.437 |
| Target Vessel Revascularization | 6.9% (41/590) | 13.9% (82/589) | 10.4% (123/1179) | -7.0% [-10.4%,-3.5%] | <0.001 |
| Target Vessel Failure | 7.6% (45/590) | 14.4% (85/589) | 11.0% (130/1179) | -6.8% [-10.4%,-3.2%] | <0.001 |
| Perforation | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| Early Stent Thrombosis | 0.2% (1/590) | 0.8% (5/589) | 0.5% (6/1179) | -0.7% [-1.5%,0.1%] | 0.124 |
| Late Stent Thrombosis | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/590) | 0.2% (1/589) | 0.3% (3/1179) | 0.2% [-0.4%,0.7%] | 1.000 |
| Cerebrovascular Accident (CVA) | 0.3% (2/590) | 0.5% (3/589) | 0.4% (5/1179) | -0.2% [-0.9%,0.6%] | 0.687 |
| Major Bleeding | 0.3% (2/590) | 0.3% (2/589) | 0.3% (4/1179) | -0.0% [-0.7%,0.7%] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

This table is based on evaluable patients – those with information beyond 330 days post-index procedure or an event through 360 days.

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## Table 11e. Major Adverse Events Out-of-Hospital to 720 Days (ITT)

| Out-of-Hospital Complications to 720 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 7.5% (44/587) | 15.7% (92/586) | 11.6% (136/1173) | -8.2% [-11.8%,-4.6%] | <0.001 |
| Death | 1.9% (11/587) | 2.2% (13/586) | 2.0% (24/1173) | -0.3% [-2.0%,1.3%] | 0.687 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.3% (2/587) | 1.2% (7/586) | 0.8% (9/1173) | -0.9% [-1.9%,0.1%] | 0.108 |
| Q Wave MI | 0.2% (1/587) | 0.5% (3/586) | 0.3% (4/1173) | -0.3% [-1.0%,0.3%] | 0.374 |
| Non-Q Wave MI | 0.2% (1/587) | 0.7% (4/586) | 0.4% (5/1173) | -0.5% [-1.3%,0.2%] | 0.218 |
| Emergent CABG | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 6.0% (35/587) | 13.8% (81/586) | 9.9% (116/1173) | -7.9% [-11.2%,-4.5%] | <0.001 |
| TL-CABG | 0.5% (3/587) | 1.0% (6/586) | 0.8% (9/1173) | -0.5% [-1.5%,0.5%] | 0.342 |
| TL-PTCA | 5.6% (33/587) | 13.0% (76/586) | 9.3% (109/1173) | -7.3% [-10.6%,-4.1%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 2.4% (14/587) | 4.1% (24/586) | 3.2% (38/1173) | -1.7% [-3.7%,0.3%] | 0.102 |
| TV/non-TL-CABG | 0.2% (1/587) | 0.3% (2/586) | 0.3% (3/1173) | -0.2% [-0.7%,0.4%] | 0.624 |
| TV/non-TL-PTCA | 2.2% (13/587) | 3.9% (23/586) | 3.1% (36/1173) | -1.7% [-3.7%,0.3%] | 0.094 |
| Target Vessel Revascularization | 7.8% (46/587) | 16.2% (95/586) | 12.0% (141/1173) | -8.4% [-12.1%,-4.7%] | <0.001 |
| Target Vessel Failure | 8.7% (51/587) | 17.6% (103/586) | 13.1% (154/1173) | -8.9% [-12.7%,-5.1%] | <0.001 |
| Perforation | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| Early Stent Thrombosis | 0.2% (1/587) | 0.9% (5/586) | 0.5% (6/1173) | -0.7% [-1.5%,0.1%] | 0.124 |
| Late Stent Thrombosis | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/587) | 0.2% (1/586) | 0.3% (3/1173) | 0.2% [-0.4%,0.7%] | 1.000 |
| Cerebrovascular Accident (CVA) | 0.7% (4/587) | 0.5% (3/586) | 0.6% (7/1173) | 0.2% [-0.7%,1.1%] | 1.000 |
| Major Bleeding | 0.3% (2/587) | 0.3% (2/586) | 0.3% (4/1173) | -0.0% [-0.7%,0.7%] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 690 days post index procedure or an event through 720 days.

This table is based on evaluable patients – those with information beyond 690 days post-index procedure or an event through 720 days.

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## Table 11f. Major Adverse Events Out-of-Hospital to 1080 Days (ITT)

| Out-of-Hospital Complications to 1080 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 9.5% (55/577) | 18.7% (108/579) | 14.1% (163/1156) | -9.1% [-13.1%,-5.1%] | <0.001 |
| Death | 3.1% (18/577) | 4.5% (26/579) | 3.8% (44/1156) | -1.4% [-3.6%,0.8%] | 0.282 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 0.7% (4/577) | 1.6% (9/579) | 1.1% (13/1156) | -0.9% [-2.1%,0.4%] | 0.264 |
| Q Wave MI | 0.2% (1/577) | 0.7% (4/579) | 0.4% (5/1156) | -0.5% [-1.3%,0.2%] | 0.374 |
| Non-Q Wave MI | 0.5% (3/577) | 0.9% (5/579) | 0.7% (8/1156) | -0.3% [-1.3%,0.6%] | 0.726 |
| Emergent CABG | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 6.8% (39/577) | 14.3% (83/579) | 10.6% (122/1156) | -7.6% [-11.1%,-4.1%] | <0.001 |
| TL-CABG | 0.5% (3/577) | 1.0% (6/579) | 0.8% (9/1156) | -0.5% [-1.5%,0.5%] | 0.506 |
| TL-PTCA | 6.4% (37/577) | 13.5% (78/579) | 9.9% (115/1156) | -7.1% [-10.5%,-3.6%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 2.9% (17/577) | 4.8% (28/579) | 3.9% (45/1156) | -1.9% [-4.1%,0.3%] | 0.128 |
| TV/non-TL-CABG | 0.2% (1/577) | 0.3% (2/579) | 0.3% (3/1156) | -0.2% [-0.8%,0.4%] | 1.000 |
| TV/non-TL-PTCA | 2.8% (16/577) | 4.7% (27/579) | 3.7% (43/1156) | -1.9% [-4.1%,0.3%] | 0.119 |
| Target Vessel Revascularization | 9.0% (52/577) | 17.4% (101/579) | 13.2% (153/1156) | -8.4% [-12.3%,-4.6%] | <0.001 |
| Target Vessel Failure | 10.4% (60/577) | 19.2% (111/579) | 14.8% (171/1156) | -8.8% [-12.8%,-4.7%] | <0.001 |
| Perforation | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| Early Stent Thrombosis | 0.2% (1/577) | 0.9% (5/579) | 0.5% (6/1156) | -0.7% [-1.5%,0.1%] | 0.218 |
| Late Stent Thrombosis | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/577) | 0.2% (1/579) | 0.3% (3/1156) | 0.2% [-0.4%,0.8%] | 0.624 |
| Cerebrovascular Accident (CVA) | 1.0% (6/577) | 1.2% (7/579) | 1.1% (13/1156) | -0.2% [-1.4%,1.0%] | 1.000 |
| Major Bleeding | 0.3% (2/577) | 0.5% (3/579) | 0.4% (5/1156) | -0.2% [-0.9%,0.6%] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 1050 days post index procedure or an event through 1080 days.

This table is based on evaluable patients – those with information beyond 1050 days post-index procedure or an event through 1080 days.

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## Table 12a. Combined Major Adverse Events to 30 Days (ITT)

| Combined Complications to 30 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 2.9% (17/596) | 3.7% (22/594) | 3.3% (39/1190) | -0.9% [-2.9%,1.2%] | 0.421 |
| Death | 0.2% (1/596) | 0.0% (0/594) | 0.1% (1/1190) | 0.2% [-0.2%,0.5%] | 1.000 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 2.7% (16/596) | 3.5% (21/594) | 3.1% (37/1190) | -0.9% [-2.8%,1.1%] | 0.410 |
| Q Wave MI | 0.3% (2/596) | 0.8% (5/594) | 0.6% (7/1190) | -0.5% [-1.4%,0.4%] | 0.287 |
| Non-Q Wave MI | 2.3% (14/596) | 2.7% (16/594) | 2.5% (30/1190) | -0.3% [-2.1%,1.4%] | 0.716 |
| Emergent CABG | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 0.8% (5/596) | 1.2% (7/594) | 1.0% (12/1190) | -0.3% [-1.5%,0.8%] | 0.579 |
| TL-CABG | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| TL-PTCA | 0.8% (5/596) | 1.2% (7/594) | 1.0% (12/1190) | -0.3% [-1.5%,0.8%] | 0.579 |
| Target Vessel Revascularization not involving the Target Lesion | 0.3% (2/596) | 0.0% (0/594) | 0.2% (2/1190) | 0.3% [-0.1%,0.8%] | 0.500 |
| TV/non-TL-CABG | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| TV/non-TL-PTCA | 0.3% (2/596) | 0.0% (0/594) | 0.2% (2/1190) | 0.3% [-0.1%,0.8%] | 0.500 |
| Target Vessel Revascularization | 1.2% (7/596) | 1.2% (7/594) | 1.2% (14/1190) | -0.0% [-1.2%,1.2%] | 1.000 |
| Target Vessel Failure | 3.2% (19/596) | 3.7% (22/594) | 3.4% (41/1190) | -0.5% [-2.6%,1.6%] | 0.638 |
| Perforation | 0.5% (3/596) | 0.3% (2/594) | 0.4% (5/1190) | 0.2% [-0.6%,0.9%] | 1.000 |
| Early Stent Thrombosis | 0.5% (3/596) | 1.2% (7/594) | 0.8% (10/1190) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| Vascular Complications | 0.3% (2/596) | 1.2% (7/594) | 0.8% (9/1190) | -0.8% [-1.8%,0.1%] | 0.108 |
| Cerebrovascular Accident (CVA) | 0.0% (0/596) | 0.2% (1/594) | 0.1% (1/1190) | -0.2% [-0.5%,0.2%] | 0.499 |
| Major Bleeding | 1.0% (6/596) | 2.2% (13/594) | 1.6% (19/1190) | -1.2% [-2.6%,0.2%] | 0.112 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

This table is based on evaluable patients – those with information beyond 25 days post-index procedure or an event through 30 days.

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## Table 12b. Combined Major Adverse Events to 180 Days (ITT)

| Combined Complications to 180 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 4.6% (27/593) | 8.9% (53/593) | 6.7% (80/1186) | -4.4% [-7.2%,-1.5%] | 0.004 |
| Death | 0.5% (3/593) | 0.5% (3/593) | 0.5% (6/1186) | 0.0% [--,--] | 1.000 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 2.7% (16/593) | 3.7% (22/593) | 3.2% (38/1186) | -1.0% [-3.0%,1.0%] | 0.410 |
| Q Wave MI | 0.3% (2/593) | 0.8% (5/593) | 0.6% (7/1186) | -0.5% [-1.4%,0.4%] | 0.452 |
| Non-Q Wave MI | 2.4% (14/593) | 2.9% (17/593) | 2.6% (31/1186) | -0.5% [-2.3%,1.3%] | 0.716 |
| Emergent CABG | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 2.2% (13/593) | 6.2% (37/593) | 4.2% (50/1186) | -4.0% [-6.3%,-1.8%] | <0.001 |
| TL-CABG | 0.0% (0/593) | 0.2% (1/593) | 0.1% (1/1186) | -0.2% [-0.5%,0.2%] | 1.000 |
| TL-PTCA | 2.2% (13/593) | 6.1% (36/593) | 4.1% (49/1186) | -3.9% [-6.1%,-1.6%] | 0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 0.8% (5/593) | 0.7% (4/593) | 0.8% (9/1186) | 0.2% [-0.8%,1.2%] | 1.000 |
| TV/non-TL-CABG | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| TV/non-TL-PTCA | 0.8% (5/593) | 0.7% (4/593) | 0.8% (9/1186) | 0.2% [-0.8%,1.2%] | 1.000 |
| Target Vessel Revascularization | 2.7% (16/593) | 6.2% (37/593) | 4.5% (53/1186) | -3.5% [-5.9%,-1.2%] | 0.005 |
| Target Vessel Failure | 4.9% (29/593) | 8.9% (53/593) | 6.9% (82/1186) | -4.0% [-6.9%,-1.2%] | 0.008 |
| Perforation | 0.5% (3/593) | 0.3% (2/593) | 0.4% (5/1186) | 0.2% [-0.6%,0.9%] | 1.000 |
| Early Stent Thrombosis | 0.5% (3/593) | 1.2% (7/593) | 0.8% (10/1186) | -0.7% [-1.7%,0.4%] | 0.342 |
| Late Stent Thrombosis | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| Vascular Complications | 0.5% (3/593) | 1.2% (7/593) | 0.8% (10/1186) | -0.7% [-1.7%,0.4%] | 0.342 |
| Cerebrovascular Accident (CVA) | 0.0% (0/593) | 0.3% (2/593) | 0.2% (2/1186) | -0.3% [-0.8%,0.1%] | 0.500 |
| Major Bleeding | 1.2% (7/593) | 2.2% (13/593) | 1.7% (20/1186) | -1.0% [-2.5%,0.5%] | 0.259 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

This table is based on evaluable patients – those with information beyond 166 days post-index procedure or an event through 180 days.

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## Table 12c. Combined Major Adverse Events to 270 Days (ITT)

| Combined Complications to 270 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 7.3% (43/592) | 14.4% (85/591) | 10.8% (128/1183) | -7.1% [-10.6%,-3.6%] | <0.001 |
| Death | 1.2% (7/592) | 0.5% (3/591) | 0.8% (10/1183) | 0.7% [-0.4%,1.7%] | 0.342 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 2.7% (16/592) | 3.9% (23/591) | 3.3% (39/1183) | -1.2% [-3.2%,0.8%] | 0.260 |
| Q Wave MI | 0.3% (2/592) | 0.8% (5/591) | 0.6% (7/1183) | -0.5% [-1.4%,0.4%] | 0.287 |
| Non-Q Wave MI | 2.4% (14/592) | 3.0% (18/591) | 2.7% (32/1183) | -0.7% [-2.5%,1.2%] | 0.481 |
| Emergent CABG | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 4.6% (27/592) | 11.8% (70/591) | 8.2% (97/1183) | -7.3% [-10.4%,-4.2%] | <0.001 |
| TL-CABG | 0.3% (2/592) | 0.5% (3/591) | 0.4% (5/1183) | -0.2% [-0.9%,0.6%] | 0.687 |
| TL-PTCA | 4.2% (25/592) | 11.3% (67/591) | 7.8% (92/1183) | -7.1% [-10.1%,-4.1%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 1.5% (9/592) | 2.2% (13/591) | 1.9% (22/1183) | -0.7% [-2.2%,0.9%] | 0.400 |
| TV/non-TL-CABG | 0.2% (1/592) | 0.0% (0/591) | 0.1% (1/1183) | 0.2% [-0.2%,0.5%] | 1.000 |
| TV/non-TL-PTCA | 1.4% (8/592) | 2.2% (13/591) | 1.8% (21/1183) | -0.8% [-2.4%,0.7%] | 0.282 |
| Target Vessel Revascularization | 5.6% (33/592) | 12.5% (74/591) | 9.0% (107/1183) | -6.9% [-10.2%,-3.7%] | <0.001 |
| Target Vessel Failure | 7.9% (47/592) | 15.1% (89/591) | 11.5% (136/1183) | -7.1% [-10.7%,-3.5%] | <0.001 |
| Perforation | 0.5% (3/592) | 0.3% (2/591) | 0.4% (5/1183) | 0.2% [-0.6%,0.9%] | 1.000 |
| Early Stent Thrombosis | 0.5% (3/592) | 1.2% (7/591) | 0.8% (10/1183) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| Vascular Complications | 0.5% (3/592) | 1.2% (7/591) | 0.8% (10/1183) | -0.7% [-1.7%,0.4%] | 0.224 |
| Cerebrovascular Accident (CVA) | 0.2% (1/592) | 0.5% (3/591) | 0.3% (4/1183) | -0.3% [-1.0%,0.3%] | 0.374 |
| Major Bleeding | 1.2% (7/592) | 2.2% (13/591) | 1.7% (20/1183) | -1.0% [-2.5%,0.5%] | 0.185 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

This table is based on evaluable patients – those with information beyond 256 days post-index procedure or an event through 270 days.

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## Table 12d. Combined Major Adverse Events to 360 Days (ITT)

| Combined Complications to 360 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 8.8% (52/590) | 15.6% (92/589) | 12.2% (144/1179) | -6.8% [-10.5%,-3.1%] | <0.001 |
| Death | 1.4% (8/590) | 0.7% (4/589) | 1.0% (12/1179) | 0.7% [-0.5%,1.8%] | 0.385 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 2.7% (16/590) | 3.9% (23/589) | 3.3% (39/1179) | -1.2% [-3.2%,0.8%] | 0.260 |
| Q Wave MI | 0.3% (2/590) | 0.8% (5/589) | 0.6% (7/1179) | -0.5% [-1.4%,0.4%] | 0.287 |
| Non-Q Wave MI | 2.4% (14/590) | 3.1% (18/589) | 2.7% (32/1179) | -0.7% [-2.5%,1.2%] | 0.481 |
| Emergent CABG | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 5.9% (35/590) | 13.1% (77/589) | 9.5% (112/1179) | -7.1% [-10.5%,-3.8%] | <0.001 |
| TL-CABG | 0.3% (2/590) | 0.7% (4/589) | 0.5% (6/1179) | -0.3% [-1.2%,0.5%] | 0.452 |
| TL-PTCA | 5.6% (33/590) | 12.4% (73/589) | 9.0% (106/1179) | -6.8% [-10.0%,-3.6%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 2.0% (12/590) | 2.5% (15/589) | 2.3% (27/1179) | -0.5% [-2.2%,1.2%] | 0.567 |
| TV/non-TL-CABG | 0.2% (1/590) | 0.0% (0/589) | 0.1% (1/1179) | 0.2% [-0.2%,0.5%] | 1.000 |
| TV/non-TL-PTCA | 1.9% (11/590) | 2.5% (15/589) | 2.2% (26/1179) | -0.7% [-2.4%,1.0%] | 0.437 |
| Target Vessel Revascularization | 7.5% (44/590) | 14.1% (83/589) | 10.8% (127/1179) | -6.6% [-10.2%,-3.1%] | <0.001 |
| Target Vessel Failure | 10.0% (59/590) | 16.6% (98/589) | 13.3% (157/1179) | -6.6% [-10.5%,-2.8%] | <0.001 |
| Perforation | 0.5% (3/590) | 0.3% (2/589) | 0.4% (5/1179) | 0.2% [-0.6%,0.9%] | 1.000 |
| Early Stent Thrombosis | 0.5% (3/590) | 1.2% (7/589) | 0.8% (10/1179) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| Vascular Complications | 0.5% (3/590) | 1.2% (7/589) | 0.8% (10/1179) | -0.7% [-1.7%,0.4%] | 0.224 |
| Cerebrovascular Accident (CVA) | 0.3% (2/590) | 0.5% (3/589) | 0.4% (5/1179) | -0.2% [-0.9%,0.6%] | 0.687 |
| Major Bleeding | 1.2% (7/590) | 2.2% (13/589) | 1.7% (20/1179) | -1.0% [-2.5%,0.5%] | 0.185 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

This table is based on evaluable patients – those with information beyond 330 days post-index procedure or an event through 360 days.

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## Table 12e. Combined Major Adverse Events to 720 Days (ITT)

| Combined Complications to 720 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 9.9% (58/587) | 18.1% (106/586) | 14.0% (164/1173) | -8.2% [-12.2%,-4.3%] | <0.001 |
| Death | 2.0% (12/587) | 2.2% (13/586) | 2.1% (25/1173) | -0.2% [-1.8%,1.5%] | 0.843 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 2.9% (17/587) | 3.9% (23/586) | 3.4% (40/1173) | -1.0% [-3.1%,1.0%] | 0.340 |
| Q Wave MI | 0.3% (2/587) | 0.9% (5/586) | 0.6% (7/1173) | -0.5% [-1.4%,0.4%] | 0.287 |
| Non-Q Wave MI | 2.6% (15/587) | 3.1% (18/586) | 2.8% (33/1173) | -0.5% [-2.4%,1.4%] | 0.602 |
| Emergent CABG | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 6.5% (38/587) | 14.2% (83/586) | 10.3% (121/1173) | -7.7% [-11.1%,-4.2%] | <0.001 |
| TL-CABG | 0.5% (3/587) | 1.0% (6/586) | 0.8% (9/1173) | -0.5% [-1.5%,0.5%] | 0.342 |
| TL-PTCA | 6.1% (36/587) | 13.3% (78/586) | 9.7% (114/1173) | -7.2% [-10.5%,-3.8%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 2.4% (14/587) | 4.1% (24/586) | 3.2% (38/1173) | -1.7% [-3.7%,0.3%] | 0.102 |
| TV/non-TL-CABG | 0.2% (1/587) | 0.3% (2/586) | 0.3% (3/1173) | -0.2% [-0.7%,0.4%] | 0.624 |
| TV/non-TL-PTCA | 2.2% (13/587) | 3.9% (23/586) | 3.1% (36/1173) | -1.7% [-3.7%,0.3%] | 0.094 |
| Target Vessel Revascularization | 8.3% (49/587) | 16.4% (96/586) | 12.4% (145/1173) | -8.0% [-11.8%,-4.3%] | <0.001 |
| Target Vessel Failure | 11.1% (65/587) | 19.8% (116/586) | 15.4% (181/1173) | -8.7% [-12.8%,-4.6%] | <0.001 |
| Perforation | 0.5% (3/587) | 0.3% (2/586) | 0.4% (5/1173) | 0.2% [-0.6%,0.9%] | 1.000 |
| Early Stent Thrombosis | 0.5% (3/587) | 1.2% (7/586) | 0.9% (10/1173) | -0.7% [-1.7%,0.4%] | 0.224 |
| Late Stent Thrombosis | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| Vascular Complications | 0.5% (3/587) | 1.2% (7/586) | 0.9% (10/1173) | -0.7% [-1.7%,0.4%] | 0.224 |
| Cerebrovascular Accident (CVA) | 0.7% (4/587) | 0.5% (3/586) | 0.6% (7/1173) | 0.2% [-0.7%,1.1%] | 1.000 |
| Major Bleeding | 1.2% (7/587) | 2.2% (13/586) | 1.7% (20/1173) | -1.0% [-2.5%,0.5%] | 0.185 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 690 days post index procedure or an event through 720 days.

This table is based on evaluable patients – those with information beyond 690 days post-index procedure or an event through 720 days.

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## Table 12f. Combined Major Adverse Events to 1080 Days (ITT)

| Combined Complications to 1080 Days | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| MACE (Death, MI, Emergent CABG, TLR) | 12.0% (69/577) | 20.7% (120/579) | 16.3% (189/1156) | -8.8% [-13.0%,-4.5%] | <0.001 |
| Death | 3.3% (19/577) | 4.5% (26/579) | 3.9% (45/1156) | -1.2% [-3.4%,1.0%] | 0.362 |
| Myocardial Infarction (Q Wave or Non-Q Wave) | 3.3% (19/577) | 4.3% (25/579) | 3.8% (44/1156) | -1.0% [-3.2%,1.2%] | 0.443 |
| Q Wave MI | 0.3% (2/577) | 1.0% (6/579) | 0.7% (8/1156) | -0.7% [-1.6%,0.3%] | 0.287 |
| Non-Q Wave MI | 2.9% (17/577) | 3.3% (19/579) | 3.1% (36/1156) | -0.3% [-2.3%,1.7%] | 0.866 |
| Emergent CABG | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| Target Lesion Revascularization | 7.3% (42/577) | 14.7% (85/579) | 11.0% (127/1156) | -7.4% [-11.0%,-3.8%] | <0.001 |
| TL-CABG | 0.5% (3/577) | 1.0% (6/579) | 0.8% (9/1156) | -0.5% [-1.5%,0.5%] | 0.506 |
| TL-PTCA | 6.9% (40/577) | 13.8% (80/579) | 10.4% (120/1156) | -6.9% [-10.4%,-3.4%] | <0.001 |
| Target Vessel Revascularization not involving the Target Lesion | 2.9% (17/577) | 4.8% (28/579) | 3.9% (45/1156) | -1.9% [-4.1%,0.3%] | 0.128 |
| TV/non-TL-CABG | 0.2% (1/577) | 0.3% (2/579) | 0.3% (3/1156) | -0.2% [-0.8%,0.4%] | 1.000 |
| TV/non-TL-PTCA | 2.8% (16/577) | 4.7% (27/579) | 3.7% (43/1156) | -1.9% [-4.1%,0.3%] | 0.119 |
| Target Vessel Revascularization | 9.5% (55/577) | 17.6% (102/579) | 13.6% (157/1156) | -8.1% [-12.0%,-4.2%] | <0.001 |
| Target Vessel Failure | 12.8% (74/577) | 21.4% (124/579) | 17.1% (198/1156) | -8.6% [-12.9%,-4.3%] | <0.001 |
| Perforation | 0.5% (3/577) | 0.3% (2/579) | 0.4% (5/1156) | 0.2% [-0.6%,0.9%] | 0.686 |
| Early Stent Thrombosis | 0.5% (3/577) | 1.2% (7/579) | 0.9% (10/1156) | -0.7% [-1.8%,0.4%] | 0.342 |
| Late Stent Thrombosis | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| Vascular Complications | 0.5% (3/577) | 1.2% (7/579) | 0.9% (10/1156) | -0.7% [-1.8%,0.4%] | 0.342 |
| Cerebrovascular Accident (CVA) | 1.0% (6/577) | 1.2% (7/579) | 1.1% (13/1156) | -0.2% [-1.4%,1.0%] | 1.000 |
| Major Bleeding | 1.2% (7/577) | 2.4% (14/579) | 1.8% (21/1156) | -1.2% [-2.7%,0.3%] | 0.185 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 1050 days post index procedure or an event through 1080 days.

This table is based on evaluable patients – those with information beyond 1050 days post-index procedure or an event through 1080 days.

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## Table 13a. Hierarchical Major Adverse Events to 30 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 2.9% (17/596) | 3.7% (22/594) | 3.3% (39/1190) | -0.9% [-2.9%,1.2%] | 0.421 |
| Death | 0.2% (1/596) | 0.0% (0/594) | 0.1% (1/1190) | 0.2% [-0.2%,0.5%] | 1.000 |
| Non-fatal Q Wave MI | 0.2% (1/596) | 0.8% (5/594) | 0.5% (6/1190) | -0.7% [-1.5%,0.1%] | 0.124 |
| Non-fatal Non-Q Wave MI without Q Wave MI | 2.3% (14/596) | 2.7% (16/594) | 2.5% (30/1190) | -0.3% [-2.1%,1.4%] | 0.716 |
| Emergent CABG without Death or MI | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| TL-CABG without Death or MI | 0.0% (0/596) | 0.0% (0/594) | 0.0% (0/1190) | 0.0% [--,--] | -- |
| TL-PTCA without Death, MI, or TL-CABG | 0.2% (1/596) | 0.2% (1/594) | 0.2% (2/1190) | -0.0% [-0.5%,0.5%] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

This table is based on evaluable patients – those with information beyond 25 days post-index procedure or an event through 30 days.

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## Table 13b. Hierarchical Major Adverse Events to 180 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 4.6% (27/593) | 8.9% (53/593) | 6.7% (80/1186) | -4.4% [-7.2%,-1.5%] | 0.004 |
| Death | 0.5% (3/593) | 0.5% (3/593) | 0.5% (6/1186) | 0.0% [--,--] | 1.000 |
| Non-fatal Q Wave MI | 0.2% (1/593) | 0.8% (5/593) | 0.5% (6/1186) | -0.7% [-1.5%,0.1%] | 0.218 |
| Non-fatal Non-Q Wave MI without Q Wave MI | 2.4% (14/593) | 2.9% (17/593) | 2.6% (31/1186) | -0.5% [-2.3%,1.3%] | 0.716 |
| Emergent CABG without Death or MI | 0.0% (0/593) | 0.0% (0/593) | 0.0% (0/1186) | 0.0% [--,--] | -- |
| TL-CABG without Death or MI | 0.0% (0/593) | 0.2% (1/593) | 0.1% (1/1186) | -0.2% [-0.5%,0.2%] | 1.000 |
| TL-PTCA without Death, MI, or TL-CABG | 1.5% (9/593) | 4.6% (27/593) | 3.0% (36/1186) | -3.0% [-5.0%,-1.1%] | 0.003 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

This table is based on evaluable patients – those with information beyond 166 days post-index procedure or an event through 180 days.

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## Table 13c. Hierarchical Major Adverse Events to 270 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 7.3% (43/592) | 14.4% (85/591) | 10.8% (128/1183) | -7.1% [-10.6%,-3.6%] | <0.001 |
| Death | 1.2% (7/592) | 0.5% (3/591) | 0.8% (10/1183) | 0.7% [-0.4%,1.7%] | 0.342 |
| Non-fatal Q Wave MI | 0.2% (1/592) | 0.8% (5/591) | 0.5% (6/1183) | -0.7% [-1.5%,0.1%] | 0.124 |
| Non-fatal Non-Q Wave MI without Q Wave MI | 2.4% (14/592) | 3.0% (18/591) | 2.7% (32/1183) | -0.7% [-2.5%,1.2%] | 0.481 |
| Emergent CABG without Death or MI | 0.0% (0/592) | 0.0% (0/591) | 0.0% (0/1183) | 0.0% [--,--] | -- |
| TL-CABG without Death or MI | 0.2% (1/592) | 0.3% (2/591) | 0.3% (3/1183) | -0.2% [-0.7%,0.4%] | 0.624 |
| TL-PTCA without Death, MI, or TL-CABG | 3.4% (20/592) | 9.6% (57/591) | 6.5% (77/1183) | -6.3% [-9.1%,-3.5%] | <0.001 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

This table is based on evaluable patients – those with information beyond 256 days post-index procedure or an event through 270 days.

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## Table 13d. Hierarchical Major Adverse Events to 360 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 8.8% (52/590) | 15.6% (92/589) | 12.2% (144/1179) | -6.8% [-10.5%,-3.1%] | <0.001 |
| Death | 1.4% (8/590) | 0.7% (4/589) | 1.0% (12/1179) | 0.7% [-0.5%,1.8%] | 0.385 |
| Non-fatal Q Wave MI | 0.2% (1/590) | 0.8% (5/589) | 0.5% (6/1179) | -0.7% [-1.5%,0.1%] | 0.124 |
| Non-fatal Non-Q Wave MI without Q Wave MI | 2.4% (14/590) | 3.1% (18/589) | 2.7% (32/1179) | -0.7% [-2.5%,1.2%] | 0.481 |
| Emergent CABG without Death or MI | 0.0% (0/590) | 0.0% (0/589) | 0.0% (0/1179) | 0.0% [--,--] | -- |
| TL-CABG without Death or MI | 0.2% (1/590) | 0.5% (3/589) | 0.3% (4/1179) | -0.3% [-1.0%,0.3%] | 0.374 |
| TL-PTCA without Death, MI, or TL-CABG | 4.7% (28/590) | 10.5% (62/589) | 7.6% (90/1179) | -5.8% [-8.8%,-2.8%] | <0.001 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

This table is based on evaluable patients – those with information beyond 330 days post-index procedure or an event through 360 days.

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## Table 13e. Hierarchical Major Adverse Events to 720 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 9.9% (58/587) | 18.1% (106/586) | 14.0% (164/1173) | -8.2% [-12.2%,-4.3%] | <0.001 |
| Death | 2.0% (12/587) | 2.2% (13/586) | 2.1% (25/1173) | -0.2% [-1.8%,1.5%] | 0.843 |
| Non-fatal Q Wave MI | 0.2% (1/587) | 0.9% (5/586) | 0.5% (6/1173) | -0.7% [-1.5%,0.1%] | 0.124 |
| Non-fatal Non-Q Wave MI without Q Wave MI | 2.4% (14/587) | 3.1% (18/586) | 2.7% (32/1173) | -0.7% [-2.6%,1.2%] | 0.481 |
| Emergent CABG without Death or MI | 0.0% (0/587) | 0.0% (0/586) | 0.0% (0/1173) | 0.0% [--,--] | -- |
| TL-CABG without Death or MI | 0.3% (2/587) | 0.9% (5/586) | 0.6% (7/1173) | -0.5% [-1.4%,0.4%] | 0.287 |
| TL-PTCA without Death, MI, or TL-CABG | 4.9% (29/587) | 11.1% (65/586) | 8.0% (94/1173) | -6.2% [-9.2%,-3.1%] | <0.001 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 690 days post index procedure or an event through 720 days.

This table is based on evaluable patients – those with information beyond 690 days post-index procedure or an event through 720 days.

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## Table 13f. Hierarchical Major Adverse Events to 1080 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Any MACE (Death, MI, Emergent CABG, TLR) | 12.0% (69/577) | 20.7% (120/579) | 16.3% (189/1156) | -8.8% [-13.0%,-4.5%] | <0.001 |
| Death | 3.3% (19/577) | 4.5% (26/579) | 3.9% (45/1156) | -1.2% [-3.4%,1.0%] | 0.362 |
| Non-fatal Q Wave MI | 0.2% (1/577) | 0.9% (5/579) | 0.5% (6/1156) | -0.7% [-1.5%,0.1%] | 0.218 |
| Non-fatal Non-Q Wave MI without Q Wave MI | 2.8% (16/577) | 3.1% (18/579) | 2.9% (34/1156) | -0.3% [-2.3%,1.6%] | 0.862 |
| Emergent CABG without Death or MI | 0.0% (0/577) | 0.0% (0/579) | 0.0% (0/1156) | 0.0% [--,--] | -- |
| TL-CABG without Death or MI | 0.3% (2/577) | 0.9% (5/579) | 0.6% (7/1156) | -0.5% [-1.4%,0.4%] | 0.452 |
| TL-PTCA without Death, MI, or TL-CABG | 5.4% (31/577) | 11.4% (66/579) | 8.4% (97/1156) | -6.0% [-9.2%,-2.9%] | <0.001 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with information beyond 1050 days post index procedure or an event through 1080 days.

This table is based on evaluable patients – those with information beyond 1050 days post-index procedure or an event through 1080 days.

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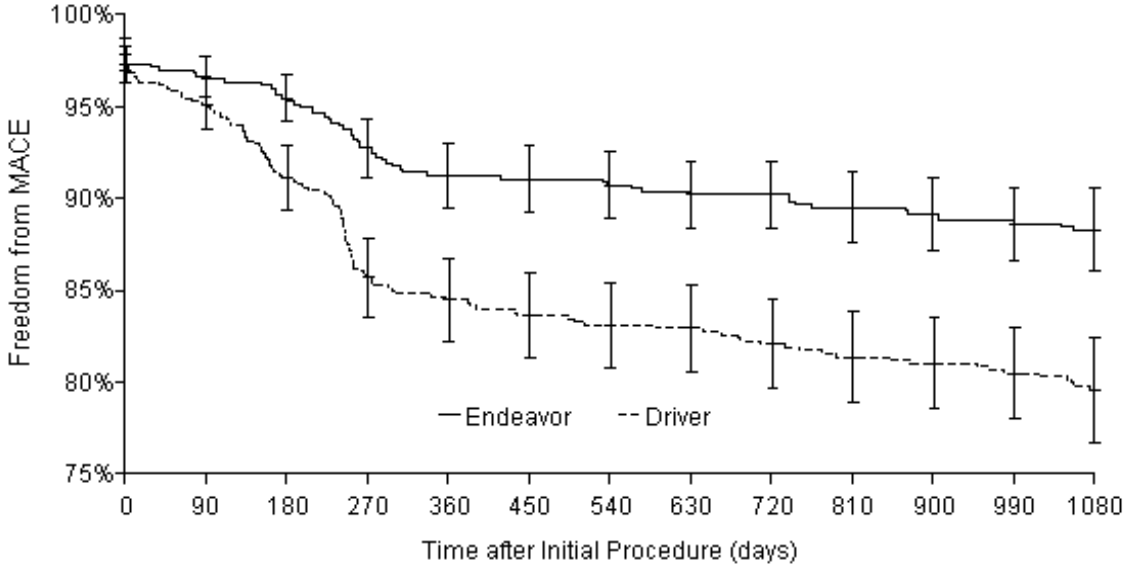
## Figure 3. Survival Free from MACE at 1080 Days (ITT)

| MACE | 0 | 90 | 180 | 270 | 360 | 450 | 540 | 630 | 720 | 810 | 900 | 990 | 1080 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Endeavor** | | | | | | | | | | | | | |
| # Entered | 597 | 584 | 572 | 564 | 547 | 534 | 531 | 528 | 524 | 522 | 513 | 511 | 508 |
| # Censored | 0 | 5 | 1 | 1 | 4 | 2 | 1 | 1 | 2 | 5 | 0 | 0 | 107 |
| # Incomplete | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| # Events | 13 | 7 | 7 | 16 | 9 | 1 | 2 | 3 | 0 | 4 | 2 | 3 | 2 |
| % Survived | 97.8% | 96.6% | 95.5% | 92.8% | 91.2% | 91.1% | 90.7% | 90.2% | 90.2% | 89.5% | 89.1% | 88.6% | 88.3% |
| SE | 0.6% | 0.7% | 0.9% | 1.1% | 1.2% | 1.2% | 1.2% | 1.2% | 1.2% | 1.3% | 1.3% | 1.3% | 1.5% |
| **Driver** | | | | | | | | | | | | | |
| # Entered | 596 | 580 | 565 | 540 | 504 | 491 | 484 | 481 | 480 | 472 | 466 | 464 | 461 |
| # Censored | 0 | 2 | 1 | 4 | 6 | 2 | 0 | 0 | 3 | 2 | 0 | 0 | 106 |
| # Incomplete | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| # Events | 16 | 13 | 24 | 32 | 7 | 5 | 3 | 1 | 5 | 4 | 2 | 3 | 5 |
| % Survived | 97.3% | 95.1% | 91.1% | 85.7% | 84.5% | 83.6% | 83.1% | 82.9% | 82.1% | 81.4% | 81.0% | 80.5% | 79.6% |
| SE | 0.7% | 0.9% | 1.2% | 1.4% | 1.5% | 1.5% | 1.6% | 1.6% | 1.6% | 1.6% | 1.6% | 1.7% | 1.9% |
| **Tests Between Groups** | | | | | | | | | | | | | |
| | Test | Chi-Square | Deg Frdm | P-value | | | | | | | | | |
| | Wilcoxon | 16.49 | 1 | <0.001 | | | | | | | | | |
| | Log-Rank | 16.48 | 1 | <0.001 | | | | | | | | | |

**Figure 3. Survival Free from MACE at 1080 Days (ITT) (Continued)**




ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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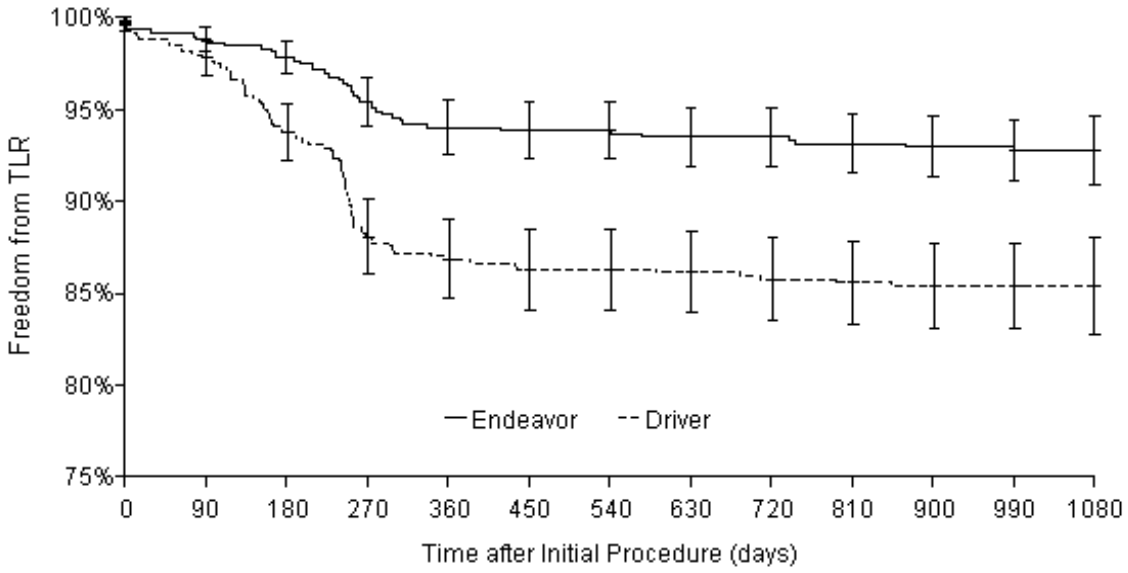
## Figure 4. Survival Free from Target Lesion Revascularization Event at 1080 Days (ITT)

| TLR | 0 | 90 | 180 | 270 | 360 | 450 | 540 | 630 | 720 | 810 | 900 | 990 | 1080 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Endeavor** | | | | | | | | | | | | | |
| # Entered | 597 | 595 | 584 | 575 | 552 | 538 | 535 | 533 | 528 | 526 | 517 | 515 | 513 |
| # Censored | 0 | 5 | 2 | 6 | 5 | 2 | 1 | 1 | 2 | 5 | 0 | 0 | 110 |
| # Incomplete | 0 | 1 | 1 | 3 | 1 | 0 | 1 | 2 | 0 | 2 | 1 | 1 | 1 |
| # Events | 2 | 5 | 6 | 14 | 8 | 1 | 0 | 2 | 0 | 2 | 1 | 1 | 0 |
| % Survived | 99.7% | 98.8% | 97.8% | 95.4% | 94.0% | 93.9% | 93.9% | 93.5% | 93.5% | 93.1% | 93.0% | 92.8% | 92.8% |
| SE | 0.2% | 0.4% | 0.6% | 0.9% | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 1.1% | 1.1% | 1.1% | 1.2% |
| **Driver** | | | | | | | | | | | | | |
| # Entered | 596 | 595 | 579 | 552 | 503 | 487 | 481 | 478 | 477 | 469 | 463 | 460 | 457 |
| # Censored | 0 | 3 | 1 | 16 | 8 | 2 | 0 | 0 | 3 | 2 | 0 | 0 | 108 |
| # Incomplete | 0 | 1 | 2 | 0 | 1 | 1 | 3 | 0 | 3 | 3 | 2 | 3 | 5 |
| # Events | 1 | 12 | 24 | 33 | 7 | 3 | 0 | 1 | 2 | 1 | 1 | 0 | 0 |
| % Survived | 99.8% | 97.8% | 93.7% | 88.1% | 86.8% | 86.3% | 86.3% | 86.1% | 85.7% | 85.6% | 85.4% | 85.4% | 85.4% |
| SE | 0.2% | 0.6% | 1.0% | 1.4% | 1.4% | 1.5% | 1.5% | 1.5% | 1.5% | 1.5% | 1.5% | 1.5% | 1.8% |
| **Tests Between Groups** | | | | | | | | | | | | | |
| | Test | Chi-Square | Deg Frdm | P-value | | | | | | | | | |
| | Wilcoxon | 17.36 | 1 | <0.001 | | | | | | | | | |
| | Log-Rank | 17.02 | 1 | <0.001 | | | | | | | | | |

**Figure 4. Survival Free from Target Lesion Revascularization Event at 1080 Days (ITT) (Continued)**




ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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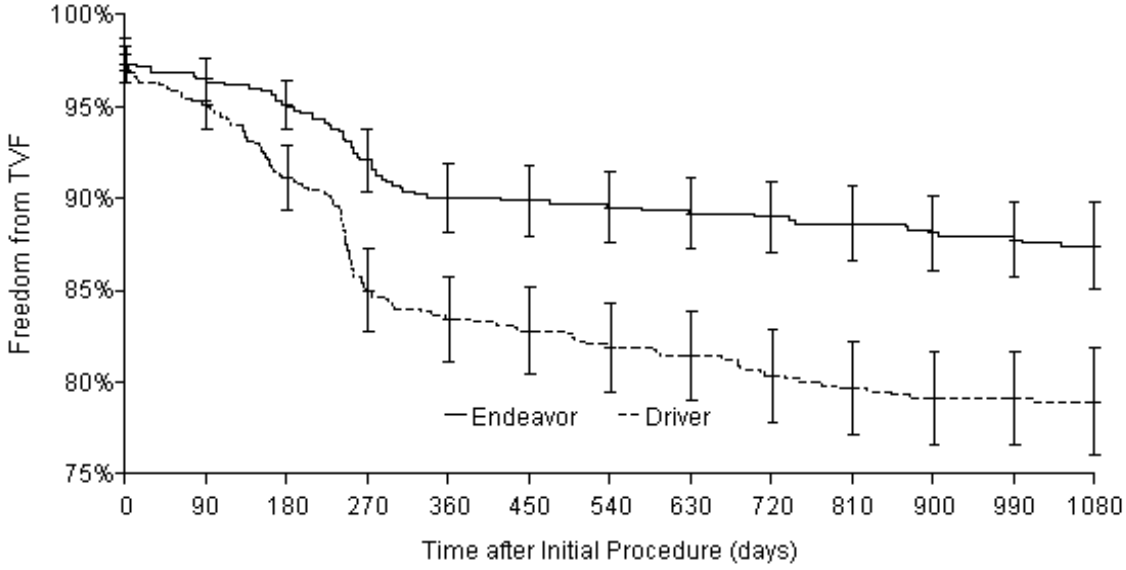
## Figure 5. Survival Free from Target Vessel Failure Event at 1080 Days (ITT)

| TVF | 0 | 90 | 180 | 270 | 360 | 450 | 540 | 630 | 720 | 810 | 900 | 990 | 1080 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Endeavor** | | | | | | | | | | | | | |
| # Entered | 597 | 584 | 570 | 561 | 541 | 525 | 522 | 519 | 515 | 512 | 503 | 500 | 497 |
| # Censored | 0 | 6 | 1 | 2 | 4 | 2 | 1 | 2 | 2 | 7 | 0 | 1 | 108 |
| # Incomplete | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| # Events | 13 | 8 | 8 | 18 | 12 | 1 | 2 | 2 | 1 | 2 | 3 | 2 | 2 |
| % Survived | 97.8% | 96.5% | 95.1% | 92.1% | 90.0% | 89.9% | 89.5% | 89.2% | 89.0% | 88.6% | 88.1% | 87.8% | 87.4% |
| SE | 0.6% | 0.8% | 0.9% | 1.1% | 1.2% | 1.3% | 1.3% | 1.3% | 1.3% | 1.3% | 1.4% | 1.4% | 1.6% |
| **Driver** | | | | | | | | | | | | | |
| # Entered | 596 | 580 | 565 | 540 | 500 | 485 | 478 | 473 | 470 | 460 | 453 | 450 | 448 |
| # Censored | 0 | 2 | 1 | 4 | 6 | 3 | 0 | 0 | 4 | 3 | 0 | 2 | 109 |
| # Incomplete | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| # Events | 16 | 13 | 24 | 36 | 9 | 4 | 5 | 3 | 6 | 4 | 3 | 0 | 1 |
| % Survived | 97.3% | 95.1% | 91.1% | 85.0% | 83.5% | 82.8% | 81.9% | 81.4% | 80.3% | 79.6% | 79.1% | 79.1% | 78.9% |
| SE | 0.7% | 0.9% | 1.2% | 1.5% | 1.5% | 1.6% | 1.6% | 1.6% | 1.7% | 1.7% | 1.7% | 1.7% | 2.0% |
| **Tests Between Groups** | | | | | | | | | | | | | |
| | Test | Chi-Square | Deg Frdm | P-value | | | | | | | | | |
| | Wilcoxon | 15.19 | 1 | <0.001 | | | | | | | | | |
| | Log-Rank | 15.19 | 1 | <0.001 | | | | | | | | | |

**Figure 5. Survival Free from Target Vessel Failure Event at 1080 Days (ITT) (Continued)**




ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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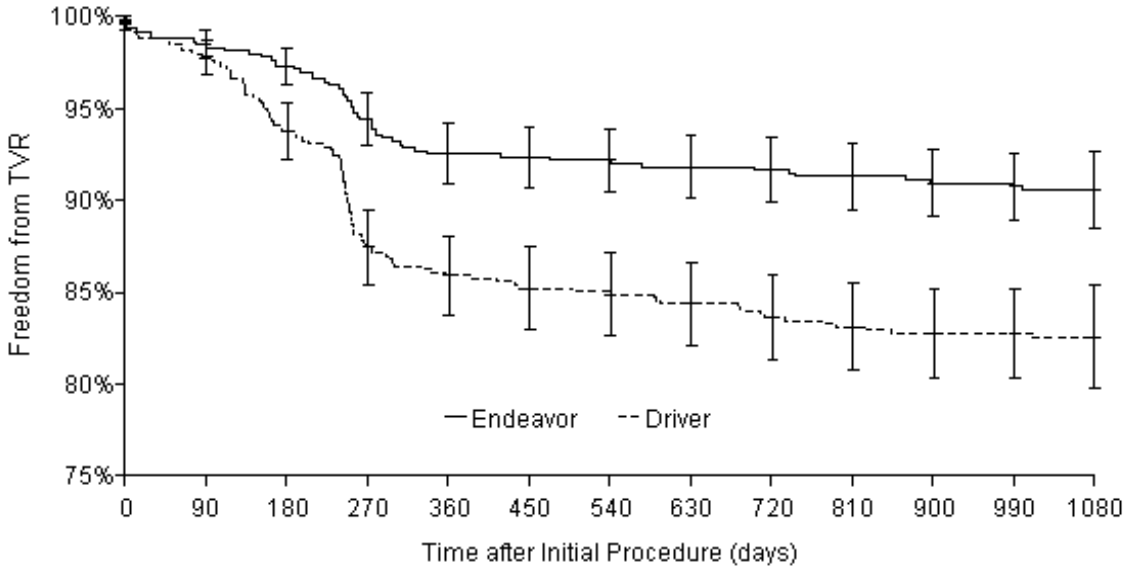
## Figure 6. Survival Free from Target Vessel Revascularization Event at 1080 Days (ITT)

| TVR | 0 | 90 | 180 | 270 | 360 | 450 | 540 | 630 | 720 | 810 | 900 | 990 | 1080 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Endeavor** | | | | | | | | | | | | | |
| # Entered | 597 | 595 | 582 | 573 | 552 | 536 | 533 | 531 | 526 | 523 | 514 | 511 | 509 |
| # Censored | 0 | 5 | 1 | 1 | 4 | 2 | 1 | 1 | 2 | 5 | 0 | 0 | 112 |
| # Incomplete | 0 | 1 | 1 | 3 | 1 | 0 | 0 | 2 | 0 | 2 | 1 | 1 | 1 |
| # Events | 2 | 7 | 7 | 17 | 11 | 1 | 1 | 2 | 1 | 2 | 2 | 1 | 1 |
| % Survived | 99.7% | 98.5% | 97.3% | 94.4% | 92.5% | 92.3% | 92.2% | 91.8% | 91.7% | 91.3% | 90.9% | 90.8% | 90.6% |
| SE | 0.2% | 0.5% | 0.7% | 1.0% | 1.1% | 1.1% | 1.1% | 1.1% | 1.2% | 1.2% | 1.2% | 1.2% | 1.4% |
| **Driver** | | | | | | | | | | | | | |
| # Entered | 596 | 595 | 580 | 553 | 512 | 497 | 490 | 485 | 482 | 472 | 464 | 460 | 458 |
| # Censored | 0 | 2 | 1 | 4 | 6 | 2 | 0 | 0 | 3 | 2 | 0 | 0 | 108 |
| # Incomplete | 0 | 1 | 2 | 0 | 0 | 1 | 3 | 0 | 3 | 3 | 2 | 2 | 5 |
| # Events | 1 | 12 | 24 | 37 | 9 | 4 | 2 | 3 | 4 | 3 | 2 | 0 | 1 |
| % Survived | 99.8% | 97.8% | 93.8% | 87.5% | 85.9% | 85.2% | 84.9% | 84.3% | 83.6% | 83.1% | 82.7% | 82.7% | 82.6% |
| SE | 0.2% | 0.6% | 1.0% | 1.4% | 1.4% | 1.5% | 1.5% | 1.5% | 1.6% | 1.6% | 1.6% | 1.6% | 1.9% |
| **Tests Between Groups** | | | | | | | | | | | | | |
| | Test | Chi-Square | Deg Frdm | P-value | | | | | | | | | |
| | Wilcoxon | 16.75 | 1 | <0.001 | | | | | | | | | |
| | Log-Rank | 16.54 | 1 | <0.001 | | | | | | | | | |

**Figure 6. Survival Free from Target Vessel Revascularization Event at 1080 Days (ITT) (Continued)**




ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.

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## Table 14. Total Stent Length Implanted per Patient (ITT)

| | | | Endeavor (N=598 patients) | | Driver (N=599 patients) | |
|---|---|---|---|---|---|---|
| Number of Stents Implanted | Total Stent Length Implanted (mm) | Length of Stents | Number of Patients | Number of Stents Implanted | Number of Patients | Number of Stents Implanted |
| 0 | | | 7 | 0 | 10 | 0 |
| 1 | 9 | 1 9mm | 3 | 3 | 0 | 0 |
| | 18 | 1 18mm | 264 | 264 | 284 | 284 |
| | 24 | 1 24mm | 180 | 180 | 162 | 162 |
| | 30 | 1 30mm | 78 | 78 | 83 | 83 |
| 2 | 26 | 1 8mm, 1 18mm | 7 | 14 | 0 | 0 |
| | 27 | 1 9mm, 1 18mm | 13 | 26 | 16 | 32 |
| | 32 | 1 8mm, 1 24mm | 4 | 8 | 0 | 0 |
| | 33 | 1 9mm, 1 24mm | 4 | 8 | 16 | 32 |
| | 36 | 2 18mm | 3 | 6 | 3 | 6 |
| | 38 | 1 8mm, 1 30mm | 4 | 8 | 1 | 2 |
| | 39 | 1 9mm, 1 30mm | 11 | 22 | 5 | 10 |
| | 42 | 1 18mm, 1 24mm | 7 | 14 | 2 | 4 |
| | 48 | 1 18mm, 1 30mm | 4 | 8 | 8 | 16 |
| | 48 | 2 24mm | 1 | 2 | 1 | 2 |
| 3 | 35 | 1 8mm, 1 9mm, 1 18mm | 0 | 0 | 1 | 3 |
| | 36 | 2 9mm, 1 18mm | 1 | 3 | 0 | 0 |
| | 40 | 2 8mm, 1 24mm | 1 | 3 | 0 | 0 |
| | 42 | 2 9mm, 1 24mm | 1 | 3 | 1 | 3 |
| | 45 | 1 9mm, 2 18mm | 1 | 3 | 1 | 3 |
| | 47 | 1 8mm, 1 9mm, 1 30mm | 0 | 0 | 1 | 3 |
| | 48 | 1 9mm, 1 15mm, 1 24mm | 1 | 3 | 0 | 0 |
| | 50 | 1 8mm, 1 18mm, 1 24mm | 1 | 3 | 0 | 0 |
| | 51 | 1 9mm, 1 18mm, 1 24mm | 0 | 0 | 1 | 3 |
| | 60 | 2 18mm, 1 24mm | 1 | 3 | 0 | 0 |
| | 66 | 1 18mm, 2 24mm | 0 | 0 | 1 | 3 |
| 4 | 43 | 2 8mm, 1 9mm, 1 18mm | 1 | 4 | 0 | 0 |
| | 54 | 2 9mm, 2 18mm | 0 | 0 | 1 | 4 |
| 6 | 123 | 1 9mm, 2 18mm, 2 24mm, 1 30mm | 0 | 0 | 1 | 6 |
| | | | | | | |
| | | **Total** | **598** | **666** | **599** | **661** |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 15. Quantitative Intravascular Ultrasound Analysis Post-Stent Implantation (ITT)

| Post-Stent | Endeavor (N=169 patients) | Driver (N=159 patients) | All Patients (N=328 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| EEM Area ($mm^2$) | | | | | |
| Mean±SD (n) | 15.64±4.46 (93) | 14.67±4.81 (98) | 15.14±4.66 (191) | 0.97 [-0.35,2.30] | 0.150 |
| Range (min,max) | (5.82,27.45) | (4.86,27.56) | (4.86,27.56) | | |
| EEM Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 369.10±118.36 (50) | 355.48±124.10 (60) | 361.67±121.16 (110) | 13.62 [-32.51,59.74] | 0.560 |
| Range (min,max) | (148.54,650.84) | (180.34,702.35) | (148.54,702.35) | | |
| Mean Stent Area ($mm^2$) | | | | | |
| Mean±SD (n) | 7.41±2.28 (141) | 7.10±2.20 (135) | 7.26±2.24 (276) | 0.31 [-0.22,0.84] | 0.256 |
| Range (min,max) | (3.25,14.84) | (3.02,14.23) | (3.02,14.84) | | |
| Stent Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 187.70±64.35 (82) | 185.08±67.21 (82) | 186.39±65.60 (164) | 2.61 [-17.68,22.91] | 0.799 |
| Range (min,max) | (66.44,393.30) | (79.91,428.09) | (66.44,428.09) | | |
| Mean Lumen Area ($mm^2$) | | | | | |
| Mean±SD (n) | 7.41±2.28 (141) | 7.10±2.20 (135) | 7.26±2.24 (276) | 0.31 [-0.22,0.84] | 0.256 |
| Range (min,max) | (3.25,14.84) | (3.02,14.23) | (3.02,14.84) | | |
| Minimal Lumen Area ($mm^2$) | | | | | |
| Mean±SD (n) | 6.57±1.92 (141) | 6.37±1.87 (135) | 6.47±1.90 (276) | 0.20 [-0.25,0.65] | 0.382 |
| Range (min,max) | (2.75,13.15) | (3.02,12.47) | (2.75,13.15) | | |
| Lumen Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 187.02±64.26 (82) | 184.85±67.15 (82) | 185.94±65.53 (164) | 2.17 [-18.10,22.44] | 0.833 |
| Range (min,max) | (66.44,393.30) | (79.91,428.09) | (66.44,428.09) | | |
| Plaque Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 191.07±74.34 (50) | 175.40±72.11 (60) | 182.53±73.21 (110) | 15.67 [-12.08,43.43] | 0.266 |
| Range (min,max) | (53.61,404.34) | (61.31,440.08) | (53.61,440.08) | | |
| Neointimal Hyperplastic Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 0.68±3.34 (82) | 0.33±1.08 (82) | 0.50±2.48 (164) | 0.35 [-0.42,1.12] | 0.369 |
| Range (min,max) | (0.00,29.04) | (0.00,8.15) | (0.00,29.04) | | |
| Volume Obstruction (%) | N/A | N/A | N/A | N/A | N/A |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of IVUS patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Table 16. Quantitative Intravascular Ultrasound Analysis at 8 Months (ITT)

| 8-Month Follow-up | Endeavor (N=169 patients) | Driver (N=159 patients) | All Patients (N=328 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| EEM Area ($mm^2$) | | | | | |
| Mean±SD (n) | 15.60±4.09 (90) | 15.65±4.20 (81) | 15.63±4.13 (171) | -0.05 [-1.30,1.20] | 0.938 |
| Range (min,max) | (6.76,23.39) | (6.27,27.14) | (6.27,27.14) | | |
| EEM Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 342.41±96.48 (62) | 347.57±124.98 (58) | 344.91±110.72 (120) | -5.16 [-45.37,35.06] | 0.802 |
| Range (min,max) | (151.91,612.18) | (111.35,943.11) | (111.35,943.11) | | |
| Mean Stent Area ($mm^2$) | | | | | |
| Mean±SD (n) | 7.60±2.10 (90) | 7.65±2.15 (81) | 7.62±2.12 (171) | -0.06 [-0.70,0.59] | 0.864 |
| Range (min,max) | (3.56,12.33) | (3.59,14.96) | (3.56,14.96) | | |
| Stent Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 170.62±57.90 (90) | 177.75±61.66 (81) | 174.00±59.64 (171) | -7.13 [-25.18,10.92] | 0.436 |
| Range (min,max) | (65.87,378.10) | (63.85,362.15) | (63.85,378.10) | | |
| Mean Lumen Area ($mm^2$) | | | | | |
| Mean±SD (n) | 5.98±1.88 (122) | 5.13±1.93 (107) | 5.58±1.95 (229) | 0.86 [0.36,1.35] | <0.001 |
| Range (min,max) | (2.44,10.62) | (1.39,12.19) | (1.39,12.19) | | |
| Minimal Lumen Area ($mm^2$) | | | | | |
| Mean±SD (n) | 4.99±1.66 (122) | 3.98±1.72 (107) | 4.52±1.76 (229) | 1.01 [0.57,1.45] | <0.001 |
| Range (min,max) | (1.51,8.93) | (1.39,9.52) | (1.39,9.52) | | |
| Lumen Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 140.47±50.21 (90) | 124.25±53.88 (81) | 132.79±52.46 (171) | 16.23 [0.51,31.94] | 0.043 |
| Range (min,max) | (55.50,326.49) | (32.24,335.59) | (32.24,335.59) | | |
| Mean NIH Area ($mm^2$) | | | | | |
| Mean±SD (n) | 1.33±0.85 (90) | 2.31±1.70 (81) | 1.79±1.41 (171) | -0.98 [-1.38,-0.58] | <0.001 |
| Range (min,max) | (0.02,3.31) | (0.08,9.94) | (0.02,9.94) | | |
| Plaque Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 208.84±72.17 (62) | 230.01±91.78 (58) | 219.07±82.57 (120) | -21.17 [-50.91,8.58] | 0.161 |
| Range (min,max) | (73.49,420.87) | (64.38,607.53) | (64.38,607.53) | | |
| Neointimal Hyperplastic Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 30.15±21.66 (90) | 53.51±39.80 (81) | 41.21±33.58 (171) | -23.36 [-32.91,-13.81] | <0.001 |
| Range (min,max) | (0.72,107.55) | (1.89,186.86) | (0.72,186.86) | | |
| Volume Obstruction (%) | | | | | |
| Mean±SD (n) | 17.34±10.27 (90) | 29.55±17.58 (81) | 23.12±15.43 (171) | -12.22 [-16.51,-7.92] | <0.001 |
| Range (min,max) | (0.22,54.66) | (1.90,77.78) | (0.22,77.78) | | |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of IVUS patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Table 17. Quantitative Intravascular Ultrasound Analysis Difference Between Post-Stent Implantation and 8-Month Follow-up (ITT)

| Difference (8-Month Follow-up - Final Post-Stent) | Endeavor (N=169 patients) | Driver (N=159 patients) | All Patients (N=328 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| EEM Area ($mm^2$) | | | | | |
| Mean±SD (n) | 0.17±1.72 (69) | 0.76±2.11 (67) | 0.46±1.94 (136) | -0.59 [-1.24,0.07] | 0.077 |
| Range (min,max) | (-3.31,6.64) | (-3.73,7.09) | (-3.73,7.09) | | |
| EEM Volume ($mm^3$) | | | | | |
| Mean±SD (n) | -12.90±35.11 (39) | 0.24±36.11 (42) | -6.08±36.02 (81) | -13.14 [-28.91,2.63] | 0.101 |
| Range (min,max) | (-113.28,47.20) | (-114.42,58.10) | (-114.42,58.10) | | |
| Mean Stent Area ($mm^2$) | | | | | |
| Mean±SD (n) | -0.11±1.09 (80) | 0.03±0.71 (72) | -0.04±0.93 (152) | -0.14 [-0.44,0.16] | 0.343 |
| Range (min,max) | (-5.77,2.95) | (-1.91,2.91) | (-5.77,2.95) | | |
| Stent Volume ($mm^3$) | | | | | |
| Mean±SD (n) | -10.71±22.35 (65) | -5.08±18.69 (64) | -7.91±20.73 (129) | -5.63 [-12.82,1.55] | 0.123 |
| Range (min,max) | (-90.99,66.43) | (-51.88,38.96) | (-90.99,66.43) | | |
| Mean Lumen Area ($mm^2$) | | | | | |
| Mean±SD (n) | -1.47±1.37 (109) | -2.16±1.91 (98) | -1.80±1.68 (207) | 0.68 [0.23,1.14] | 0.004 |
| Range (min,max) | (-6.85,1.95) | (-11.22,4.25) | (-11.22,4.25) | | |
| Minimal Lumen Area ($mm^2$) | | | | | |
| Mean±SD (n) | -1.52±1.29 (109) | -2.47±1.83 (98) | -1.97±1.63 (207) | 0.95 [0.52,1.38] | <0.001 |
| Range (min,max) | (-6.83,1.97) | (-10.25,4.25) | (-10.25,4.25) | | |
| Lumen Volume ($mm^3$) | | | | | |
| Mean±SD (n) | -42.63±32.18 (65) | -61.04±47.73 (64) | -51.76±41.53 (129) | 18.41 [4.25,32.57] | 0.012 |
| Range (min,max) | (-128.36,41.92) | (-233.43,-1.08) | (-233.43,41.92) | | |
| Plaque Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 27.32±30.94 (39) | 62.22±49.09 (42) | 45.42±44.69 (81) | -34.89 [-53.20,-16.59] | <0.001 |
| Range (min,max) | (-35.95,88.72) | (-12.63,183.82) | (-35.95,183.82) | | |
| Neointimal Hyperplastic Volume ($mm^3$) | | | | | |
| Mean±SD (n) | 31.92±22.83 (65) | 55.84±41.78 (64) | 43.79±35.55 (129) | -23.92 [-35.63,-12.22] | <0.001 |
| Range (min,max) | (0.72,107.55) | (2.47,186.86) | (0.72,186.86) | | |
| Volume Obstruction (%) | N/A | N/A | N/A | N/A | N/A |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of IVUS patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Table 18. Qualitative Intravascular Ultrasound Analysis - Incomplete Stent Apposition (ITT)

| Measures | Endeavor (N=169 patients) | Driver (N=159 patients) | All Patients (N=328 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Incomplete Stent Apposition at Post Procedure | 24.8% (36/145) | 19.6% (28/143) | 22.2% (64/288) | 5.2% [-4.3%,14.8%] | 0.322 |
| Incomplete Stent Apposition at 8 Month Follow-up | 16.8% (21/125) | 14.5% (16/110) | 15.7% (37/235) | 2.3% [-7.0%,11.5%] | 0.721 |
| Resolved | 7.0% (8/114) | 6.7% (7/104) | 6.9% (15/218) | 0.3% [-6.4%,7.0%] | 1.000 |
| Persistent | 17.5% (20/114) | 14.4% (15/104) | 16.1% (35/218) | 3.1% [-6.6%,12.8%] | 0.583 |
| Late Acquired | 0.0% (0/114) | 0.0% (0/104) | 0.0% (0/218) | 0.0% [--,--] | -- |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with available data for related parameter.

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## Table 19a. Major Protocol Deviation by Site (ITT)

| Site | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| 302 | 1 | 0 | 1 |
| 310 | 1 | 0 | 1 |
| 314 | 3 | 1 | 4 |
| 315 | 1 | 1 | 2 |
| 402 | 1 | 0 | 1 |
| 404 | 0 | 1 | 1 |
| 408 | 1 | 0 | 1 |
| 409 | 4 | 1 | 5 |
| 411 | 0 | 1 | 1 |
| 412 | 2 | 0 | 2 |
| 414 | 0 | 1 | 1 |
| 422 | 2 | 0 | 2 |
| 423 | 0 | 1 | 1 |
| 424 | 3 | 0 | 3 |
| 425 | 1 | 2 | 3 |
| 426 | 1 | 0 | 1 |
| 428 | 1 | 0 | 1 |
| 437 | 0 | 1 | 1 |
| 438 | 1 | 2 | 3 |
| 441 | 0 | 1 | 1 |
| 444 | 0 | 1 | 1 |
| 501 | 2 | 2 | 4 |
| 502 | 1 | 1 | 2 |
| 503 | 0 | 1 | 1 |
| 508 | 0 | 1 | 1 |
| 510 | 1 | 0 | 1 |
| 513 | 1 | 2 | 3 |
| 514 | 4 | 5 | 9 |
| 516 | 0 | 1 | 1 |
| 517 | 3 | 5 | 8 |
| 518 | 2 | 1 | 3 |
| 533 | 2 | 2 | 4 |
| 537 | 1 | 0 | 1 |
| 538 | 1 | 1 | 2 |
| 539 | 0 | 1 | 1 |
| 540 | 1 | 1 | 2 |
| Total | 42 | 38 | 80 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 19b. Major Protocol Deviation by Type (ITT)

| Major Protocol Deviation | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| The subject has single vessel disease or has multivessel disease with only moderate stenosis (mac 50-60% or total occlusion (100%) for which no interventions are planned at the time of study inclusion. | 9 | 8 | 17 |
| The target lesion / vessel must meet the following criteria:<br>a) The target lesion is a single de novo lesion that has not been previously treated with any interventional procedure. Only one lesion may be treated per subject.<br>b) The target vessel must be a native coronary artery with a stenosis of >=50% and <100%.<br>c) The target lesion must be >=14 mm and <=27 mm in length.<br>d) The target vessel reference diameter must be >=2.25 mm and <=3.5 mm. (Measurements may be made by careful visual estimate, on-line quantitative coronary angiography, or intravascular ultrasound.) | 5 | 2 | 7 |
| Female subjects of childbearing potential must have a negative pregnancy test within seven (7) days before the procedure. | 0 | 1 | 1 |
| A documented left ventricular ejection fraction < 30%. | 0 | 3 | 3 |
| A known hypersensitivity or contraindication to aspirin, heparin, clopidogrel, cobalt, nickel, chromium or a sensitivity to contrast media, which cannot be adequately pre-medicated. | 3 | 3 | 6 |
| A platelet count <100,000 cells/mm³ or >700,000 cells/mm³, or a WBC <3,000 cells/mm³. | 1 | 2 | 3 |
| Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes > 2X the upper laboratory normal with the presence of a CK-MB elevated above the Institution's upperlimit of normal). | 4 | 4 | 8 |
| Creatinine >2.0 mg/dl | 0 | 1 | 1 |
| A previous coronary interventional procedure within the 30 days prior to the procedure except as specified. | 2 | 1 | 3 |
| The subject requires planned interventional treatment of either the target or any non-target vessel within 30 days post-procedure. | 1 | 1 | 2 |
| The target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc.). | 0 | 1 | 1 |
| Previous stenting anywhere in the target vessel. | 3 | 3 | 6 |
| The target vessel has evidence of thrombus or is excessively tortuous (2 bends > 90 to reach the target lesion). | 2 | 0 | 2 |
| Significant (>50%) stenosis proximal or distal to the target lesion that might require revascularization or impede run off. | 1 | 1 | 2 |
| Target lesion located in native vessel distally to anastomosis with vein graft or LIMA. | 0 | 1 | 1 |
| History of a stroke or transient ischemic attack within the prior 6 months. | 2 | 0 | 2 |
| The subject has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions. | 2 | 1 | 3 |
| Any previous or planned treatment with anti-restenotic therapies including, but no limited to, drug-eluting stents and brachytherapy. | 2 | 1 | 3 |
| Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints. [Note: Trials requiring extended follow-up for productsthat were investigational, but have since become commercially available, are not considered investigational trials.] | 1 | 0 | 1 |
| Consent signed after pre-procedure sedation given | 3 | 1 | 4 |
| Consent signed by relative who is not legal guardian | 1 | 2 | 3 |
| Consent documented in chart, but not found | 0 | 1 | 1 |
| Total | 42 | 38 | 80 |

*(Footnotes on next page)*

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 20a. Minor Protocol Deviation by Site (ITT)

| Site | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| 301 | 12 | 13 | 25 |
| 302 | 18 | 21 | 39 |
| 307 | 16 | 23 | 39 |
| 308 | 15 | 16 | 31 |
| 309 | 7 | 20 | 27 |
| 310 | 9 | 4 | 13 |
| 313 | 15 | 28 | 43 |
| 314 | 84 | 50 | 134 |
| 315 | 46 | 33 | 79 |
| 317 | 5 | 7 | 12 |
| 401 | 31 | 27 | 58 |
| 402 | 3 | 0 | 3 |
| 403 | 1 | 3 | 4 |
| 404 | 66 | 77 | 143 |
| 405 | 13 | 16 | 29 |
| 406 | 17 | 14 | 31 |
| 407 | 6 | 0 | 6 |
| 408 | 29 | 37 | 66 |
| 409 | 39 | 25 | 64 |
| 410 | 11 | 23 | 34 |
| 411 | 39 | 28 | 67 |
| 412 | 43 | 62 | 105 |
| 413 | 32 | 32 | 64 |
| 414 | 23 | 24 | 47 |
| 417 | 16 | 6 | 22 |
| 418 | 27 | 27 | 54 |
| 419 | 17 | 5 | 22 |
| 420 | 10 | 11 | 21 |
| 422 | 52 | 33 | 85 |
| 423 | 33 | 20 | 53 |
| 424 | 167 | 145 | 312 |
| 425 | 93 | 90 | 183 |
| 426 | 18 | 16 | 34 |
| 428 | 7 | 10 | 17 |
| 437 | 22 | 20 | 42 |
| 438 | 17 | 20 | 37 |
| 439 | 4 | 6 | 10 |
| 440 | 11 | 10 | 21 |
| 441 | 9 | 5 | 14 |
| 442 | 4 | 4 | 8 |
| 444 | 20 | 14 | 34 |
| 501 | 46 | 70 | 116 |
| 502 | 22 | 28 | 50 |
| 503 | 65 | 68 | 133 |
| 504 | 191 | 170 | 361 |
| 505 | 17 | 28 | 45 |
| 506 | 80 | 77 | 157 |
| 507 | 86 | 103 | 189 |
| 508 | 163 | 186 | 349 |
| 509 | 42 | 43 | 85 |
| 510 | 19 | 21 | 40 |

## Table 20a. Minor Protocol Deviation by Site (ITT) (Continued)

| Site | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| 511 | 47 | 48 | 95 |
| 512 | 74 | 101 | 175 |
| 513 | 224 | 210 | 434 |
| 514 | 149 | 130 | 279 |
| 515 | 19 | 32 | 51 |
| 516 | 10 | 16 | 26 |
| 517 | 129 | 129 | 258 |
| 518 | 76 | 93 | 169 |
| 519 | 68 | 37 | 105 |
| 520 | 58 | 60 | 118 |
| 531 | 35 | 47 | 82 |
| 532 | 25 | 24 | 49 |
| 533 | 104 | 103 | 207 |
| 534 | 55 | 56 | 111 |
| 537 | 122 | 142 | 264 |
| 538 | 23 | 40 | 63 |
| 539 | 55 | 64 | 119 |
| 540 | 90 | 92 | 182 |
| 541 | 7 | 13 | 20 |
| 542 | 8 | 5 | 13 |
| 543 | 7 | 6 | 13 |
| Total | 3223 | 3267 | 6490 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 20b. Minor Protocol Deviation by Type (ITT)

| Minor Protocol Deviation | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| Incorrect ASA dose given | 9 | 4 | 13 |
| Incorrect Ticlid/Plavix dose given | 5 | 4 | 9 |
| Water soluble ASA not given | 2 | 0 | 2 |
| Patient discharged on incorrect ASA dose | 1 | 1 | 2 |
| Patient discharged on incorrect Ticlid/Plavix dose | 0 | 1 | 1 |
| Ticlid/Plavix not given | 28 | 32 | 60 |
| ASA not given | 64 | 64 | 128 |
| NTG not given pre-stent | 0 | 1 | 1 |
| NTG not given post-stent | 6 | 3 | 9 |
| Patient did not take required ASA | 40 | 55 | 95 |
| Patient did not take required Ticlid/Plavix | 23 | 23 | 46 |
| Incorrect medication given | 14 | 8 | 22 |
| WBC with diff. not drawn | 267 | 291 | 558 |
| CK/MB not drawn | 159 | 153 | 312 |
| Pre-procedure CK not drawn | 22 | 25 | 47 |
| Post-procedure CK not drawn | 138 | 142 | 280 |
| CK isoenzymes not analyzed (if indicated) | 9 | 19 | 28 |
| Diff. not analyzed (if indicated) | 48 | 45 | 93 |
| Pre-procedure ECG not done | 17 | 25 | 42 |
| Pre-procedure ECG done outside protocol specifications | 16 | 15 | 31 |
| Post procedure/discharge ECG not done | 34 | 25 | 59 |
| Lab value not obtained | 959 | 950 | 1909 |
| Stent deployed above nominal pressure | 1 | 0 | 1 |
| Follow-up phone call/visit not made | 78 | 87 | 165 |
| Follow-up phone call/visit outside protocol time frame | 489 | 454 | 943 |
| Follow-up labs not done | 263 | 261 | 524 |
| Follow-up labs drawn outside protocol time frame | 96 | 96 | 192 |
| Follow-up angiogram not done for pt in angio subset | 19 | 30 | 49 |
| Other | 416 | 453 | 869 |
| Total | 3223 | 3267 | 6490 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.
The protocol deviation type of other were specified in Listing 2.

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## Table 21a. Adverse Events (to 1080 Days) (ITT)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| *TOTAL* | *481(80.4%)* | *489(81.6%)* | *970(81.0%)* |
| *BLOOD AND LYMPHATIC SYSTEM DISORDERS* | *7(1.2%)* | *14(2.3%)* | *21(1.8%)* |
| AGRANULOCYTOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANAEMIA NOS | 3(0.5%) | 8(1.3%) | 11(0.9%) |
| HAEMOLYTIC ANAEMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LEUKOCYTOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LEUKOPENIA NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| LYMPHADENOPATHY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MACROCYTIC ANAEMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MICROCYTIC ANAEMIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NORMOCHROMIC NORMOCYTIC ANAEMIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| THROMBOCYTOPENIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *CARDIAC DISORDERS* | *254(42.5%)* | *253(42.2%)* | *507(42.4%)* |
| ACUTE CORONARY SYNDROME | 1(0.2%) | 5(0.8%) | 6(0.5%) |
| ACUTE MYOCARDIAL INFARCTION | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| ANGINA PECTORIS | 192(32.1%) | 194(32.4%) | 386(32.2%) |
| ANGINA PECTORIS AGGRAVATED | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| ANGINA UNSTABLE | 10(1.7%) | 17(2.8%) | 27(2.3%) |
| AORTIC VALVE STENOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ARRHYTHMIA NOS | 0(0.0%) | 3(0.5%) | 3(0.3%) |
| ATRIAL FIBRILLATION | 12(2.0%) | 18(3.0%) | 30(2.5%) |
| ATRIAL FIBRILLATION AGGRAVATED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ATRIAL FLUTTER | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| ATRIOVENTRICULAR BLOCK NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| BRADYARRHYTHMIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BRADYCARDIA NOS | 11(1.8%) | 5(0.8%) | 16(1.3%) |
| CARDIAC ARREST | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC FAILURE CONGESTIVE | 3(0.5%) | 5(0.8%) | 8(0.7%) |
| CARDIAC FAILURE NOS | 0(0.0%) | 5(0.8%) | 5(0.4%) |
| CARDIAC FLUTTER | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COR PULMONALE CHRONIC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CORONARY ARTERY ATHEROSCLEROSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CORONARY ARTERY DISEASE NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CORONARY ARTERY DISSECTION | 7(1.2%) | 6(1.0%) | 13(1.1%) |
| CORONARY ARTERY EMBOLISM | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| CORONARY ARTERY OCCLUSION | 5(0.8%) | 7(1.2%) | 12(1.0%) |
| CORONARY ARTERY STENOSIS | 2(0.3%) | 4(0.7%) | 6(0.5%) |
| EXTRASYSTOLES NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LEFT VENTRICULAR FAILURE | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| MITRAL VALVE INCOMPETENCE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MITRAL VALVE PROLAPSE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MYOCARDIAL INFARCTION | 21(3.5%) | 27(4.5%) | 48(4.0%) |
| MYOCARDIAL ISCHAEMIA | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| PALPITATIONS | 5(0.8%) | 5(0.8%) | 10(0.8%) |
| PAROXYSMAL ARRHYTHMIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PERICARDITIS NOS | 3(0.5%) | 0(0.0%) | 3(0.3%) |
| POST MYOCARDIAL INFARCTION SYNDROME | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PULMONARY OEDEMA NOS | 4(0.7%) | 4(0.7%) | 8(0.7%) |
| SICK SINUS SYNDROME | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SINUS BRADYCARDIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| SUPRAVENTRICULAR TACHYCARDIA | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| TACHYCARDIA NOS | 4(0.7%) | 0(0.0%) | 4(0.3%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| VENTRICULAR ARRHYTHMIA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VENTRICULAR EXTRASYSTOLES | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| VENTRICULAR FIBRILLATION | 5(0.8%) | 3(0.5%) | 8(0.7%) |
| VENTRICULAR HYPOKINESIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VENTRICULAR SEPTAL DEFECT ACQUIRED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VENTRICULAR TACHYCARDIA | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| *EAR AND LABYRINTH DISORDERS* | *12(2.0%)* | *6(1.0%)* | *18(1.5%)* |
| CERUMEN IMPACTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CHOLESTEATOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TINNITUS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VERTIGO | 9(1.5%) | 6(1.0%) | 15(1.3%) |
| VESTIBULAR NEURONITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *ENDOCRINE DISORDERS* | *1(0.2%)* | *6(1.0%)* | *7(0.6%)* |
| ACQUIRED HYPOTHYROIDISM | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERPARATHYROIDISM NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THYROTOXICOSIS | 1(0.2%) | 4(0.7%) | 5(0.4%) |
| *EYE DISORDERS* | *9(1.5%)* | *6(1.0%)* | *15(1.3%)* |
| CATARACT | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CATARACT UNILATERAL | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CONJUNCTIVITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| EYE DISORDER NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| EYE HAEMORRHAGE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GLAUCOMA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| KERATITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MACULAR DEGENERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RETINAL DEGENERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RETINAL DETACHMENT | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| RETINOPATHY NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| VISION BLURRED | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| VISUAL ACUITY REDUCED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *GASTROINTESTINAL DISORDERS* | *70(11.7%)* | *72(12.0%)* | *142(11.9%)* |
| ABDOMINAL DISTENSION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ABDOMINAL PAIN NOS | 4(0.7%) | 4(0.7%) | 8(0.7%) |
| ABDOMINAL PAIN UPPER | 5(0.8%) | 6(1.0%) | 11(0.9%) |
| ANAL HAEMORRHAGE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLITIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLONIC POLYP | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CONSTIPATION | 6(1.0%) | 2(0.3%) | 8(0.7%) |
| DIARRHOEA NOS | 6(1.0%) | 9(1.5%) | 15(1.3%) |
| DIVERTICULITIS NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| DIVERTICULUM NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| DRY MOUTH | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DUODENAL ULCER HAEMORRHAGE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DUODENITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DYSPEPSIA | 9(1.5%) | 6(1.0%) | 15(1.3%) |
| ENTERITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ERUCTATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FAECAL IMPACTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FAECES DISCOLOURED | 1(0.2%) | 0(0.0%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| FAECES PALE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FLATULENCE | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| FOOD POISONING NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTRIC DISORDER | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| GASTRIC HAEMORRHAGE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GASTRIC ULCER HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTRITIS NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GASTROINTESTINAL DISORDER NOS | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| GASTROINTESTINAL HAEMORRHAGE NOS | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| GASTROINTESTINAL UPSET | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GASTROOESOPHAGEAL REFLUX DISEASE | 2(0.3%) | 3(0.5%) | 5(0.4%) |
| GINGIVAL BLEEDING | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| GINGIVITIS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| HAEMATEMESIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HAEMORRHOIDS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HIATUS HERNIA | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| ILEUS PARALYTIC | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| INGUINAL HERNIA NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| INTESTINAL FUNCTIONAL DISORDER NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTESTINAL OBSTRUCTION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTESTINAL PERFORATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTRA ABDOMINAL HAEMORRHAGE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LOOSE STOOLS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MOUTH HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NAUSEA | 19(3.2%) | 17(2.8%) | 36(3.0%) |
| OESOPHAGEAL SPASM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OESOPHAGITIS NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| PEPTIC ULCER | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RECTAL HAEMORRHAGE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| REFLUX OESOPHAGITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SIGMOIDITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| STOMACH DISCOMFORT | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| STOMATITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TOOTHACHE | 3(0.5%) | 0(0.0%) | 3(0.3%) |
| VOLVULUS OF BOWEL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VOMITING NOS | 5(0.8%) | 4(0.7%) | 9(0.8%) |
| *GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS* | *134(22.4%)* | *118(19.7%)* | *252(21.1%)* |
| ADVERSE DRUG REACTION NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ASTHENIA | 5(0.8%) | 3(0.5%) | 8(0.7%) |
| CARDIAC DEATH | 3(0.5%) | 5(0.8%) | 8(0.7%) |
| CHEST PAIN | 39(6.5%) | 44(7.3%) | 83(6.9%) |
| CONDITION AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DEATH NOS | 8(1.3%) | 9(1.5%) | 17(1.4%) |
| DISCOMFORT NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| EXERCISE TOLERANCE DECREASED | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| FALL | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| FATIGUE | 24(4.0%) | 21(3.5%) | 45(3.8%) |
| FEELING ABNORMAL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GENERAL PHYSICAL HEALTH DETERIORATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HERNIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| INFLUENZA LIKE ILLNESS | 0(0.0%) | 3(0.5%) | 3(0.3%) |
| INJECTION SITE BRUISING | 5(0.8%) | 2(0.3%) | 7(0.6%) |
| INJECTION SITE HAEMORRHAGE | 41(6.9%) | 24(4.0%) | 65(5.4%) |
| INJECTION SITE INFLAMMATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INJECTION SITE IRRITATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| INJECTION SITE MASS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| INJECTION SITE PAIN | 9(1.5%) | 4(0.7%) | 13(1.1%) |
| INJECTION SITE RASH | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| INJECTION SITE REACTION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INJECTION SITE SWELLING | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LETHARGY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MALAISE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MASS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MUCOSAL INFLAMMATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NECROSIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| OEDEMA NOS | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| OEDEMA PERIPHERAL | 1(0.2%) | 4(0.7%) | 5(0.4%) |
| PAIN NOS | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| PYREXIA | 6(1.0%) | 3(0.5%) | 9(0.8%) |
| WEAKNESS | 2(0.3%) | 3(0.5%) | 5(0.4%) |
| *HEPATOBILIARY DISORDERS* | *8(1.3%)* | *8(1.3%)* | *16(1.3%)* |
| BILE DUCT STONE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BILIARY COLIC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CHOLECYSTITIS ACUTE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHOLECYSTITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHOLELITHIASIS | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| GALLBLADDER PAIN | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HEPATIC FUNCTION ABNORMAL NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HEPATOCELLULAR DAMAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| JAUNDICE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LIVER FATTY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *IMMUNE SYSTEM DISORDERS* | *5(0.8%)* | *7(1.2%)* | *12(1.0%)* |
| ANAPHYLACTIC REACTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DRUG HYPERSENSITIVITY | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| HEART TRANSPLANT REJECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERSENSITIVITY NOS | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| IODINE ALLERGY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *INFECTIONS AND INFESTATIONS* | *50(8.4%)* | *48(8.0%)* | *98(8.2%)* |
| ABSCESS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BREAST ABSCESS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BRONCHITIS NOS | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| CELLULITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHOLANGITIS ACUTE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLITIS PSEUDOMEMBRANOUS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CYSTITIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| EMPYEMA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ERYSIPELAS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ESCHERICHIA URINARY TRACT INFECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTROENTERITIS NOS | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| GASTROINTESTINAL INFECTION NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| HELICOBACTER INFECTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HERPES ZOSTER | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| INFECTION NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| INFLUENZA | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| INJECTION SITE INFECTION | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| LARYNGITIS CHRONIC NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LOWER RESPIRATORY TRACT INFECTION NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| LUNG INFECTION NOS | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| NASOPHARYNGITIS | 5(0.8%) | 10(1.7%) | 15(1.3%) |
| PNEUMONIA FUNGAL NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PNEUMONIA NOS | 6(1.0%) | 5(0.8%) | 11(0.9%) |
| POST HERPETIC NEURALGIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PYELONEPHRITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RESPIRATORY TRACT INFECTION NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| SCABIES INFESTATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SEPSIS NOS | 3(0.5%) | 0(0.0%) | 3(0.3%) |
| SINUSITIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TONSILLITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TOOTH ABSCESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TOOTH CARIES NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TOOTH INFECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| UPPER RESPIRATORY TRACT INFECTION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| URINARY TRACT INFECTION NOS | 5(0.8%) | 7(1.2%) | 12(1.0%) |
| VIRAL INFECTION NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| WOUND INFECTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *INJURY, POISONING AND PROCEDURAL COMPLICATIONS* | *27(4.5%)* | *38(6.3%)* | *65(5.4%)* |
| ABRASION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANKLE FRACTURE | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| ARTERIAL INJURY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLISTER | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BONE INJURY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COMPLICATIONS DUE TO INTERNAL JOINT PROSTHESIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CONCUSSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CORONARY ARTERY RESTENOSIS | 5(0.8%) | 7(1.2%) | 12(1.0%) |
| DEVICE FAILURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FACIAL BONES FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FEMORAL NECK FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FRACTURE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| JAW FRACTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| JOINT SPRAIN | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| KIDNEY RUPTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LIMB INJURY NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| LOWER LIMB FRACTURE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MEDICAL DEVICE COMPLICATION | 3(0.5%) | 0(0.0%) | 3(0.3%) |
| MULTIPLE FRACTURES | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MUSCLE RUPTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MUSCLE STRAIN | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MYOCARDIAL REPERFUSION INJURY | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| POST PROCEDURAL DIARRHOEA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| POST PROCEDURAL HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| POST PROCEDURAL PAIN | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RADIUS FRACTURE | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| SKIN INJURY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SPINAL FRACTURE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SPLENIC RUPTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| STENT OCCLUSION | 4(0.7%) | 18(3.0%) | 22(1.8%) |
| SYNOVIAL RUPTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| UPPER LIMB FRACTURE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VASCULAR INJURY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *INVESTIGATIONS* | *84(14.0%)* | *74(12.4%)* | *158(13.2%)* |
| ALANINE AMINOTRANSFERASE INCREASED | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| ANGIOGRAM NOS | 13(2.2%) | 14(2.3%) | 27(2.3%) |
| ARTERIOGRAM CORONARY | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| ARTHROSCOPY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ASPARTATE AMINOTRANSFERASE INCREASED | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| BIOPSY PROSTATE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BLEEDING TIME PROLONGED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLOOD BILIRUBIN INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLOOD CHOLESTEROL INCREASED | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | 6(1.0%) | 8(1.3%) | 14(1.2%) |
| BLOOD CREATINE PHOSPHOKINASE MB INCREASED | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| BLOOD CREATININE INCREASED | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| BLOOD GLUCOSE FLUCTUATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLOOD GLUCOSE INCREASED | 10(1.7%) | 2(0.3%) | 12(1.0%) |
| BLOOD IRON DECREASED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BLOOD POTASSIUM DECREASED | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| BLOOD POTASSIUM INCREASED | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| BLOOD PRESSURE INCREASED | 4(0.7%) | 2(0.3%) | 6(0.5%) |
| BLOOD PRESSURE SYSTOLIC INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLOOD SODIUM DECREASED | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| BLOOD TRIGLYCERIDES INCREASED | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| BLOOD UREA INCREASED | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| BLOOD URIC ACID INCREASED | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| BODY TEMPERATURE INCREASED | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| BRONCHOSCOPY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CARDIAC ENZYMES INCREASED | 6(1.0%) | 9(1.5%) | 15(1.3%) |
| CARDIAC MURMUR NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC STRESS TEST ABNORMAL | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CARDIAC TROPONIN INCREASED | 3(0.5%) | 6(1.0%) | 9(0.8%) |
| CARDIAC TROPONIN T INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIOVASCULAR EVALUATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIOVASCULAR FUNCTION TEST ABNORMAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CATHETERISATION CARDIAC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COAGULATION TIME NOS PROLONGED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLONOSCOPY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CYSTOSCOPY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ELECTROCARDIOGRAM ABNORMAL NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| ELECTROCARDIOGRAM ST SEGMENT DEPRESSION | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| ELECTROCARDIOGRAM ST SEGMENT ELEVATION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| EXERCISE TEST ABNORMAL | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| FULL BLOOD COUNT ABNORMAL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GAMMA GLUTAMYLTRANSFERASE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GAMMA GLUTAMYLTRANSFERASE INCREASED | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GLYCOSYLATED HAEMOGLOBIN INCREASED | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| HAEMATOCRIT DECREASED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HAEMOGLOBIN DECREASED | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| HEART RATE INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HEART RATE IRREGULAR | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| LABORATORY TEST ABNORMAL NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| LIVER FUNCTION TESTS NOS ABNORMAL | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| LOW DENSITY LIPOPROTEIN INCREASED | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| PLATELET COUNT INCREASED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SCAN NOS THYROID GLAND | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SCINTIGRAPHY NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| WEIGHT DECREASED | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| WEIGHT INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *METABOLISM AND NUTRITION DISORDERS* | *21(3.5%)* | *35(5.8%)* | *56(4.7%)* |
| ANOREXIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DEHYDRATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DIABETES MELLITUS NOS | 3(0.5%) | 11(1.8%) | 14(1.2%) |
| DIABETIC COMPLICATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DIABETIC KETOACIDOSIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| FLUID OVERLOAD | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GOUT | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| HYPERCALCAEMIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERCHOLESTEROLAEMIA | 2(0.3%) | 3(0.5%) | 5(0.4%) |
| HYPERGLYCAEMIA NOS | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| HYPERKALAEMIA | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| HYPERLIPIDAEMIA NOS | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| HYPERNATRAEMIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HYPERTRIGLYCERIDAEMIA | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| HYPERURICAEMIA | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| HYPOCALCAEMIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HYPOGLYCAEMIA AGGRAVATED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HYPOGLYCAEMIA NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HYPOKALAEMIA | 0(0.0%) | 3(0.5%) | 3(0.3%) |
| HYPONATRAEMIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PODAGRA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS* | *72(12.0%)* | *71(11.9%)* | *143(11.9%)* |
| ARTHRALGIA | 5(0.8%) | 10(1.7%) | 15(1.3%) |
| ARTHRITIS NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| BACK DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BACK PAIN | 25(4.2%) | 26(4.3%) | 51(4.3%) |
| BACK STIFFNESS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CHEST WALL PAIN | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| DIGITAL NECROSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FEMUR FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GROIN PAIN | 2(0.3%) | 0(0.0%) | 2(0.2%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| INTERVERTEBRAL DISC HERNIATION | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| JOINT SWELLING | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| LIMB DISCOMFORT NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| LOCALISED OSTEOARTHRITIS | 1(0.2%) | 5(0.8%) | 6(0.5%) |
| MUSCLE CRAMPS | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| MUSCLE DISORDER NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MUSCLE HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MUSCLE STIFFNESS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| MUSCLE WEAKNESS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MUSCULOSKELETAL CHEST PAIN | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| MUSCULOSKELETAL DISCOMFORT | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| MUSCULOSKELETAL PAIN | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| MYALGIA | 4(0.7%) | 8(1.3%) | 12(1.0%) |
| NECK PAIN | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| OSTEOARTHRITIS NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| OSTEOPENIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PAIN IN LIMB | 17(2.8%) | 6(1.0%) | 23(1.9%) |
| PATELLA FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PERIPHERAL SWELLING | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| RHEUMATOID ARTHRITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SWELLING NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TENDON DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TENDONITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TOE DEFORMITIES NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| *NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)* | *20(3.3%)* | *21(3.5%)* | *41(3.4%)* |
| ADENOCARCINOMA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLADDER CANCER NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| BLADDER CANCER STAGE IV | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BLADDER NEOPLASM NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BONE NEOPLASM MALIGNANT | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BRONCHIAL CARCINOMA | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| CARCINOMA NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| CHRONIC LYMPHOCYTIC LEUKAEMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLON ADENOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLORECTAL CANCER NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CYST NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GASTRIC CANCER NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GLIOMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LUNG CANCER STAGE UNSPECIFIED (EXCL METASTATIC TUMOURS TO LUNG) | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| LUNG CANCER STAGE UNSPECIFIED EXCL METASTATIC TUMOURS TO LUNG | 4(0.7%) | 0(0.0%) | 4(0.3%) |
| LUNG NEOPLASM NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LYMPHOMA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MALIGNANT MELANOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MENINGIOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NON HODGKIN S LYMPHOMA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OESOPHAGEAL CARCINOMA NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PANCREATIC CARCINOMA NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PROSTATE CANCER METASTATIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PROSTATE CANCER NOS | 2(0.3%) | 5(0.8%) | 7(0.6%) |
| SMALL INTESTINE CARCINOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| *NERVOUS SYSTEM DISORDERS* | *72(12.0%)* | *67(11.2%)* | *139(11.6%)* |
| AGEUSIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| AMNESIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| AMYOTROPHIC LATERAL SCLEROSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| APHASIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CAROTID ARTERY STENOSIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CAUDA EQUINA SYNDROME | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CEREBRAL INFARCTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CEREBROVASCULAR ACCIDENT | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| CLUSTER HEADACHES | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CONVULSIONS NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| DIZZINESS | 15(2.5%) | 16(2.7%) | 31(2.6%) |
| DYSAESTHESIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GUILLAIN BARRE SYNDROME | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HEADACHE NOS | 17(2.8%) | 13(2.2%) | 30(2.5%) |
| HEADACHE NOS AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HEMIPARESIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HEMIPLEGIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERTONIA | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| HYPOAESTHESIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HYPOTONIA | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| INTERCOSTAL NEURALGIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| INTRACRANIAL HAEMORRHAGE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LOSS OF CONSCIOUSNESS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MUSCLE CONTRACTIONS INVOLUNTARY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NEUROLOGICAL DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NEUROLOGICAL FINDINGS ABNORMAL NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NEUROLOGICAL SYMPTOMS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NEUROPATHY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PARAESTHESIA | 4(0.7%) | 1(0.2%) | 5(0.4%) |
| PARKINSON S DISEASE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| POLYNEUROPATHY NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| SLEEP APNOEA SYNDROME | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| SPINAL STENOSIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SYNCOPE | 9(1.5%) | 6(1.0%) | 15(1.3%) |
| TENSION HEADACHES | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TRANSIENT ISCHAEMIC ATTACK | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| TREMOR | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VASOVAGAL ATTACK | 4(0.7%) | 11(1.8%) | 15(1.3%) |
| *PSYCHIATRIC DISORDERS* | *16(2.7%)* | *13(2.2%)* | *29(2.4%)* |
| ANGER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANXIETY | 7(1.2%) | 1(0.2%) | 8(0.7%) |
| ANXIETY DISORDER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CONFUSION | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| DEPRESSED MOOD | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DEPRESSION | 5(0.8%) | 5(0.8%) | 10(0.8%) |
| INSOMNIA | 4(0.7%) | 2(0.3%) | 6(0.5%) |
| LIBIDO DECREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NERVOUSNESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SLEEP DISORDER NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| *RENAL AND URINARY DISORDERS* | *12(2.0%)* | *18(3.0%)* | *30(2.5%)* |
| ANURIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLADDER DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLADDER NECK OBSTRUCTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CALCULUS RENAL NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| CALCULUS URETERIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HAEMATURIA | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| LOIN PAIN | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NEPHROPATHY NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RENAL ANEURYSM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| RENAL ARTERY STENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| RENAL COLIC | 3(0.5%) | 0(0.0%) | 3(0.3%) |
| RENAL CYST NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| RENAL FAILURE ACUTE | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RENAL FAILURE ACUTE ON CHRONIC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| RENAL FAILURE CHRONIC | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RENAL FAILURE NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| RENAL IMPAIRMENT NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| URETHRAL PAIN | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| URETHRAL STRICTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| URINARY BLADDER POLYP | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| URINARY RETENTION | 1(0.2%) | 4(0.7%) | 5(0.4%) |
| *REPRODUCTIVE SYSTEM AND BREAST DISORDERS* | *4(0.7%)* | *5(0.8%)* | *9(0.8%)* |
| BENIGN PROSTATIC HYPERPLASIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| BREAST PAIN | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| ERECTILE DYSFUNCTION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| GENITAL PAIN NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PROSTATITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| UTERINE HAEMORRHAGE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS* | *70(11.7%)* | *84(14.0%)* | *154(12.9%)* |
| AIRWAY OBSTRUCTION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ASPIRATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ASTHMA AGGRAVATED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ASTHMA NOS | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| CHRONIC OBSTRUCTIVE AIRWAYS DISEASE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED | 0(0.0%) | 4(0.7%) | 4(0.3%) |
| COUGH | 13(2.2%) | 10(1.7%) | 23(1.9%) |
| COUGH AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DIAPHRAGMATIC HERNIA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DYSPNOEA EXACERBATED | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| DYSPNOEA EXERTIONAL | 6(1.0%) | 5(0.8%) | 11(0.9%) |
| DYSPNOEA NOS | 29(4.8%) | 53(8.8%) | 82(6.9%) |
| EPISTAXIS | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| HAEMOPTYSIS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| LARYNGEAL OEDEMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LUNG DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LUNG INDURATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NASAL PASSAGE IRRITATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NOCTURNAL DYSPNOEA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ORTHOPNOEA | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| PHARYNGOLARYNGEAL PAIN | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PLEURAL EFFUSION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PLEURISY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PLEURITIC PAIN | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PNEUMONIA ASPIRATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PNEUMOTHORAX NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PRODUCTIVE COUGH | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PULMONARY CONGESTION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| PULMONARY EMBOLISM | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| RESPIRATORY DISTRESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RESPIRATORY FAILURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SNEEZING | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THROAT IRRITATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| THROAT TIGHTNESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| WHEEZING | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *SKIN AND SUBCUTANEOUS TISSUE DISORDERS* | *23(3.8%)* | *28(4.7%)* | *51(4.3%)* |
| ANGIONEUROTIC OEDEMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLD SWEAT | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CONTUSION | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| DECUBITUS ULCER | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| DERMATITIS ALLERGIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DERMATITIS EXFOLIATIVE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ECZEMA | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| ERYTHEMA | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| EXANTHEM | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| HAIR GROWTH ABNORMAL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INCREASED TENDENCY TO BRUISE | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| NIGHT SWEATS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PHOTODERMATOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PRURITUS GENERALISED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PRURITUS NOS | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| RASH MACULO PAPULAR | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RASH NOS | 2(0.3%) | 7(1.2%) | 9(0.8%) |
| RASH PRURITIC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SKIN LESION NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| SKIN NECROSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SWEATING INCREASED | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| URTICARIA NOS | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| *SURGICAL AND MEDICAL PROCEDURES* | *111(18.6%)* | *140(23.4%)* | *251(21.0%)* |
| ANGIOPLASTY | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| ANORECTAL OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ANTICOAGULANT THERAPY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| AORTIC ANEURYSM REPAIR | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| AORTIC VALVE REPLACEMENT | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| BLADDER REPAIR | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BLADDER TUMOUR RESECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BREAST LUMP REMOVAL NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BREAST RECONSTRUCTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CARDIAC PACEMAKER INSERTION | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| CARDIAC PACEMAKER REPLACEMENT | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| CATARACT EXTRACTION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CHOLECYSTECTOMY | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CIRCUMCISION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLECTOMY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLECTOMY PARTIAL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CORONARY ANGIOPLASTY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CORONARY ARTERY SURGERY | 5(0.8%) | 9(1.5%) | 14(1.2%) |
| CORONARY REVASCULARISATION | 74(12.4%) | 85(14.2%) | 159(13.3%) |
| DIABETES MELLITUS MANAGEMENT | 0(0.0%) | 3(0.5%) | 3(0.3%) |
| EYE OPERATION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| EYELID OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HERNIA REPAIR NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HIP ARTHROPLASTY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HIP OPERATION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| HOSPITALISATION | 6(1.0%) | 11(1.8%) | 17(1.4%) |
| HYSTERECTOMY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| IMPLANTABLE DEFIBRILLATOR INSERTION | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| INGUINAL HERNIA REPAIR | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| INTERVERTEBRAL DISC OPERATION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| INTESTINAL OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| KNEE ARTHROPLASTY | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| KNEE OPERATION | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| LUNG OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MENISCUS OPERATION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| NAIL OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NASAL OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NEPHRECTOMY | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| NERVE OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OESOPHAGEAL OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ORCHIDECTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ORTHOPEDIC PROCEDURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PARATHYROIDECTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PERIPHERAL ARTERY ANGIOPLASTY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PITUITARY TUMOUR REMOVAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| POLYPECTOMY | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| PROSTATECTOMY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PROSTATIC OPERATION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RADIOACTIVE IODINE THERAPY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RADIOTHERAPY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| REHABILITATION THERAPY | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| SHOULDER OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SMALL INTESTINAL RESECTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| THYROIDECTOMY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TOE AMPUTATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TRABECULECTOMY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TRANSURETHRAL PROSTATECTOMY | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| URINARY BLADDER EXCISION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VASCULAR BYPASS GRAFT NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VENTRICULAR SEPTAL DEFECT REPAIR | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 21a. Adverse Events (to 1080 Days) (ITT) (Continued)

| Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| *VASCULAR DISORDERS* | *76(12.7%)* | *78(13.0%)* | *154(12.9%)* |
| ANGINA PECTORIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| AORTIC ANEURYSM | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| AORTIC STENOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ARTERIAL ANEURYSM NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ARTERIAL RESTENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIAL RUPTURE NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ARTERIAL STENOSIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIOSCLEROSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIOVENOUS FISTULA ACQUIRED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ATHEROSCLEROSIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CAROTID ARTERY STENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CIRCULATORY COLLAPSE | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| CYANOSIS PERIPHERAL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DEEP VENOUS THROMBOSIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| EMBOLISM NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FEMORAL ARTERIAL STENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FEMORAL ARTERY OCCLUSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HAEMATOMA NOS | 22(3.7%) | 29(4.8%) | 51(4.3%) |
| HAEMORRHAGE NOS | 3(0.5%) | 5(0.8%) | 8(0.7%) |
| HOT FLUSHES NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| HYPERTENSION AGGRAVATED | 3(0.5%) | 4(0.7%) | 7(0.6%) |
| HYPERTENSION NOS | 11(1.8%) | 12(2.0%) | 23(1.9%) |
| HYPERTENSIVE CRISIS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| HYPOTENSION NOS | 11(1.8%) | 10(1.7%) | 21(1.8%) |
| ILIAC ARTERY STENOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTERMITTENT CLAUDICATION | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| INTRACARDIAC THROMBUS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| ISCHAEMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LABILE BLOOD PRESSURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ORTHOSTATIC HYPOTENSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PALLOR | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PERIPHERAL COLDNESS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PERIPHERAL ISCHAEMIA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PERIPHERAL OCCLUSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PERIPHERAL REVASCULARISATION | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| PERIPHERAL VASCULAR DISORDER NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PETECHIAE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PHLEBITIS NOS | 4(0.7%) | 0(0.0%) | 4(0.3%) |
| RAYNAUD S PHENOMENON | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VARICOSE VEINS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VASCULAR PSEUDOANEURYSM | 6(1.0%) | 7(1.2%) | 13(1.1%) |
| VENOUS THROMBOSIS SUPERFICIAL LIMB | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| WOUND HAEMORRHAGE | 1(0.2%) | 1(0.2%) | 2(0.2%) |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

NOS - Not Otherwise Specified.
NOTE: AEs missing event dates are included in this listing.
All events are stratified by System Organ Class and Preferred Term using MedDRA version 5.

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## Table 21b. Adverse Events by Site (ITT)

| Site | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| 301 | 0.57% (9/1568) | 1.53% (26/1704) | 1.07% (35/3272) |
| 302 | 1.98% (31/1568) | 2.64% (45/1704) | 2.32% (76/3272) |
| 307 | 0.51% (8/1568) | 0.82% (14/1704) | 0.67% (22/3272) |
| 308 | 1.66% (26/1568) | 1.29% (22/1704) | 1.47% (48/3272) |
| 309 | 1.15% (18/1568) | 2.05% (35/1704) | 1.62% (53/3272) |
| 310 | 0.57% (9/1568) | 0.94% (16/1704) | 0.76% (25/3272) |
| 313 | 3.38% (53/1568) | 2.52% (43/1704) | 2.93% (96/3272) |
| 314 | 5.36% (84/1568) | 3.52% (60/1704) | 4.40% (144/3272) |
| 315 | 4.85% (76/1568) | 5.81% (99/1704) | 5.35% (175/3272) |
| 317 | 0.32% (5/1568) | 0.18% (3/1704) | 0.24% (8/3272) |
| 401 | 0.45% (7/1568) | 0.94% (16/1704) | 0.70% (23/3272) |
| 403 | 0.26% (4/1568) | 0.00% (0/1704) | 0.12% (4/3272) |
| 404 | 2.74% (43/1568) | 2.88% (49/1704) | 2.81% (92/3272) |
| 405 | 0.51% (8/1568) | 0.12% (2/1704) | 0.31% (10/3272) |
| 406 | 0.89% (14/1568) | 1.35% (23/1704) | 1.13% (37/3272) |
| 407 | 0.19% (3/1568) | 0.00% (0/1704) | 0.09% (3/3272) |
| 408 | 0.83% (13/1568) | 1.23% (21/1704) | 1.04% (34/3272) |
| 409 | 0.64% (10/1568) | 0.76% (13/1704) | 0.70% (23/3272) |
| 410 | 0.45% (7/1568) | 0.47% (8/1704) | 0.46% (15/3272) |
| 411 | 0.45% (7/1568) | 0.59% (10/1704) | 0.52% (17/3272) |
| 412 | 1.28% (20/1568) | 0.82% (14/1704) | 1.04% (34/3272) |
| 413 | 0.19% (3/1568) | 0.76% (13/1704) | 0.49% (16/3272) |
| 414 | 0.51% (8/1568) | 1.06% (18/1704) | 0.79% (26/3272) |
| 417 | 0.06% (1/1568) | 0.23% (4/1704) | 0.15% (5/3272) |
| 418 | 0.77% (12/1568) | 0.76% (13/1704) | 0.76% (25/3272) |
| 419 | 0.38% (6/1568) | 0.12% (2/1704) | 0.24% (8/3272) |
| 420 | 0.06% (1/1568) | 0.29% (5/1704) | 0.18% (6/3272) |
| 422 | 2.87% (45/1568) | 1.70% (29/1704) | 2.26% (74/3272) |
| 423 | 0.57% (9/1568) | 0.94% (16/1704) | 0.76% (25/3272) |
| 424 | 4.97% (78/1568) | 6.04% (103/1704) | 5.53% (181/3272) |
| 425 | 3.38% (53/1568) | 3.29% (56/1704) | 3.33% (109/3272) |
| 426 | 0.89% (14/1568) | 0.18% (3/1704) | 0.52% (17/3272) |
| 428 | 0.32% (5/1568) | 0.41% (7/1704) | 0.37% (12/3272) |
| 437 | 0.77% (12/1568) | 1.41% (24/1704) | 1.10% (36/3272) |
| 438 | 0.19% (3/1568) | 0.76% (13/1704) | 0.49% (16/3272) |
| 439 | 0.32% (5/1568) | 0.18% (3/1704) | 0.24% (8/3272) |
| 440 | 0.13% (2/1568) | 0.23% (4/1704) | 0.18% (6/3272) |
| 441 | 0.96% (15/1568) | 1.12% (19/1704) | 1.04% (34/3272) |
| 442 | 0.00% (0/1568) | 0.12% (2/1704) | 0.06% (2/3272) |
| 444 | 0.77% (12/1568) | 0.41% (7/1704) | 0.58% (19/3272) |
| 501 | 0.38% (6/1568) | 0.94% (16/1704) | 0.67% (22/3272) |
| 502 | 0.96% (15/1568) | 0.65% (11/1704) | 0.79% (26/3272) |
| 503 | 0.38% (6/1568) | 0.82% (14/1704) | 0.61% (20/3272) |
| 504 | 2.81% (44/1568) | 2.41% (41/1704) | 2.60% (85/3272) |
| 505 | 0.06% (1/1568) | 0.59% (10/1704) | 0.34% (11/3272) |
| 506 | 0.83% (13/1568) | 1.00% (17/1704) | 0.92% (30/3272) |
| 507 | 2.42% (38/1568) | 0.82% (14/1704) | 1.59% (52/3272) |
| 508 | 2.55% (40/1568) | 3.05% (52/1704) | 2.81% (92/3272) |
| 509 | 0.77% (12/1568) | 0.41% (7/1704) | 0.58% (19/3272) |
| 510 | 5.55% (87/1568) | 4.23% (72/1704) | 4.86% (159/3272) |
| 511 | 0.51% (8/1568) | 0.82% (14/1704) | 0.67% (22/3272) |

## Table 21b. Adverse Events by Site (ITT) (Continued)

| | | | |
|---|---|---|---|
| 512 | 1.53% (24/1568) | 2.00% (34/1704) | 1.77% (58/3272) |
| 513 | 3.83% (60/1568) | 3.17% (54/1704) | 3.48% (114/3272) |
| 514 | 4.66% (73/1568) | 4.17% (71/1704) | 4.40% (144/3272) |
| 515 | 0.96% (15/1568) | 1.58% (27/1704) | 1.28% (42/3272) |
| 516 | 0.64% (10/1568) | 0.41% (7/1704) | 0.52% (17/3272) |
| 517 | 1.59% (25/1568) | 1.64% (28/1704) | 1.62% (53/3272) |
| 518 | 1.98% (31/1568) | 3.35% (57/1704) | 2.69% (88/3272) |
| 519 | 0.89% (14/1568) | 0.53% (9/1704) | 0.70% (23/3272) |
| 520 | 1.28% (20/1568) | 1.17% (20/1704) | 1.22% (40/3272) |
| 531 | 3.25% (51/1568) | 3.35% (57/1704) | 3.30% (108/3272) |
| 532 | 1.47% (23/1568) | 2.05% (35/1704) | 1.77% (58/3272) |
| 533 | 2.36% (37/1568) | 1.70% (29/1704) | 2.02% (66/3272) |
| 534 | 0.83% (13/1568) | 1.12% (19/1704) | 0.98% (32/3272) |
| 537 | 1.72% (27/1568) | 2.17% (37/1704) | 1.96% (64/3272) |
| 538 | 0.19% (3/1568) | 0.41% (7/1704) | 0.31% (10/3272) |
| 539 | 1.40% (22/1568) | 0.76% (13/1704) | 1.07% (35/3272) |
| 540 | 6.25% (98/1568) | 4.05% (69/1704) | 5.10% (167/3272) |
| 541 | 0.45% (7/1568) | 0.06% (1/1704) | 0.24% (8/3272) |
| 542 | 0.19% (3/1568) | 0.12% (2/1704) | 0.15% (5/3272) |
| 543 | 0.19% (3/1568) | 0.00% (0/1704) | 0.09% (3/3272) |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 22a. Serious Adverse Events (to 1080 Days) (ITT)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| *TOTAL* | *317(53.0%)* | *345(57.6%)* | *662(55.3%)* |
| *BLOOD AND LYMPHATIC SYSTEM DISORDERS* | *1(0.2%)* | *6(1.0%)* | *7(0.6%)* |
| AGRANULOCYTOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANAEMIA NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| HAEMOLYTIC ANAEMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HAEMORRHAGIC DISORDER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPOCHROMIC ANAEMIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MACROCYTIC ANAEMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *CARDIAC DISORDERS* | *151(25.3%)* | *185(30.9%)* | *336(28.1%)* |
| ACUTE CORONARY SYNDROME | 3(0.5%) | 5(0.8%) | 8(0.7%) |
| ACUTE MYOCARDIAL INFARCTION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| ACUTE PULMONARY OEDEMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANGINA PECTORIS | 91(15.2%) | 112(18.7%) | 203(17.0%) |
| ANGINA PECTORIS AGGRAVATED | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ANGINA UNSTABLE | 13(2.2%) | 16(2.7%) | 29(2.4%) |
| AORTIC VALVE STENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARRHYTHMIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ATRIAL FIBRILLATION | 11(1.8%) | 14(2.3%) | 25(2.1%) |
| ATRIAL FIBRILLATION AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ATRIAL FLUTTER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ATRIOVENTRICULAR BLOCK COMPLETE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ATRIOVENTRICULAR BLOCK NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| BRADYARRHYTHMIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BRADYCARDIA NOS | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| CARDIAC ARREST | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CARDIAC FAILURE CONGESTIVE | 3(0.5%) | 4(0.7%) | 7(0.6%) |
| CARDIAC FAILURE NOS | 1(0.2%) | 5(0.8%) | 6(0.5%) |
| CARDIAC TAMPONADE | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| CARDIOMEGALY NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CORONARY ARTERY DISEASE AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CORONARY ARTERY DISEASE NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| CORONARY ARTERY DISSECTION | 4(0.7%) | 4(0.7%) | 8(0.7%) |
| CORONARY ARTERY EMBOLISM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CORONARY ARTERY OCCLUSION | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| CORONARY ARTERY STENOSIS | 8(1.3%) | 5(0.8%) | 13(1.1%) |
| CORONARY ARTERY THROMBOSIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ELECTROMECHANICAL DISSOCIATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ISCHAEMIC CARDIOMYOPATHY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MITRAL VALVE INCOMPETENCE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| MYOCARDIAL INFARCTION | 29(4.8%) | 39(6.5%) | 68(5.7%) |
| MYOCARDIAL ISCHAEMIA | 2(0.3%) | 5(0.8%) | 7(0.6%) |
| PALPITATIONS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| PERICARDITIS NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| POST MYOCARDIAL INFARCTION SYNDROME | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PULMONARY OEDEMA AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PULMONARY OEDEMA NOS | 3(0.5%) | 4(0.7%) | 7(0.6%) |
| SICK SINUS SYNDROME | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| SINOATRIAL NODE DYSFUNCTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SINUS BRADYCARDIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SINUS TACHYCARDIA | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| SUPRAVENTRICULAR TACHYCARDIA | 2(0.3%) | 0(0.0%) | 2(0.2%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| TACHYARRHYTHMIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TACHYCARDIA NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| VENTRICLE RUPTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VENTRICULAR EXTRASYSTOLES | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| VENTRICULAR FAILURE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VENTRICULAR FIBRILLATION | 6(1.0%) | 5(0.8%) | 11(0.9%) |
| VENTRICULAR HYPOKINESIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| VENTRICULAR SEPTAL DEFECT ACQUIRED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VENTRICULAR TACHYCARDIA | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| *EAR AND LABYRINTH DISORDERS* | *3(0.5%)* | *0(0.0%)* | *3(0.3%)* |
| VERTIGO | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| VERTIGO POSITIONAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VESTIBULAR DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *ENDOCRINE DISORDERS* | *2(0.3%)* | *4(0.7%)* | *6(0.5%)* |
| ACQUIRED HYPOTHYROIDISM | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERPARATHYROIDISM NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THYROTOXICOSIS | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| *EYE DISORDERS* | *3(0.5%)* | *3(0.5%)* | *6(0.5%)* |
| CATARACT | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CONJUNCTIVAL HYPERAEMIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIABETIC RETINOPATHY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RETINAL DEGENERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RETINAL DETACHMENT | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VISION ABNORMAL NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *GASTROINTESTINAL DISORDERS* | *25(4.2%)* | *26(4.3%)* | *51(4.3%)* |
| ABDOMINAL HAEMATOMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ABDOMINAL PAIN NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ABDOMINAL PAIN UPPER | 4(0.7%) | 1(0.2%) | 5(0.4%) |
| ACUTE DIVERTICULITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLITIS ISCHAEMIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CONSTIPATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIARRHOEA NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| DIVERTICULITIS INTESTINAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIVERTICULITIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIVERTICULUM INTESTINAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIVERTICULUM INTESTINAL HAEMORRHAGIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DIVERTICULUM NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DUODENAL ULCER HAEMORRHAGE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DUODENITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DYSPEPSIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| FAECAL IMPACTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FOOD POISONING NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTRIC DISORDER | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GASTRIC HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTRIC POLYPS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GASTRIC ULCER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTRIC ULCER HAEMORRHAGE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GASTRITIS NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GASTROINTESTINAL DISORDER NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| GASTROINTESTINAL HAEMORRHAGE NOS | 3(0.5%) | 1(0.2%) | 4(0.3%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| GASTROINTESTINAL ULCER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GASTROOESOPHAGEAL REFLUX DISEASE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HAEMORRHOIDS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HIATUS HERNIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ILEUS PARALYTIC | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| INGUINAL HERNIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTESTINAL OBSTRUCTION NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| INTESTINAL POLYP | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MEGACOLON ACQUIRED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NAUSEA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OESOPHAGEAL SPASM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PANCREATITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PEPTIC ULCER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RECTAL HAEMORRHAGE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| RECTOCELE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RUPTURED DIVERTICULUM OF COLON | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TOOTH DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| UPPER GASTROINTESTINAL HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VOLVULUS OF BOWEL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VOMITING NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| *GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS* | *47(7.9%)* | *54(9.0%)* | *101(8.4%)* |
| ADVERSE DRUG REACTION NOS | 6(1.0%) | 2(0.3%) | 8(0.7%) |
| ADVERSE EVENT NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC DEATH | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| CHEST DISCOMFORT | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| CHEST PAIN | 21(3.5%) | 21(3.5%) | 42(3.5%) |
| CHEST PAIN AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DEATH NOS | 14(2.3%) | 20(3.3%) | 34(2.8%) |
| FALL | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| GENERAL PHYSICAL HEALTH DETERIORATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HERNIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INFLUENZA LIKE ILLNESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INJECTION SITE HAEMORRHAGE | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| MALAISE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| OEDEMA PERIPHERAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PAIN NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PYREXIA | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| WEAKNESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *HEPATOBILIARY DISORDERS* | *4(0.7%)* | *8(1.3%)* | *12(1.0%)* |
| BILE DUCT STONE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BILIARY COLIC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CHOLANGITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHOLECYSTITIS ACUTE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHOLECYSTITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHOLELITHIASIS | 3(0.5%) | 4(0.7%) | 7(0.6%) |
| HEPATIC CONGESTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| JAUNDICE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *IMMUNE SYSTEM DISORDERS* | *1(0.2%)* | *2(0.3%)* | *3(0.3%)* |
| ANAPHYLACTIC REACTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CONTRAST MEDIA REACTION | 1(0.2%) | 1(0.2%) | 2(0.2%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| *INFECTIONS AND INFESTATIONS* | *24(4.0%)* | *23(3.8%)* | *47(3.9%)* |
| BACTERIURIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BREAST ABSCESS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BRONCHITIS CHRONIC NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BRONCHITIS NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| CANDIDA PNEUMONIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CELLULITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLITIS PSEUDOMEMBRANOUS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CYTOMEGALOVIRUS COLITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTROENTERITIS NOS | 5(0.8%) | 3(0.5%) | 8(0.7%) |
| GASTROINTESTINAL INFECTION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GROIN INFECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HERPES SIMPLEX | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HERPES ZOSTER | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| IMPLANT INFECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INFECTION NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| INFLUENZA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LOBAR PNEUMONIA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LOWER RESPIRATORY TRACT INFECTION NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| LUNG INFECTION NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| PNEUMONIA NOS | 6(1.0%) | 7(1.2%) | 13(1.1%) |
| PYELONEPHRITIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RESPIRATORY TRACT INFECTION NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| SEPSIS NOS | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| SEPTIC SHOCK | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TOOTH ABSCESS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TOOTH INFECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| URINARY TRACT INFECTION NOS | 2(0.3%) | 3(0.5%) | 5(0.4%) |
| *INJURY, POISONING AND PROCEDURAL COMPLICATIONS* | *20(3.3%)* | *43(7.2%)* | *63(5.3%)* |
| ABRASION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANKLE FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COMPLICATIONS DUE TO INTERNAL JOINT PROSTHESIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CONCUSSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CORONARY ARTERY RESTENOSIS | 6(1.0%) | 16(2.7%) | 22(1.8%) |
| DEVICE FAILURE | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| DRUG TOXICITY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FEMORAL NECK FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FEMUR FRACTURE | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| FRACTURE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HUMERUS FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INJURY NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| JAW FRACTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LACERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LOWER LIMB FRACTURE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LUMBAR VERTEBRAL FRACTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MULTIPLE FRACTURES | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PATELLA FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PNEUMOTHORAX TRAUMATIC | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| POST PROCEDURAL PAIN | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| POSTOPERATIVE STITCH SINUS | 1(0.2%) | 0(0.0%) | 1(0.1%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| RADIUS FRACTURE | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RIB FRACTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SPLENIC RUPTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| STENT OCCLUSION | 2(0.3%) | 15(2.5%) | 17(1.4%) |
| SURGICAL PROCEDURE REPEATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SYNOVIAL RUPTURE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *INVESTIGATIONS* | *24(4.0%)* | *21(3.5%)* | *45(3.8%)* |
| ANGIOGRAM NOS | 6(1.0%) | 6(1.0%) | 12(1.0%) |
| ARTERIOGRAM CORONARY | 4(0.7%) | 3(0.5%) | 7(0.6%) |
| BIOPSY PROSTATE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BLOOD PRESSURE SYSTOLIC INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BODY TEMPERATURE INCREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC ENZYMES INCREASED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CARDIAC PACEMAKER EVALUATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC STRESS TEST ABNORMAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC TROPONIN INCREASED | 0(0.0%) | 4(0.7%) | 4(0.3%) |
| CARDIOVASCULAR EVALUATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIOVASCULAR FUNCTION TEST ABNORMAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CATHETERISATION CARDIAC | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| COLONOSCOPY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIAGNOSTIC PROCEDURE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ELECTROCARDIOGRAM ST SEGMENT DEPRESSION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ELECTROCARDIOGRAM ST SEGMENT ELEVATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HAEMOGLOBIN DECREASED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HEART RATE IRREGULAR | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| INVESTIGATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MEDICAL OBSERVATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PHYSICAL EXAMINATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SCAN NOS THYROID GLAND | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| WEIGHT DECREASED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| WHITE BLOOD CELL COUNT DECREASED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| X-RAY NOS CHEST ABNORMAL | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *METABOLISM AND NUTRITION DISORDERS* | *5(0.8%)* | *14(2.3%)* | *19(1.6%)* |
| DIABETES MELLITUS AGGRAVATED | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| DIABETES MELLITUS INADEQUATE CONTROL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DIABETES MELLITUS NON-INSULIN-DEPENDENT | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DIABETES MELLITUS NOS | 0(0.0%) | 6(1.0%) | 6(0.5%) |
| DIABETIC KETOACIDOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FLUID OVERLOAD | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERGLYCAEMIA NOS | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| HYPOGLYCAEMIA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HYPOKALAEMIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPONATRAEMIA | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| *MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS* | *8(1.3%)* | *12(2.0%)* | *20(1.7%)* |
| ARTHRALGIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ARTHRITIS NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| BACK PAIN | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| DIGITAL NECROSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTERVERTEBRAL DISC HERNIATION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| LOCALISED OSTEOARTHRITIS | 1(0.2%) | 2(0.3%) | 3(0.3%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| MUSCLE NECROSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MUSCULOSKELETAL CHEST PAIN | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PAIN IN JAW | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PAIN IN LIMB | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| RHEUMATOID ARTHRITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RHEUMATOID ARTHRITIS AGGRAVATED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SPINAL OSTEOARTHRITIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SYNOVITIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TOE DEFORMITIES NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)* | *25(4.2%)* | *13(2.2%)* | *38(3.2%)* |
| BLADDER CANCER NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| BLADDER CANCER STAGE III | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BLADDER CANCER STAGE IV | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BONE NEOPLASM MALIGNANT | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BRONCHIAL CARCINOMA | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CHOLESTEATOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLON ADENOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLON CANCER NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| COLORECTAL CANCER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ENDOMETRIAL CANCER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| GASTRIC CANCER NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| LARYNGEAL CANCER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LUNG CANCER METASTATIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| LUNG CANCER STAGE UNSPECIFIED (EXCL METASTATIC TUMOURS TO LUNG) | 5(0.8%) | 1(0.2%) | 6(0.5%) |
| LUNG NEOPLASM NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LYMPHOMA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MALIGNANT MELANOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| MENINGIOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| METASTASES TO PERITONEUM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NON-HODGKIN'S LYMPHOMA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OESOPHAGEAL CARCINOMA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PANCREATIC CARCINOMA NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PITUITARY TUMOUR BENIGN NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PROSTATE CANCER METASTATIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PROSTATE CANCER NOS | 2(0.3%) | 4(0.7%) | 6(0.5%) |
| RENAL CELL CARCINOMA STAGE UNSPECIFIED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SMALL CELL LUNG CANCER STAGE UNSPECIFIED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SMALL INTESTINE CARCINOMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *NERVOUS SYSTEM DISORDERS* | *35(5.9%)* | *29(4.8%)* | *64(5.3%)* |
| AMNESIA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| AMYOTROPHIC LATERAL SCLEROSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| BRAIN OEDEMA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CAROTID ARTERY STENOSIS | 3(0.5%) | 2(0.3%) | 5(0.4%) |
| CAUDA EQUINA SYNDROME | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CEREBRAL HAEMORRHAGE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CEREBRAL INFARCTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CEREBROVASCULAR ACCIDENT | 4(0.7%) | 5(0.8%) | 9(0.8%) |
| CONVULSIONS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| DIZZINESS | 4(0.7%) | 4(0.7%) | 8(0.7%) |
| EPILEPSY NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| HAEMORRHAGIC TRANSFORMATION STROKE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HEADACHE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HEMIPARESIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HEMIPLEGIA | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HYPERTONIA | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| LOSS OF CONSCIOUSNESS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| LUMBAR SPINAL STENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NEURALGIA NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NEUROLOGICAL DISORDER NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| PARAESTHESIA | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| PARKINSON'S DISEASE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| POLYNEUROPATHY NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SLEEP APNOEA SYNDROME | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| SPEECH DISORDER | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SUBDURAL HAEMATOMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SYNCOPE | 8(1.3%) | 1(0.2%) | 9(0.8%) |
| SYNCOPE AGGRAVATED | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TENSION HEADACHES | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TRANSIENT ISCHAEMIC ATTACK | 3(0.5%) | 3(0.5%) | 6(0.5%) |
| VASOVAGAL ATTACK | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| *PSYCHIATRIC DISORDERS* | *2(0.3%)* | *2(0.3%)* | *4(0.3%)* |
| ANXIETY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DEPRESSION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| PSYCHOSOMATIC DISEASE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PSYCHOTIC DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *RENAL AND URINARY DISORDERS* | *8(1.3%)* | *11(1.8%)* | *19(1.6%)* |
| BLADDER NECK OBSTRUCTION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CYSTOCELE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HAEMATURIA | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| NEPHROPATHY TOXIC | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| RENAL COLIC | 3(0.5%) | 0(0.0%) | 3(0.3%) |
| RENAL FAILURE ACUTE | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| RENAL FAILURE CHRONIC | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RENAL FAILURE NOS | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| RENAL IMPAIRMENT NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| URETHRAL STRICTURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| URINARY RETENTION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| URINARY TRACT DISORDER NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| URINARY TRACT OBSTRUCTION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *REPRODUCTIVE SYSTEM AND BREAST DISORDERS* | *2(0.3%)* | *2(0.3%)* | *4(0.3%)* |
| BENIGN PROSTATIC HYPERPLASIA | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| PROSTATIC DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| UTERINE HAEMORRHAGE | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS* | *23(3.8%)* | *30(5.0%)* | *53(4.4%)* |
| APNOEA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ASTHMA AGGRAVATED | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ASTHMA NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CHRONIC OBSTRUCTIVE AIRWAYS DISEASE | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| DYSPNOEA EXERTIONAL | 1(0.2%) | 1(0.2%) | 2(0.2%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| DYSPNOEA NOS | 13(2.2%) | 17(2.8%) | 30(2.5%) |
| EMPHYSEMA | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| EPISTAXIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HAEMOPTYSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PLEURAL EFFUSION | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| PNEUMONIA ASPIRATION | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| PULMONARY CONGESTION | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| PULMONARY EMBOLISM | 4(0.7%) | 1(0.2%) | 5(0.4%) |
| RESPIRATORY FAILURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THROAT TIGHTNESS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| *SKIN AND SUBCUTANEOUS TISSUE DISORDERS* | *2(0.3%)* | *4(0.7%)* | *6(0.5%)* |
| CONTUSION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| DECUBITUS ULCER | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| EXANTHEM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| RASH NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| SKIN LESION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| SKIN NECROSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *SURGICAL AND MEDICAL PROCEDURES* | *153(25.6%)* | *211(35.2%)* | *364(30.4%)* |
| ANGIOPLASTY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ANTICOAGULANT THERAPY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| AORTIC ANEURYSM REPAIR | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| AORTIC BYPASS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| AORTIC VALVE REPLACEMENT | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| ARTERIAL ANEURYSM REPAIR | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ARTERIAL BYPASS OPERATION | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| ARTERIO-VENOUS FISTULA OPERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BLADDER TUMOUR RESECTION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BRAIN TUMOUR OPERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| BUNION OPERATION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| CARDIAC PACEMAKER INSERTION | 6(1.0%) | 5(0.8%) | 11(0.9%) |
| CATARACT EXTRACTION | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CHOLECYSTECTOMY | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CHOLELITHOTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| COLECTOMY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| COLECTOMY PARTIAL | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| CORONARY ARTERY SURGERY | 6(1.0%) | 12(2.0%) | 18(1.5%) |
| CORONARY REVASCULARISATION | 106(17.7%) | 153(25.5%) | 259(21.6%) |
| DIABETES MELLITUS MANAGEMENT | 2(0.3%) | 3(0.5%) | 5(0.4%) |
| EMBOLECTOMY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| EYE OPERATION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| GASTRIC OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| GASTRIC POLYPECTOMY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HEART TRANSPLANT | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HERNIA REPAIR NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| HIP ARTHROPLASTY | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| HIP OPERATION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| HOSPITALISATION | 16(2.7%) | 12(2.0%) | 28(2.3%) |
| HYSTERECTOMY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| IMPLANTABLE DEFIBRILLATOR INSERTION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| INGUINAL HERNIA REPAIR | 2(0.3%) | 2(0.3%) | 4(0.3%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| INTERVERTEBRAL DISC OPERATION | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| KNEE ARTHRODESIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| KNEE ARTHROPLASTY | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| KNEE OPERATION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| LAPAROTOMY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| LUNG OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MALIGNANT BREAST LUMP REMOVAL | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| MENISCUS OPERATION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| NASAL OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| NEPHRECTOMY | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| NERVE OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OESOPHAGEAL OPERATION NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| OPERATION NOS | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| ORCHIDECTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ORTHOPEDIC PROCEDURE | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PACKED RED BLOOD CELL TRANSFUSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PARATHYROIDECTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PERIPHERAL ARTERY ANGIOPLASTY | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| PLATELET TRANSFUSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| POLYPECTOMY | 3(0.5%) | 1(0.2%) | 4(0.3%) |
| PROSTATIC OPERATION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| RADIOTHERAPY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| REHABILITATION THERAPY | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| SHOULDER OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| STENT REMOVAL NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TESTICULAR OPERATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THROMBECTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THYROID OPERATION NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THYROIDECTOMY NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| TOE AMPUTATION | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| TRABECULECTOMY | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| TRANSURETHRAL PROSTATECTOMY | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| VASCULAR BYPASS GRAFT NOS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| VENTRICULAR SEPTAL DEFECT REPAIR | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VITRECTOMY | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| *VASCULAR DISORDERS* | *23(3.8%)* | *22(3.7%)* | *45(3.8%)* |
| AORTIC ANEURYSM | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| AORTIC STENOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ARTERIAL RESTENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIAL RUPTURE NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIAL STENOSIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIAL THROMBOSIS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIOSCLEROSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| ARTERIOVENOUS FISTULA, ACQUIRED | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| CIRCULATORY COLLAPSE | 2(0.3%) | 1(0.2%) | 3(0.3%) |
| DEEP VENOUS THROMBOSIS NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FEMORAL ARTERIAL STENOSIS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| FEMORAL ARTERY ANEURYSM | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| FEMORAL ARTERY OCCLUSION | 1(0.2%) | 0(0.0%) | 1(0.1%) |

## Table 22a. Serious Adverse Events (to 1080 Days) (ITT) (Continued)

| Serious Adverse Events (to 1080 Days) | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| HAEMATOMA NOS | 1(0.2%) | 3(0.5%) | 4(0.3%) |
| HAEMORRHAGE NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| HYPERTENSION NOS | 5(0.8%) | 2(0.3%) | 7(0.6%) |
| HYPERTENSIVE CRISIS | 1(0.2%) | 1(0.2%) | 2(0.2%) |
| HYPOTENSION NOS | 0(0.0%) | 2(0.3%) | 2(0.2%) |
| HYPOVOLAEMIC SHOCK | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| ILIAC ARTERY STENOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| INTERMITTENT CLAUDICATION | 1(0.2%) | 2(0.3%) | 3(0.3%) |
| INTRACARDIAC THROMBUS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| NECROSIS OF ARTERY | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| PERIPHERAL ISCHAEMIA NOS | 2(0.3%) | 0(0.0%) | 2(0.2%) |
| PERIPHERAL REVASCULARISATION | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| PERIPHERAL VASCULAR DISORDER NOS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| THROMBOSIS | 0(0.0%) | 1(0.2%) | 1(0.1%) |
| VARICOSE VEINS NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VASCULAR DISORDER NOS | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| VASCULAR PSEUDOANEURYSM | 2(0.3%) | 2(0.3%) | 4(0.3%) |
| VENOUS THROMBOSIS SUPERFICIAL LIMB | 1(0.2%) | 0(0.0%) | 1(0.1%) |
| WOUND HAEMORRHAGE | 0(0.0%) | 1(0.2%) | 1(0.1%) |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

NOS - Not Otherwise Specified.
NOTE: SAEs missing event dates are included in this listing.
All events are stratified by System Organ Class and Preferred Term using MedDRA version 5.

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## Table 22b. Serious Adverse Events by Site (ITT)

| Site | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| 301 | 0.50% (4/799) | 1.20% (12/997) | 0.89% (16/1796) |
| 302 | 1.00% (8/799) | 1.50% (15/997) | 1.28% (23/1796) |
| 307 | 0.63% (5/799) | 1.60% (16/997) | 1.17% (21/1796) |
| 308 | 1.13% (9/799) | 0.80% (8/997) | 0.95% (17/1796) |
| 309 | 1.50% (12/799) | 3.01% (30/997) | 2.34% (42/1796) |
| 310 | 0.13% (1/799) | 1.10% (11/997) | 0.67% (12/1796) |
| 313 | 1.50% (12/799) | 1.10% (11/997) | 1.28% (23/1796) |
| 314 | 2.13% (17/799) | 2.11% (21/997) | 2.12% (38/1796) |
| 315 | 2.75% (22/799) | 3.11% (31/997) | 2.95% (53/1796) |
| 317 | 0.13% (1/799) | 0.00% (0/997) | 0.06% (1/1796) |
| 401 | 0.63% (5/799) | 1.30% (13/997) | 1.00% (18/1796) |
| 403 | 0.25% (2/799) | 0.00% (0/997) | 0.11% (2/1796) |
| 404 | 2.25% (18/799) | 2.61% (26/997) | 2.45% (44/1796) |
| 405 | 0.75% (6/799) | 0.00% (0/997) | 0.33% (6/1796) |
| 406 | 1.38% (11/799) | 0.90% (9/997) | 1.11% (20/1796) |
| 407 | 0.25% (2/799) | 0.00% (0/997) | 0.11% (2/1796) |
| 408 | 0.50% (4/799) | 0.70% (7/997) | 0.61% (11/1796) |
| 409 | 0.50% (4/799) | 0.90% (9/997) | 0.72% (13/1796) |
| 410 | 0.50% (4/799) | 0.10% (1/997) | 0.28% (5/1796) |
| 411 | 0.13% (1/799) | 0.90% (9/997) | 0.56% (10/1796) |
| 412 | 0.88% (7/799) | 0.20% (2/997) | 0.50% (9/1796) |
| 413 | 0.25% (2/799) | 1.30% (13/997) | 0.84% (15/1796) |
| 414 | 1.00% (8/799) | 0.60% (6/997) | 0.78% (14/1796) |
| 417 | 0.00% (0/799) | 0.20% (2/997) | 0.11% (2/1796) |
| 418 | 0.50% (4/799) | 0.70% (7/997) | 0.61% (11/1796) |
| 419 | 0.25% (2/799) | 0.20% (2/997) | 0.22% (4/1796) |
| 420 | 0.00% (0/799) | 0.20% (2/997) | 0.11% (2/1796) |
| 422 | 3.25% (26/799) | 1.91% (19/997) | 2.51% (45/1796) |
| 423 | 0.50% (4/799) | 0.60% (6/997) | 0.56% (10/1796) |
| 424 | 3.38% (27/799) | 5.62% (56/997) | 4.62% (83/1796) |
| 425 | 1.13% (9/799) | 1.60% (16/997) | 1.39% (25/1796) |
| 426 | 0.38% (3/799) | 0.00% (0/997) | 0.17% (3/1796) |
| 428 | 0.00% (0/799) | 0.40% (4/997) | 0.22% (4/1796) |
| 437 | 1.38% (11/799) | 1.40% (14/997) | 1.39% (25/1796) |
| 438 | 0.13% (1/799) | 0.40% (4/997) | 0.28% (5/1796) |
| 439 | 0.38% (3/799) | 0.20% (2/997) | 0.28% (5/1796) |
| 441 | 0.38% (3/799) | 0.40% (4/997) | 0.39% (7/1796) |
| 444 | 0.50% (4/799) | 0.70% (7/997) | 0.61% (11/1796) |
| 501 | 0.13% (1/799) | 0.80% (8/997) | 0.50% (9/1796) |
| 502 | 1.50% (12/799) | 1.60% (16/997) | 1.56% (28/1796) |
| 503 | 0.50% (4/799) | 0.70% (7/997) | 0.61% (11/1796) |
| 504 | 3.50% (28/799) | 1.91% (19/997) | 2.62% (47/1796) |
| 505 | 0.00% (0/799) | 0.70% (7/997) | 0.39% (7/1796) |
| 506 | 0.75% (6/799) | 1.71% (17/997) | 1.28% (23/1796) |
| 507 | 5.13% (41/799) | 1.40% (14/997) | 3.06% (55/1796) |
| 508 | 3.38% (27/799) | 2.81% (28/997) | 3.06% (55/1796) |
| 509 | 0.75% (6/799) | 0.20% (2/997) | 0.45% (8/1796) |
| 510 | 5.63% (45/799) | 4.91% (49/997) | 5.23% (94/1796) |
| 511 | 1.13% (9/799) | 1.71% (17/997) | 1.45% (26/1796) |
| 512 | 1.88% (15/799) | 1.60% (16/997) | 1.73% (31/1796) |
| 513 | 6.01% (48/799) | 3.91% (39/997) | 4.84% (87/1796) |

## Table 22b. Serious Adverse Events by Site (ITT) (Continued)

| Site | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) |
|---|---|---|---|
| 514 | 3.75% (30/799) | 4.91% (49/997) | 4.40% (79/1796) |
| 515 | 1.25% (10/799) | 1.20% (12/997) | 1.22% (22/1796) |
| 516 | 1.38% (11/799) | 1.10% (11/997) | 1.22% (22/1796) |
| 517 | 3.25% (26/799) | 4.11% (41/997) | 3.73% (67/1796) |
| 518 | 2.50% (20/799) | 4.81% (48/997) | 3.79% (68/1796) |
| 519 | 2.13% (17/799) | 0.90% (9/997) | 1.45% (26/1796) |
| 520 | 1.63% (13/799) | 2.21% (22/997) | 1.95% (35/1796) |
| 531 | 3.00% (24/799) | 2.61% (26/997) | 2.78% (50/1796) |
| 532 | 2.50% (20/799) | 2.31% (23/997) | 2.39% (43/1796) |
| 533 | 4.26% (34/799) | 2.41% (24/997) | 3.23% (58/1796) |
| 534 | 0.63% (5/799) | 0.90% (9/997) | 0.78% (14/1796) |
| 537 | 2.38% (19/799) | 3.21% (32/997) | 2.84% (51/1796) |
| 538 | 0.13% (1/799) | 0.50% (5/997) | 0.33% (6/1796) |
| 539 | 1.50% (12/799) | 0.90% (9/997) | 1.17% (21/1796) |
| 540 | 6.01% (48/799) | 4.21% (42/997) | 5.01% (90/1796) |
| 541 | 0.13% (1/799) | 0.10% (1/997) | 0.11% (2/1796) |
| 542 | 0.25% (2/799) | 0.00% (0/997) | 0.11% (2/1796) |
| 543 | 0.25% (2/799) | 0.00% (0/997) | 0.11% (2/1796) |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 23. Site Reported Major Adverse Events to 1080 Days (ITT)

| Complications | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| Mace | 12.4% (74/598) | 22.5% (135/599) | 17.5% (209/1197) | -10.2% [-14.4%,-5.9%] | <0.001 |
| Death | 3.2% (19/598) | 4.3% (26/599) | 3.8% (45/1197) | -1.2% [-3.3%,1.0%] | 0.362 |
| Emergent CABG | 0.3% (2/598) | 1.2% (7/599) | 0.8% (9/1197) | -0.8% [-1.8%,0.1%] | 0.178 |
| MI | 5.0% (30/598) | 6.2% (37/599) | 5.6% (67/1197) | -1.2% [-3.8%,1.4%] | 0.451 |
| Q Wave MI | 1.5% (9/598) | 2.3% (14/599) | 1.9% (23/1197) | -0.8% [-2.4%,0.7%] | 0.400 |
| Non-Q Wave MI | 3.5% (21/598) | 4.3% (26/599) | 3.9% (47/1197) | -0.8% [-3.0%,1.4%] | 0.552 |
| TLR | 6.2% (37/598) | 15.9% (95/599) | 11.0% (132/1197) | -9.7% [-13.2%,-6.2%] | <0.001 |
| TVR not Involve the Target Lesion | 6.0% (36/598) | 7.0% (42/599) | 6.5% (78/1197) | -1.0% [-3.8%,1.8%] | 0.558 |
| Major Bleeding Events | 0.7% (4/598) | 1.5% (9/599) | 1.1% (13/1197) | -0.8% [-2.0%,0.3%] | 0.264 |
| Major Vascular Events | 0.3% (2/598) | 1.0% (6/599) | 0.7% (8/1197) | -0.7% [-1.6%,0.3%] | 0.287 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients.

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## Table 24. Laboratory - Cardiac Enzymes Findings

| Laboratory - CK, CKMB | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **CK** | | | | | |
| Pre-Procedure Peak>2 ULN | 0.9% (5/570) | 1.1% (6/565) | 1.0% (11/1135) | -0.2% [-1.3%,1.0%] | 0.772 |
| Post-Procedure Peak>2 ULN | 3.1% (18/578) | 3.3% (19/579) | 3.2% (37/1157) | -0.2% [-2.2%,1.9%] | 1.000 |
| Post-Procedure Peak>3 ULN | 2.4% (14/578) | 0.9% (5/579) | 1.6% (19/1157) | 1.6% [0.1%,3.0%] | 0.040 |
| Post-Procedure Peak>4 ULN | 1.7% (10/578) | 0.3% (2/579) | 1.0% (12/1157) | 1.4% [0.2%,2.6%] | 0.022 |
| Post-Procedure Peak>5 ULN | 0.5% (3/578) | 0.0% (0/579) | 0.3% (3/1157) | 0.5% [-0.1%,1.1%] | 0.124 |
| **CKMB** | | | | | |
| Pre-Procedure Peak>1 ULN | 15.1% (61/403) | 14.7% (56/382) | 14.9% (117/785) | 0.5% [-4.5%,5.5%] | 0.920 |
| Post-Procedure Peak>1 ULN | 27.1% (120/442) | 29.4% (131/445) | 28.3% (251/887) | -2.3% [-8.2%,3.6%] | 0.457 |
| Post-Procedure Peak>2 ULN | 10.2% (45/442) | 10.6% (47/445) | 10.4% (92/887) | -0.4% [-4.4%,3.6%] | 0.912 |
| Post-Procedure Peak>3 ULN | 6.1% (27/442) | 5.8% (26/445) | 6.0% (53/887) | 0.3% [-2.9%,3.4%] | 0.888 |
| Post-Procedure Peak>4 ULN | 3.2% (14/442) | 3.4% (15/445) | 3.3% (29/887) | -0.2% [-2.5%,2.1%] | 1.000 |
| Pre-Procedure CK>2 ULN and CKMB>1 ULN | 1.0% (4/400) | 1.1% (4/380) | 1.0% (8/780) | -0.1% [-1.5%,1.4%] | 1.000 |
| Post-Procedure CK>2 ULN and CKMB>1 ULN | 3.2% (14/442) | 3.1% (14/445) | 3.2% (28/887) | 0.0% [-2.3%,2.3%] | 1.000 |
| Pre- and Post-Procedure CK>2 ULN and CKMB>1 ULN | 0.3% (1/384) | 0.3% (1/368) | 0.3% (2/752) | -0.0% [-0.7%,0.7%] | 1.000 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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## Table 25. Medication - Anti-coagulants Use (ITT)

| Anti-coagulant | Endeavor (N=598 patients) | Driver (N=599 patients) | All Patients (N=1197 Patients) | Difference [95% CI] | P-value |
|---|---|---|---|---|---|
| **Pre-Procedure** | | | | | |
| Aspirin | 97.0% (579/597) | 97.6% (580/594) | 97.3% (1159/1191) | -0.7% [-2.5%,1.2%] | 0.592 |
| Clopidogrel | 86.8% (518/597) | 85.4% (508/595) | 86.1% (1026/1192) | 1.4% [-2.5%,5.3%] | 0.504 |
| Ticlopidine | 4.4% (26/597) | 4.4% (26/595) | 4.4% (52/1192) | -0.0% [-2.3%,2.3%] | 1.000 |
| **During Procedure** | | | | | |
| Aspirin | 39.9% (238/597) | 39.1% (233/596) | 39.5% (471/1193) | 0.8% [-4.8%,6.3%] | 0.813 |
| Clopidogrel | 20.8% (124/597) | 18.6% (111/596) | 19.7% (235/1193) | 2.1% [-2.4%,6.7%] | 0.382 |
| Ticlopidine | 3.5% (21/597) | 3.2% (19/596) | 3.4% (40/1193) | 0.3% [-1.7%,2.4%] | 0.872 |
| GP IIb/IIIa | 13.2% (79/597) | 10.4% (62/594) | 11.8% (141/1191) | 2.8% [-0.9%,6.5%] | 0.151 |
| **Post-Procedure** | | | | | |
| Aspirin | 93.3% (556/596) | 93.8% (558/595) | 93.5% (1114/1191) | -0.5% [-3.3%,2.3%] | 0.814 |
| Clopidogrel | 91.0% (543/597) | 91.3% (544/596) | 91.1% (1087/1193) | -0.3% [-3.5%,2.9%] | 0.919 |
| Ticlopidine | 3.9% (23/597) | 4.0% (24/596) | 3.9% (47/1193) | -0.2% [-2.4%,2.0%] | 0.883 |
| Aspirin and (Clopidogrel or Ticlopidine) | 92.8% (554/597) | 93.3% (556/596) | 93.0% (1110/1193) | -0.5% [-3.4%,2.4%] | 0.820 |
| **At Discharge** | | | | | |
| Aspirin | 97.8% (583/596) | 99.2% (590/595) | 98.5% (1173/1191) | -1.3% [-2.7%,0.0%] | 0.094 |
| Clopidogrel | 96.5% (575/596) | 96.5% (574/595) | 96.5% (1149/1191) | 0.0% [-2.1%,2.1%] | 1.000 |
| Ticlopidine | 3.5% (21/596) | 3.4% (20/595) | 3.4% (41/1191) | 0.2% [-1.9%,2.2%] | 1.000 |
| Aspirin and (Clopidogrel or Ticlopidine) | 97.8% (583/596) | 99.0% (589/595) | 98.4% (1172/1191) | -1.2% [-2.6%,0.2%] | 0.164 |
| **At 30-Days** | | | | | |
| Aspirin | 97.3% (572/588) | 96.4% (563/584) | 96.8% (1135/1172) | 0.9% [-1.1%,2.9%] | 0.409 |
| Clopidogrel | 94.4% (555/588) | 93.5% (546/584) | 93.9% (1101/1172) | 0.9% [-1.8%,3.6%] | 0.542 |
| Ticlopidine | 3.8% (22/585) | 3.4% (20/583) | 3.6% (42/1168) | 0.3% [-1.8%,2.5%] | 0.875 |
| Aspirin and (Clopidogrel or Ticlopidine) | 95.4% (561/588) | 94.2% (552/586) | 94.8% (1113/1174) | 1.2% [-1.3%,3.7%] | 0.361 |
| **At 6-Month** | | | | | |
| Aspirin | 96.9% (561/579) | 94.7% (549/580) | 95.8% (1110/1159) | 2.2% [-0.1%,4.5%] | 0.079 |
| Clopidogrel | 65.5% (377/576) | 62.9% (365/580) | 64.2% (742/1156) | 2.5% [-3.0%,8.0%] | 0.391 |
| Ticlopidine | 2.1% (12/569) | 2.3% (13/571) | 2.2% (25/1140) | -0.2% [-1.9%,1.5%] | 1.000 |
| Aspirin and (Clopidogrel or Ticlopidine) | 64.8% (375/579) | 61.9% (359/580) | 63.3% (734/1159) | 2.9% [-2.7%,8.4%] | 0.330 |
| **At 9-Month** | | | | | |
| Aspirin | 94.5% (551/583) | 92.9% (539/580) | 93.7% (1090/1163) | 1.6% [-1.2%,4.4%] | 0.279 |
| Clopidogrel | 46.1% (268/581) | 42.1% (244/579) | 44.1% (512/1160) | 4.0% [-1.7%,9.7%] | 0.174 |
| Ticlopidine | 0.7% (4/581) | 1.9% (11/577) | 1.3% (15/1158) | -1.2% [-2.5%,0.1%] | 0.074 |
| Aspirin and (Clopidogrel or Ticlopidine) | 43.1% (251/583) | 40.3% (234/580) | 41.7% (485/1163) | 2.7% [-3.0%,8.4%] | 0.372 |
| **At 12-Month** | | | | | |
| Aspirin | 94.4% (538/570) | 91.8% (525/572) | 93.1% (1063/1142) | 2.6% [-0.3%,5.5%] | 0.102 |
| Clopidogrel | 33.0% (188/570) | 32.5% (186/572) | 32.7% (374/1142) | 0.5% [-5.0%,5.9%] | 0.900 |
| Ticlopidine | 0.2% (1/565) | 0.4% (2/568) | 0.3% (3/1133) | -0.2% [-0.8%,0.4%] | 1.000 |
| Aspirin and (Clopidogrel or Ticlopidine) | 29.5% (168/570) | 29.0% (166/572) | 29.2% (334/1142) | 0.5% [-4.8%,5.7%] | 0.897 |
| **At 24-Month** | | | | | |
| Aspirin | 91.5% (520/568) | 92.3% (519/562) | 91.9% (1039/1130) | -0.8% [-4.0%,2.4%] | 0.663 |
| Clopidogrel | 16.7% (94/563) | 17.3% (96/555) | 17.0% (190/1118) | -0.6% [-5.0%,3.8%] | 0.811 |
| Ticlopidine | 0.0% (0/558) | 0.2% (1/551) | 0.1% (1/1109) | -0.2% [-0.5%,0.2%] | 0.497 |
| Aspirin and (Clopidogrel or Ticlopidine) | 11.4% (65/569) | 13.5% (76/562) | 12.5% (141/1131) | -2.1% [-5.9%,1.8%] | 0.322 |
| **At 36-Month** | | | | | |
| Aspirin | 88.8% (494/556) | 89.4% (489/547) | 89.1% (983/1103) | -0.5% [-4.2%,3.1%] | 0.773 |
| Clopidogrel | 14.0% (77/551) | 13.8% (75/545) | 13.9% (152/1096) | 0.2% [-3.9%,4.3%] | 0.931 |
| Ticlopidine | 0.2% (1/552) | 0.2% (1/544) | 0.2% (2/1096) | -0.0% [-0.5%,0.5%] | 1.000 |
| Aspirin and (Clopidogrel or Ticlopidine) | 8.6% (48/557) | 9.1% (50/548) | 8.9% (98/1105) | -0.5% [-3.9%,2.8%] | 0.833 |

ITT population is all subjects who met the study entry criteria, signed the written informed consent and were randomized. Four (4) of the 1,197 patients were randomized but did not undergo a procedure and no data was collected on these patients.
N = the number of randomized patients, denominators indicate the total number of patients with available data for related parameter.

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## Table 26. Summary of Device Performance

| | ENDEAVOR II | |
|---|---|---|
| **Performance Malfunction Description** | **Endeavor DES** | **Driver** |
| **Stent delivery failure** | **2** | **2** |
| Delivery, first attempt only | 0 | 1 |
| Delivery, never delivered | 2 | 1 |
| **Other malfunction** | **1** | **2** |
| Device Failure - Delivery Balloon | 0 | 1 |
| Device Failure - Stent Misplacement | 1 | 1 |
| **Outcome if delivery failure or device malfunction** | **3** | **4** |
| Associated AE | 0 | 1 |
| Failed stents all withdrawn | 2 | 2 |
| Stent deployed at unintended site | 1 | 1 |
| Stent embolized | 0 | 0 |
| **Treatment if stent never delivered** | **2** | **1** |
| Non-study stent | 0 | 0 |
| PTCA only | 2 | 1 |
| CABG | 0 | 0 |

**Table 27. Narrative Summaries of Device Performance**

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | **DRIVER** | **Device Performance Malfunction–Delivery, First Attempt Only** |
| | | | On 1/7/2004 the patient underwent the index procedure with pre-treatment balloon angioplasty. There was an unsuccessful attempt to cross the lesion in the distal CX with the assigned DRIVER stent and it was withdrawn. An unassigned stent was deployed to a lesion in the proximal CX followed by successful delivery of one assigned DRIVER stent in the distal CX (target lesion). The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "two lesions treated in the same vessel." The post-procedure course was uncomplicated and the patient was discharged on 1/8/2004 on ASA and clopidogrel. |
| | | **ENDEAVOR DES** | **Device Performance Malfunction–Never Delivered** |
| | | | On 10/2/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty. Post-dilation there was a site reported grade B dissection followed by an unsuccessful attempt to cross the lesion in the proximal RCA with the assigned DRIVER stent due to "significant" calcification, therefore it was withdrawn. The patient underwent successful balloon angioplasty in the proximal RCA. Tirofiban was administered and there were no clinical sequelae. The site reported a 0% final residual stenosis with a grade A dissection and TIMI 3 flow. The Angiographic Core Lab reported the "original CD" of the index procedure could not be copied; therefore no reading is forthcoming. The post-procedure course was uncomplicated and the patient was discharged on 10/7/2003 on ASA and clopidogrel. |
| | | **DRIVER** | **Device Performance Malfunction–Never Delivered** |
| | | | On 12/5/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty and attempted delivery of one assigned DRIVER stent; however attempts to cross the lesion in the distal RCA were unsuccessful and the device was withdrawn. Eptifibatide was administered. The site reported "suboptimal" results with a 60% final residual stenosis. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "PTCA only without stent deployment." There were no clinical sequelae. The post-procedure course was uncomplicated and the patient was discharged on 12/8/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | **ENDEAVOR DES** | **Device Performance Malfunction–Never Delivered** |
| | | | On 10/23/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty and attempted delivery of the DRIVER stent in the 1st OM; however attempts to place two separate DRIVER stents in the 1st OM were unsuccessful and the devices were withdrawn. Balloon angioplasty was performed. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/24/2003 on ASA and clopidogrel. |
| | | **DRIVER** | **Device Performance Malfunction–Stent Misplacement** |
| | | | On 10/27/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of one DRIVER stent in the distal CX. According to the Cardiac Catheterization Report there was a "considerable inspiration" by the patient which caused a shift of the stent to the proximal CX, therefore a second study stent was placed distal to and abutting the first stent. There were no clinical sequelae. The Angiographic Core Lab reported an 8% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/27/2003 on ASA and clopidogrel. |
| | | **ENDEAVOR DES** | **Device Performance Malfunction–Stent Misplacement** |
| | | | On 11/21/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of one DRIVER stent in the 1st OM. A narrative reported that the stent was placed "too far distally so a second study stent was placed proximal to and abutting the first stent." There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/21/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Device Performance Malfunction–Balloon Rupture** |
| | | | On 11/28/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty; however during stent deployment at 14 atm, the site reported a balloon rupture and abrupt closure with no dissection and TIMI 0 flow. The Angiographic Core Lab reported "no reflow following stent deployment." The patient experienced recurrent angina and ECG changes consistent with ischemia followed by cardiac arrest which was successfully treated with implantation of a temporary pacemaker with a return to normal sinus rhythm and TIMI 3 flow. One DRIVER stent was placed in the distal CX. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK was 47 and the CKMB was elevated at 12 (nl 10, ratio 1.2). The CK peaked approximately 8 hours post-procedure at 82 (nl 174, ratio <1) with a CKMB of 24 (nl 10, ratio 2.4). The ECG Core Lab reported new, persistent, major inferolateral T wave inversions and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 12/2/2003 on ASA and clopidogrel. |

## Table 28. Narrative Summaries of Major Adverse Cardiac Events

The narratives presented below are sorted by patient ID in the hierarchical order of MACE (Cardiac Death, Non-Cardiac Death, Q wave MI, Non-Q wave MI, Emergent CABG, Target Lesion Revascularization). All deaths regardless of time from procedure are reported.

Cerebrovascular Accidents have also been narrated for this study; these narratives are presented at the end of this section.

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 92 days post-procedure** |
| | | | The patient was a 74 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class II stable angina and a positive functional ischemia study. On 8/25/2003 he underwent the index procedure with pre-treatment balloon angioplasty and the delivery of one assigned stent in the mid RCA. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/27/2003 on ASA and clopidogrel. A narrative reported the patient "defaulted" for a planned staged procedure to the LAD (10/19/2003 & 11/9/2003). On 11/25/2003 the patient was rehospitalized for chest pain with site reported ischemic ECG changes with ST elevation in V 1-4 and chest pain unrelieved with nitroglycerin. The patient became unresponsive shortly after admission at 08:59 to the ER with a wide complex tachycardia on the monitor. CPR was initiated and epinephrine, atropine, amiodarone, calcium, and defibrillation were administered but despite maximum resuscitative efforts he expired at 10:40 on 11/25/2003. A single CK on 11/25/2003 at 09:14 was 12814 (nl 218, ratio 59) and the CKMB was not performed. The ECGs are not available per site. The site reported a Q wave MI with the notation "acute anterior ST elevation" MI. On 12/15/2004 the CEC ruled the event met criteria consistent with a non-target vessel Q wave MI. A Study Exit Form reported the patient died of myocardial infarction and the Coroner's Report indicates that the cause of death was ischemic heart disease. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 276 days post-procedure, Target Lesion Revascularization–PTCA 244 days post-procedure**<br>The patient was a 72 year-old man with a history of hypertension and premature CAD in a first degree relative who presented with CCS Class II stable angina. On 9/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/11/2003 on ASA and clopidogrel. The site reported clopidogrel was stopped on 2/10/2004 per protocol. A narrative reported the patient was rehospitalized on 5/11/2004 with "severe chest pain." The ECG Core Lab reported on an ischemic ECG on 5/11/2004 was not interpretable due to missing precordial leads on the submitted tracing. A protocol re-study on 5/11/2004 with a positive functional ischemia study revealed a total occlusion with presence of thrombus and TIMI 0 flow reported by the Angiographic Core Lab with the notation "no PCI was done to open the stenosis." There were no cardiac enzyme elevations per site. On 5/11/2004 there was a site reported repeat revascularization with cutting balloon angioplasty of the proximal LAD. On 11/17/2004 the CEC ruled the event on 5/11/2004 did not meet the criteria for a late stent thrombosis. On 6/12/2004 the patient was found dead at home from an “unknown” cause. The site reported the probable cause of death was “heart failure.” The site reported that no autopsy was performed and no death certificate is available. On 9/9/2004 the CEC ruled the event met the criteria for a cardiac death. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | ENDEAVOR DES | **Cardiac Death 175 days post-procedure**<br>The patient was a 61 year-old man with a history of smoking, hypertension, premature CAD in a first degree relative, and a MI in 1995 who presented with Braunwald Class I unstable angina and a positive functional ischemia study. On 12/15/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/16/2003 on ASA and clopidogrel. On 2/10/2004 the patient was hospitalized after he fell at home due to "vertigo" and was diagnosed with a cerebral concussion with head wound. A Narrative reported an EEG showed right-sided temporal dysrhythmia. He was treated medically for "arterial hypertension." On 6/7/2004 the patient apparently died at home "in his sleep." The Study Exit Form reported the official cause of death is "probably sudden death" and noted that no autopsy was performed and no death certificate is available. |
| | | DRIVER | **Cardiac Death 38 days post-procedure**<br>The patient was a 65 year-old man with a history of hypertension who presented with a MI on 11/2/2003. On 11/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty and successful delivery of one assigned stent in the mid RCA. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/8/2003 on ASA and clopidogrel. On 12/7/2003 the patient was rehospitalized at a non-enrolling facility for dyspnea in the absence of recurrent angina. The CK peaked at 64 (nl 174, ratio <1) with a CKMB of 6.1 (nl 7, ratio <1). No ECGs are available per query response. He was treated with diuretics; however, on 12/15/2003 the patient experienced an acute episode of dyspnea and subsequently expired on 12/15/2003. The site reported the official cause of death as acute respiratory insufficiency. No autopsy was performed and no further information is forthcoming per query response. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | ENDEAVOR DES | **Cardiac Death, Cardiac Tamponade 1 day post-procedure, Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis day of procedure** |
| | | | The patient was a 52 year-old woman with a history of current smoking, dyslipidemia and premature CAD in a first degree relative who presented with CCS Class IV unstable angina. On 9/1/2003 she underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by the delivery of one assigned stent in the mid RCA. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported a 45% final residual in-lesion stenosis, no thrombus, no perforation or dissection and TIMI 3 flow with the notation "linear haziness, very faint, after stenting in baseline film." About 30 minutes post-procedure the patient experienced recurrent chest pain with ST elevation and was brought back to the Cardiac Catheterization Lab. Repeat angiography on 9/1/2003 for recurrent chest pain without a functional ischemia study revealed a 100% occlusion and a spiral dissection from the distal end of the stent in the mid RCA reported on a discharge narrative. The Angiographic Core Lab reported a total occlusion of the mid RCA without thrombus. The patient underwent emergent revascularization with placement of a total of three non-study stents in the mid RCA and distal RCA. The patient was transferred to the CCU and tirofiban was initiated. The pre-procedure CK and CKMB were 55 and 5 respectively. About 16 hours post-procedure the CK peaked at 1119 (nl 170, ratio 6.6) with a CKMB of 119 (nl 25, ratio 4.8). The site reported a Q wave MI. The ECG Core Lab reported new intermittent inferoposterior ST elevations, new intermittent RV4 ST elevations, new persistent anterolateral/apical ST elevations, inferior ST elevations, intermittent hyperacute inferior T waves, intermittent inferolateral T wave inversions and new inferior Q waves. It further noted "fluctuation of widths and magnitudes of pre-existing inferior Q waves plus loss of anterior R waves." About midnight that evening the patient developed electromechanical dissociation. An emergent echocardiogram revealed a cardiac tamponade however pericardiocentesis did not improve the circulatory status. Despite maximum efforts the patient subsequently expired on 9/2/2003. The autopsy report noted a "recent anterior wall myocardial infarction with rupture of the right ventricle." There was a "heart tamponade with a fresh blood clot of 500 cc." The report listed the direct cause of death as heart tamponade. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 663 days post-procedure**<br>The patient was a 49 year-old man with a history of dyslipidemia, hypertension, and a MI on 11/23/2003 who presented with MI and Braunwald Class II C angina. On 12/1/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/2/2003 on ASA and clopidogrel. An Autopsy Summary indicates the patient complained of chest pain at home on 9/24/2005 and suffered a cardiac arrest while on route to the hospital in the ambulance. CPR was initiated however he could not be resuscitated. Query responses indicate that cardiac enzymes were not done and ECGs are not available. The Summary reported the cause of death was myocardial ischemia and coronary artery atherosclerosis. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 960 days post-procedure, Target Vessel Revascularization–PTCA 826 days post-procedure**<br>The patient was a 68 year-old man with a history of MI on 11/24/2003, CABG surgery to a non-target vessel, diabetes, dyslipidemia, and hypertension who presented with CCS Class III unstable angina. On 12/19/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent [Driver] in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal LAD with a 35% final residual in-lesion stenosis with no dissection, TIMI 3 flow, and spasm present. The post-procedure course was uncomplicated and the patient was discharged on 12/20/2003 on ASA and clopidogrel. Repeat angiography on 3/3/2006 for recurrent angina and without a positive functional ischemia study revealed a site reported widely patent LAD stent and "blocked vein grafts." The Angiographic Core Lab reported a 46% in-lesion restenosis and noted moderate late lumen loss and no PCI. The site reported no intervention was performed on the date of the angiography due to recurring episodes of severe epistaxis and "disordered clotting." Clopidogrel was stopped on 3/8/2006 and resumed on 3/21/2006. On 3/24/2006 the patient subsequently underwent repeat revascularization with balloon angioplasty of the ostial LAD with stent placement in the LMCA and the proximal CX. The Angiographic Core Lab reported a 42% in-lesion restenosis and noted a lesion in the left main/LAD/CX bifurcation proximal to the study stent with the comment remote target vessel revascularization of the ostial LAD and non-target vessel revascularization of the CX. The site also reported an IABP was placed following the revascularization and removed on 3/27/2006. No additional information about this event is available per a query response. According to a narrative the site reported the patient was hospitalized for dehydration on 7/7/2006. During this hospitalization he developed angina and symptoms of heart failure. He also continued to have episodes of severe epistaxis and clopidogrel was stopped on 7/16/2006 and restarted on 7/18/2006. On 7/28/2006 the site reported the patient sustained a non-Q wave MI. Per a query response the only cardiac enzymes measured were troponin levels and source documentation does not report CK or CKMB results. A troponin on 7/18/2006 was 0.058 (nl 0.01, ratio 5.8) and a troponin on 7/30/2006 was 0.455 (ratio 45.5). (cont) |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **(cont)**<br>The ECG Core Lab reported new major persistent anteroseptal ST depressions and no new Q waves and noted inadequate tracing quality with the comment poor ECG reproduction. Additionally during this hospitalization the narrative indicates on 8/5/2006 the patient was found in his hospital bed pulseless and cyanotic but was more alert when laid flat. An echocardiogram showed poor left and right ventricular function with no evidence of pericardial effusion or tamponade. His condition continued to deteriorate throughout the day and he became bradycardic with signs of "extreme" heart failure. Resuscitation was attempted; however despite the use of ACLS protocol the patient was pronounced dead at 15:30 on 8/5/2006. The official cause of death was reported as ischemic heart disease, diabetes, and renal failure and the categorical cause of death as cardiac. No autopsy was performed. Additional admission information was requested; however in a query response the site reported the submitted narrative information "is the discharge summary." |
| | | DRIVER | **Cardiac Death 498 days post-procedure, Target Lesion Revascularization–PTCA 245 days post-procedure**<br>The patient was an 84 year-old man with a history of hypertension who presented with Braunwald Class II unstable angina. On 9/15/2003 he underwent the index procedure with pre-treatment balloon angioplasty; however there was a site reported grade A dissection following pre-treatment. One assigned stent was delivered to the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/25/2003 on ASA and clopidogrel. A protocol re-study on 5/17/2004 without recurrent clinical symptoms and without a functional ischemia study revealed a 100% in-stent occlusion reported by the Angiographic Core Lab with the notation "complete occlusion of stent, type 4 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty; however the attempt to open the occlusion of the proximal CX was unsuccessful as reported by the site and confirmed by the Angiographic Core Lab. The patient was rehospitalized at a non-study hospital on 1/24/2005 for dyspnea. A Death Report noted the patient was diagnosed with acute heart failure and a non-ST elevation MI. The site confirmed that CK and CKMB results, and ECG tracings are not available. The patient's condition decompensated despite maximum medical efforts and he subsequently died on 1/25/2005 from MI, acute left ventricular heart failure and multiple organ failure. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | ENDEAVOR DES | **Cardiac Death 243 days post-procedure, Target Lesion Revascularization–CABG 242 days post-procedure**<br>The patient was a 78 year-old man with a history of hypertension and a MI on 10/2/2003 who presented with Braunwald Class III angina. On 10/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There was a site reported grade B dissection following pre-treatment. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/15/2003 on ASA and clopidogrel. On 5/27/2004 the patient was rehospitalized for progressive dyspnea. Repeat angiography on 5/27/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 95% in-lesion restenosis reported by the Angiographic Core Lab. According to the Surgical Report angiography revealed "high-grade stenosis in the flow of the LAD with occlusion of the RCA." The Report further reported mitral valve incompetence and suggested the occurrence of "acute ischemia during the last few days." The patient was judged to be an "extremely high operative risk;" however on 6/11/2004 the patient underwent CABG surgery with a SVG to the LAD, a SVG to the R-PDA and mitral valve reconstruction with a Carpentier-Edwards Physio-Ring. An IABP was inserted, a temporary pacemaker was applied and protamine was infused; however, "due to considerably restricted LV function and only marginally stable hemodynamics" the chest was left open and the patient was transferred to the CCU. The patient developed anuria and "absolute tachyarrhythmia" and on 6/12/2004 the patient expired. No autopsy was performed and the Study Exit Form listed the official cause of death as cardiac failure. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 873 days post-procedure** |
| | | | The patient was a 75 year-old woman with a history of prior PCI of a non-target vessel, diabetes, dyslipidemia, and hypertension who presented with CCS Class II angina. On 12/1/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the1st RPL. The Angiographic Core Lab reported on a lesion in the R-PAV and noted abrupt closure of the target vessel due to the straightening effect of the wire with TIMI 3 flow following removal of the wire and a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/3/2003 on ASA and clopidogrel. Repeat angiography on 11/19/2004 for recurrent clinical symptoms and without a positive functional ischemia study revealed a total occlusion of a lesion in the R-PAV with TIMI 0 flow reported by the Angiographic Core Lab. An Interventional Catheterization Report noted complete blockage of the stent. The site reported no intervention was performed because of the small size of the vessel and "conservative therapy" was initiated. On 4/21/2006 the patient had a follow up visit with her family doctor and had no complaints. On 4/22/2006 the patient died alone at home. The official cause of death is listed on the Study Exit Form as sudden death with an unknown categorical cause and no autopsy was done. The site confirmed that no further information is available. |
| | | ENDEAVOR DES | **Cardiac Death 628 days post-procedure** |
| | | | The patient was a 68 year-old man with a history of hypertension and a MI in 1999 who presented with CCS Class II stable angina and a positive functional ischemia study. On 10/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty. There was a site reported grade B dissection following pre-treatment. One assigned stent was delivered to the target lesion in the 2nd OM and a second assigned stent was placed distal to and overlapping the first stent to stabilize the lesion. The stents were post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 7% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. In response to a query a narrative reported the patient was rehospitalized on 6/29/2005 due to syncope and died later that day of sudden death. No autopsy was performed. The site confirmed a Discharge Letter was requested; however no additional information is available. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 134 days post-procedure**<br>The patient was a 69 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with a positive functional ischemia study. On 9/19/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/20/2003 on ASA and clopidogrel. On 1/31/2004 the site reported the patient collapsed at home and was transported to the ER where he became unconscious and suddenly developed apnea and asystole. CPR, defibrillation and medication were initiated but despite resuscitative efforts for a period about 30 minutes, the patient expired. The site reported that no cardiac enzymes or ECGs are available. A Study Exit Form reported the patient died on 1/31/2004 of acute myocardial infarction. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 493 days post-procedure**<br>The patient was a 78 year-old man with a history of hypertension and premature CAD in a first degree relative who presented with CCS Class II stable angina. On 9/29/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "linear haziness at proximal portion of stent--not a frank dissection." The post-procedure course was uncomplicated and the patient was discharged on 10/1/2003 on ASA and clopidogrel. A Discharge Summary reported on 12/24/2004 the patient collapsed with chest pain and presented to the ER of a non-study hospital was diagnosed with an "acute rear-wall infarction" with ST depression noted on the ECGs. The CK peaked on 12/25/2004 at 1001 (nl 171, ratio 5.9). The site reported a Q wave MI and confirmed the ECG tracings for 12/24/2004 were not provided by the non-study hospital. The CEC ruled the event met the criteria for a non-target vessel non-Q wave MI. On 12/28/2004 the patient was transferred to the investigational institution. Repeat angiography on 12/29/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 21% in-lesion restenosis reported by the Angiographic Core Lab. A Discharge Summary reported a 70% stenosis of the LAD, a 90% lesion of the 1st diagonal, and RCA closure. The patient underwent unsuccessful revascularization of the proximal RCA and a perforation was noted. Protamine was required which resulted in a total occlusion. On 12/30/2004 there was a re-elevation of CK to 948 (nl 174, ratio 5.5); however the CKMB was not reported. Based on ECGs dated 12/28/2004 and 12/30/2004, the ECG Core Lab reported the ECGs were uninterpretable for new MI due to LBBB. The CEC ruled the event met the criteria for a non-target vessel non-Q wave MI. Repeat angiography at a non-study hospital on 1/10/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 33% in-lesion restenosis reported by the Angiographic Core Lab with the notation of moderate neointimal hyperplasia. No revascularization was performed at this time and he was subsequently discharged to a rehabilitation facility. On 1/31/2005 the patient was transferred from a rehabilitation facility to the study site due to an acute gastroenteritis and a deterioration of his condition. The Discharge Summary reported a single CK value drawn at a non-study site on 1/31/2005 [no time given] of 303 (nl unk, ratio unk) and no CKMB was done. It also noted that the ECG showed a complete left bundle branch block and ST abnormalities in V4, V5 and V6 with ST elevations in the area of lead III and AVF. A query response confirmed that no ECGs were provided by the non-study hospital; therefore the ECG Core Lab report is not available. During the hospitalization the patient developed pneumonia and acute renal failure. Despite maximum medical treatment he died of heart failure on 2/3/2005 at 05:00. The site reported that it was unknown if an autopsy was performed. The CEC ruled the event met the criteria for a Cardiac Death. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Cardiac Death 681 days post-procedure**<br>The patient was a 63-old man with a history of dyslipidemia, hypertension and a MI in 1991 who presented without angina and without a positive functional ischemia study. On 11/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/12/2003 on ASA and clopidogrel. In a narrative the site reported that the patient suffered an episode of ventricular fibrillation while on holiday. An ER physician began cardiopulmonary resuscitation and the patient was transferred to a hospital; however resuscitative efforts were not successful and he expired on 09/22/2005 at 14:07. No autopsy was performed and no death certificate is available. The site reported that the categorical cause of death was cardiac and the official cause of death as ventricular fibrillation, unsuccessful cardiopulmonary resuscitation. |
| | | ENDEAVOR DES | **Cardiac Death 872 days post-procedure**<br>The patient was an 82 year-old woman with a history of hypertension who presented with Braunwald Class I B angina. On 1/8/2004 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/9/2004 on ASA and clopidogrel. During March 2004 the patient was hospitalized for dyspnea and treated with diuretics. The site reported that on 5/29/2006 the patient died while in a nursing home from left sided heart failure and dementia and further reported the categorical cause of death is cardiac. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Cardiac Death 510 days post-procedure**<br>The patient was a 72 year-old man with a history of current smoking, diabetes, hypertension, percutaneous revascularization and CABG surgery of non-target vessels who presented with CCS Class III unstable angina. On 10/27/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by delivery of one assigned stent in the 1st OM. The stent was post-dilated. The post-procedure course was uncomplicated and the patient was discharged on 10/29/2003 on ASA and clopidogrel. A query response reported that the patient was rehospitalized for progressive heart failure, pneumonia and sepsis. A Death Report dated 3/24/2005 indicated that the patient was rehospitalized due to a progressive left groin infection after a repeat angiography in 6/2004 and reported death was secondary to septic cardiovascular failure, left lung pneumonia, biventricular cardiac decompensation and severe generalized arteriosclerosis. The site reported that on 3/20/2005 the patient died of cardiopulmonary insufficiency with a categorical cause of death cardiac. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Cardiac Death 390 days post-procedure, Target Vessel Revascularization–CABG 379 days post-procedure, Target Vessel Revascularization–PTCA 289 days post-procedure** |
| | | | The patient was a 79 year-old man with a history of MI in 9/2003, dyslipidemia, hypertension and former smoking who presented with CCS Class I stable angina. On 10/29/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/31/2003 on ASA, clopidogrel and enoxaparin sodium. As part of a staged procedure, repeat angiography on 8/13/2004 in the absence of recurrent angina or a positive functional ischemia study revealed a 36% in-lesion restenosis reported by the Angiographic Core Lab. A Cardiac Catheterization Report noted a high-grade stenosis of the diagonal branch at its origin at the LAD; middle-grade stenosis of the LAD itself at the origin of the diagonal branch, and high-grade stenosis of the proximal LAD prior to the proximal end of the study stent. The patient underwent repeat revascularization with placement of one stent in the diagonal branch and one stent in the proximal LAD overlapping the proximal end of the study stent per site. On 11/5/2004 the patient was rehospitalized for evaluation of three vessel coronary disease. A planned repeat angiography on 11/8/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 29% in-lesion restenosis reported by the Angiographic Core Lab. The translated Discharge Summary reported a 70% in-stent restenosis of the RCA, a 70% main-stem stenosis, and a 90% stenosis of the 1st diagonal. No revascularization was performed at this time. On 11/9/2004 the patient was transferred to the investigational institution for cardiac surgery. On 11/11/2004 the patient underwent an ablation of the left atrial endocardium and CABG surgery with a LIMA to the mid LAD, an ACVB [aorto-coronary-venous-bypass] to the 1st OM, and an ACVB to the R-PDA. An Operative Report dated 11/21/2004 indicates the patient underwent emergent re-thoracotomy for post-CABG mediastinitis; however despite treatment the patient died on 11/22/2004. The site reported the categorical cause of death as non-cardiac and the official cause of death was post-operative mediastinitis. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Cardiac Death 750 days post-procedure**<br>The patient was a 74 year-old man with a history of hypertension who presented without angina or a functional ischemia study. On 12/23/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/27/2003 on ASA and clopidogrel. The site reported the patient died of unknown cause on 1/11/2006. No autopsy was performed and the categorical cause of death is unknown. In a query response to a request for a narrative explaining source of information concerning the patient's death the site confirmed no additional information is available. The CEC ruled the event met the criteria for a cardiac death based on the available information. |
| | | DRIVER | **Cardiac Death 499 days post-procedure**<br>The patient was a 47 year-old man with a history of smoking and dyslipidemia who presented with Braunwald Class II unstable angina. On 11/19/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by delivery of one assigned stent in the mid RCA. Post-stenting balloon angioplasty was performed. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. A narrative reported that the patient's hospital stay was prolonged due to pulmonary edema and an elevated troponin level which peaked at 0.191 (nl 0.1, ratio 1.9). He was discharged on 11/23/2003 on ASA and clopidogrel. A Discharge Summary indicates that the patient underwent multiple rehospitalizations for pulmonary edema and was again rehospitalized on 3/19/2005. On 3/20/2005 he underwent a cardiac transplant. The patient was extubated post-surgery and was feeling well; however on 3/21/2005 he developed severe hemodynamic collapse with bradycardia and was subsequently brought back to the operating room where a blood clot was removed from the posterior wall of the left ventricle. The patient's condition did not improve and he subsequently suffered severe multiple organ failure. Despite maximum efforts he expired on 4/1/2005. No autopsy was performed and the site reported heart transplant failure as the official cause of death. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Cardiac Death 560 days post-procedure, Non-Q wave MI 538 days post-procedure, Target Lesion Revascularization–PTCA 541 days post-procedure** |
| | | | The patient was a 56 year-old woman with a history of diabetes, dyslipidemia, hypertension, a percutaneous revascularization of a non-target vessel, and a MI on 3/25/2002 who presented with CCS Class IV unstable angina. On 12/15/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 36% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated with an increased creatinine to 3.3 mg % and the patient was discharged on 12/24/2003 on ASA and clopidogrel. On 6/5/2005 the patient was rehospitalized with a site reported acute anterior wall MI with a troponin elevation to 13.3 (nl 0.1, ratio 133). The CK peaked on 6/5/2005 at 13:37 at 606 (nl 220, ratio 2.8) and the CKMB was not performed. The site reported a Q wave MI. The ECG Core Lab reported a new anterior MI with loss of R waves, age undetermined; new since the 12/24/2003 latest reference ECG. It further reported the ECG tracing quality was inadequate due to severe artifact, lead misplacement, variation in precordial lead placement and noted poor persistent R wave progression and noted that original copies of the tracings were not available for review "despite request." After reviewing the submitted ECG tracings the CEC ruled the event met the criteria for a non-Q wave MI. Repeat angiography on 6/8/2005 for recurrent clinical symptoms without a functional ischemia study revealed an in-stent total occlusion reported by the Angiographic Core Lab. The site reported a total occlusion of the distal edge of the target lesion. The patient underwent successful balloon angioplasty with placement of a CYPHER™ stent of the proximal LAD and was discharged on 6/19/2005. After review of the cine films, the CEC concluded that this was not a definite late stent thrombosis. Their rationale was: (1) there was normal flow through the stent and into a septal branch at the distal stent edge; (2) there was slow flow beyond the stent; and (3) review of the subsequent intervention suggested the culprit stenosis/occlusion was distal to the stent. The patient was rehospitalized on 6/21/2005. A narrative on the Study Exit Form indicates following a catheterization the patient developed a femoral thrombosis which required an embolectomy. She developed sepsis and subsequently died on 6/27/2005. No autopsy was performed. Sepsis is reported as the official cause of the cardiac death. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Cardiac Death 182 days post-procedure**<br>The patient was a 71 year-old woman with a history of current smoking, diabetes, dyslipidemia, hypertension and a MI on 8/15/2003 who presented with MI and CCS Class II stable angina. On 10/9/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/13/2003 on ASA and clopidogrel. The site reported that the patient went to bed without complaints and on 4/8/2004 she was found dead in bed at home. No autopsy was performed. The Study Exit Form reported the official cause of the "non-cardiac" death was pulmonary embolism. The site reported that the cause of death was established by the physician "based on visual assessment" and confirmed that no additional information is available. On 12/15/2004 the CEC ruled the event met the criteria for a cardiac death. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Cardiac Death 291 days post-procedure**<br>The patient was a 53 year-old woman with a history of MI on 8/18/2003, hypertension and dyslipidemia who presented with CCS Class III angina. On 10/22/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal CX. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/24/2003 on ASA and clopidogrel. A protocol re-study on 8/4/2004 in the absence of recurrent angina and without a positive functional ischemia study revealed a 22% in-lesion restenosis reported by the Angiographic Core Lab with the notation "stent is patent; no in-stent restenosis; no procedure was done on this follow-up." In a query response the Core Lab further confirmed that there was "no evidence of stent fracture seen." The discharge Information Sheet reported no "progression of the lesions in the coronary arteries." The patient's husband reported that the patient died on 8/8/2004. In a query response the site reported the patient was rehospitalized on 8/8/2004 for "sternocardial pain and anxiety" and died at 16:35 that same day. There was no history of a fall or "any kind of accident." Stat CKMB and troponin T levels drawn at 16:01 were 1.65 (nl 4.94, ratio <1) and 0.01 (nl 0.03, ratio <1) respectively. The ECG Core Lab determined that ECG tracings submitted for 8/8/2004 were "not interpretable." No Discharge Summary was submitted. An autopsy listed extensive sclerosis of the left coronary artery with stent and noted "rupture of the proximal section of the stent and interruption of the flow in the coronary artery," post-infarction scarring 5 X 4 cm of the anterior left ventricular wall and a 1.5 cm area of the "paracentral section of the apex." It also noted distention of the ventricles, degeneration of heart muscles, passive hemorrhage of the lunges and other internal organs. The site reported the official cause of death was Acute Coronary Syndrome. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Cardiac Death 229 days post-procedure** |
| | | | The patient was a 52 year-old man with a history of dyslipidemia and current smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 12/4/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. A second assigned stent was placed distal to and overlapping the first assigned stent as treatment for a site reported grade A distal dissection. The Angiographic Core Lab reported a 28% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/5/2003 on ASA and clopidogrel. On 7/20/2004 the patient died. The site reported a "sudden death, unknown cause." An autopsy was not performed. A narrative reported that the patient's private physician was not involved in the patient's care at the time of death. No further information will be forthcoming. |
| | | DRIVER | **Non-cardiac Death 1016 days post-procedure** |
| | | | The patient was a 47 year-old man with a history of MI in 6/2001, prior PCI of the target vessel, diabetes, dyslipidemia, hypertension, and current smoking who presented with CCS Class II angina. On 9/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 38% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/12/2003 on ASA and clopidogrel. Throughout the follow-up period it was documented that the patient was non-compliant with medications and MD visits and was lost to follow up for a period of time in 2004. Protocol re-study on 5/3/2004 revealed a 55% focal body in-stent restenosis reported by the Angiographic Core Lab and no intervention was performed. Multiple hospitalizations were documented beginning in 12/2004 for COPD exacerbation and continuing through 2005 and 2006 for CHF, CRF, and fluid overload. In March 2006 he was hospitalized for ischemic cardiomyopathy and in April and May 2006 for End Stage Renal Disease. During the May 2006 hospitalization he refused dialysis and hospice care. He was transferred to a hospice facility on an unknown date where he continued to refuse dialysis and subsequently died on 6/22/2006. A Death Certificate lists the cause of death as end stage renal failure. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 1053 days post-procedure**<br>The patient was a 64 year-old woman with a history of MI on 12/14/2003, diabetes, dyslipidemia, and hypertension who presented with CCS Class III angina. On 1/12/2004 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 36% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/13/2004 on ASA and clopidogrel. On 11/30/2006 the site reported the patient died while in the hospital at a non-study site. The site reported the categorical cause of death is listed as non-cardiac and the official cause of death is ischemic bowel. A Discharge Summary was requested; however in the query response the site submitted the Death Certificate, which listed ischemic bowel as the cause of death. No autopsy was performed. |
| | | DRIVER | **Non-cardiac Death 774 days post-procedure, Stroke 773 days post-procedure**<br>The patient was a 79 year-old man with a history of hypertension and current smoking who presented without angina and unknown functional ischemia study results. On 12/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 40% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/19/2003 on ASA and clopidogrel. A translated Discharge Summary states the patient was admitted to the hospital on 1/29/2006 with a principal diagnosis of pneumonia and an additional diagnosis of a brain stem stroke. The patient was reported to be drowsy on admission with weakness noted in all limbs and with a question of a bilateral facial droop. A CT of the brain showed no obvious infarct or hemorrhage. The site reported the following deficits were permanent: decreased level of consciousness, cranial nerve/facial, sensory, coordination and motor. The Report further states that comfort measures were started and the patient stopped breathing and was declared dead on 1/30/2006. No autopsy was performed. The categorical cause of death was listed as non-cardiac and the official cause of death was reported as pneumonia, brainstem stroke, and sick sinus syndrome. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 978 days post-procedure**<br>The patient was a 62 year-old woman with a history of dyslipidemia, percutaneous revascularization of a non-target vessel, and a MI on 12/6/2003 who presented with CCS Class IV angina. On 12/9/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab noted a grade B dissection of the target lesion after pre-dilation and reported on a lesion in the ramus with a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/10/2003 on ASA and clopidogrel. The patient was rehospitalized for hemoptysis and diagnosed with probable small cell lung carcinoma in September 2005. On 8/13/2006 she died and no autopsy was performed. A Death Certificate listed the official cause of death as probable small cell carcinoma of the lung. No additional details were provided. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 740 days post-procedure**<br>The patient was a 75 year-old woman with a history of diabetes, dyslipidemia, premature CAD in a first degree relative, and CABG surgery of a non-target vessel who presented with a MI on 1/6/2004. On 1/7/2004 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. The site reported a 0% final residual stenosis. The Angiographic Core Lab reported a 45% final residual in-lesion stenosis with no dissection and TIMI 3 flow. On 1/7/2004 at 07:55 the pre-procedure CK and CKMB were elevated at 425 (nl 190, ratio 2.2) and 46.5 (nl 9.3, ratio 5) respectively. Post-procedure on 1/7/2004 at 21:10 the CK peaked at 578 (ratio 3) with a decreased CKMB of 33.3 (ratio 3.6). The ECG Core Lab reported uninterpretable ECG tracings due to left bundle branch block. The CEC ruled the event met the criteria for a pre-procedure MI. The patient was discharged on 1/9/2004 on ASA and clopidogrel. In May 2005 source documentation indicates the patient was rehospitalized for a surgical laparotomy with a small bowel resection and bilateral oophorectomy for jejunal adenocarcinoma with widespread peritoneal involvement including bilateral ovarian metastases. A Discharge Summary reported the patient was rehospitalized on 6/10/2005 with chest pain. The site reported a NSTEMI with a troponin 0.1 (nl unk, ratio unk). A single CK of 42 (nl 190, ratio <1), drawn on 6/11/2005 was submitted and no CKMB was done. The ECG Core Lab reported the ECG tracings were uninterpretable due to LBBB, poor tracing quality and a variation in pre-cordial lead placement. The site reported "no thrombolytic criteria were met" and the patient was treated medically. The CEC ruled the event did not meet the criteria for a Protocol-defined MI. She was rehospitalized for palliative radiation in July 2005 and again on 12/28/2005 for a lower respiratory tract infection and aspiration pneumonia and was treated with IV antibiotics and given diuretics for fluid overload and CHF. She was discharged to hospice care on 1/05/2006 with a DNR status. She subsequently died on 1/16/2006 and the site reported the official cause of death as metastatic small bowel cancer. A Death Certificate listed the cause of death as aspiration pneumonia and CHF with additional causes listed as partial bowel obstruction secondary to cancer of the bowel, advanced metastatic cancer "adeno ca jejunum" and CHF with IHD. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 949 days post-procedure**<br>The patient was an 80 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class III unstable angina. On 11/13/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/14/2003 on ASA and clopidogrel. Protocol re-study on 7/21/2004 in the absence of recurrent angina or a functional ischemia study revealed a 22% in-lesion restenosis with the presence of thrombus and TIMI 3 flow reported by the Angiographic Core Lab with the notation of mild neointimal hyperplasia inside the stent and a proximal significant lesion. No intervention was performed. The site reported the patient died on 6/19/2006 while in a nursing home due to digestive cancer and acute renal failure. The official cause of death was listed as bony metastasis of colorectal cancer and the categorical cause of death was listed as non-cardiac. No autopsy was performed and in a query response the site confirms that no additional information is available regarding the patient's death. |
| | | DRIVER | **Non-cardiac Death 1055 days post procedure**<br>The patient was a 70 year-old man with a history of prior CABG in a non-target vessel, diabetes, dyslipidemia, and hypertension who presented with CCS Class III stable angina. On 10/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the distal RCA, revealing a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. Protocol re-study on 6/14/2004 in the absence of clinical symptoms or a functional ischemia study revealed a 31% in-lesion restenosis reported by The Angiographic Core Lab. No revascularization was performed. In October 2004 the patient experienced generalized pain. The patient had a history of poorly differentiated adenocarcinoma of the prostate, first diagnosed in 2001. A CT scan revealed a "flare-up" of a prostatic malignancy with extensive skeletal metastases. He underwent radiation, chemotherapy, and hormonal therapy. The patient died on 8/30/2006. The site reported the official cause of death was prostate cancer. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 642 days post-procedure** |
| | | | The patient was a 67 year-old man with a history of current smoking and dyslipidemia who presented with CCS Class I stable angina. On 11/19/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/21/2003 on ASA and clopidogrel. The patient was rehospitalized on 12/1/2004 with a right focal spasm involving an acute turning of his head and movement of his tongue to the right. This was associated with an inability to speak and twitching in both arms according to a translated Neurological Report on 12/10/2004. Following diagnostic studies, including a brain MRI he was diagnosed with bronchogenic carcinoma with brain metastasis and died on 8/22/2005. No autopsy was performed and the site reported bronchogenic carcinoma as the official cause of death. |
| | | ENDEAVOR DES | **Non-cardiac Death 565 days post-procedure** |
| | | | The patient was a 62 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class I stable angina. On 11/17/2003 the patient underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/18/2003 on ASA and clopidogrel. On 2/16/2004 the patient was hospitalized for "perianal bleeding" and an endoscopic examination was scheduled. On 6/23/2004 the patient was rehospitalized for occult rectal bleeding. The Discharge Summary noted a colonoscopy on 6/25/2004 revealed a "moderately differentiated [G2] adenocarcinoma" of the cecum. On 6/28/2004 the patient underwent a right hemicolectomy and implantation of a venous indwelling catheter system and port system. Coronary angiography and chemotherapy was planned. Repeat angiography on 7/15/2004 with an unknown clinical status revealed a 29% in-lesion restenosis reported by the Angiographic Core Lab. The event was judged to be remotely related to ABT-758 according to the sponsor; however the CEC ruled the event was not related to the device. The site reported the patient died of cancer on 6/4/2005. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **ENDEAVOR DES** | **Non-cardiac Death 262 days post-procedure, Stroke 261 days post-procedure** |
| | | | The patient was a 68 year-old man with a history of smoking, dyslipidemia and a CABG (date unknown) who presented without clinical symptoms. On 9/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient's admission was prolonged for an endoscopic surgical procedure and he was discharged on 9/24/2003 on ASA and clopidogrel. A Treatment Record reported relatives found the patient in a comatose state on 6/3/2004. The onset was unknown. He was examined in the ER and rehospitalized. The patient was found to be "deeply comatose" with no response to painful stimuli, spontaneous "twitching" of the right hand and legs, and fixed and dilated pupils. He was intubated and vented. A head CT on 6/3/2004 revealed moderate transentorial herniation, massive subdural hematoma with left midbrain displacement. The Study Exit Form indicates that the patient died from an intracerebral hemorrhage on 6/4/2004. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 905 days post-procedure**<br>The patient was a 63 year-old woman with a history of MI on an unknown date, dyslipidemia, and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 11/6/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the mid RCA with a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/8/2003 on ASA and clopidogrel. While hospitalized on 2/3/2006 for brachiocephalic artery stent placement, a chest X-ray produced abnormal findings and a CT of the thorax was done for "urgent suspicion" of a bronchial carcinoma. Plans were made for an inpatient admission in March 2006 for further diagnostic work-up. The site reported the patient was hospitalized from 3/13/2006 to 4/3/2006 for palliative radiotherapy and chemotherapy treatment. A translated Discharge Summary reported a diagnosis of non-small cell bronchial carcinoma of the upper lobe of the right lung with bone and liver metastases. The patient was discharged home with a plan to receive an additional cycle of chemotherapy treatments on an outpatient basis. The site reported the patient died on 4/29/2006 with the official cause of death listed as bronchogenic carcinoma and the categorical cause of death as non-cardiac. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 1048 days post-procedure**<br>The patient was a 62 year-old man with a history of former smoking, dyslipidemia, and hypertension who presented with CCS Class III unstable angina. On 10/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the 2nd OM with a 36% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/21/2003 on ASA and clopidogrel. The patient was rehospitalized on 8/19/2006 for treatment of bronchitis; however the site reported the patient's condition worsened. A Discharge Report noted the patient developed a NSTEMI on 8/25/2006. No cardiac enzymes were submitted for this date; however on 8/27/2006 at 07:19 there was a troponin elevation of 0.21 (nl 0.1, ratio 2.1). The first submitted CK on 8/27/2006 at 07:19 at a non-study hospital was 42 (nl 174, ratio <1) followed by daily decreases in CK of 30, 23, and 10. No CKMBs were performed and the site reported the ECGs are not available; therefore the ECG Core Lab report is not available. The CEC ruled the event did not meet the criteria for a Protocol MI. The site further reported that repeat angiography was not performed due to the patient's condition. The patient developed acute renal failure and subsequently died on 9/2/2006. No autopsy was performed and the site reported respiratory insufficiency was the official cause of the non-cardiac death. A Death Report noted the immediate cause of death as respiratory failure due to pneumonia with underlying conditions of COPD and pulmonary emphysema. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 1057 days post-procedure**<br>The patient was a 67 year-old man with a history of a MI on 10/23/2003, diabetes, hypertension, and current smoking who presented with CCS Class I angina. On 11/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/8/2003 on ASA and clopidogrel. Two hospitalizations were reported in 2005 for lung cancer. A translated Death Report notes the patient was admitted to the hospital on 9/23/2006 for respiratory problems and pneumonia and generalized decline in his condition with known bronchial carcinoma. His condition further deteriorated while hospitalized and he died on 9/29/2006 with diagnoses listed as pneumonia and metastasizing bronchial carcinoma. The site reported the categorical cause of death was non-cardiac. The official cause of death was listed as bronchial carcinoma and no autopsy was done. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 774 days post-procedure, Q wave MI day of procedure**<br>The patient was a 69 year-old man with a history of hypertension and a MI on 11/4/2003 who presented with CCS Class II stable angina. On 11/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty. Post-dilation there was a grade B dissection with a thrombotic occlusion of the PDA per Cardiac Catheterization Report. The Angiographic Core Lab noted the presence of a thrombus in the baseline lesion morphology. Abciximab was administered. Following pre-treatment one assigned stent was delivered in the proximal RCA with no improvement of the dissection. The site reported that while advancing the stent, the guidewire "dislocated several times." Two non-study stents were implanted in the mid and proximal segments of the RCA to treat the dissection but TIMI 2 flow persisted due to the presence of thrombus. There were no clinical sequelae. The Angiographic Core Lab reported the presence of a distal embolus with a 22% final residual in-lesion stenosis with no dissection and TIMI 2 flow with the notation a "dissection in the proximal RCA required additional stenting." The pre-procedure CK and CKMB were 1.3 and 0.73 respectively. Approximately 24 hours post-procedure the CK was 15.2 (nl 3.17, ratio 5) with a CKMB of 2.82 (nl 0.41, ratio 7).<br>The CK and CKMB continued to elevate and on 11/22/2003 the CK peaked at 31.1 (nl 3.17, ratio 10) with a CKMB of 4.29 (nl 0.41, ratio 11). The site reported a Q wave MI. The ECG Core Lab reported new, persistent, major ST-T changes of evolving acute inferior myocardial injury or infarction, intermittent inferior and RV ST elevations, intermittent anterolateral/apical T wave inversions and new inferior Q waves. The patient was discharged on 11/25/2003 on ASA and clopidogrel. Source documents revealed the patient had a prior history of left nephrectomy in 11/1995 due to renal cancer and underwent a prostatectomy in 2/1997 for cancer of the prostate. In November 2005 the patient was hospitalized for chemotherapy treatment for carcinoma of the femur. A translated Death Report notes the patient was hospitalized on an oncology ward beginning on 12/14/2005 for the diagnoses of metastasizing renal cell carcinoma with central and pulmonary metastases. He was transferred for palliative care on 12/20/2005 following termination of oncological therapy and died on 1/2/2006 after developing double pneumonia in addition to his tumor symptoms. The Death Report states an autopsy confirmed these findings and the official cause of death was listed as renal carcinoma and the categorical cause of death was non-cardiac. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 818 days post-procedure, Target Lesion Revascularization–PTCA 746 days post-procedure**<br>The patient was a 51 year-old man with a history of current smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, a MI on 10/26/1995 and percutaneous revascularization of the target vessel who presented with CCS Class III unstable angina. On 11/14/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the distal RCA with a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/15/2003 on ASA and clopidogrel. The patient was rehospitalized on 10/6/2005 for lung carcinoma and the site reported a CT revealed restenosis of the target lesion. Repeat angiography on 11/29/2005 without recurrent clinical symptoms and with a positive functional ischemia study revealed a 66% intra-stent restenosis reported by the Angiographic Core Lab. The site reported 70% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty of the distal RCA identified by the site as a target lesion revascularization. On 2/8/2006 the patient was transferred from a prolonged admission at a non-study facility with a diagnosis of left lung carcinoma with brain/spine metastases, paraneoplastic Guillain-Barre syndrome and suspected pneumonia. Despite antibiotic therapy he died on 2/9/2006. No autopsy was performed and the official cause of death is listed as global respiratory failure due to Guillain-Barre Syndrome and non-small cell lung cancer of the left lung. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 533 days post-procedure, Target Vessel Revascularization–PTCA 12 days post-procedure** |
| | | | The patient was a 75 year-old man with a history of dyslipidemia, hypertension and a MI in 1993 who presented with CCS Class III stable angina. On 12/2/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/3/2003 on ASA and clopidogrel. On 12/13/2003 the patient was rehospitalized with chest pain. Repeat angiography on 12/14/2003 for recurrent angina without a positive functional ischemia study revealed a site reported 60% renarrowing of the target lesion. The Angiographic Core Lab reported a 20% in-lesion renarrowing. The patient underwent successful repeat revascularization with balloon angioplasty of the 3rd diagonal and was discharged on 12/18/2003. The patient was rehospitalized on 5/8/2005 for global cardiac decompensation, COPD exacerbation, and a known ischemic cardiomyopathy according to a translated Medical Report. A Laboratory Report noted the CK on 5/9/2005 at 09:12 was 65 (nl 190, ratio <1) with a non-concurrent CKMB peak on 5/8/2005 at 20:26 at 32 (ratio 1.3). The CK and CKMB declined to 24 (ratio <1) and 16 (ratio <1) on 5/14/2005 at 10:34. On 5/18/2005 the patient developed acute circulatory, respiratory insufficiency, and CPR was initiated. There was an increase of CK to 60 (ratio <1), an elevation of CKMB to 83 (ratio 3.5) with an elevated troponin T of 0.12 (nl 0.1, ratio 1.2) on 5/18/2005 at 07:27. The ECG Core Lab reported on tracings dated 5/18/2005 at 07:25 of inadequate quality due to severe artifact and reported a MI with loss of anterior and lateral R waves with new persistent major anterior ST depression, new inferior ST depression, and new persistent major T wave inversions. (tracings available with additional comments for the CEC) The patient was transferred urgently to the Intensive Care Unit. High-dose catecholamine treatment temporarily improved the patient's condition and he was brought to the Catheterization Lab. Repeat angiography on 5/18/2005 at 07:58 revealed good results following previous PCI in the LAD, a chronic occlusion of the CX, and a RCA with wall changes without relevant stenosis according to the Catheterization Report. The Angiographic Core Lab reported a 21% in-lesion restenosis with the notation of a patent study stent with radiolucent images present in the pulmonary artery, probably a pulmonary embolism. No revascularization was performed. The site reported acute coronary syndrome could be excluded and noted the visualization of a new lung embolism along with older embolisms of the left upper and left lower lobes. Despite lysis therapy the patient's condition did not improve and the site reported he subsequently died on 5/18/2005 at 12:39 with the official cause of death as pulmonary embolism and further noted that the categorical cause of death was non-cardiac. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 380 days post-procedure**<br>The patient was a 73 year-old man with a history of current smoking, dyslipidemia, and hypertension who presented with CCS Class III stable angina. On 10/31/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/1/2003 on ASA and clopidogrel. The patient underwent multiple rehospitalizations for pancreatic cancer between 5/3/2004 and 9/9/2004 according to translated Discharge Summaries. He was rehospitalized on 11/5/2004 due to vomiting and underwent gastroscopy which revealed no active bleed. A surgical intervention revealed advanced tumor infiltration and metastases of the adenocarcinoma. The patient's condition subsequently deteriorated and he died on 11/14/2004 due to pancreatic cancer. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 871 days post-procedure, Non-Q wave MI day of procedure**<br>The patient was a 57 year-old man with a history of diabetes and a MI on 11/19/2003 who presented with an unknown Class angina. On 12/25/2003 he underwent the index procedure with pre-treatment balloon angioplasty and the delivery of two assigned stents for a long lesion in the proximal LAD. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK was 33 and the troponin and CKMB levels were not done. Approximately 24 hours post-procedure the CK peaked at 404 (nl 110, ratio 3.7) and the CKMB was not reported. The site noted that CKMBs are not performed at the site and reported a Q wave MI with a post-procedure elevation of troponin to 1.14 (nl 0.1, ratio 11.4), ST elevation in V1-V3 and a Q wave in V2. The ECG Core Lab reported new, intermittent, major anterior T wave depressions and no new Q waves. On 5/18/2004 the CEC ruled that the event met the criteria for a non-Q wave MI. The patient was discharged on 12/30/2003 on ASA and clopidogrel. On 1/13/2004 the patient was hospitalized for an episode of severe shortness of breath, diagnosed with pleural effusion and 1200 ml of pleural fluid was removed and the patient was discharged on 1/16/2004. On 5/14/2006 the site reported that the family notified them of the patients' death from cancer. The Study Exit Form reported the official cause of death was cancer and the categorical cause of death was listed as non-cardiac. No autopsy was performed and no death certificate is available. In a query response the site reported no documentation of treatment at the non-study hospital is available. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-cardiac Death 1073 days post-procedure**<br>The patient was an 83 year-old man with a history of a MI in 1994, dyslipidemia, and hypertension who presented with CCS Class II angina. On 11/18/2003 he underwent the index procedure with no pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal RCA with a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/19/2003 on ASA and clopidogrel. On 10/10/2006 the patient was hospitalized for abdominal pain and was diagnosed with intestinal obstruction. On 10/15/2006 he underwent surgery for the intestinal blockage and an obstructive growth was found in the sigmoid colon. A subtotal colectomy with ileostomy was performed. Respiratory deterioration occurred on the day after the operation and the patient was put on a ventilator. He became hemodynamically unstable and was started on inotropes and vasopressors and an echocardiogram revealed greatly diminished left ventricular function. Renal failure followed along with severe metabolic disturbances which did not respond to treatment and the patient died on 10/26/2006. The death certificate lists the cause of death as respiratory failure, cardiovascular, and multi-organ failure syndrome with secondary illnesses listed as acute renal failure and cancer of the colon with sub-total colectomy. The categorical cause of death is listed as non-cardiac and no autopsy was performed. |
| | | ENDEAVOR DES | **Non-cardiac Death 39 days post-procedure**<br>The patient was a 68 year-old man with a history of diabetes, dyslipidemia, hypertension, and a MI on 11/27/2003 who presented with CCS Class II stable angina. On 12/30/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. During the hospitalization radiological changes were noted on the patient's lung X-rays and he was discharged to ambulatory care on 1/6/2004 on ASA and ticlopidine. On 1/6/2004 the patient was rehospitalized for diagnostic testing following the findings of his chest X-ray. A narrative reported that a lung tumor was diagnosed. The patient's wife confirmed that the patient died on 2/7/2004. The site reported the official cause of death was carcinoma of the lung with metastases. An autopsy was not done and the death certificate is not available. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 1035 days post-procedure, Target Lesion Revascularization–PTCA 258 and 677 days post-procedure, Device Performance Malfunction–Never Delivered** |
| | | | The patient was a 78 year-old man with a history of dyslipidemia, hypertension and percutaneous revascularization in a non-target vessel who presented with CCS Class II stable angina. On 10/23/2003 he underwent the index procedure with pre-treatment balloon angioplasty; however two attempts to deliver the assigned stent to the target lesion in the 1st OM were unsuccessful and the devices were withdrawn. Balloon angioplasty was performed. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. In a query response the site confirmed no stent was implanted during the index procedure; however the Angiographic Core Lab confirmed that one stent was implanted. The post-procedure course was uncomplicated and the patient was discharged on 10/24/2003 on ASA and clopidogrel. Protocol re-study on 7/7/2004 with recurrent clinical symptoms and without a positive functional ischemia study revealed a 69% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation "focal body in-stent restenosis, target lesion revascularization, at the end ostial 90% stenosis of the side branch [the 2nd OM]." The site reported a target lesion revascularization with an 80% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty and stent placement of the proximal CX and the 1st OM. The site reported the patient was rehospitalized on 8/30/2005 for atypical chest symptoms. A translated summary reported the patient experienced sweating and chest pain and was transferred due to left heart decompensation, increasing dyspnea and hypertensive crisis. Repeat angiography on 8/30/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 66% margin in-stent restenosis reported by the Angiographic Core Lab with the notation PCI for in-stent restenosis, target lesion revascularization. A translated Catheterization Summary noted ostial stenosis of the CX. The patient underwent repeat revascularization with balloon angioplasty and placement of a Taxus™ stent in the proximal CX, reported by the site as a target vessel revascularization. The CEC ruled the event met the criteria for a clinically driven target lesion revascularization. A Discharge Summary reported the patient was hospitalized on 8/22/2006 for dyspnea, pulmonary edema, and left decompensation with hypertensive crisis. The patient's condition continued to deteriorate despite treatment and intubation. He developed septic shock with multiple organ failure. Further treatment failed and he died on 8/23/2006 according to the translated source document and the Study Exit Form. The site reported the categorical cause of death as non-cardiac and the official cause of death as septic shock. No autopsy was performed. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-cardiac Death 764 days post-procedure (estimated date)** |
| | | | The patient was a 78 year-old man with a history of MI on 12/4/2003, prior PCI and CABG of a non-target vessel, and dyslipidemia who presented with CCS Class IV angina. On 1/12/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/13/2004 on ASA and clopidogrel. On 12/20/2005 the patient was hospitalized and diagnosed with metastatic pancreatic cancer. Treatment with corticosteroids was started as chemotherapy was not an option. The site reported the patient died at home sometime in February 2006. The official cause of death was listed as pancreatic cancer and the categorical cause of death was non-cardiac. No autopsy was performed. A narrative reported that no further information is available. |
| | | DRIVER | **Q wave MI, Clinical Perforation day of procedure** |
| | | | The patient is a 77 year-old woman with dyslipidemia and hypertension who presented with CCS Class I angina. On 10/31/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and the delivery of one assigned stent in the distal LAD. The stent was post-dilated. The Cardiac Catheterization Report indicates that during post-dilation the patient complained of back pain and a grade C proximal dissection with dye extravasation was noted. Intravenous protamine was initiated to reverse the effect of heparin and a covered Jostent was implanted and post-dilated. Angiography revealed a site reported side branch occlusion with coronary spasm of the distal LAD. A transthoracic ECHO revealed no presence of tamponade; however minimal pericardial fluid was detected. Heparin was resumed and chest pain was successfully treated with intracoronary nitrates. The Angiographic Core Lab reported a perforation, an abrupt closure with no reflow, an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 21 and 3.2 respectively. Approximately 24 hours post-procedure the CK peaked at 610 (nl 204, ratio 3) with a non-concurrent CKMB peak at 16 hours of 93.8 (nl 5, ratio 19). The site reported a Q wave MI. The ECG Core Lab reported a new anteroseptal Q wave MI with new persistent atrial fibrillation and new intermittent isolated ventricular premature depolarizations. The patient was discharged on 11/8/2003 on ASA and ticlopidine. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis 3 days post-procedure**<br>The patient is a 49 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III angina. On 8/28/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by the delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis, no thrombus or dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/28/2003 on ASA and clopidogrel. On 8/31/2003 the patient was rehospitalized at an outlying hospital with chest pain. The CK peaked at 6790 (nl 200, ratio 34) with a CKMB peak >500 (nl 5, ratio >100). The site confirmed that the patient took all prescribed doses of clopidogrel since index discharge on 8/28/2003 and reported a Q wave MI. After site reaffirmation of correct precordial lead placement over the left chest in all ECGs submitted, the ECG Core Lab reported incomplete ECG tracings (only bed-side monitor 2-channel rhythm strips after 8/31/2003 at 14:13). The patient was transferred to the investigational institution and repeat angiography on 8/31/2003 for recurrent angina without a functional ischemia study revealed a site reported 100% occlusion of the proximal LAD and a thrombus distally before the stent. A narrative indicates that "thrombus was also seen in the stent itself." The Angiographic Core Lab reported a total occlusion of the target site with presence of thrombus. The patient underwent successful revascularization with balloon angioplasty of the proximal LAD. A IIb/IIIa inhibitor was administered and a temporary pacemaker was implanted for AV block. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis 2 days post-procedure**<br>The patient is a 50 year-old woman with a history of current smoking, diabetes, dyslipidemia, hypertension, premature CAD in a first degree relative and a MI on 9/12/2003 who presented with CCS Class IV unstable angina. On 9/23/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/23/2003 on ASA and clopidogrel. On 9/25/2003 the patient was rehospitalized at an outlying hospital with chest pain and ECG changes of a MI then transferred to the investigational institution for PTCA. A narrative reported that the patient had not taken clopidogrel for two days prior to admission because it was unavailable at the pharmacy. The CK peaked at 1593 (nl 170, ratio 9.4) with a CKMB of 46 (nl 25, ratio 1.8). The site reported a QMI. The ECG Core Lab reported a new intermittent junctional rhythm, Mobitz I and third degree AV block with PR prolongation and further reported a new inferior Q wave MI with new intermittent major inferior ST elevations and high lateral ST depressions. Repeat angiography on 9/25/2003 for MI without a functional ischemia study revealed a site reported 100% occlusion with thrombus. The Angiographic Core Lab reported a 100% occlusion and no thrombus. The patient underwent successful emergent revascularization with balloon angioplasty in the proximal RCA and the mid RCA with placement of a stent proximal to the study stent and was transferred back to the referring hospital for additional treatment. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis 10 days post-procedure** |
| | | | The patient is a 55 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class II stable angina and a positive functional ischemia study. On 9/29/2003 he underwent the index procedure with placement of the assigned stent in the mid LAD. A second assigned stent was placed proximal to and abutting the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB levels were elevated at 424 (nl 140, ratio 3.02) and 35 (nl 24, ratio 1.5) respectively. At 12 hours post-procedure the CK decreased to 245 (ratio 1.8) with a decrease in CKMB to 27 (ratio 1.1). At 20 hours post-procedure the CK continued to decrease to 223 (ratio 1.6) with an increase in CKMB to 34 (nl 24, ratio 1.4). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 10/2/2003 on ASA and clopidogrel. On 10/9/2003 the patient presented to the emergency room of the enrolling hospital with recurrent clinical symptoms. The site confirmed that following the index discharge the patient never took his prescribed medications including clopidogrel. The CK peaked at 6104 (nl 140, ratio 43.6) with a CKMB of 381 (nl 24, ratio 15.9). The ECG Core Lab reported new major, intermittent, anterior hyperacute T waves and new persistent extensive anterior ST-T changes of an evolving acute anterior myocardial injury or infarction and new extensive anterior Q waves. Repeat angiography on 10/9/2003 for recurrent clinical symptoms without a functional ischemia study revealed a 17% in-lesion renarrowing reported by the Angiographic Core Lab with the notation “target lesion revascularization for thrombus.” The site reported a 50% renarrowing. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. The site reported “rescue PTCA and fibrinolysis performed.” |

| Site | Pt | Treatment Group | Case Summary |
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| | | **ENDEAVOR DES** | **Q Wave MI, Subacute Closure/Stent Thrombosis 2 days post-procedure, Target Lesion Revascularization–PTCA 2 and 242 days post-procedure** |
| | | | The patient is a 50 year-old man with a history of current smoking, dyslipidemia, hypertension, and a MI on 9/30/2003 who presented with CCS Class III stable angina. On 10/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no post-procedure cardiac enzyme elevations and site reported that the post-procedure ECG was not done. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. In the early morning hours of 10/12/2003 the patient was rehospitalized with chest pain unrelieved by nitroglycerin. The site reported an AMI with new ischemic ECG changes. Post-procedure clopidogrel use was confirmed by the site. On 10/12/2003 at 02:41 the initial CK and CKMB were 45 (nl 174, ratio <1) and 16 (nl 25, ratio <1) respectively. Emergent repeat angiography at 03:20 on 10/12/2003 for recurrent clinical symptoms without a functional ischemia study revealed a 100% total occlusion with an "acute stent thrombosis" and TIMI 0 flow reported by the Angiographic Core Lab with the notation "under deployment post-PCI in the index procedure." The patient underwent revascularization with balloon angioplasty and placement of a stent in the proximal LAD. Post-treatment at 08:57 the CK peaked at 1625 (ratio 9.3) with a CKMB of 171 (ratio 6.8). The ECG Core Lab commented on inadequate ECG tracings "in the absence of a post-procedure ECG as reference" and reported a new persistent complete right bundle branch block, new, persistent, major, anteroseptal ST elevation, anterior ST elevation, anteroseptal T wave inversion, anterior T wave inversion, with increase in ST elevation and T wave inversions pre-existing in leads V3 and V4, and a loss of anterior R waves. It further commented that the "date of onset of ST-T abnormalities and new Q waves was undetermined." There is a "variation in precordial lead placement with Q waves unchanged in leads V1 and V2, new QS replacing increased S complexes in lead V3 and extensive loss of R waves in lead V4; thus the criteria of Q waves in 2 contiguous leads for the diagnosis of anterior Q wave MI was not met." On 9/9/2004 the CEC ruled the event met the criteria for a Q wave MI. A protocol re-study on 6/8/2004 without recurrent clinical symptoms with a positive functional ischemia study revealed a 56% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent stenosis pattern. The site reported an 80% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Q wave MI day of procedure** |
| | | | The patient is a 69 year-old man with a history of hypertension and a MI on 11/4/2003 who presented with CCS Class II stable angina. On 11/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty. Post-dilation there was a grade B dissection with a thrombotic occlusion of the PDA per Cardiac Catheterization Report. The Angiographic Core Lab noted the presence of a thrombus in the baseline lesion morphology. Abciximab was administered. Following pre-treatment one assigned stent was delivered in the proximal RCA with no improvement of the dissection. The site reported that while advancing the stent, the guidewire "dislocated several times." Two non-study stents were implanted in the mid and proximal segments of the RCA to treat the dissection but TIMI 2 flow persisted due to the presence of thrombus. There were no clinical sequelae. The Angiographic Core Lab reported the presence of a distal embolus with a 22% final residual in-lesion stenosis with no dissection and TIMI 2 flow with the notation a "dissection in the proximal RCA required additional stenting." The pre-procedure CK and CKMB were 1.3 and 0.73 respectively. Approximately 24 hours post-procedure the CK was 15.2 (nl 3.17, ratio 5) with a CKMB of 2.82 (nl 0.41, ratio 7). The CK and CKMB continued to elevate and on 11/22/2003 the CK peaked at 31.1 (nl 3.17, ratio 10) with a CKMB of 4.29 (nl 0.41, ratio 11). The site reported a Q wave MI. The ECG Core Lab reported new, persistent, major ST-T changes of evolving acute inferior myocardial injury or infarction, intermittent inferior and RV ST elevations, intermittent anterolateral/apical T wave inversions and new inferior Q waves. The patient was discharged on 11/25/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Q wave MI 733 days post-procedure, Target Vessel Revascularization–PTCA 734 days post-procedure** |
| | | | The patient is a 56 year-old man with a history of dyslipidemia and a MI in July 2003 who presented with CCS Class I stable angina. On 11/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 93 and 1.91 respectively. Approximately 8 hours post-procedure the CK peaked at 354 (nl 204, ratio 1.7); however the CKMB was not done. At 16 hours post-procedure the CKMB peaked at 20.5 (nl 4.92, ratio 4.2). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 11/12/2003 on ASA and ticlopidine. The patient was rehospitalized in a non-study hospital on 11/9/2005 for recurrent clinical symptoms and a site reported anterior wall QMI. The site confirmed no CKs were performed at the non-study hospital. Two CKMB results were reported and the highest CKMB drawn on 11/10/2005 at an unknown time was 476 (nl 24, ratio 20). In a query response, the site confirmed the ECG tracings are not available but noted the data "from a Discharge Paper" dated 2/19/2005 noted elevated ST segment (Pardee's wave) in leads I, AVL, V1-V6 and ST depression in leads AVR & AVL." The ECG Core Lab report is not available due to the unavailability of the ECG tracings from the non-study hospital. Repeat angiography on 11/10/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a site reported 90% restenosis of the target vessel proximal to the study stent. The Angiographic Core Lab reported a 33% in-lesion restenosis with the notation of a patent study stent and PCI for proximal LAD lesion/bifurcation lesion, remote target vessel revascularization. The site reported the patient underwent repeat revascularization with balloon angioplasty and stent placement in the mid LAD and was discharged on 11/19/2005 |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI day of procedure** |
| | | | The patient is a 66 year-old woman with a history of hypertension who presented with CCS Class III angina and a MI on 10/25/2003. On 10/28/2003 she underwent the index procedure with pre-treatment balloon angioplasty followed by the delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "under deployment of stent at end of procedure." The pre-procedure CK and CKMB were 72 and 3.6 respectively. Approximately 24 hours post-procedure the CK peaked at 416 (nl 164, ratio 2.5) with a CKMB of 33.1 (nl 5, ratio 6.6). The ECG Core Lab reported intermittent isolated ventricular premature depolarizations, no new major ST-T abnormalities and no new Q waves. The patient was discharged on 10/30/2003 on ASA and clopidogrel. |
| | | DRIVER | **Non-Q wave MI day of procedure** |
| | | | The patient is a 62 year-old man with a history of dyslipidemia, premature CAD in a first degree relative and a MI on 9/4/2003 who presented with a Braunwald Class II angina. On 9/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. There was a site reported 80% stenosis with no dissection following pre-treatment. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK was 118 and the CKMB was not done. The CK peaked 24 hours post-procedure at 388 (nl 170, ratio 2.3) with a CKMB of 15 (nl 12, ratio 1.3). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T wave abnormalities and no new Q waves. The patient was discharged on 9/19/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Non-Q wave MI day of procedure** |
| | | | The patient is a 70 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III unstable angina. On 11/5/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There was a site reported grade C dissection after pre-treatment. A second study stent was placed distal to and overlapping the first stent to stabilize the lesion. The stent was post-dilated resulting in a site reported occlusion of the side branch. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 31 and 12 respectively. The CK peaked 16 hours post-procedure at 589 (nl 195, ratio 3) with a non-concurrent CKMB peak at 8 hours of 18.5 (nl 5, ratio 3.7). The ECG Core Lab reported new persistent ST elevations of an evolving acute anterior MI, with intermittent anterior ST elevations, intermittent anterior hyperacute T waves, minimal inferior ST elevations and no new Q waves with the notation “appreciable post-procedural decrease in precordial QRS voltage, most marked in lead V5.” The patient was discharged on 11/6/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure, Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 118 days post-procedure** |
| | | | The patient is a 58 year-old man with a history of smoking and hypertension who presented with CCS Class III unstable angina and a positive functional ischemia study. On 12/27/2003 he underwent the index procedure with pre-treatment balloon angioplasty. During pre-treatment there was a site reported grade F dissection with insertion of the guide catheter. The site reported abrupt closure, a total occlusion, TIMI 0 flow, recurrent angina, and ischemic ECG changes. One assigned stent was delivered in the mid RCA. The stent was post-dilated and five additional assigned stents were placed proximal to and distal to the first assigned stent to successfully resolve the dissection and cover gaps between the stents. The stents were post-dilated. The site reported a 0% final residual stenosis with a grade B dissection and TIMI 3 flow. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis, a grade E dissection, staining and TIMI 3 flow with the notation "dissection type E at the target vessel corrected with multiple stents - 5 stents." On 12/27/2003 at 06:15 the pre-procedure CK was 92 (nl 195, ratio <1) and the CKMB was not done. Post-procedure on 12/28/2003 at 09:07 the CK peaked at 562 (ratio 2.9) with a non-concurrent CKMB peak on 12/27/2003 at 23:31 of 15.8 (nl 9.8, ratio 1.6). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 12/28/2003 on ASA and clopidogrel. On 4/22/2004 the patient was rehospitalized for unstable "rest" angina. The troponin I peaked on 4/22/2004 at 22:41 at 3.3 (nl 0.5, ratio 6.6). A Summary reported the ECG showed bradycardia and "small inferior ischemia." The site reported that there are "no ischemic ECGs" available for ECG Core Lab evaluation. Repeat angiography on 4/23/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed an 82% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty in the proximal RCA, the mid RCA and the distal RCA. The Discharge Letter reported two Taxus™ stents were placed in the first two segments of the RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure** |
| | | | The patient is a 48 year-old man with a history of current smoking, dyslipidemia and hypertension who presented with a MI on 11/14/2003. On 11/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by the delivery of one assigned stent in the mid RCA. The site reported abrupt closure during post-dilation with no reflow, angina, ischemic ECG changes and TIMI 1 flow which improved to slow flow "at the end of the procedure." The Angiographic Core Lab reported a 47% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 124 and 3 respectively. Approximately 24 hours post-procedure the CK peaked at 601 (nl 230, ratio 2.6) with a CKMB of 54 (nl 6, ratio 9). The site reported a Q wave MI. The ECG Core Lab reported an evolving acute inferior myocardial infarction with loss of R waves and noted a posterior acute injury without significant change in pre-procedure Q waves, ST elevations and T wave inversions with the notation "there is roughly a 50% reduction in the amplitudes of the R waves in leads II, III and AVF on 11/22/2003." On 2/25/2004 the CEC ruled that the event met the criteria for a non-Q wave MI. The patient was discharged on 11/22/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI, Clinical Perforation/Cardiac Tamponade day of procedure**<br>The patient is a 63 year-old man with a history of hypertension who presented with a Braunwald Class I unstable angina. On 11/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. The site reported ischemic ECG changes with abrupt closure, grade E dissection, TIMI 1 flow, perforation and "coronary rupture" after stent deployment. The Angiographic Core Lab noted a "perforation at distal end of stent." The perforation was successfully treated with deployment of a covered Jomed stent. Additionally, the proximal segment of the proximal CX was treated with the second assigned stent, abutting the first stent. An emergent echocardiogram revealed cardiac tamponade which required pericardiocentesis. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no abrupt closure, no dissection and TIMI 3 flow with the notation that there were "three stents deployed (with one being a covered stent for perforation). "No distal edge possible due to aneurysmal formation following perforation and covered stent placement at that site." The pre-procedure CK was elevated at 509 (nl 232, ratio 2.2) with a CKMB of 0.53 (nl 3.6, ratio <1). About 8 hours post-procedure the CK decreased to 308 with an increased CKMB of 8.2 (nl 3.6, ratio 2.3). The CK peaked approximately 24 hours post-procedure at 525 (nl 232, ratio 2.3) with a non-concurrent peak CKMB at 16 hours of 35 (nl 3.6, ratio 9.7). The ECG Core Lab reported new major, persistent, anterolateral/apical T wave inversions, new intermittent anteroseptal and high lateral ST elevations, with new intermittent inferolateral ST depressions and no new Q waves. The patient was transfused with 2 units of packed red blood cells for a decrease in hemoglobin from 14.9 gm/dL to 8.9 gm/dL and a hematocrit decrease of 45% to 26.3% and was discharged on 11/19/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI day of procedure** |
| | | | The patient is a 70 year-old man with a history of dyslipidemia and a MI in June 2003 who presented with CCS Class II stable angina and a positive functional ischemia study. On 1/9/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 104 and 6 respectively. Approximately 16 hours post-procedure the CK peaked at 634 (nl 200, ratio 3.2) with a CKMB of 19 (nl 10, ratio 1.9). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 1/9/2004 on ASA and clopidogrel. |
| | | ENDEAVOR DES | **Non-Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure day of procedure** |
| | | | The patient is a 47 year-old man with a history of current smoking, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class II unstable angina and a positive functional ischemia study. On 1/7/2004 at 16:13 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. Heparin was administered. During the stenting procedure there was a site reported distal grade A dissection, intimal flap, side branch occlusion and with a 90% renarrowing and TIMI 1 flow. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with the presence of staining and TIMI 3 flow with the notation “on index film: last frame shows type C dissection.” The site reported that the procedure ended at 16:50. Post-procedure the patient experienced angina with ischemic ECG changes and was brought back to the cath lab. Repeat angiography at 17:00 revealed a site reported “extensive distal dissection originating from within the stent.” The Angiographic Core Lab reported a 23% renarrowing with no thrombus and TIMI 3 flow with the notation “type E dissection with target lesion revascularization performed.” The patient underwent repeat revascularization with placement of four stents in the mid RCA. The pre-procedure CK was 108 and the CKMB was not done. Approximately 16 hours post-procedure the CK peaked at 1044 (nl 195, ratio 5.4) with a CKMB of 94 (nl 12, ratio 7.8). The site reported a non-Q wave MI. The ECG Core Lab reported new intermittent, major, inferior ST elevations and no new Q waves. The patient was discharged on 1/12/2004 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure, Target Lesion Revascularization–PTCA 132 days post-procedure** |
| | | | The patient is a 67 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 11/4/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 47 and 9.2 respectively. Approximately 24 hours post-procedure the CK peaked at 348 (nl 174, ratio 2) with a non-concurrent CKMB peak of 48 (nl 10, ratio 4.8). The site reported a prolonged hospitalization due to asymptomatic CK elevation without ECG changes; however reported a post-procedure/discharge ECG was not performed. On 4/21/2004 the CEC ruled the event met the criteria for a non-Q wave MI. The patient was discharged on 11/11/2003 on ASA and clopidogrel. On 3/15/2004 the patient was rehospitalized for chest pain. Repeat angiography on 3/15/2004 for recurrent angina with a positive functional ischemia study revealed a 75% in-lesion restenosis reported by the Angiographic Core Lab with the notation “type 3 in-stent restenosis.” On 3/15/2004 the patient underwent repeat revascularization with balloon angioplasty of the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI day of procedure**<br>The patient is a 75 year-old man with a history of hypertension who presented with CCS Class IV unstable angina. At 16:50 on 8/18/2003 he underwent the index procedure. There was a site reported grade A dissection following pre-treatment balloon angioplasty and IVUS. One assigned stent was placed in the proximal LAD; however there was no improvement of the dissection grade per site. There were no clinical sequelae. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn at 15:00 was elevated at 279 (nl 174, ratio 1.6) with a CKMB of 24 (nl 24, ratio 1) and a troponin of 0.09 (nl 0.1, ratio <1). The post-procedure CKs were 671 and 712 with a peaked CK approximately 24 hours post-procedure at 744 (nl 174, ratio 4.3). There was a non-concurrent CKMB peak at approximately 8 hours post-procedure of 63 (nl 24, ratio 2.6). The CKMBs at 16 and 24 hours post-procedure decreased to 53 and 46 (nl 24, ratio 1.9) respectively. The ECG Core Lab reported new major, intermittent, anterior, and anteroseptal ST elevations and persistent high lateral and anterior T wave inversions and no new Q waves. A narrative indicates that the baseline ECG did not show acute MI but the SAE form further reported that the patient was enrolled "with an ongoing non-Q wave MI which was not detected prior to inclusion." There were no further complications and the patient was discharged on 8/22/2003 on ASA and clopidogrel. |
| | | ENDEAVOR DES | **Non-Q wave MI day of procedure**<br>The patient is a 67 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 7/22/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal LAD. Post-stenting the patient experienced a 10-minute episode of chest pain but no ECG changes were noted per narrative. The site reported distal embolization with increased CK and CKMB and a non-Q wave MI. The Angiographic Core Lab reported a 1% final residual in-lesion stenosis with no distal embolization, no dissection and TIMI 3 flow. The pre-procedure CK was 100 and the CKMB was not done. Approximately 16 hours post-procedure the CK peaked at 683 (nl 174, ratio 3.9) with a CKMB of 79 (nl 24, ratio 3.3). The ECG Core Lab reported new, persistent, inferior T wave inversions and no new Q waves. The patient was discharged on 7/24/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Non-Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis 12 days post-procedure**<br>The patient is a 66 year-old man with a history of hypertension who presented with CCS Class II stable angina. On 10/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. After pre-dilation a grade C dissection was noted by the Angiographic Core Lab. There were no clinical sequelae. The Angiographic Core Lab reported a 39% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/12/2003 on ASA and clopidogrel. On 10/17/2003 the patient experienced an episode of upper GI bleeding requiring transfusion, and the ASA and clopidogrel were discontinued. At about 09:00 on 10/22/2003 he presented with anterior ST elevations on ECG and chest pain unrelieved by nitroglycerin. Approximately eight hours after presentation, the CK peaked at 1088 (nl 174, ratio 6.3) with a CKMB of 112 (nl 24, ratio 4.7). The site reported a Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves with the notation “minimal ST depressions in leads III and AVF, not meeting criteria for ischemia.” On 6/2/2004 the CEC ruled that the event met the criteria for a non-Q wave MI. Repeat angiography on 10/22/2003 for recurrent clinical symptoms without a functional ischemia study revealed a 100% in-lesion occlusion reported by the Angiographic Core Lab with the notation of a type 4 in-stent restenosis pattern. The site reported a total occlusion with subacute stent thrombosis of the target lesion. The patient underwent repeat revascularization of the mid LAD and the distal LAD with deployment of a Coroflex stent “distal to the DRIVER stent.” The patient was asymptomatic at the time of discharge on 10/30/2003. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI day of procedure** |
| | | | The patient is a 67 year-old woman with a history of dyslipidemia, hypertension, premature CAD in a first degree relative and percutaneous coronary revascularization in a non-target vessel who presented with CCS Class I angina. On 12/2/2003 she underwent the index procedure with pre-treatment balloon angioplasty followed by delivery of one assigned stent in the mid LAD. There was a site reported grade B dissection following pre-treatment. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no abrupt closure, no dissection, and TIMI 3 flow. Post-procedure the patient experienced mild, transient angina, CK elevation and a positive Troponin T, with inferior T wave inversions in leads V2 and V3 according to the Discharge Summary. The site attributed the events to the possibility of an "occlusion of a small septal branch during the LAD stenting" and reported a non-ST elevation MI. The pre-procedure CK was 183 with an elevated CKMB of 17.7 (nl 10, ratio 1.8). Approximately 24 hours post-procedure the CK peaked at 577 (nl 174, ratio 3.3) with a CKMB of 52.3 (nl 10, ratio 5.2). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The site reported that the T wave inversions resolved by discharge. The patient was discharged on 12/4/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI, Subacute Closure/Stent Thrombosis 1 day post-procedure, Target Lesion Revascularization–PTCA 2 days post-procedure** |
| | | | The patient is a 78 year-old woman with a history of smoking, diabetes, dyslipidemia, hypertension and a MI on 9/12/2003 who presented with CCS Class II angina. On 9/22/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. The pre-procedure CK and CKMB were 155 and 10 respectively. The post-procedure CK decreased to 100 and 73 with decreases in CKMB of 8 and 6; however the CK drawn 24-hours post-procedure on 9/23/2003 at 12:00 was elevated at 94 (nl 171, ratio <1) with a CKMB of 7 (nl 28, ratio <1). A narrative indicates the patient developed angina 36 hours post-procedure with minimal ST depressions in leads V5 and V6. The patient's angina reportedly resolved after medication. On 9/24/2003 at 04:00 the CK was 1658 (nl 171, ratio 9.7) with a CKMB of 204 (nl 28, ratio 7.3). The site reported a non-Q wave MI and confirmed clopidogrel was given between 9/22/2003 and 9/24/2003. The ECG Core Lab reported new, persistent, high lateral T wave inversions and no new Q waves. Repeat angiography on 9/24/2003 for clinical symptoms without a functional ischemia study revealed an 80% renarrowing with "subacute stent thrombosis" of the target lesion reported by the site and a 57% final in-lesion renarrowing with no thrombus and TIMI 3 flow reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD and was discharged on 9/27/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI 2 days post-procedure** |
| | | | The patient is a 77 year-old man with a history of smoking, dyslipidemia and hypertension who presented with CCS Class III unstable angina. On 9/30/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A Hospital Discharge Summary noted that implantation of the stent resulted in an occlusion of a small diagonal branch. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. The pre-procedure CK and CKMB were 105 and 8 respectively. Approximately 16 hours post-procedure on 9/30/2003 at 04:40 the CK peaked at 287 (nl 171, ratio 1.7) with a CKMB of 32 (nl 28, ratio 1.1) and on 10/1/2003 at 16:40 the CK was 247 (ratio 1.4) with a CKMB of 24 (ratio <1). The ECG Core Lab reported on tracings dated 9/29/2003 and 9/30/2003 with an inadequate quality due to severe artifact with no new major ST-T abnormalities and no new Q waves. On 10/2/2003 at 08:29 there was a re-elevation of the CK to 582 (ratio 3.4) with a CKMB 29 (ratio 1.03). The ECG Core Lab reported on ischemic ECG tracings dated 10/2/2003 and 10/8/2003 and noted inadequate quality due to severe artifact and lead misplacement with no new major ST-T abnormalities and no new Q waves with the notation “arm leads reversed on 10/2/2003 at 09:20.” The site reported a non-Q wave MI with no new ECG changes. Repeat angiography was not performed. The patient was discharged on 10/9/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure**<br>The patient is a 67 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina. On 12/10/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. A second assigned stent was delivered distal to and abutting the first stent for a long lesion. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab noted formation of a thrombus which was not present at baseline and reported a 17% final residual in-lesion stenosis with a grade C dissection and TIMI 3 flow with the notation "abrupt closure of diagonal branch, PCI of the diagonal branch with residual stenosis distal to the 1st stent" with deployment of a second study stent distal to and overlapping. The pre-procedure CK was 84 and the CKMB was not done. Approximately 16 hours post-procedure the CK peaked at 668 (nl 174, ratio 3.8) with a CKMB of 74 (nl 24, ratio 3.1). The site noted that the patient was asymptomatic and without ECG changes but reported a non-Q wave MI. The ECG Core Lab reported incomplete ECGs on 12/11/2003 and 12/13/2003 and noted all available ECGs or portions thereof showed left bundle branch block. On 5/26/2004 the CEC ruled that the event met the criteria for a non-Q wave MI. The patient was discharged on 12/16/2003 on ASA and clopidogrel. |
| | | ENDEAVOR DES | **Non-Q wave MI day of procedure**<br>The patient is a 57 year-old man with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class II stable angina. On 10/21/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. The pre-procedure CK and CKMB were elevated at 261 (nl 173, ratio 1.5) and 12 (nl 5, ratio 2.4). Approximately 24 hours post-procedure the CK peaked at 774 (nl 173, ratio 4.5) with a CKMB of 68 (nl 5, ratio 13.6). The ECG Core Lab reported new persistent anteroseptal ST elevations and no new Q waves. The patient was discharged on 10/25/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis 14 days post-procedure** |
| | | | The patient is a 61 year-old man with a history of current smoking, dyslipidemia, hypertension, percutaneous revascularization in a non-target vessel and a MI in 1999 who presented with CCS Class I stable angina. On 11/24/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. The Angiographic Core Lab reported a 1% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/25/2003 on ASA and clopidogrel. On 12/8/2003 the patient was rehospitalized for "acute angina." The CK peaked at 2740 (nl 173, ratio 16) with a CKMB of 488 (nl 5, ratio 98). The ECG Core Lab reported new persistent atrial fibrillation, new intermittent isolated ventricular premature depolarizations, no new major ST-T abnormalities and no new Q waves. The site reported that the patient admitted he had not taken his clopidogrel tablets. Repeat angiography on 12/8/2003 for recurrent clinical symptoms without a positive functional ischemia study revealed a thrombus and a 100% in-stent occlusion reported by the Angiographic Core Lab with the notation "subacute thrombosis of the study stent." The patient underwent repeat revascularization with balloon angioplasty and placement of two stents in the proximal LAD and the 1st OM. During the procedure, an episode of ventricular tachycardia was successfully treated with defibrillation. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Non-Q wave MI, Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis 3 days post-procedure**<br>The patient is a 63 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with a MI on 1/2/2004 and CCS Class IV angina. On 1/5/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A second study stent was placed proximal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. On 1/4/2004 at 08:00 the pre-procedure CK was elevated at 281 (nl 173, ratio 1.6) with a CKMB of 26 (nl 5, ratio 5.2). Post-procedure the cardiac enzymes decreased and on 1/6/2004 the CK was 123 at 07:00 with a CKMB of 3.8 (ratio <1). The ECG Core Lab reported on inadequate tracings dated 1/4/2004 and 1/6/2004 with no new major ST-T abnormalities and no new Q waves with the notation "variation in precordial lead placement." On 1/8/2004 during the index admission the patient developed retrosternal pain and the site reported a non-Q wave MI with a troponin peak of 3.9 (nl 0.1, ratio 39). On 1/8/2004 at 16:00 the CK peaked at 1445 (ratio 8.4) with a CKMB of 194 (ratio 39). The ECG Core Lab reported on inadequate tracings dated 1/6/2004 and 1/8/2004 with variation in precordial lead placement and noted new, persistent, anterior ST elevations, new, persistent, anterior, hyperacute T waves and no new Q waves. The site confirmed that the patient received all post-procedure doses of clopidogrel. Repeat angiography on 1/8/2004 for recurrent clinical symptoms without a functional ischemia study revealed a thrombus with a 100% occlusion and TIMI 0 flow reported by the Angiographic Core Lab with the notation "subacute thrombosis of the stents." The patient underwent repeat revascularization with balloon angioplasty of the mid LAD and was discharged on 1/15/2004 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI 842 days post-procedure, Target Lesion Revascularization–PTCA 264, 384, 686, and 845 days post-procedure**<br>The patient is a 71 year-old woman with a history of diabetes, dyslipidemia, hypertension, a CABG of a non-target vessel on an unknown date and MI on 1/10/1990 who presented with CCS Class III unstable angina. On 10/23/2003 she underwent the index procedure with pre-treatment balloon angioplasty and IVUS. There was a site reported grade A dissection post-dilation. One assigned stent was delivered to the 1st diagonal. A second study stent was placed proximal to and overlapping the first stent to stabilize the lesion. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with a grade B dissection and TIMI 3 flow. There were no clinical sequelae. The post-procedure course was uncomplicated and the patient was discharged on 10/23/2003 on ASA and clopidogrel. On 7/11/2004 the patient was rehospitalized for chest pain. The site reported negative troponin and ECG testing. Repeat angiography on 7/13/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 79% proliferative in-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal. The patient was rehospitalized on 11/10/2004 for chest pain and dyspnea. Repeat angiography on 11/10/2004 for recurrent clinical symptoms and a positive functional ischemia study revealed a 95% proliferative in-stent restenosis reported by the Angiographic Core Lab. The patient subsequently underwent repeat revascularization of the 1st diagonal with balloon angioplasty and placement of a CYPHER™ stent. Repeat angiography on 9/8/2005 for recurrent clinical symptoms without a functional ischemia study revealed an 86% intra-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with cutting balloon angioplasty of the 1st diagonal. On 2/11/2006 the patient was hospitalized for recurrent chest pain for a site reported Q wave MI. No cardiac enzymes were submitted for this date at this time. The first reported CK on 2/13/2006 at 07:38 was 391 (nl 110, ratio 3.6) and no CKMB was done. On 2/13/2006 at 11:27 the CK was 300 (ratio 2.7) and on 2/16/2006 the final CK reported was 139 (ratio 1.3) and no CKMBs were measured. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. After reviewing the event ECGs, the CEC determined the event met the criteria for a non-Q wave MI. Repeat angiography on 2/14/2006 for recurrent angina and without a positive functional ischemia study revealed a site reported total occlusion of the target lesion. The Angiographic Core Lab reported an 81% proliferative in-stent restenosis with TIMI 2 flow and noted "subtotal occlusion due to in-stent restenosis, target lesion revascularization." The patient underwent repeat revascularization of the 1st diagonal, reported by the site as a target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Non-Q wave MI day of procedure** |
| | | | The patient is a 66 year-old man with a history of current smoking, dyslipidemia and premature CAD in a first degree relative who presented with CCS Class II stable angina and a positive functional ischemia study. On 12/22/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. A second study stent was delivered proximal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 91 and 0.1 respectively. Approximately 24-36 hours post-procedure the CK peaked at 560 (nl 200, ratio 2.8) with a non-concurrent CKMB peak at 24 hours of 24.7 (nl 6, ratio 4.1). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 1/9/2004 on ASA, ticlopidine and acenocoumarol. |
| | | **ENDEAVOR DES** | **Non-Q wave MI day of procedure, Target Lesion Revascularization–PTCA 247 days post-procedure** |
| | | | The patient is a 64 year-old man with a history of dyslipidemia, hypertension, premature CAD in a first degree relative and a MI in 1997 who presented with CCS Class III stable angina and a positive functional ischemia study. On 10/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 5% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 107 and 9 respectively. Approximately 24 hours post-procedure the CK peaked at 377 (nl 170, ratio 2.2) with a CKMB of 27 (nl 16, ratio 1.7). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 10/24/2003 on ASA and clopidogrel. A protocol re-study on 6/23/2004 with "NA" clinical symptoms and with a "NA" functional ischemia study revealed a 72% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B proximal edge restenosis." The site reported 15% restenosis of the target lesion and a "70% stenosis proximal to the stent." The patient underwent repeat revascularization with balloon angioplasty of the proximal CX. On 12/1/2004 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI 227 days post-procedure, Target Lesion Revascularization–PTCA 246 days post-procedure** |
| | | | The patient is a 59 year-old man with a history of current smoking, dyslipidemia, hypertension and a MI on 3/19/1989 who presented with CCS Class II stable angina and a positive functional ischemia study. On 11/4/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/9/2003 on ASA and clopidogrel. On 6/18/2004 the patient experienced a cardiac arrest while walking. The site reported this was not preceded by clinical symptoms including angina. CPR was initiated by the patient's wife and he was transported to the ER of a non-study hospital "within 5 minutes." He was subsequently defibrillated several times. The patient was ventilated for 8 days according to the Discharge Summary. The preliminary CK on 6/18/2004 was 183 (nl 170, ratio 1.1) with a CKMB of 48 (nl 16, ratio 3). The CK peaked on an "unknown" later date at 5718 (ratio 34) with a CKMB peak of 97 (ratio 6.1). The site reported a QMI with ST segment changes and noted the ECGs for 6/18/2004 are unavailable. A query response revealed that the patient was transferred to the study site on 7/5/2004. The ECG Core Lab reported on tracings dated 7/7/2004 with persistent new major anterior ST elevations, new persistent anterior T wave inversions and no new Q waves with the notation "pre-existing T wave inversions in leads V4-V6 become more prominent and symmetrical." On 3/30/2005 the CEC ruled the event on 6/18/2004 met the criteria for a non-Q wave MI. Repeat angiography on 7/7/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 100% in-lesion occlusion reported by the Angiographic Core Lab with the notation "distal LAD filled through collaterals, total occlusion of the study [device] stent." On 7/7/2004 the patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Non-Q wave MI day of procedure** |
| | | | The patient is a 65 year-old woman with a history of dyslipidemia, hypertension, CABG surgery involving the target vessel and a MI on 1/31/2002 who presented with CCS Class III stable angina and a positive functional ischemia study. On 12/2/2003 she underwent the index procedure with pre-treatment balloon angioplasty; however following pre-treatment there was a site reported grade B dissection. One assigned stent was delivered in the proximal CX and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 5% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 99 and 14 respectively. Approximately 24 hours post-procedure the CK peaked at 344 (nl 170, ratio 2.02) with a CKMB of 42 (nl 16, ratio 2.6). The site reported a non-Q wave MI. The ECG Core Lab reported new, persistent inferior ST depressions, persistent anterior T wave inversions, and no new Q waves with the notation "minimal T wave flattening in leads V2-V6." The patient was discharged on 12/8/2003 on ASA and clopidogrel. |
| | | **ENDEAVOR DES** | **Non-Q wave MI 1043 days post-procedure** |
| | | | The patient is a 67 year-old woman with a history of MI in 1996, diabetes, dyslipidemia, hypertension, and premature CAD in a 1st degree relative who presented with CCS Class II angina and a positive functional ischemia study. On 12/11/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/15/2003 on ASA and clopidogrel. On 10/19/2006 the patient was hospitalized for a site-reported NSTEMI. A CKMB reported on 10/19/2006 was 33 (nl 24, ratio 1.4) and a CKMB on 10/20/2006 was 49 (ratio 2.04). No additional cardiac enzymes were provided. No ECGs are able to be obtained for this event; therefore the ECG Core Lab report will not be available. The SAE narrative reports no pathological Q-waves. The CEC determined the event met the criteria for a non-Q wave MI. Repeat angiography on 10/19/2006 for recurrent clinical symptoms and with a negative functional ischemia study revealed no restenosis of the study stent and a 90% stenosis of both the proximal and distal CX according to a query response. The patient underwent repeat revascularization of the proximal and the distal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Non-Q wave MI day of procedure**<br>The patient is a 64 year-old woman with a history of dyslipidemia, hypertension and a MI in 1992 who presented with CCS Class II stable angina and a positive functional ischemia study. On 10/15/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 102 and 11 respectively. About 6 hours post-procedure the enzymes decreased with a CK of 84 and CKMB of 9. A narrative reported that about 5 hours post-procedure the patient experienced ventricular fibrillation and cardiac arrest. Electrical defibrillation was successful and about 30 minutes later the patient was brought back to the Cardiac Catheterization Lab for emergent repeat angiography which revealed "good flow" through the lumen of the target vessel reported by the site. The Angiographic Core Lab report is not available at this time. Post defibrillation, approximately 24 hours post-procedure the CK peaked at 671 (nl 195, ratio 3.4) with a CKMB of 50 (nl 25, ratio 2). The site reported a non-Q wave MI. The ECG Core Lab reported new major intermittent, inferior ST elevations despite left bundle branch block and noted the tracings were uninterpretable for MI due to the left bundle branch block. The patient was discharged on 10/20/2003 on ASA and clopidogrel. |
| | | ENDEAVOR DES | **Non-Q wave MI day of procedure**<br>The patient is a 74 year-old man with a history of diabetes, dyslipidemia, percutaneous revascularization in a non-target vessel and a MI on 10/28/2003 who presented with CCS Class II stable angina. On 12/12/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 14% residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 80 and 3.74 respectively. Approximately 24 hours post-procedure the CK peaked at 675 (nl 204, ratio 3.3) with a non-concurrent CKMB at 16 hours of 71.9 (nl 4.92, ratio 14.6). The site reported a non-Q wave MI. The ECG Core Lab reported inadequate tracings due to severe artifact and noted no new major ST-T abnormalities and no new Q waves. The patient was discharged on 12/15/2003 on ASA and ticlopidine. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Non-Q wave MI day of procedure** |
| | | | The patient is a 65 year-old man with a history of hypertension and premature CAD in a first degree relative who presented with Braunwald Class II unstable angina. On 1/13/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. The pre-procedure CK and CKMB were 211 and 14 respectively. Approximately 24 hours post-procedure the CK peaked at 450 (nl 222, ratio 2.02) with a CKMB of 34 (nl 14, ratio 2.4). The site reported a non-Q wave MI. The ECG Core Lab reported on an inadequate tracing with right arm and left arm leads reversed in pre-procedure ECG with variation in precordial lead placement and noted new, major, intermittent, anterior T wave inversions, new, major, intermittent, anterolateral T wave inversions of acute evolving injury or infarction and no new Q waves. The patient was discharged on 1/19/2004 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI, Target Lesion Revascularization–PTCA 142 days post-procedure**<br>The patient is a 62 year-old man with a history of dyslipidemia, hypertension and premature CAD in a first degree relative who presented without angina or a positive functional ischemia study. On 11/3/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/4/2003 on ASA and clopidogrel. A narrative concerning the admission on 3/24/2004 reported the patient was rehospitalized at a non-study institution for a 1 week history of recurrent chest pain in March 2004. It further reported "a positive troponin T and CKMB elevation" and noted the patient was transferred to the investigational institution with "unstable angina." The cardiac enzymes reported on a lab report revealed a CK on 3/24/2004 at 11:10 was 414 (nl 195, ratio 2.1) with a CKMB of 24% (nl 6% ratio 4). The troponin T on 3/24/2004 at 11:10 was 0.37 (nl .1, ratio 3.7). The ECG Core Lab noted inadequate ECG tracing quality due to severe artifact and variation in precordial lead placement and reported new persistent major anterolateral/apical ST depression and new persistent major anterolateral/apical T wave inversions "vs. ST-T changes of LVH" and noted no new Q waves. No MI was reported; however on 4/13/2005 the CEC ruled the event met the criteria for a non-Q wave MI. Repeat angiography on 3/24/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 49% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B in-stent restenosis, new stent deployed as target vessel revascularization at the proximal edge of the target stent." On 3/24/2004 he underwent repeat revascularization with balloon angioplasty of the proximal LAD and was discharged on 3/25/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure** |
| | | | The patient is a 77 year-old woman with a history of dyslipidemia and hypertension who presented with Braunwald Class II unstable angina and a positive functional ischemia study. On 12/17/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. Post-stenting there was a site reported grade B distal dissection. A second assigned stent was placed distal to and overlapping the first stent to cover the dissection. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 46 and 22. Only one post-procedure set of cardiac enzymes was reported. Approximately 16 hours post-procedure the CK was 397 (nl 195, ratio 2.04) with a CKMB of 56 (nl 12, ratio 4.6). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 12/18/2003 on ASA and clopidogrel. |
| | | ENDEAVOR DES | **Non-Q wave MI 906 days post-procedure** |
| | | | The patient is a 76 year-old man with a history of MI on 11/30/2003, CABG surgery of a non-target vessel, dyslipidemia, and hypertension who presented with CCS Class IV angina. On 1/6/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/7/2004 on ASA and clopidogrel. The site reported the patient experienced angina beginning on 6/29/2006 and was hospitalized on 6/30/2006 for a non-Q wave MI. On 6/30/2006 at an unknown time the CK was 510 (nl 200, ratio 2.6) with a CKMB of 63 (nl 16, ratio 3.9). The final set of enzymes reported on 7/19/2006 was a CK of 117 (ratio <1) and the CKMB was 50 (ratio 3.1). In a query response the site reported no ECGs are available for this event as it occurred at a non-study site, therefore the ECG Core Lab report will not be available. The site reported that no angiography was performed and the patient was treated with medications and discharged on 7/19/2006. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure** |
| | | | The patient is a 65 year-old man with a history of dyslipidemia and percutaneous revascularization in a non-target vessel who presented without the presence of angina and with a positive functional ischemia study. On 9/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 25 and 6 respectively. Approximately 24 hours post-procedure the CK peaked at 399 (nl 171, ratio 2.3) with a CKMB of 63 (nl 10, ratio 6.3). The ECG Core Lab reported intermittent isolated atrial premature contractions, no new major ST-T abnormalities and no new Q waves. Repeat angiography on 9/19/2003 for recurrent clinical symptoms revealed a 23% in-lesion renarrowing with no thrombus and TIMI 3 flow reported by the Angiographic Core Lab. The site reported an occlusion of a very small "RIVP-periphery," which was identified as the R-PDA per query response. No revascularization was performed and the patient was discharged on 9/22/2003 on ASA and clopidogrel. |
| | | ENDEAVOR DES | **Non-Q wave MI day of the procedure** |
| | | | The patient is a 71 year-old woman with a history of smoking, diabetes, hypertension, dyslipidemia and a MI in June 2003 who presented with a positive functional ischemia study. On 10/23/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. Stenting was complicated by a site reported grade F dissection which propagated both proximally and distally to the target site. Post-dilation improved the proximal dissection; however a distal grade F dissection remained. The patient experienced chest pain and ischemic ECG changes, a side branch occlusion and TIMI 0 flow were noted. The Angiographic Core Lab reported abrupt closure after stent deployment with the notation "distal bed lost." Two additional assigned stents were deployed distally in the distal CX and the fourth assigned stent was deployed in the proximal CX. The Angiographic Core Lab reported a 100% final residual in-lesion stenosis with presence of thrombus, no dissection and TIMI 0 flow. The pre-procedure CK and CKMB were 62 and 15 respectively. Approximately 24 hours post-procedure the CK peaked at 617 (nl 171, ratio 3.6) with a CKMB of 96 (nl 10, ratio 9.6). The ECG Core Lab reported new, intermittent, major anterior and anteroseptal T wave inversions and no new Q waves. The patient was discharged on 10/30/2003 on ASA and clopidogrel. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Non-Q wave MI day of procedure, Target Lesion Revascularization–CABG 252 days post-procedure** |
| | | | The patient is a 72 year-old man with a history of current smoking, diabetes, dyslipidemia and hypertension who presented with CCS Class II stable angina and a positive functional ischemia study. On 10/24/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal LAD. A second assigned stent was placed distal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 38% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 122 and 13 respectively. Approximately 24 hours post-procedure the CK peaked at 365 (nl 171, ratio 2.13) with a CKMB of 46 (nl 10, ratio 4.6). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The patient was discharged on 10/26/2003 on ASA and clopidogrel. A protocol re-study on 6/23/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 69.0% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 2 in-stent stenosis pattern. The site reported 90% restenosis of the target lesion. Revascularization was not performed at this time. The patient was rehospitalized on 6/30/2004 and the Operative Report indicates the patient was admitted for surgical treatment of “angina pectoris symptoms.” On 7/2/2004 he underwent elective CABG surgery with a LIMA to the distal LAD, an SVG to the 1st diagonal, an SVG to the 1st OM, and a SVG to the distal RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–CABG 300 days post-procedure**<br>The patient is a 54 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class II unstable angina and a positive functional ischemia study. On 11/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/15/2003 on ASA and clopidogrel. Repeat angiography on 5/10/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 68% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 2 in-stent stenosis pattern. The site reported 99% restenosis of the target lesion. No revascularization was performed at this time. A narrative reported that the patient was placed on a waiting list for elective CABG surgery. On 9/8/2004 the patient underwent CABG surgery with bypass grafts to the LAD and the 1st diagonal reported by the site as target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–CABG 499 days post-procedure, Target Vessel Revascularization–PTCA 262 days post-procedure** |
| | | | The patient is a 62 year-old man with a history of smoking, diabetes, dyslipidemia and hypertension who presented with CCS Class II unstable angina and a positive functional ischemia study. On 12/1/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/2/2003 on ASA and clopidogrel. On 8/19/2004 the patient was rehospitalized for recurrent chest pain. Repeat angiography on 8/19/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 46% in-lesion restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD, the mid LAD and the 2nd diagonal and stent placement in the proximal LAD. Repeat angiography on 4/8/2005 for recurrent angina without a positive functional ischemia study revealed a 70% intra-stent restenosis reported by the Angiographic Core Lab. No revascularization was performed at this time and the patient remained hospitalized. On 4/13/2005 the patient underwent elective CABG surgery with a LIMA to the mid LAD and a radial artery graft sequentially to D2 and D3 according to the Operative Report. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–CABG 130 days post-procedure** |
| | | | The patient is a 65 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with a positive functional ischemia study. On 10/20/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS followed by delivery of one assigned stent in the proximal LAD. Post-stenting there was a site reported grade A dissection, which was treated with placement of a second assigned stent distal to and overlapping the first stent. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/22/2003 on ASA and clopidogrel. Repeat angiography on 2/16/2004 for recurrent angina without a functional ischemia study revealed an 81% in-lesion restenosis reported by the Angiographic Core Lab. No revascularization was performed at this time. On 2/27/2004 the patient was rehospitalized and underwent an Aortic Valve Replacement and elective CABG surgery of the proximal LAD and the 1st OM. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–CABG 370 days post-procedure, Target Lesion Revascularization–PTCA 208 days post-procedure** |
| | | | The patient is a 72 year-old woman with a history of diabetes, hypertension and premature CAD in a first degree relative who presented with CCS Class II stable angina. On 9/24/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis, no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/26/2003 on clopidogrel. On 4/19/2004 the patient was admitted for recurrent angina. Repeat angiography on 4/19/2004 for recurrent angina without a positive functional ischemia study revealed a 97% in-lesion restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD. A narrative reported that the patient was scheduled for elective CABG surgery due to restenosis of the assigned stent and of non-target lesions. The repeat angiography was performed at an outlying institution and the film is unavailable per site. On 9/28/2004 the patient underwent elective CABG surgery with bypass grafts to the proximal LAD, the distal CX and the proximal RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–CABG 267 days post-procedure**<br>The patient is a 63 year-old man with a history of MI in 2000, diabetes, hypertension and dyslipidemia who presented with a positive functional ischemia study. On 9/22/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The Angiographic Core Lab reported a 36% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/23/2003 on ASA and clopidogrel. A protocol re-study on 5/7/2004 in the presence of clinical symptoms and in the absence of a functional ischemia study revealed a 60% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis; no PCI was done." Revascularization was not performed at this time. On 6/14/2004 the patient was rehospitalized for CABG surgery and on 6/15/2004 the patient underwent elective CABG surgery with a LIMA to the LAD and a single bypass graft to the 1st diagonal and R-PAV, reported as a target vessel/non-target vessel revascularization by the site. The post-surgical course was complicated by renal failure and bacteremia which were treated with dialysis and antibiotics respectively. The patient was discharged on 6/27/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–CABG 363 days post-procedure, Target Lesion Revascularization–PTCA 196 days post-procedure** |
| | | | The patient is a 59 year-old man with a history of current smoking, dyslipidemia, hypertension, and premature CAD in a first degree relative who presented with CCS Class IV unstable angina. On 9/4/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The site reported a 0% final residual stenosis. The Angiographic Core Lab reported a 46% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/6/2003 on ASA and clopidogrel. On 3/18/2004 the patient was rehospitalized for recurrent angina. Repeat angiography on 3/18/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed no thrombus and a 92% restenosis of the target lesion reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis, target lesion revascularization." The patient underwent repeat revascularization with balloon angioplasty in the proximal RCA and was discharged on 3/19/2004. Repeat angiography on 7/29/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 65% intra-stent restenosis reported by the Angiographic Core Lab with the notation that no PCI was performed. In a query response the site confirmed that CABG surgery was planned and on 9/1/2004 the patient underwent elective CABG surgery with bypass grafts to the proximal RCA and proximal LAD, reported by the site as a target vessel/non-target vessel revascularization. There were no complications reported and the patient was discharged on 9/8/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–CABG 685 days post-procedure**<br>The patient is a 74 year-old woman with a history of dyslipidemia and hypertension who presented without angina. On 12/4/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/5/2003 on ASA and clopidogrel. Repeat angiography on 10/18/2005 for recurrent clinical symptoms with a positive functional ischemia study revealed a site reported NA% restenosis of the target lesion. A translated Discharge Summary noted a 70% outlet stenosis of a large RCA and a 30% in-stent restenosis of a previous stent (12/2003). The Angiographic Core Lab report is not available. No revascularization was performed at this time. On 10/19/2005 the patient underwent CABG surgery with bypass grafts to the distal RCA, the distal LAD, the 1st diagonal and the 1st OM. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–CABG 239 days post-procedure**<br>The patient is a 54 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 10/28/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/29/2003 on ASA and clopidogrel. A protocol re-study on 6/15/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 58% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 2 in-stent restenosis pattern. No revascularization was performed at this time and CABG surgery was recommended according to a narrative. On 6/23/2004 the patient underwent elective CABG surgery with a LIMA to the LAD and a bypass graft to the OM and was discharged on 6/29/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 273 days post-procedure**<br>The patient is a 45 year-old man with a history of current smoking and dyslipidemia who presented with CCS Class II stable angina. On 9/1/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. The stent was post-dilated and there were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/2/2003 on ASA and clopidogrel. A protocol re-study on 5/31/2004 with recurrent clinical symptoms and a positive functional ischemia study revealed a 65% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent restenosis pattern. The patient underwent repeat revascularization with balloon angioplasty and placement of a Taxus™ stent in the proximal RCA and was discharged on 6/1/2004. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 274 days post-procedure**<br>The patient is a 71 year-old man with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class III stable angina. On 10/28/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 4% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "tortuous and angulated target site in the mid LAD." The post-procedure course was uncomplicated and the patient was discharged on 10/29/2003 on ASA and clopidogrel. Repeat angiography on 7/28/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 56% in-lesion restenosis with the notation of a type 2 in-stent stenosis pattern. The Cardiac Catheterization Report indicates that the patient underwent repeat revascularization with balloon angioplasty of the mid LAD with placement of one CYPHER™ stent distal to and overlapping the study device and one CYPHER™ stent proximal to and overlapping the study stent. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 240 days post-procedure** |
| | | | The patient is a 65 year-old man with a history of dyslipidemia who presented with a positive functional ischemia study. On 9/29/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/30/2003 on ASA and clopidogrel. A protocol re-study on 5/26/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 92% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent restenosis pattern. The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER™ stent in the proximal LAD and balloon angioplasty of the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 253 days post-procedure** |
| | | | The patient is a 57 year-old man with a history of MI on 12/12/2003, hypertension and dyslipidemia who presented with an unknown CCS Class of angina. On 12/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A second assigned stent was placed proximal to and overlapping the first assigned stent as treatment for a long lesion. The Angiographic Core Lab reported a 0.6% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/19/2003 on ASA and clopidogrel. Protocol re-study on 8/27/2004 in the absence of recurrent angina or a functional ischemia study revealed a 73% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1C in-stent restenosis; TVR was done; no GAP between the target stent and segment." On 11/14/2004 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty in the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 243 days post-procedure**<br>The patient is a 57 year-old woman with a history of diabetes, dyslipidemia, and premature CAD in a first degree relative who presented with a MI on 10/2/2003 and a positive functional ischemia study. On 10/16/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the distal RCA. A second study stent was placed distal to and overlapping the first study stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 29% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/17/2003 on ASA and clopidogrel. A protocol re-study on 6/15/2004 in the absence of recurrent angina and without a functional ischemia study revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 2 in-stent stenosis pattern. The site reported restenosis of the "proximal stent." The patient underwent repeat revascularization with balloon angioplasty and placement of a drug eluting stent in the mid RCA and was discharged on 6/16/2004. On 11/3/2004 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 252 days post-procedure**<br>The patient is a 67 year-old man with a history of dyslipidemia, hypertension and premature CAD in a first degree relative who presented with a MI on 10/23/2003. On 11/6/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the distal RCA. The stent was post-dilated which resulted in a site reported grade A distal dissection. A second stent was placed distal to and overlapping the first stent to stabilize the lesion. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/7/2003 on ASA and clopidogrel. A protocol re-study on 7/15/2004 in the absence of recurrent angina and without a positive functional ischemia study revealed a 76% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty and placement of a Taxus™ Express 2™ stent in the distal RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 159 days post-procedure**<br>The patient is a 43 year-old woman with a history of current smoking who presented with Braunwald Class I unstable angina. On 11/14/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/15/2003 on ASA and clopidogrel. On 4/18/2004 the patient was hospitalized at an outlying hospital for recurrent chest pain. Cardiac enzyme testing was within normal range and she was transferred to the investigational institution for further testing. Repeat angiography on 4/21/2004 for recurrent clinical symptoms without a functional ischemia study revealed an 83% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent stenosis." The patient underwent repeat revascularization with balloon angioplasty and placement of a stent of the proximal RCA and was discharged on 4/22/2004. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 273 days post-procedure**<br>The patient is a 52 year-old woman with a history of smoking, dyslipidemia and hypertension who presented with CCS Class II unstable angina and a positive functional ischemia study. On 9/29/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/30/2003 on ASA and clopidogrel. The patient was rehospitalized on 6/28/2004 for the 9-month follow-up but the exercise stress test was stopped due to chest pain at 4 minutes and 19 seconds. The site reported there were no ECG changes. Repeat angiography on 6/28/2004 for recurrent clinical symptoms and with a positive functional ischemia study revealed a 62% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty of the RCA and cutting balloon angioplasty of the distal stent in the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 174 days post-procedure**<br>The patient is a 35 year-old man with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class II stable angina. On 11/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS in the mid RCA. During pre-treatment there was a site reported grade F spiral dissection, intimal flap and coronary artery spasm with abrupt closure, a total occlusion and TIMI 0 flow. This was associated with recurrent angina and ischemic ECG changes and treated with placement of three assigned stents in the RCA to cover the dissection. The Angiographic Core Lab reported on a lesion in the proximal RCA with a 12% final residual in-lesion stenosis with a grade D dissection and TIMI 3 flow. There were no cardiac enzyme elevations post-procedure. The ECG Core Lab reported new, persistent, high lateral T wave inversions and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. Repeat angiography on 5/5/2004 for recurrent angina with a positive functional ischemia study revealed an 85% in-lesion restenosis of a lesion in the proximal RCA reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 167 days post-procedure**<br>The patient is a 53 year-old man with a history of dyslipidemia and premature CAD in a first degree relative who presented with CCS Class IV stable angina and a positive functional ischemia study. On 10/2/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS, and delivery of one assigned stent in the proximal LAD. The stent was post-dilated. A second assigned stent was placed distal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/3/2003 on ASA and clopidogrel. On 3/16/2004 the patient was rehospitalized with chest pain. Repeat angiography on 3/17/2004 for recurrent angina with a positive functional ischemia study revealed a 79% in-lesion restenosis reported by the Angiographic Core Lab. The patient underwent successful repeat revascularization with balloon angioplasty of the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 237 days post-procedure** |
| | | | The patient is a 70 year-old woman with a history of dyslipidemia, hypertension, premature CAD in a first degree relative and MI in 9/2003 who presented with CCS Class III stable angina. On 10/15/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/15/2003 on ASA and clopidogrel. On 6/7/2004 the patient was hospitalized for a protocol re-study which was performed earlier than scheduled due to recurrent clinical symptoms. Repeat angiography on 6/8/2004 for recurrent angina without a positive functional ischemia study revealed a 79% in-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD and the 1st diagonal. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 110 days post-procedure** |
| | | | The patient is a 63 year-old woman with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class II stable angina. On 11/12/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/13/2003 on ASA and clopidogrel. On 2/29/2004 the patient was rehospitalized for a percutaneous renal artery procedure and recurrent angina. Repeat angiography on 3/1/2004 for recurrent angina without a functional ischemia study revealed a 51% in-lesion restenosis reported by the Angiographic Core Lab. The site further reported moderate stenosis of the proximal stent. The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the proximal RCA. During the procedure there was a site reported coronary spasm nearly occluding the RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 162 days post-procedure** |
| | | | The patient is a 54 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 11/20/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/21/2003 on ASA and clopidogrel. On 4/29/2004 the patient was rehospitalized for re-angiography. Repeat angiography on 4/30/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 57% restenosis reported by the Angiographic Core Lab. It further commented "in-stent restenosis type 2" with "residual distal LAD stenosis-- non-target lesion." The site reported 90% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 153 days post-procedure**<br>The patient is a 63 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with a positive functional study. On 12/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The site reported a 0% final residual stenosis. The Angiographic Core Lab noted the presence of coronary spasm and reported a 45% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/19/2003 on ASA and clopidogrel. A functional ischemia study on 3/22/2004 noted "ischemia of the anterior septo-apical area and inferior wall with necrosis of the lower third of the lateral wall" which was "comparable" to a study performed in 12/2003. On 5/11/2004 the patient was rehospitalized for a positive functional ischemia report performed on 3/22/2004. Repeat angiography on 5/12/2004 without the presence of angina revealed a 50% restenosis reported by the Angiographic Core Lab with comment "in-stent restenosis." Revascularization was not performed at this time and hospitalization was scheduled. On 5/17/2004 the patient was rehospitalized for elective PTCA. Repeat angiography on 5/18/2004 revealed a 65% in-stent restenosis reported by the Angiographic Core Lab. He underwent repeat revascularization with balloon angioplasty of the proximal LAD, the mid LAD and the distal LAD and was discharged on 5/19/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 384 days post-procedure**<br>The patient is a 64 year-old man with a history of dyslipidemia, hypertension, CABG surgery of a non-target vessel, and PCI with stenting of target vessel (date unknown) who presented with Braunwald Class IIIB unstable angina. On 12/23/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/24/2003 on ASA and clopidogrel. Repeat angiography on 1/10/2005 for recurrent clinical symptoms without a functional ischemia study revealed a site reported 75% restenosis of the target lesion. The Angiographic Core Lab reported a 67% intra-stent restenosis with the notation of PCI for in-stent restenosis. The patient underwent repeat revascularization of the distal RCA and was treated with a Taxus™ stent implantation with a good angiographic result and no procedural complications. The patient was discharged on 1/11/2005. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 112 days post-procedure**<br>The patient is a 59 year-old man with a history of current smoking, dyslipidemia, premature CAD in a first degree relative and CABG who presented with CCS Class III stable angina and a positive functional ischemia study. On 1/6/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/7/2004 on ASA and clopidogrel. A functional ischemia study on 4/6/2004 was stopped after the patient experienced “a burning chest pain” which was associated with ST depression >1 mm in the lateral leads. On 4/26/2004 the patient was rehospitalized for recurrent clinical symptoms. Repeat angiography on 4/27/2004 for recurrent angina with a positive functional ischemia study revealed a site reported 64% in-lesion restenosis reported by the Angiographic Core Lab report with the notation “type 3 in-stent restenosis.” The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 262 days post-procedure**<br>The patient is a 59 year-old man with a history of dyslipidemia, hypertension, premature CAD in a first degree relative, and a percutaneous revascularization of a non-target vessel who presented with CCS Class III stable angina. On 8/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/11/2003 on ASA and clopidogrel. A protocol re-study on 4/29/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 76% in-lesion restenosis reported by the Angiographic Core Lab. The site reported a 95% in-stent restenosis of the target lesion. The patient underwent successful repeat revascularization with balloon angioplasty of the proximal RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 160 days post-procedure**<br>The patient is a 71 year-old man with a history of MI in 1994, diabetes, dyslipidemia and hypertension who presented with CCS Class III angina and a positive stress test. On 8/29/2003 he underwent the index procedure with delivery of one assigned stent in the proximal LAD. A grade B dissection was noted after pre-treatment, which improved post-stent delivery to grade A. A second assigned stent was delivered proximal to and abutting the primary stent to further stabilize the lesion. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB values were 84 and 71 respectively. Only one set of cardiac enzymes was drawn at 8 hours post-procedure. The CK was 95 (nl 190, ratio <1) with a CKMB of 74 (nl 16, ratio 4.6). The post-procedure Troponin was <0.01 (nl 0.05, ratio <1). A comment on a Narrative Form reported CKMB was “falsely increased due to macro CK type I.” The ECG Core Lab noted an inadequate tracing quality due to severe artifact and reported no new major ST-T abnormalities and no new Q waves. There were no further complications and the patient was discharged on 8/29/2003 on ASA and clopidogrel. Repeat angiography on 2/5/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 68% in-lesion restenosis reported by the Angiographic Core Lab. The site reported a “diffuse” restenosis in the LAD with a 90-99% subtotal proximal lesion. The patient underwent repeat revascularization with balloon angioplasty and stent placement in the proximal LAD and the proximal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA [2] 239 days post-procedure**<br>The patient is a 43 year-old man with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class IV unstable angina. On 10/14/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/14/2003 on ASA and clopidogrel. A protocol re-study on 6/9/2004 at 15:49 without recurrent angina and without a positive functional ischemia study revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis, target lesion revascularization." The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD. Following revascularization the patient developed recurrent chest pain with ST depression and he was brought back to the cardiac catheterization lab. Repeat angiography at 19:00 revealed a 25% in-lesion re-narrowing reported by the Angiographic Core Lab with the notation "probable early clinical event after the first procedure, PCI for discomfort and target lesion -- radiolucency." The site reported 70% restenosis of the proximal LAD and a "severe ostial lesion of the 1st diagonal related to previous stent and further severe lesion distally at trifurcation." The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD and the 1st diagonal. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 133 days post-procedure**<br>The patient is a 55 year-old man with a history of current smoking, dyslipidemia, and a MI on 9/21/2003 who presented with CCS Class IV unstable angina. On 10/24/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/28/2003 on ASA and clopidogrel. Repeat angiography on 3/5/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 71% in-lesion restenosis reported by the Angiographic Core Lab. A Cardiac Catheterization report noted "severe asymmetric stenosis" distal to the study stent. On 3/5/2004 the patient underwent repeat revascularization with balloon angioplasty of the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 155 days post-procedure**<br>The patient is a 42 year-old man with a history of current smoking, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class III stable angina. On 10/27/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/27/2003 on ASA and clopidogrel. The patient was rehospitalized on 3/24/2004 to an outlying hospital with unstable angina and transferred to the investigational institution for further study. On 3/30/2004 the patient was rehospitalized at an outlying hospital for unstable angina. Repeat angiography on 3/30/2004 for recurrent angina without a functional ischemia study revealed a 74% in-lesion restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the mid RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 47 days post-procedure**<br>The patient is a 34 year-old man with a history of recent smoking and a MI on 11/6/2003 who presented with CCS Class III angina. On 11/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS followed by the delivery of one assigned stent in the mid LAD. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. The post-procedure course was uncomplicated and the patient was discharged on 11/17/2003 on ASA and clopidogrel. The patient was rehospitalized for coronary syndrome and no MI was reported. Repeat angiography on 1/3/2004 for clinical symptoms without a functional ischemia study revealed a 75% in-lesion restenosis with no thrombus reported by the Angiographic Core Lab. The site reported an in-stent restenosis and possible thrombus within the study stent and confirmed post-procedure compliance of clopidogrel. A narrative noted a non-study IVUS was performed. The patient underwent repeat revascularization with balloon angioplasty and stent placement of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 63, 189 and 359 days post-procedure, Target Vessel Revascularization–PTCA 189 days post-procedure** |
| | | | The patient is a 70 year-old man with a history of current smoking, dyslipidemia and a MI in 1989 who presented with a Braunwald Class II unstable angina. On 12/24/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/24/2003 on ASA and clopidogrel. Repeat angiography on 1/21/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 25% in-lesion restenosis reported by the Angiographic Core Lab. No revascularization was performed at this time and a query response reported that the patient was rehospitalized on 2/25/2004 due to the findings of the repeat angiography on 1/21/2004. Repeat angiography on 2/25/2004 revealed a 59% in-lesion restenosis reported by the Angiographic Core Lab. It further commented "important intimal hyperplasia, target lesion revascularization." The translated cardiac catheterization report noted that a fractional flow reserve test noted a "moderately diseased ostium" and additional disease proximal to the LAD stent. On 2/25/2004 the patient underwent repeat revascularization with balloon angioplasty, cutting balloon angioplasty, and placement of a Maverick stent in the mid LAD. On 6/30/2004 the patient was rehospitalized for increasing chest pain. Repeat angiography for recurrent angina without a functional ischemia study revealed an 85% in-lesion reported by the Angiographic Core Lab. The site reported "significant in-stent restenosis and significant stenosis proximal to the stent." The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD and the mid LAD. The patient was rehospitalized on 12/12/2004 for recurrent angina. Repeat angiography on 12/17/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent restenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD, the distal RCA and the 1st RPL with placement of a stent in the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 86 days post-procedure**<br>The patient is an 80 year-old man with a history of dyslipidemia and a MI on 6/13/2003 who presented with CCS Class I stable angina and a positive functional ischemia study. On 1/6/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st diagonal. Post-stenting, there was a site reported plaque shift in the LAD, which was treated with placement of a non-study stent in the ostium of the first diagonal. A grade A dissection distal to the non-study stent was treated by placement of a second non-study stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/7/2004 on ASA and clopidogrel. Repeat angiography at an outlying institution on 3/23/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 71% in-lesion restenosis reported by the Angiographic Core Lab. The site confirmed no revascularization was performed at this time. Repeat angiography on 4/1/2004 revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab with the notation “type 1B in-stent restenosis, target lesion revascularization, bifurcation lesion LAD-diagonal.” The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal, the proximal LAD and the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 870 days post-procedure**<br>The patient is a 54 year-old man with a history of dyslipidemia who presented with CCS Class III angina and a positive functional ischemia study. On 11/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/10/2003 on ASA and clopidogrel. The patient was rehospitalized on 3/10/2006 for elective angiography due to recurrent clinical symptoms. Repeat angiography on 3/17/2006 for recurrent clinical symptoms with a positive functional ischemia study (12/6/2005) revealed a 50-75% mid RCA restenosis with a 50-75% stenosis of the RCA reported in a Discharge Summary. The Angiographic Core Lab report is not available and no intervention was performed on this date. A re-study on 3/29/2006 revealed a 57% intra-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. A Discharge Report noted a 65% stenosis of the mid RCA. On 03/29/2006 the patient underwent repeat revascularization with placement of a TAXUS™ Liberte stent in the mid RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 132 days post-procedure**<br>The patient is a 58 year-old woman with a history of current smoking, dyslipidemia, hypertension, and premature CAD in a first degree relative who presented with Braunwald Class II unstable angina. On 12/11/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the mid RCA with a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/11/2003 on ASA and clopidogrel. Repeat angiography on 4/21/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 72% in-lesion restenosis of a lesion in the mid RCA reported by the Angiographic Core Lab with the notation “type 3 in-stent restenosis, treated with a new stent deployment as a target lesion revascularization.” The patient underwent repeat revascularization with balloon angioplasty and stent placement in the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 297 days post-procedure**<br>The patient is a 73 year-old man with a history of dyslipidemia, hypertension, premature CAD in a first degree relative, percutaneous revascularization of a non-target vessel, and a MI in May 2002 who presented with CCS Class IV unstable angina. On 12/22/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/23/2003 on ASA and clopidogrel. On 10/8/2004 the patient was rehospitalized and diagnosed with pulmonary edema secondary to LV impairment and medications were altered. Repeat angiography on 10/14/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a site reported 95% restenosis of the target lesion. In a query response the site confirmed the cine was sent to the Core Lab; however the Angiographic Core Lab confirmed that they never received a CD for 10/14/2004, therefore the analysis is not available. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 190 days post-procedure**<br>The patient is a 74 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class IV unstable angina. On 11/10/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The site reported a 0% final residual stenosis. The Angiographic Core Lab reported a 54% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/12/2003 on ASA and clopidogrel. A functional ischemia test performed on 4/26/2004 was "clinically negative and electrically non-interpretable, with scintigraphic aspect of myocardial ischemia at level of apex and apical third of the lateral wall." On 5/17/2004 the patient was rehospitalized for "silent myocardial ischemia." Repeat angiography on 5/18/2004 without the presence of angina and with a positive functional ischemia study revealed a 58% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent stenosis pattern. The site reported a 90% restenosis of the target lesion and a "tight stenosis of the distal LAD." On 5/18/2004 the patient underwent repeat revascularization with balloon angioplasty and implantation of three Taxus™ stents in the mid LAD and the distal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 296 days post-procedure** |
| | | | The patient is an 81 year-old woman with a history of diabetes, hypertension and a MI on 11/17/2003 who presented with CCS Class IV unstable angina. On 11/25/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated by a site reported possible sepsis and ischemic hypovolemic shock on 11/26/2003 thought due to diuretic treatment of pulmonary edema diagnosed on admission on 11/19/2004, prior to the index procedure. The patient was treated with antibiotics and pressors with gradual improvement. Repeat angiography on 12/2/2003 revealed a 15% renarrowing reported by the Angiographic Core Lab. No revascularization was performed at this time. The patient was discharged on 12/19/2003 on ASA and clopidogrel. On 9/15/2004 the patient was rehospitalized for recurrent angina. Repeat angiography on 9/16/2004 for recurrent angina without a positive functional ischemia study revealed a 57% in-lesion restenosis reported by the Angiographic Core Lab with the notation “type 2 in-stent restenosis, PCI was done as a target vessel revascularization.” The site reported 78% in-stent restenosis of the target lesion and reported a target lesion revascularization. The patient underwent successful repeat revascularization with balloon angioplasty and cutting balloon angioplasty of the 1st OM. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 164 days post-procedure**<br>The patient is a 56 year-old man with a history of current smoking, diabetes, dyslipidemia, and premature CAD in a first degree relative who presented with a positive functional ischemia study. On 11/25/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There was a site reported distal grade A dissection post-stenting which was treated with placement of a second assigned stent distal to and overlapping the first stent. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with a grade A dissection and TIMI 3 flow. The patient was discharged on 11/26/2003 on ASA and clopidogrel. On 5/6/2004 the patient was rehospitalized for "silent myocardial ischemia." The Discharge Summary indicates a functional ischemia study performed in April 2004 revealed "an inferior ischaemia." Repeat angiography on 5/7/2004 without the presence of angina and with a positive functional ischemia study revealed a 72% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis, a new stent deployed, target lesion revascularization." The site reported a target vessel revascularization with a mid RCA stenosis and a 30% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty and placement of a "coated" stent in the mid RCA. On 11/3/2004 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 433 and 545 days post-procedure, Target Vessel Revascularization–PTCA 545 days post-procedure** |
| | | | The patient is a 52 year-old man with a history of former smoking, dyslipidemia, and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 10/14/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/17/2003 on ASA and clopidogrel. On 12/19/2004 the patient was rehospitalized for angina. Repeat angiography on 12/20/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a site reported 75% in-stent restenosis of the target lesion. The Angiographic Core Lab reported a 57% intra-stent restenosis with the notation of a target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD. On 4/9/2005 the patient was rehospitalized for increasing episodes of angina. Repeat angiography on 4/11/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 65% intra-stent restenosis reported by the Angiographic Core Lab. The site reported 90% in-stent restenosis of the target lesion and a 50% stenosis of the LMCA. The patient underwent repeat revascularization with balloon angioplasty and placement of one CYPHER™ stent in the distal segment of the LMCA and the proximal LAD. Balloon angioplasty was also performed in the 1st diagonal and the patient was subsequently discharged on 4/13/2005. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 28 days post-procedure**<br>The patient is a 72 year-old man with a history of diabetes and hypertension who presented with CCS Class II stable angina. On 12/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty. The site reported that the assigned stent was not implanted in the mid RCA due to heavy calcification. The Angiographic Core Lab noted "no stenting or rheolytic therapy done" and reported an 82% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation that a thrombus is present at baseline and in final. It further noted that no PCI done during index cine, film identified as clinical event, shows PCI performed." There were no clinical sequelae. The post-procedure course was uncomplicated and the patient was discharged on 12/22/2003 on ASA and clopidogrel. On 1/14/2004 the patient was rehospitalized for an elective revascularization. Repeat angiography on 1/15/2004 with an absence of clinical symptoms without a functional ischemia study revealed a 76% in-lesion stenosis reported by the Angiographic Core Lab. The patient underwent successful revascularization with rotational atherectomy in the mid RCA and was discharged on 1/19/2004. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 171 days post-procedure**<br>The patient is a 64 year-old woman with a history of current smoking and dyslipidemia who presented with CCS Class III unstable angina. On 11/11/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal RCA with a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/12/2003 on ASA and clopidogrel. The patient was rehospitalized on 4/29/2004. Repeat angiography on 4/30/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 68% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 1C in-stent stenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 118 and 239 days post-procedure** |
| | | | The patient is a 68 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class IV unstable angina. On 12/3/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/4/2003 on ASA and clopidogrel. On 3/29/2004 the patient was rehospitalized for recurrent angina and a functional ischemia study was "negative" according to the Discharge Summary. Repeat angiography on 3/30/2004 for recurrent clinical symptoms with a negative functional ischemia study revealed a site reported 80% "in-stent" restenosis of the target lesion. The Angiographic Core Lab report is not available at this time. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD and was discharged on 3/31/2004. Repeat angiography on 7/29/2004 with recurrent angina and with a positive functional ischemia study revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis, target lesion revascularization with stenting." The site reported that the patient underwent repeat revascularization of the proximal LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 99 days post-procedure** |
| | | | The patient is a 72 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III angina. On 8/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty and IVUS. There was a site reported grade A dissection reported after pre-treatment. One assigned stent was delivered in the mid LAD and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/21/2003 on ASA and clopidogrel. On 11/27/2003 the patient was transferred to the investigational institution from an outlying hospital for recurrent angina. Repeat angiography on 11/27/2003 for recurrent angina and a positive functional ischemia study revealed a 62% in-stent restenosis reported by the Angiographic Core Lab. The patient underwent revascularization with placement of one CYPHER™ stent in the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Target Lesion Revascularization–PTCA 245 days post-procedure** |
| | | | The patient is a 78 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class III stable angina. On 9/15/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 29% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/17/2003 on ASA and clopidogrel. A protocol re-study on 5/17/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed an 88% type II in-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA. |
| | | **ENDEAVOR DES** | **Target Lesion Revascularization–PTCA 287 days post-procedure** |
| | | | The patient is a 65 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class II stable angina. On 11/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. A second assigned stent was delivered distal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/18/2003 on ASA and clopidogrel. Repeat angiography on 8/30/2004 for recurrent angina without a positive functional ischemia study revealed a 52% in-lesion restenosis reported by the Angiographic Core Lab. At the request of the CEC, the Angiographic Core Lab further commented “PCI for type 1B in-stent restenosis, target lesion revascularization, stent deployed for in-stent restenosis in the proximal edge.” The site reported a target vessel revascularization with a 0% restenosis of the target lesion and a 70% proximal lesion. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 274 days post-procedure**<br>The patient is a 54 year-old man with a history of current smoking and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 11/27/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/28/2003 on ASA and clopidogrel. A "control" re-study on 8/27/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 69% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B stent stenosis treated with a stent as target lesion revascularization." The site reported a target vessel revascularization with a 0% restenosis of the target lesion. The Discharge Report noted a 90% stenosis of the mid RCA with the notation "stenosis immediately proximal to the RCA stent." The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the mid RCA. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 337 days post-procedure**<br>The patient is a 65 year old woman with a history of dyslipidemia, hypertension, and premature CAD in a first degree relative who presented with Braunwald Class II unstable angina and a positive functional ischemia study. On 12/16/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There was a site reported grade A dissection post-dilation. A second assigned stent was implanted distal to and overlapping the first stent to stabilize the lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/17/2003 on ASA and clopidogrel. Repeat angiography on 11/17/2004 without recurrent clinical symptoms and with a positive functional ischemia study revealed a 54% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B in-stent restenosis: target lesion revascularization." The Cardiac Catheterization Report dated 11/17/2004 reported an 80% stenosis before the stent in the LAD and noted the "stents themselves were intact." The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD and the 1st diagonal with implantation of a Taxus™ stent in the LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 239 days post-procedure** |
| | | | The patient is a 75 year-old man with a history of current smoking, hypertension and premature CAD in a first degree relative who presented with a positive functional ischemia study. On 8/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/20/2003 on ASA and clopidogrel. A protocol re-study on 4/13/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis, 2 new stents were deployed, 80% ostial lesion of the AC marginal." The site reported the patient underwent repeat revascularization with balloon angioplasty of the mid RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 74 days post-procedure** |
| | | | The patient is a 77 year-old man with a history of hypertension who presented with CCS Class II stable angina. On 10/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. On 12/23/2003 the patient was rehospitalized for recurrent clinical symptoms. A narrative reported there were no ECG changes and troponin levels were not performed. Repeat angiography for recurrent angina without a functional ischemia study revealed a site reported 99% "in-stent" restenosis of the target lesion. In response to a query the Angiographic Core Lab confirmed the cine is not available for review. The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER™ stent in the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 575 days post-procedure**<br>The patient is a 69 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class II stable angina. On 10/1/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned device in the ramus. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/2/2003 on ASA and clopidogrel. On 4/27/2005 the patient was rehospitalized because of recurrent angina. Repeat angiography on 4/28/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 66% multifocal in-stent restenosis reported by the Angiographic Core Lab. The site reported an 80% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty and placement of a Taxus™ stent in the ramus, identified by the site as a target lesion revascularization. He was discharged on 4/29/2005. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 250 days post-procedure**<br>The patient is a 56 year-old woman with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class II stable angina. On 10/10/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. Repeat angiography on 6/16/2004 for a “scheduled PTCA” with recurrent angina and without a functional ischemia study revealed a 65% in-lesion restenosis reported by the Angiographic Core Lab with the notation “type 2 in-stent restenosis, stent is not patent, target lesion revascularization.” The site reported a non-target lesion revascularization. The Discharge Summary reported a “high-grade extensive in-stent recurrence (50%) and a high-grade proximal denovo stenosis” of the proximal LAD. The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal. On 11/17/2004 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 227 days post-procedure**<br>The patient is a 73 year-old man with a history of dyslipidemia and a MI on 6/4/2003 who presented with a positive functional ischemia study. On 10/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/22/2003 on ASA and clopidogrel. On 6/3/2004 the patient was rehospitalized for unstable angina. Repeat angiography on 6/3/2004 for recurrent clinical symptoms revealed a 55% in-lesion restenosis reported by the Angiographic Core Lab. On 6/3/2004 the patient underwent repeat revascularization with balloon angioplasty of the mid LAD and the proximal RCA. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 223 days post-procedure**<br>The patient is a 67 year-old man with a history of dyslipidemia, hypertension, CABG surgery of a non-target vessel and a MI on 11/7/2003 who presented with CCS Class II stable angina. On 11/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/14/2003 on ASA and clopidogrel. The site reported the patient was rehospitalized in an “other” hospital with chest pain. A protocol re-study performed at the non-study institution on 6/23/2004 for recurrent clinical symptoms and without a functional ischemia study revealed a site reported “NA”% restenosis of the target lesion. A narrative further noted that the “angio CD” is not available. In response to a query the site reported that the Cardiac Catheterization Report is not available; therefore no further information is forthcoming. The patient underwent repeat revascularization with balloon angioplasty of the proximal CX, reported by the site as a target lesion revascularization. On 1/5/2005 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 242 days post-procedure**<br>The patient is a 45 year-old man with a history of current smoking, dyslipidemia, hypertension and a MI on 9/8/2003 who presented with CCS Class IV angina. On 9/15/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS, and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/17/2003 on ASA and clopidogrel. Repeat angiography on 5/14/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 70% in-lesion restenosis reported by the Angiographic Core Lab. The site reported a 99% "high-grade in-stent" restenosis. The patient underwent successful repeat revascularization with balloon angioplasty of the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 251 days post-procedure**<br>The patient is a 76 year-old man with a history of current smoking, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class II stable angina. On 10/9/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. A protocol re-study on 6/16/2004 with recurrent clinical symptoms without a positive a functional ischemia test revealed a 62% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty with stent implantation distal to the proximal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 231 days post-procedure** |
| | | | The patient is a 51 year-old man with a history of smoking and dyslipidemia who presented with CCS Class II stable angina. On 8/19/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/20/2003 on ASA and clopidogrel. On 4/6/2004 the patient was rehospitalized one week early for a planned angiography due to a new onset of angina. A protocol re-study on 4/6/2004 for recurrent angina without a functional ischemia study revealed 65% restenosis of the mid LAD reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 131 days post-procedure** |
| | | | The patient is a 52 year-old woman with a history of current smoking, diabetes and dyslipidemia who presented with CCS Class II angina. On 9/17/2003 she underwent the index procedure with pre-treatment balloon angioplasty and the delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 8% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/19/2003 on ASA and clopidogrel. On 1/26/2004 the patient was rehospitalized with chest pain. Repeat angiography on 1/26/2004 for clinical symptoms and a positive functional ischemia study revealed a 68% in-lesion restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 169 days post-procedure**<br>The patient is a 71 year-old man with a history of dyslipidemia and premature CAD in a first degree relative who presented with CCS Class III unstable angina. On 9/23/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/24/2003 on ASA and clopidogrel. The patient was rehospitalized on 3/9/2004 for recurrent clinical symptoms. Repeat angiography on 3/10/2004 for recurrent angina without a positive functional ischemia study revealed an 85% in-lesion restenosis reported by the Angiographic Core with the notation "1C in-stent stenosis pattern." A Discharge Summary reported "severe in-stent restenosis in the LAD" with additional stenosis in non-target vessels. The patient underwent repeat revascularization with cutting balloon angioplasty of the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 228 days post-procedure**<br>The patient is a 75 year-old man with a history of dyslipidemia and hypertension who presented without angina. On 10/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the R-PDA. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/18/2003 on ASA and clopidogrel. Repeat angiography on 6/1/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 77% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty of the R-PDA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 79 days post-procedure**<br>The patient is a 51 year-old man with a history of premature CAD in a first degree relative who presented with CCS Class III stable angina. On 11/26/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 38% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/27/2003 on ASA and clopidogrel. On 2/13/2004 the patient was rehospitalized for recurrent angina. Repeat angiography on 2/13/2004 for recurrent angina without a positive functional ischemia study revealed an 89% in-lesion reported by the Angiographic Core Lab. It further commented "type 1B in-stent restenosis--target lesion revascularization." The Cardiac Catheterization report noted a "subtotal stenosis of the RCA, proximally to the already implanted stent" with a 99% restenosis in the proximal RCA, a 25% lesion "in the stent" of the mid third of the RCA and additional disease in a non-target vessel. The patient underwent repeat revascularization with balloon angioplasty and placement of a VELOCITY™ stent in the "middle third" of the RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 252 days post-procedure**<br>The patient is a 66 year-old woman with a history of smoking, diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with Braunwald Class I unstable angina and a positive functional ischemia study. On 9/9/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A second assigned stent was placed distal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The site reported a 0% final residual stenosis. The Angiographic Core Lab reported a 50% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/10/2003 on ASA and clopidogrel. A protocol re-study on 5/18/2004 without recurrent clinical symptoms and without a functional ischemia study revealed a 92% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis." The patient underwent successful repeat revascularization with balloon angioplasty of the mid LAD and was discharged after a two day hospitalization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 221 and 626 days post-procedure** |
| | | | The patient is a 79 year-old woman with a history of diabetes, dyslipidemia, hypertension, and a MI on 9/24/2003 who presented with Braunwald Class II angina. On 9/26/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/9/2003 on ASA and clopidogrel. A protocol re-study on 5/4/2004 with recurrent clinical symptoms and without a positive functional ischemia study revealed a 72% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent stenosis pattern. The patient underwent successful repeat revascularization with balloon angioplasty of the mid LAD. According to a translated Discharge Letter and a Cardiac Catheterization Report on 6/13/2005, repeat angiography without recurrent clinical symptoms and with a positive function ischemia study revealed a LAD stent obstruction after the D1 branch and a total occlusion of a very small CX. The Angiographic Core Lab reported a 95% type IV (occlusive) intra-stent restenosis with the presence of thrombus and TIMI 1 flow. The patient underwent repeat revascularization with balloon angioplasty and stent-in-stent implantation of a Taxus™ stent in the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 246 days post-procedure**<br>The patient is a 72 year-old man with a history of smoking, dyslipidemia, hypertension and a CABG of a non-target vessel who presented with Braunwald Class II unstable angina. On 9/30/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. A second assigned stent was placed proximal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/1/2003 on ASA and clopidogrel. A protocol re-study on 6/2/2004 with recurrent clinical symptoms and without a functional ischemia study revealed a 53% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 1C in-stent stenosis pattern. The patient underwent successful repeat revascularization with balloon angioplasty of the proximal CX and the 1st OM. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 106, 166 and 231 days post-procedure** |
| | | | The patient is a 67 year-old woman with a history of current smoking, diabetes, dyslipidemia, hypertension, percutaneous revascularization of a non-target vessel, and a MI in 1996 who presented with CCS Class II angina. On 11/6/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A second assigned stent was placed distal to and overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis, a grade C dissection with staining, no perforation and TIMI 3 flow. The post-procedural course was uncomplicated and the patient was discharged on 11/7/2003 on ASA and clopidogrel. A narrative dated 2/20/2004 indicates that the patient was rehospitalized for 1 week with recurrent thoracic pain and no cardiac enzyme results were performed. The ECG Core Lab reported new, persistent, major, anterior T wave depressions and no new Q waves. Repeat angiography on 2/20/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 100% total occlusion in-stent with no thrombus and TIMI 1 flow reported by the Angiographic Core Lab. The site reported a 100% total occlusion of the target lesion. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. Repeat angiography on 4/20/2004 for recurrent clinical symptoms without a functional ischemia study revealed a site reported 98% restenosis of the target lesion. In response to a query the Angiographic Core Lab confirmed the cine is not available for review. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. Repeat angiography on 6/24/2004 for recurrent clinical symptoms without a functional ischemia study revealed 78% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 2 in-stent stenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 250 days post-procedure** |
| | | | The patient is a 65 year-old man with a history of hypertension and prior percutaneous revascularization in a non-target vessel who presented with CCS Class II stable angina. On 11/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 33% final residual stenosis with no dissection and TIMI 3 flow. The site reported a 0% final residual stenosis. The post-procedure course was uncomplicated and the patient was discharged on 11/8/2003 on ASA and clopidogrel. A protocol re-study on 7/14/2004 with recurrent clinical symptoms and without a functional ischemia study revealed a 66% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 2 in-stent restenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the distal CX. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 252 days post-procedure** |
| | | | The patient is a 64 year-old man who presented with CCS Class II angina and a positive functional ischemia study. On 10/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the distal CX. A second assigned stent was placed distal to and overlapping the first stent for treatment of a long lesion. The Angiographic Core Lab reported on a lesion in the proximal CX with a 27% final residual in-lesion stenosis, no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/18/2003 on ASA and clopidogrel. The patient was rehospitalized on 6/22/2004 and a functional ischemia study revealed "significant horizontal and downslope ST segment depression" with exertion in leads 1, V3-V6. A protocol re-study on 6/24/2004 in the presence of clinical symptoms revealed a 44% in-lesion restenosis in the proximal CX reported by the Angiographic Core Lab with the notation of a "60% eccentric stenosis in the LAD." The Discharge Report noted reported the proximal CX was "without stenosis" however there was a "short 80% stenosis" ("probably the stent overlap"). The patient underwent revascularization with balloon angioplasty and IVUS in the distal CX, reported as a target lesion revascularization "in the overlapping area of the stents." |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 792 days post-procedure**<br>The patient is a 75 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 10/20/2003 she underwent the index procedure with no pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/22/2003 on ASA and clopidogrel. Repeat angiography on 12/20/2005 for recurrent angina with a negative functional ischemia study revealed a 50.3% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. A Discharge Summary reported a 70% in-stent restenosis and a short section of new stenosis distal from the index stent. The patient underwent repeat revascularization with balloon angioplasty of the index stent and placement of an additional stent distal to the target lesion in the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 341 days post-procedure**<br>The patient is a 68 year-old woman with a history of hypertension and percutaneous revascularization of a non-target vessel who presented without angina. On 11/5/2003 she underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/7/2003 on enoxaparin, phenprocoumon and clopidogrel. On 10/11/2004 the patient was rehospitalized for recurrent angina. Repeat angiography on 10/11/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 51% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 1C in-stent restenosis pattern. The site reported a70% restenosis of the target lesion on the Repeat Angiography Form and noted a 60% in-stent restenosis in the “RIVA stent” reported on the Cardiac Catheterization Report. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD, reported by the site as a target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 254 days post-procedure, Target Vessel Revascularization–PTCA 451 days post-procedure** |
| | | | The patient is a 72 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 11/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/24/2003 on ASA and clopidogrel. A Discharge Letter reported the patient was rehospitalized on 7/27/2004 for a re-study. A protocol re-study on 7/28/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed 54% in-lesion restenosis reported by the Angiographic Core Lab with the notation “target lesion revascularization was done with stenting” for a type 1B in-stent stenosis pattern. The site reported a 70% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty with stent placement in the proximal LAD. Planned repeat angiography on 2/10/2005 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 12% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent patent, PCI for diagonal artery, remote target vessel revascularization." The Cardiac Catheterization Report noted a 70 to 80% lesion at the outlet of a diagonal branch off the stented area in the LAD. The patient underwent repeat revascularization with balloon angioplasty and stenting of the 1st diagonal. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 253 days post-procedure**<br>The patient is a 74 year-old man with a history of current smoking, diabetes, dyslipidemia, hypertension, a percutaneous revascularization of a non-target vessel, and a MI on 10/16/2003 who presented without angina. On 11/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/20/2003 on ASA and clopidogrel. A protocol re-study on 7/28/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed an 86% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent stenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 153 days post-procedure**<br>The patient is a 50 year-old man with a history of current smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, percutaneous revascularization of a non-target vessel, and MI on 5/19/2003 who presented with CCS Class III stable angina. On 1/7/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab commented that the procedure was performed "through a SVG lesion in the first diagonal distal to the anastomotic site of the SVG" and noted stenting of the distal SVG and diagonal. It further reported on a lesion in the 1st diagonal (identified by the Core Lab as the target lesion) with a 36% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/9/2004 on ASA and clopidogrel. On 6/2/2004 the patient was rehospitalized for recurrent angina. On 6/7/2004 a functional ischemia study revealed a "clinically negative ergometry with the absence of cardiac exhaustion." Repeat angiography on 6/8/2004 with recurrent angina pectoris and with a negative functional ischemia study revealed a 77% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis, target lesion revascularization." The patient underwent repeat revascularization with balloon angioplasty of the 1st OM and was discharged on 6/10/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **ENDEAVOR DES** | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 740 days post-procedure** |
| | | | The patient is a 72 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III angina. On 1/9/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st diagonal. According to the Angiographic Core Lab there was a grade B dissection after balloon pre-dilation. There were no clinical sequelae. The Angiographic Core Lab reported on lesion in the 2nd diagonal with a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/12/2004 on ASA and clopidogrel. Repeat angiography on 1/18/2006 for recurrent angina and without a positive functional ischemia study revealed a 75% stenosis of both the 1st and 2nd diagonal according to a translated Interventional Catheterization Report. In a query response the site reported no cine is available for this event as the angiography occurred at a non-study site, therefore the Angiographic Core Lab report will not be available. The patient underwent in-stent balloon angioplasty in the 2nd diagonal and balloon angioplasty with placement of a Taxus™ stent in the 1st diagonal, reported by the site as both a target lesion revascularization and a non-target vessel revascularization. |
| | | **DRIVER** | **Target Lesion Revascularization–PTCA 245 days post-procedure** |
| | | | The patient is a 51 year-old man with a history of dyslipidemia who presented with CCS Class I stable angina and a positive functional ischemia study. On 10/21/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/22/2003 on ASA and clopidogrel. A protocol re-study on 6/22/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 71% in-lesion restenosis reported by the Angiographic Core Lab with the notation “type 2 in-stent restenosis.” The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 77 days post-procedure** |
| | | | The patient is a 76 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 12/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. A second assigned stent was implanted proximal to without overlapping the first stent for a long lesion. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/12/2003 on ASA and clopidogrel. Repeat angiography on 2/26/2004 for recurrent clinical symptoms without a functional ischemia study revealed an 87% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA and the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 591 days post-procedure** |
| | | | The patient is a 47 year-old man with a history of former smoking, diabetes, dyslipidemia and hypertension who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 12/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/18/2003 on ASA and clopidogrel. The patient was rehospitalized on 7/26/2005 for recurrent exertional angina. Repeat angiography on 7/27/2005 for recurrent clinical symptoms and a positive functional ischemia study revealed a 53% marginal in-stent restenosis reported by the Angiographic Core Lab. A narrative reported a 45% restenosis of the target lesion with the notation of 3 vessel disease: an occluded RCA, an 80% stenosis of the OM and an eccentric stenosis proximal to the study stent. No intervention was performed at this time and IVUS of the LAD along with revascularization of the 1st OM were planned. On 7/29/2005 the patient underwent repeat revascularization with balloon angioplasty and placement of one Taxus™ stent in the 1st OM. Post-stenting IVUS was performed and an additional Taxus™ stent placed proximal to and overlapping the first stent. IVUS was then performed in the LAD and a re-study revealed no significant change from the previous study on 7/27/2005 as reported by the Angiographic Core Lab. He underwent repeat revascularization with balloon angioplasty and placement of one Taxus™ stent covering the restenotic lesion and the original stent in the proximal LAD. The patient was discharged on 8/1/2005. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 310 days post-procedure**<br>The patient is a 49 year-old man with a history of current smoking and dyslipidemia who presented with CCS Class III unstable angina. On 12/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/17/2003 on ASA and clopidogrel. A narrative reported the patient developed recurrent angina. A functional ischemia study on 9/23/2004 was positive for ischemia with "depression of horizontal ST (2 mm) in leads V3-V6 from the 6th minute of exercising." Repeat angiography on 10/21/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a left diffuse restenosis in the "previously stented lesion in his LAD (maximal stenosis: 80%)" and a new lesion in the LAD "distal to the stent" according to the narrative. The Angiographic Core Lab reported a 53% in-lesion restenosis with the notation "type 1C in-stent restenosis." The site reported that the patient underwent successful repeat revascularization with balloon angioplasty and overlapping placement of three CYPHER™ stents in the proximal LAD and the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 243 days post-procedure**<br>The patient is a 71 year-old man with a history of dyslipidemia who presented with CCS Class IV angina, a MI on 11/3/2003 and a positive functional ischemia study. On 11/6/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The stent was post-dilated. A second assigned stent was placed distal to and overlapping the first stent for a site reported haziness. There were no clinical sequelae. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/9/2003 on ASA and clopidogrel. A protocol re-study on 7/6/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 79% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1C in-stent restenosis, significant ostial LAD lesion and left main disease." The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 161 days post-procedure**<br>The patient is a 54 year-old man with a history of dyslipidemia and premature CAD in a first degree relative who presented with Braunwald Class II unstable angina. On 11/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty followed by delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. No MACE events were reported and the patient was discharged on 11/21/2003 on ASA and clopidogrel. Repeat angiography on 4/25/2004 for recurrent angina with a positive functional ischemia study revealed 91% in-lesion restenosis reported by the Angiographic Core Lab with the notation " >50% stenosis inside the study stent and at the distal edge." On 4/25/2004 the patient underwent repeat revascularization with balloon angioplasty of the proximal RCA, the mid RCA and the distal CX. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 189 days post-procedure**<br>The patient is a 61 year-old man with no prior history of CAD who presented with CCS Class II stable angina. On 11/25/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. A second assigned stent was placed proximal to and overlapping the first stent for a site reported "filling defect." There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/26/2003 on ASA and clopidogrel. On 6/1/2004 the patient was hospitalized for chest pain and an elective angiography. Repeat angiography for recurrent clinical symptoms with a positive functional ischemia study revealed the presence of a thrombus, a 100% in-stent restenosis and TIMI 0 flow reported by the Angiographic Core Lab. No MI was reported by the site. The patient underwent repeat revascularization with balloon angioplasty of the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 117 days post-procedure**<br>The patient is a 70 year-old woman with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class II unstable angina. On 1/8/2004 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/9/2004 on ASA and clopidogrel. On 5/3/2004 the patient was rehospitalized. Repeat angiography on 5/4/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed an 82% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty and stent placement of the proximal LAD and the mid LAD. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 853 days post-procedure**<br>The patient is a 44 year-old man with a history of an MI in 1995, prior PCI of a non-target vessel, dyslipidemia, hypertension, current smoking, and premature CAD in a 1st degree relative who presented with CCS Class IV unstable angina. On 10/9/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/10/2003 on ASA and clopidogrel. Repeat angiography on 2/8/2006 for recurrent angina and without a functional ischemia study revealed a new 90% lesion of the mid RCA, a 40% lesion of the proximal RCA, and a 40-50% lesion of the distal RCA according to an Interventional Catheterization Report. In a query response the site reported no cine is available for this event as the angiography occurred at a non-study site, therefore the Angiographic Core Lab report will not be available. The patient underwent balloon angioplasty with stent placement in the mid RCA, reported by the site as a target vessel revascularization at a location other than the target lesion. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 164 days post-procedure**<br>The patient is a 68 year-old man with no prior history of CAD who presented with CCS Class IV unstable angina. On 1/1/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/5/2004 on ASA and clopidogrel. On 6/11/2004 the patient was rehospitalized for recurrent angina and a site reported positive functional ischemia study with "significant ST depression in leads V3-V5." Repeat angiography on 6/13/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 78% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a 1C in-stent stenosis pattern. The patient underwent repeat revascularization with balloon angioplasty and cutting balloon angioplasty of the distal CX. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 262 days post-procedure**<br>The patient is a 58 year-old woman with a history of diabetes, dyslipidemia, hypertension and percutaneous revascularization of a non-target lesion presented with CCS Class II unstable angina. On 1/4/2004 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/6/2004 on ASA and clopidogrel. On 9/15/2004 the patient was rehospitalized for "acute coronary syndrome" with ischemic ECGs and diagnosed with a site reported non-Q wave MI. The CK peaked on 9/15/2004 at 47 (nl 110, ratio <1) no CKMBs were performed. The ECG Core Lab reported on tracings with inadequate quality due to lead misplacement and reported no new major ST-T abnormalities and no new Q waves. The site confirmed that no thrombolytics were administered. On 12/15/2004 the CEC ruled the event did not meet the criteria for a non-Q wave MI. Repeat angiography on 9/22/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 55% in-lesion restenosis reported by Angiographic Core Lab with the notation "type 2 in-stent restenosis," target lesion revascularization. The site reported an 80% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty of the distal RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 231 days post-procedure**<br>The patient is a 57 year-old woman with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 11/4/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/5/2003 on ASA and clopidogrel. A protocol re-study on 6/22/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 51% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis, target vessel revascularization." The site reported a target lesion revascularization with a 90% in-stent restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty with placement of a CYPHER™ stent in the mid RCA. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 95 days post-procedure**<br>The patient is an 81 year-old man with a history of dyslipidemia and percutaneous coronary revascularization in a non-target vessel who presented with CCS Class II angina and a positive functional ischemia study. On 11/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. Post-stenting there was a site reported distal grade C dissection with "minimal" dye extravasation and TIMI 3 flow. This was post-dilated without improvement of the dissection grade. A narrative indicates that an echocardiogram revealed "an absence of pericardial fluid." The site reported a 0% final residual stenosis with a grade C dissection and TIMI 3 flow. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection, no staining and TIMI 3 flow. The patient was discharged on 11/16/2003 on ASA and clopidogrel. In February 2004 the patient was rehospitalized with angina. Repeat angiography on 2/16/2004 for recurrent clinical symptoms without a functional ischemia study revealed 83% in-lesion restenosis with TIMI 1 flow reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 436 days post-procedure**<br>The patient is a 67 year-old man with a history of diabetes and hypertension who presented with CCS Class III unstable angina and a positive functional ischemia study. On 1/13/2004 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/14/2004 on ASA and clopidogrel. The site reported the patient was rehospitalized on 3/24/2005 at a non-study hospital for persistent strong chest pain. Repeat angiography on 3/24/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a site reported 99% restenosis of the target lesion. The site confirmed the cine was not sent to the Angiographic Core Lab, therefore, the report is not available. The translated Cardiac Catheterization Report noted a 99% in-stent restenosis in the distal LAD, described as the site of PTCA in January 2004, with an additional 95% lesion in a small distal vessel. On 3/24/2005 the patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER™ stent in the mid LAD; however the translated Catheterization Report noted intervention in the distal LAD. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 196 days post-procedure**<br>The patient is a 63 year-old man with a history of diabetes and hypertension who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 11/25/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. A second assigned stent was placed proximal to and abutting the first stent for a long lesion. The stents were post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal RCA with an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/26/2003 on ASA and clopidogrel. On 6/7/2004 patient was rehospitalized for a two month duration of chest pain. Repeat angiography on 6/8/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 74% in-lesion restenosis of a lesion in the proximal RCA reported by the Angiographic Core Lab with the notation “type 3 in-stent restenosis, target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty of the mid RCA and was discharged on 6/10/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 707 and 994 days post-procedure** |
| | | | The patient is a 58 year-old man with a history of diabetes who presented without angina and without a positive functional ischemia study. On 12/2/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported an 8% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/3/2003 on ASA and clopidogrel. The patient was rehospitalized with unstable angina on 11/7/2005. Repeat angiography on 11/8/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a site reported total occlusion of the target lesion. The Angiographic Core Lab reported a total occlusion of the stent with TIMI 0 flow and noted "subtotal occlusion in proximal part of stent, distal part occluded with bridge collateral." The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER™ stent in the mid RCA and a Vision™ stent in the distal RCA, reported as a target lesion and target vessel revascularization. The CEC ruled the event met the criteria for a clinically driven target lesion revascularization. On 8/20/2006 the patient was hospitalized for a site reported non-Q wave MI. No cardiac enzymes were done at that time. A troponin of 0.22 (nl 2, ratio <1) was reported on 8/22/2006. In a query response the site states no ECGs are available for this event as it occurred at a non-study site, therefore the ECG Core Lab report will not be available. The site provided a summary of the ECG findings in a query response that states Q waves were present in lead III. Repeat angiography on 8/22/2006 for recurrent angina and without a functional ischemia study revealed a site reported 99% stenosis of the target lesion. The Angiographic Core Lab reported an 83% intra-stent restenosis with the notation target lesion revascularization. The patient underwent balloon angioplasty in the mid RCA, reported by the site as a target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 308 days post-procedure**<br>The patient is a 55 year-old man with a history of MI in 2001 and dyslipidemia who presented with CCS Class I angina. On 10/21/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 28% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/23/2003 on ASA and clopidogrel. A protocol re-study on 8/3/2004 in the absence of recurrent angina or a functional ischemia study revealed an 81% in-lesion restenosis reported by the Angiographic Core Lab. Additional repeat angiography on 8/24/2004 revealed a 74% in-lesion restenosis reported by the Angiographic Core Lab. On 8/24/2004 the patient underwent revascularization in the distal CX, reported as a target lesion revascularization. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 293 days post-procedure**<br>The patient is a 53 year-old man with a history of MI on 10/9/2003, hypertension and dyslipidemia who presented with CCS Class II angina. On 11/5/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. The Angiographic Core Lab reported on a lesion in the mid LAD with a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "stent underdeployed due to calcification." The post-procedure course was uncomplicated and the patient was discharged on 11/7/2003 on ASA and ticlopidine. A protocol re-study on 8/20/2004 in the presence of clinical symptoms and in the absence of a positive functional ischemia study revealed a 59% in-lesion restenosis in the mid LAD reported by the Angiographic Core Lab. Additional angiography on 8/24/2004 revealed a 72% in-lesion restenosis in the mid LAD reported by the Angiographic Core Lab. On 8/24/2004 the patient underwent balloon angioplasty and delivery of brachytherapy in the proximal LAD, reported by the site as a target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 280 days post-procedure**<br>The patient is a 54 year-old man with a history of smoking, dyslipidemia, hypertension and MI in 2000 who presented with CCS Class III stable angina. On 10/3/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/6/2003 on ASA and clopidogrel. A protocol re-study on 7/9/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 54% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B in-stent restenosis." The site reported a target vessel revascularization with a 0% restenosis of the target lesion and a 70% lesion proximal to the study stent. The patient underwent repeat revascularization with balloon angioplasty and stent implantation in the proximal LAD and the mid RCA. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA, Target Vessel Revascularization–PTCA 254 days post-procedure**<br>The patient is a 55 year-old man with a history of dyslipidemia and a MI on 4/4/1999 who presented with CCS Class II stable angina and a positive functional ischemia study. On 10/14/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the distal CX with a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/16/2003 on ASA and clopidogrel. A protocol re-study on 6/24/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 95% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis, new stent deployed at proximal edge, remote target vessel revascularization and target vessel revascularization done to get TIMI 3 flow." The site reported 100% total occlusion of the "proximal end of the study stent." The patient underwent repeat revascularization with balloon angioplasty of the proximal CX and the distal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 188 days post-procedure**<br>The patient is a 47 year-old man with a history of smoking, hypertension and a MI on 8/28/2003 who presented with CCS Class I stable angina. On 11/28/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/1/2003 on ASA and clopidogrel. On 6/2/2004 the patient was rehospitalized for recurrent unstable angina. Repeat angiography on 6/3/2004 for recurrent angina without a functional ischemia study revealed a 100% in-lesion occlusion reported by the Angiographic Core Lab with the notation "type 4 stenosis of study stent, numbers are taken from final, treated with stenting as target lesion revascularization." The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the proximal RCA and balloon angioplasty of the 1st OM and was discharged on 6/4/2004. |
| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 990 days post-procedure**<br>The patient is a 64 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class III angina. On 1/12/2004 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the distal CX with a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow and noted the presence of abrupt closure. The post-procedure course was uncomplicated and the patient was discharged on 1/14/2004 on ASA and clopidogrel. Repeat angiography on 9/28/2006 for recurrent angina and with a negative functional ischemia study revealed a site reported 0% stenosis of the target lesion. The Angiographic Core Lab reported a 12% in-lesion restenosis and noted "study stent patent, but 1st OM, a large side branch departing from mid part of study stent, had an ostial stenosis. This lesion was treated with balloon inflation while the proximal part of the balloon was located in the study stent; therefore, resulting in a remote target vessel revascularization and target lesion revascularization without ISR in the study stent." An Interventional Catheterization report was requested; however, a query response only provided a brief summary that noted critical stenosis in the OM, PCI performed. The patient underwent balloon angioplasty in the 1st OM, reported by the site as a non-target vessel revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 251 days post-procedure**<br>The patient is a 57 year-old man with a history of MI on 11/12/2002 who presented with CCS Class III stable angina. On 10/21/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 5% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/23/2003 on ASA and ticlopidine. A protocol re-study on 6/28/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed an 82% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent stenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA, Subacute Closure/Stent Thrombosis day of procedure, Target Vessel Revascularization–PTCA 88 and 159 days post-procedure** |
| | | | The patient is a 58 year-old woman with a history of current smoking and hypertension who presented with Braunwald Class III unstable angina. On 10/17/2003 at 13:20 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. The Angiographic Core Lab reported a 39% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The site reported that IIb/IIIa inhibitors were not administered during the procedure. About 17:00 post-procedure the patient experienced recurrent angina and ischemic ECG changes and was brought back to the Cardiac Catheterization Lab. Repeat angiography on 10/17/2003 at 17:30 for clinical symptoms without a functional ischemia study revealed a site reported grade E dissection "not visible at the end of the index procedure." The Angiographic Core Lab reported on a lesion in the mid RCA with a 100% in-stent total occlusion with TIMI 0 flow with the notation of eccentric stenosis about 50% distal to the distal end of the deployed stent in index procedure (best seen in RAO view) not a frank dissection and commented "acute stent thrombosis." The patient underwent repeat revascularization with stent placement in the distal RCA. The pre-procedure CK was 112 (nl 222, ratio <1). The post-procedure CKs were 67, 74 and 59. No CKMB results were reported. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 10/23/2003 on ASA and clopidogrel. On 1/13/2004 the patient was rehospitalized for angina. Repeat angiography on 1/13/2004 for recurrent clinical symptoms and a positive functional ischemia study revealed a 42% in-lesion restenosis reported by the Angiographic Core Lab with the notation in-stent restenosis "at a portion of the RCA not included in the analysis segment chosen during QCA of index lesion" and further commented that the in-stent restenosis did not occur "in the stent deployed during index procedure." The patient underwent repeat revascularization with balloon angioplasty of the distal RCA and was discharged. On 3/23/2004 the patient was rehospitalized for stable angina. Repeat angiography on 3/24/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 36% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a "mild degree" of hyperplasia inside the study stent. On 3/24/2004 she underwent repeat revascularization with balloon angioplasty of the R-PAV. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 210 days post-procedure**<br>The patient is a 73 year-old man with a history of hypertension and a MI on 9/28/2000 who presented with CCS Class IV unstable angina. On 11/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery on one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 11/11/2003 at 14:05 were 207 (222, ratio <1) and 34 (nl 14, ratio 2.4). The site reported a single post-procedure CK and CKMB drawn on 11/12/2003 at 06:00 were 366 (ratio 1.6) and 36 (ratio 2.6). A narrative reported the patient's hospitalization was prolonged due to chest pain and to "control the cardiac enzyme level." No cardiac enzyme results were provided between 11/12/2003 and 11/17/2003. The CK results from 11/17/2003 to 11/20/2003 were 61, 62 & 24 (ratios <1). The troponin I level on 11/17/2003 was 1.015 (nl .09, ratio 11.3). The ECG Core Lab reported persistent, new major, anterior T wave inversions and no new Q waves. On 11/17/2004 the CEC ruled the event did not meet the criteria for a non-Q wave MI. The patient was discharged on 11/21/2003 on ASA, clopidogrel and nadroparin calcium. On 6/7/2004 the patient was rehospitalized with chest pain. Repeat angiography on 6/8/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 77% restenosis reported by the Angiographic Core Lab with the notation "diffuse proliferative in-stent restenosis." The patient underwent repeat revascularization with balloon angioplasty with placement of a CYPHER™ stent in the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 49 days post-procedure**<br>The patient is a 73 year-old man without a history of coronary risk factors who presented with CCS Class I stable angina and a positive functional ischemia study. On 12/4/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 37% final residual in-lesion stenosis with no dissection and TIMI 3 flow. It further commented there was an "under deployment of the distal end of the stent." The post-procedure course was uncomplicated and the patient was discharged on 12/5/2003 on ASA and clopidogrel. On 1/22/2004 the patient was rehospitalized for a planned revascularization of a non-target vessel. Repeat angiography on 1/22/2004 without the presence of angina and without a functional ischemia study revealed an 88% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a type 3 in-stent restenosis pattern, "target lesion revascularization." The patient underwent repeat revascularization of the mid LAD and the distal CX. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 355 days post-procedure**<br>The patient is a 67 year-old man with a history of hypertension who presented with CCS Class IV unstable angina. On 12/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one stent in the 1st diagonal. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the ramus with a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/12/2003 on ASA and clopidogrel. On 11/29/2004 the patient was rehospitalized. Repeat angiography on 11/29/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 67% in-lesion restenosis reported by the Angiographic Core Lab on a lesion in the ramus with the notation of a type 2 in-stent restenosis pattern. The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal and was discharged on 11/30/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 151 days post-procedure**<br>The patient is a 61 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class II stable angina. On 10/24/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 4% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/25/2003 on ASA and clopidogrel. A functional ischemia study on 3/19/2004 revealed a site reported ST depression in leads V5-V6 with the presence of angina. On 3/23/2004 the patient was rehospitalized for CCS Class III angina. Repeat angiography on 3/23/2004 for recurrent angina with a positive functional ischemia study revealed a 76% in-lesion restenosis reported by the Angiographic Core Lab. The site reported 99% "in-stent" restenosis of the target lesion. On 3/23/2004 the patient underwent repeat revascularization with balloon angioplasty of the proximal RCA and the following day on 3/24/2004 she underwent revascularization of the distal CX and was discharged on 3/25/2004. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 204 days post-procedure**<br>The patient is a 43 year-old man with a history of hypertension, dyslipidemia and current smoking who presented with CCS Class II angina and a positive functional ischemia study. On 12/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/12/2003 on ASA and clopidogrel. Repeat angiography on 7/2/2004 revealed a 79% intra-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization, non-target vessel PCI for CX ostium." The translated Cardiac Catheterization report noted that the patient underwent repeat revascularization on 7/2/2004 with balloon angioplasty and placement of one Taxus™ stent in the proximal LAD and also in the proximal CX. Balloon angioplasty of the 1st diagonal was performed through the meshwork of the stent. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 91 and 169 days post-procedure, Target Vessel Revascularization–PTCA 169 days post-procedure** |
| | | | The patient is a 58 year-old man with a history of smoking, dyslipidemia, hypertension, and percutaneous revascularization in a non-target vessel who presented with CCS Class II angina and a positive functional ischemia study. On 9/9/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and the delivery of one assigned stent in the proximal LAD. A second assigned stent was placed proximal to and overlapping the first stent for tandem stenosis. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the mid LAD with a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/10/2003 on ASA and clopidogrel. The patient was rehospitalized in December 2003. Repeat angiography on 12/9/2003 for recurrent clinical symptoms and a positive functional ischemia study revealed a 50% in-lesion restenosis reported by the Angiographic Core Lab on a lesion in the mid LAD. The patient underwent revascularization with balloon angioplasty of the proximal LAD and the 1st diagonal. A protocol re-study on 2/25/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed an 80% in-lesion restenosis of a lesion in the mid LAD reported by the Angiographic Core Lab with comment “target lesion revascularization and PCI for ostial CX lesion and left main PTCA for ostial lesion.” The site reported “restenosis in the stent and in stent proximal to study stent.” The patient underwent repeat revascularization of the proximal LAD, the mid LAD, the 1st diagonal, the left main coronary artery and the proximal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 400, 540 and 709 days post-procedure, Target Vessel Revascularization–PTCA 540 days post-procedure** |
| | | | The patient is a 57 year-old man with a history of dyslipidemia who presented with CCS Class IV unstable angina. On 9/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/18/2003 on ASA and clopidogrel. Repeat angiography on 10/21/2004 without clinical symptoms and with a positive functional ischemia study revealed a 65% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis, target lesion revascularization." The patient underwent repeat revascularization with balloon angioplasty and brachytherapy of the proximal RCA. On 3/9/2005 the patient was rehospitalized with angina. Repeat angiography on 3/10/2005 for clinical symptoms without a functional ischemia study revealed an 84% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis, target lesion revascularization." The patient underwent repeat revascularization with balloon angioplasty and stent placement in the proximal RCA and the mid RCA. Repeat angiography on 8/26/2005 for recurrent clinical symptoms with a recent positive functional ischemia study revealed a 90% proliferative in-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization of the proximal RCA and the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Lesion Revascularization–PTCA 148 days post-procedure**<br>The patient is a 67 year-old man with a history of dyslipidemia and hypertension who presented with no angina or MI. On 10/1/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. A second assigned stent was delivered proximal to and overlapping the first stent for stabilization. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/2/2003 on ASA and clopidogrel. On 2/11/2004 the patient was rehospitalized for recurrent clinical symptoms. No cardiac enzyme data was reported for this date; however the site reported "no MI occurred." The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. Repeat angiography on 2/11/2004 for recurrent angina without a functional ischemia study revealed no thrombus and a 100% in-stent occlusion reported by the Angiographic Core Lab. The Cardiac Catheterization Report noted an in-stent occlusion of the RCA and significant disease in non-target vessels. Revascularization was not performed at this time and bypass surgery was recommended. After "much deliberation" and consultation with surgeons and interventional cardiologists the patient opted for repeat PTCA. On 2/25/2004 the patient was rehospitalized. The site reported a single CK at 41 (nl 171, ratio <1) and CKMB was not done. Repeat angiography on 2/26/2004 revealed a 100% occlusion reported by the Angiographic Core Lab with the notation "in-stent restenosis type 4." The patient underwent elective repeat revascularization with balloon angioplasty of the mid RCA and was discharged on 2/27/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Lesion Revascularization–PTCA 418 days post-procedure**<br>The patient is a 62 year-old man with a history of dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class IV unstable angina. On 11/26/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the R-PAV. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the R-PDA with a 7% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK was 108 with an elevated CKMB of 26 (nl 10, ratio 2.6). Approximately 16 hours post-procedure the CK peaked at 124 (nl 171, ratio <1) with a CKMB of 31 (nl 10, 3.1). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 11/27/2003 on ASA and clopidogrel. Repeat angiography on 1/17/2005 for recurrent clinical symptoms without a functional ischemia study revealed a 72% intra-stent restenosis reported on a lesion in the R-PDA by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the proximal R-PAV. |
| | | DRIVER | **Target Lesion Revascularization–PTCA 63 days post-procedure**<br>The patient is a 68 year-old man with a history of hypertension, premature CAD in a first degree relative and a CABG of a non-target vessel who presented with Braunwald Class I unstable angina and a positive functional ischemia study. On 12/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the ramus. The stent was post-dilated. The Angiographic Core Lab reported a 29% final residual in-lesion stenosis with no dissection and TIMI 3 flow. There were no clinical sequelae. The post-procedure course was uncomplicated and the patient was discharged on 12/17/2003 on ASA and clopidogrel. The site reported that the patient developed recurrent angina seven weeks post-procedure and was rehospitalized on 2/16/2004. Repeat angiography on 2/18/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed a 95% restenosis with TIMI 1 flow reported by the Angiographic Core Lab with comment “in-stent restenosis with in-stent sub-occlusion due to important intimal hyperplasia but not completely occlusive.” The patient underwent repeat revascularization with balloon angioplasty of the ramus and the proximal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Target Vessel Revascularization–CABG 682 days post-procedure** |
| | | | The patient is a 55 year-old woman with a history of dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 11/14/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/17/2003 on ASA and clopidogrel. On 7/21/2005 the patient was rehospitalized due to unstable angina. Repeat angiography on 7/25/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 24% in-lesion restenosis reported by the Angiographic Core Lab with the notation of >50% left main disease. A narrative reported no revascularization was performed at this time and on 9/26/2005 the patient was rehospitalized and underwent CABG surgery with a bypass graft to the proximal LAD, the mid LAD, the proximal RCA, the mid RCA and the 1st OM. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–CABG 255 days post-procedure**<br>The patient is a 63 year-old man with a history of diabetes, hypertension and percutaneous revascularization in a non-target vessel who presented with CCS Class IV unstable angina. On 9/5/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/6/2003 on ASA and clopidogrel. A functional ischemia study on 5/4/2004 was discontinued for right chest pain and was reported as "positive." Repeat angiography on 5/5/2004 for recurrent clinical symptoms and with a positive functional ischemia study revealed a 27% in-lesion restenosis reported by the Angiographic Core Lab with the notation of distal "left main stenosis." The site reported 60% stenosis of the main branch "including stenosis at the origins of the LAD and RCX (plaque at the bifurcation)," moderate stenosis of the LAD and an "excellent result" in area of PTCA and stenting in the "medial portion of the RCX." It appears that no intervention was performed at this time. On 5/17/2004 the patient was rehospitalized for surgical intervention of "progressive" left main disease. The site reported a target vessel and non-target vessel revascularization. The patient underwent CABG surgery of the mid LAD, the distal CX and the ramus. |
| | | DRIVER | **Target Vessel Revascularization–PTCA 329 days post-procedure**<br>The patient is a 55 year-old man with a history of current smoking, diabetes, dyslipidemia and hypertension who presented with CCS Class IV unstable angina. On 9/15/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/16/2003 on ASA and clopidogrel. A protocol re-study on 8/9/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 62% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 3 in-stent restenosis." The site reported an 80% restenosis of the target lesion. On 8/9/2004 the patient underwent repeat revascularization with balloon angioplasty, brachytherapy and stent placement of the mid LAD and the 2nd diagonal. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 275 days post-procedure**<br>The patient is a 53 year-old man with a history of dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 12/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A second assigned stent was delivered distal to and overlapping the first stent to stabilize the lesion. The Angiographic Core Lab reported on a lesion in the proximal LAD with a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/17/2003 on ASA and clopidogrel. Repeat angiography on 9/16/2004 for recurrent angina without a positive functional ischemia study revealed a 14% in-lesion restenosis reported by the Angiographic Core Lab. The Cardiac Catheterization Report noted "there is no restenosis" of the study stent and reported an occlusion of a diagonal branch, which is "jailed outside the stent." The patient underwent an unsuccessful attempt to revascularize the 2nd diagonal. |
| | | DRIVER | **Target Vessel Revascularization–PTCA 412 days post-procedure**<br>The patient is a 67 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 12/31/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 6% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 1/2/2004 on ASA and clopidogrel. On 2/13/2005 the patient was rehospitalized for angiography. Repeat angiography on 2/14/2005 without recurrent clinical symptoms and with a positive functional ischemia study (performed 1/31/2005) revealed a 14% in-lesion restenosis reported by the Angiographic Core Lab. On 2/15/2005 the patient underwent repeat revascularization with balloon angioplasty and placement of at total of three Taxus™ stents in the 1st OM, the proximal RCA, and the mid RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 595 days post-procedure** |
| | | | The patient is a 68 year-old man with a history of current smoking, diabetes, and hypertension who presented with Braunwald Class II B unstable angina. On 11/6/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/10/2003 on ASA and clopidogrel. Repeat angiography on 6/22/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 38% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent. On 6/23/2005 the patient underwent repeat revascularization direct stenting using a Taxus™ stent of the proximal RCA, reported by the site as a target vessel revascularization. |
| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 474 days post-procedure** |
| | | | The patient is a 57 year-old man with a history of dyslipidemia who presented with Braunwald Class IB angina. On 11/21/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/23/2003 on ASA and clopidogrel. On 3/8/2005 patient was rehospitalized for chest pain. Repeat angiography on 3/9/2005 revealed 26% in-lesion reported by the Angiographic Core Lab. The site reported a 40% restenosis of the target lesion. The patient underwent repeat revascularization with balloon angioplasty of the distal RCA reported by the site as a target vessel revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 588 days post-procedure**<br>The patient is a 47 year-old man with a history of current smoking, diabetes, and hypertension who presented with CCS Class IV unstable angina. On 8/22/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/23/2003 on ASA and clopidogrel. A narrative reported that the patient was rehospitalized for chest pain at an outlying hospital early in 2005. Repeat angiography on 3/24/2005 for recurrent angina without a positive functional ischemia study revealed a site reported 80% stenosis of the 1st OM and an elective PTCA was planned. Repeat angiography on 4/1/2005 revealed a 50% restenosis of the target lesion of type 1B reported by the Angiographic Core Lab. The patient underwent repeat revascularization with placement of a bare metal stent in the 1st OM and discharged on the day of the procedure. The site reported a non-target vessel revascularization. The CEC ruled the event met the criteria for a clinically driven target vessel revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 30 days post-procedure**<br>The patient is a 71 year-old man with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class III stable angina. On 11/17/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 5% final residual in-lesion stenosis, no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/17/2003 on clopidogrel. On 12/2/2003 the patient was admitted to an outlying hospital for recurrent angina. Repeat angiography on 12/8/2003 for recurrent angina without a functional ischemia study revealed an 18% in-lesion renarrowing reported by the Angiographic Core Lab. The site additionally reported a "possible stenosis of the 1st diagonal." No revascularization was performed at this time and the patient was later transferred to the investigational institution. Repeat angiography on 12/17/2003 for recurrent angina revealed a 13% in-lesion renarrowing reported by the Angiographic Core Lab with the notation of a "non-target lesion revascularization at bifurcation between the mid LAD and the 1st diagonal. Previously deployed stent is widely patent." The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal and placement of a stent in the distal LAD. |
| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 138 days post-procedure**<br>The patient is a 44 year-old man with a history of smoking and dyslipidemia who presented with CCS Class III stable angina and a positive functional ischemia study. On 12/10/2003 he underwent the index procedure with placement pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 7% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/10/2003 on ASA and clopidogrel. On 4/26/2004 the patient was rehospitalized for recurrent clinical symptoms. Repeat angiography on 4/26/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 27% in-lesion restenosis reported by the Angiographic Core Lab with the notation "no in-stent restenosis, target lesion is patent, new stent was deployed to the distal RCA and another stent to the proximal CX." The site reported the patient underwent repeat revascularization with balloon angioplasty of the mid RCA and the proximal CX. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 999 days post-procedure**<br>The patient is a 47 year-old man with a history of dyslipidemia, current smoking, and premature CAD in a 1st degree relative who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 12/04/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/05/2003 on ASA and clopidogrel. Repeat angiography on 8/29/2006 for recurrent angina with a positive functional ischemia study revealed a new circumflex lesion as reported by the site. The Angiographic Core Lab reported a 21% in-lesion restenosis with the notation study stent patent, remote target vessel revascularization of proximal CX, one stent with small gap to study stent. The patient underwent repeat revascularization with placement of a Taxus® stent in the proximal CX, reported as a target vessel revascularization by the site. |
| | | DRIVER | **Target Vessel Revascularization–PTCA 712 days post-procedure**<br>The patient is an 82 year-old woman with a history of hypertension, a MI on 9/11/2003 and a PCI in a non-target vessel who presented with CCS Class III unstable angina. On 9/25/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure was uncomplicated and the patient was discharged on 9/26/2003 on ASA and clopidogrel. Repeat angiography on 9/6/2005 for recurrent clinical symptoms without a functional ischemia study revealed a 43% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent patent, proximal CX lesion, remote target vessel revascularization." In a query response the Core Lab confirmed the lesion was >5 mm proximal to the study stent. A translated Catheterization Report noted an 80% lesion prior to the study stent with no in-stent restenosis. The patient underwent repeat revascularization with direct stenting in the distal CX, identified by the site as a target lesion revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 1009 days post-procedure** |
| | | | The patient is a 72 year-old man with no prior history of CAD who presented with CCS Class II stable angina and a positive functional ischemia study. On 8/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. There was a site reported grade A dissection following stenting. A second assigned stent was placed to cover the dissection. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal RCA, revealing a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/10/2003 on ASA and clopidogrel. Repeat angiography on 5/12/2006 for recurrent clinical symptoms without a functional ischemia study revealed no residual stenosis at the proximal RCA site as noted in a Discharge Summary. In a query response the site states no cine is available for this event as the angiography occurred at a non-study site, therefore the Angiographic Core Lab report is not available. An Interventional Catheterization Summary reported two vessel disease with an 80% stenosis of the distal RCA and additional disease in a non-target vessel. The patient underwent balloon angioplasty with placement of a Taxus™ stent in the distal RCA, reported by the site as a target vessel revascularization. |
| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 243 days post-procedure** |
| | | | The patient is a 66 year-old man with a history of dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class IV unstable angina. On 10/16/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/18/2003 on ASA and clopidogrel. A protocol re-study on 6/15/2004 for recurrent clinical symptoms without a positive functional ischemia study revealed an 11% in-lesion restenosis reported by the Angiographic Core Lab with the notation “no in-stent restenosis.” The site reported a target vessel revascularization with an 80% restenosis “just proximal to the stent.” On 6/15/2004 the patient underwent repeat revascularization with balloon angioplasty with stent implantation in the proximal LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | **DRIVER** | **Target Vessel Revascularization–PTCA 247 days post-procedure**<br>The patient is a 60 year-old man with a history of smoking, dyslipidemia and hypertension who presented with Braunwald Class I unstable angina. On 9/9/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/11/2003 on ASA and clopidogrel. On 5/13/2004 the patient was rehospitalized for recurrent clinical symptoms. A protocol restudy on 5/13/2004 for recurrent clinical symptoms without a functional ischemia study revealed a 37% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent is patent, PCI to distal RCA." The patient underwent repeat revascularization with balloon angioplasty of the distal RCA. |
| | | **ENDEAVOR DES** | **Target Vessel Revascularization–PTCA 701 days post-procedure**<br>The patient is an 80 year-old man with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class IV unstable angina. On 10/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/9/2003 on ASA and clopidogrel. On 9/7/2005 the patient was rehospitalized for dyspnea. Repeat angiography on 9/7/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a 22% in-lesion restenosis reported by the Angiographic Core Lab and it further noted a revascularization of the diagonal. The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal and was discharged on 9/10/2005. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 323 and 698 days post-procedure** |
| | | | The patient is a 71 year-old man with a history of dyslipidemia, hypertension, PTCA in a non-target vessel, and a MI on 9/2/2003 who presented without angina or a functional ischemia study. On 10/15/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow and confirmed the index information is not available for the Angiographic Core Lab's analysis. The post-procedure course was uncomplicated and the patient was discharged on 10/16/2003 on ASA and clopidogrel. Repeat angiography on 9/2/2004 without recurrent clinical symptoms and without a functional ischemia study revealed a site reported NA% restenosis of the target lesion. A Cardiac Catheterization Report noted an 80% stenosis of the "main stem," a 70% stenosis of the distal LAD, an 80% stenosis of the mid RCA, and a 60% stenosis of the proximal CX. The Angiographic Core Lab report is not available. The Core Lab's Director noted the initial baseline film is not available; however the 6/22/2004 and 9/2/2004 follow-up films were reviewed and further noted the LAD stents were widely patent. "There was a progression of the mid body of the left main that did not appear related to the initial procedure; this was ultimately stented." The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER™ stent in the left main coronary artery, reported by the site as a non-target vessel. The CEC determined the event met the criteria for a clinically driven target vessel revascularization. Repeat angiography on 9/12/2005 for recurrent clinical symptoms without a functional ischemia study revealed a site reported 80% restenosis of the target lesion. The Angiographic Core Lab report is not available. The patient underwent repeat revascularization with balloon angioplasty with placement of a CYPHER™ stent in the left main coronary artery, reported by the site as a both a non-target vessel and a target vessel revascularization. The CEC determined the event met the criteria for a clinically driven target vessel revascularization. Additional information is not available. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 248 days post-procedure**<br>The patient is a 64 year-old man with a history of hypertension and dyslipidemia who presented with a positive functional ischemia study. On 10/13/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the in the proximal LAD. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab was unable to furnish a baseline reading for a lesion in the mid LAD, noting "no final image without any guidewire on device was provided." The post-procedure course was uncomplicated and the patient was discharged on 10/15/2003 on ASA and clopidogrel. A protocol re-study on 6/17/2004 in the absence of recurrent angina or a functional ischemia study revealed a 28% in-lesion restenosis in the mid LAD reported by the Angiographic Core Lab with the notation "study stent patent; mid LAD lesion distal to the segment of analysis; PCI for this new lesion, remote TVR; new stent deployed from the study stent." The patient underwent percutaneous revascularization in the mid LAD, reported as a target vessel revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 498 days post-procedure**<br>The patient is a 67 year-old man with a history of current smoking, dyslipidemia, hypertension, and a MI on 12/24/1998 who presented with CCS Class IV unstable angina. On 12/1/2003 he underwent the index procedure with pre-treatment balloon angioplasty. There was a site reported grade B dissection following pre-dilation. One assigned stent was delivered in the 1st OM, successfully covering the dissection. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/3/2003 on ASA and clopidogrel. On 4/11/2005 a narrative reported the patient was rehospitalized for an acute NSTEMI with an elevated troponin I of 0.92 (nl 0.2, ratio 4.6). In a query response the site confirmed that no further lab testing is available for this event. The ECG Core Lab reported on a tracing dated 4/12/2005 of inadequate quality due to severe artifact with no new major ST-T abnormalities and no new Q waves. The CEC ruled the event did not meet the criteria for a Protocol MI. The site further reported an in-stent thrombosis was suspected and anticoagulants were administered. Repeat angiography on 4/12/2005 for recurrent clinical symptoms without a positive functional ischemia study revealed a site reported <30% restenosis of the target lesion. The Angiographic Core Lab reported a 39% in-lesion restenosis with the notation of a patent study stent, remote target lesion revascularization of the proximal CX. The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the proximal CX, identified by the site as a non-target vessel. The CEC ruled the event meet the criteria for a clinically driven target vessel revascularization. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 279 days post-procedure**<br>The patient is an 80 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class III stable angina and a positive functional ischemia study. On 11/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/20/2003 on ASA and clopidogrel. On 8/23/2004 the patient was rehospitalized for unstable angina and cardiac enzyme testing was within normal range. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. Repeat angiography on 8/23/2004 for recurrent clinical symptoms with a positive functional ischemia study revealed a 42% in-lesion restenosis reported by the Angiographic Core Lab. A narrative reported a 30% restenosis of the target lesion and a "critical stenosis in the LAD." The patient underwent repeat revascularization with balloon angioplasty of the 2nd RPL and the proximal LAD with direct stenting of the LAD; the site identified both lesions as non-target vessels. On 3/30/2005 the CEC ruled the event met the criteria for a clinically driven target vessel revascularization. |
| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 896 days post-procedure**<br>The patient is a 61 year-old man with a history of prior PCI of a non-target vessel who presented with CCS Class II angina. On 11/24/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. The Angiographic Core Lab reported a grade B dissection after balloon pre-dilation that was covered with the study stent and spasm of the distal edge of the stent relieved with NTG. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection, TIMI 3 flow, and spasm present. The post-procedure course was uncomplicated and the patient was discharged on 11/26/2003 on ASA and clopidogrel. Repeat angiography on 5/8/2006 for recurrent angina and with a positive functional ischemia study revealed a site reported 0% stenosis of the target lesion. The Angiographic Core Lab reported a 15% in-lesion restenosis with the notation progression of stenosis proximal of the study stent, remote target vessel revascularization with one stent with overlap to study stent. A handwritten translated Catheterization Report noted a 70% stenosis of the mid RCA. The patient underwent repeat revascularization of the mid RCA and the mid LAD. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 240 days post-procedure** |
| | | | The patient is a 62 year-old man with a history of dyslipidemia who presented with CCS Class I stable angina and a positive functional ischemia study. On 8/12/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedural course was uncomplicated and the patient was discharged on 8/13/2003 on ASA and clopidogrel. A protocol re-study on 4/8/2004 without the presence of clinical symptoms and without a positive functional ischemia study revealed a 25% in-lesion restenosis reported by the Angiographic Core Lab with the notation "no significant lesion inside of the stent." It further reported PCI for "lesion in the target vessel." The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA. |

| Site | Pt | Treatment Group | Case Summary |
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| | | ENDEAVOR DES | **Target Vessel Revascularization–PTCA 246 and 372 days post-procedure**<br>The patient is a 67 year-old man with a history of current smoking, diabetes and hypertension who presented with CCS Class III unstable angina and a positive functional ischemia study. On 9/10/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. Post-stenting, the Cardiac Catheterization Report indicates a "suspected severe stenosis" of the proximal RCA was treated with balloon angioplasty and placement of a Zeta stent. The Angiographic Core Lab reported on a lesion in the distal RCA (target lesion) with a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow and noted a 20% final residual in-lesion stenosis in the proximal RCA (non-target). The pre-procedure CK and CKMB on 9/10/2003 at 09:45 were elevated at 212 (nl 171, ratio 1.2) and 13 (nl 10, ratio 1.3) respectively. Post-procedure on 9/11/2003 at 11:59 the CK was 1232 (ratio 7.2) with a CKMB of 26 (ratio 2.6) and at 21:48 the CK decreased to 1115 (ratio 6.5) with a CKMB of 25 (ratio 2.5). The ECG Core Lab reported on ECG tracings dated 9/9/2003 to 9/10/2003 of inadequate quality due to variation in precordial lead placement and noted no new major ST-T abnormalities and no new Q waves. The site reported an asymptomatic non-Q wave MI on 9/11/2003 without ECG changes. Repeat angiography on 9/11/2003 at 14:30 for elevated cardiac enzymes without the presence of angina and without a functional ischemia study revealed a site reported 0% renarrowing of the target lesion with a possible side branch occlusion reported by the site. The Angiographic Core Lab reported on a lesion in the distal RCA with a 21% renarrowing with no thrombus and TIMI 3 flow. Revascularization was not performed at this time. On 9/13/2003 at 09:40 there was a re-elevation of CK of 1503 (ratio 8.8) with a CKMB of 18 (ratio 1.8). The ECG Core Lab reported no new findings for ischemic tracings dated 9/10/2003 to 9/15/2003. After reviewing the data the CEC ruled the event met the criteria for a pre-procedure MI. The patient was discharged on 9/16/2003 on ASA and clopidogrel. A protocol re-study on 5/13/2004 without recurrent clinical symptoms and without a positive functional ischemia study revealed a 12% restenosis of the distal RCA (target lesion) and an 85% in-stent restenosis of a lesion in the proximal RCA reported by the Angiographic Core Lab. The site reported a 10% restenosis of the target lesion and a 95% restenosis of the proximal RCA. The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA, the mid LAD and the proximal CX. Repeat angiography on 9/16/2004 without recurrent angina and without a functional ischemia study revealed a 67% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis; remote TVR was done to CASS # 1 with balloon and brachytherapy." The site reported restenosis of the ostial RCA. The patient underwent balloon angioplasty and brachytherapy in the proximal RCA, reported as a target vessel revascularization. The patient was discharged on 9/17/2004. |

| Site | Pt | Treatment Group | Case Summary |
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| | | DRIVER | **Target Vessel Revascularization–PTCA 776 days post-procedure** |
| | | | The patient is a 67 year-old man with a history of hypertension who presented with CCS Class IV unstable angina and a positive functional ischemia study. On 12/9/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 7% final residual in-lesion stenosis with a grade B dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/10/2003 on ASA and clopidogrel. Repeat angiography on 1/23/2006 for recurrent angina and with a negative functional ischemia study revealed a 25% in-lesion restenosis reported by the Angiographic Core Lab with the notation remote target vessel revascularization of the mid/distal LAD. A Cardiac Catheterization Report noted no relevant stenosis in the study stent, an 80% stenosis of the medial RIVA (LAD), and progression of CHD in the distal RIVA. The site reported the patient underwent repeat revascularization with stent placement in the mid LAD, reported by the site as a target vessel revascularization. |
| | | ENDEAVOR DES | **Stroke 291 days post-procedure** |
| | | | The patient is a 77 year-old man with a history of MI in 1999, hypertension and dyslipidemia who presented with CCS Class II angina. On 10/9/2003 he underwent the index procedure with pre-treatment balloon angioplasty and placement of the assigned stent in the proximal RCA. The stent was post-dilated. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/11/2003 on ASA and clopidogrel. On 7/26/2004 the patient was admitted to a non-study hospital with decreased consciousness, altered mentation, speech deficits and motor deficits in the arms and legs. The site reported an “acute left CVA”. He was discharged on 8/6/2004 with a permanent deficit. The site reported a good recovery of right hemiparesis but persistent expressive aphasia. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Stroke 949 days post-procedure**<br>The patient is a 67 year-old man with a history of a MI on 7/20/1993, dyslipidemia, hypertension and premature CAD in a 1st degree relative who presented with CCS Class II angina and a positive functional ischemia study. On 12/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the R-PAV. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the distal RCA with a 0% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/12/2003 on ASA and clopidogrel. On 7/17/2006 the patient sought treatment at a non-study hospital following gradual onset of headache, vertigo and nausea. While in the emergency room he developed slurred speech, right-sided incoordination and tingling in the right arm. The site reported a stroke. A head CT scan showed a right cerebellar infarct. On 7/22/2006 he developed left arm weakness and blurring of right eye vision. A repeat head CT scan showed no further infarct or hemorrhage. An echocardiogram revealed thrombus formation in the apex of the left ventricle. On 7/25/2006 he was transferred to a rehabilitation facility for physical, occupational, and speech therapy for an extensive right cerebellar infarct and lateral medullary syndrome. He was discharged home on 8/21/2006 with permanent residual deficits. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | DRIVER | **Stroke 198 days post-procedure**<br>The patient is a 61 year-old man with a history of premature CAD in a first degree relative and a percutaneous revascularization in a non-target vessel who presented with CCS Class IV unstable angina. On 11/5/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. The site reported an episode of procedural coronary artery spasm. The Angiographic Core Lab reported a 39% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/6/2003 on ASA and clopidogrel. A protocol re-study on 5/20/2004 at 11:26 performed four weeks prior to schedule for recurrent clinical symptoms without a functional ischemia study revealed a 34% in-lesion restenosis reported by the Angiographic Core Lab. The site reported 40% restenosis with "distal edge narrowing" of the target lesion with the notation there was progression of disease in the RCA. The patient underwent repeat revascularization with balloon angioplasty with placement of two stents in the proximal RCA and the mid RCA. Early in the morning, approximately 01:00 on 5/21/2004 the patient experienced left arm and left leg weakness. A CT of the head revealed no intracranial lesion and no bleed. The Neurological Event Form reported speech, motor, sensory and coordination deficits and noted that the longest duration of a deficit was >24 hours. |
| | | DRIVER | **Stroke 21 days post-procedure**<br>The patient is a 70 year-old man with a history of dyslipidemia, hypertension and a MI on 8/20/1999 who presented with CCS Class III angina. On 10/23/2003 he underwent the index procedure with pre-treatment balloon angioplasty, IVUS and delivery of one assigned stent in the mid RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 29% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/24/2003 on ASA and clopidogrel. On 11/13/2003 the patient experienced speech difficulties and motor and coordination deficits involving the right upper and right lower extremities. The site reported that a CT scan on 11/13/2003 revealed a subdural hematoma with a mass effect. Clopidogrel and ASA were discontinued and the patient was transferred to the neurosurgical service. Further details of the hospitalization were not provided. The patient apparently underwent a surgical intervention. The site reported the patient's neurological deficits were permanent and he was discharged on 11/25/2003. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | ENDEAVOR DES | **Stroke 1056 days post-procedure**<br>The patient is a 63 year-old man with a history of dyslipidemia, hypertension and current smoking who presented with CCS Class IV unstable angina. On 8/25/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 8/25/2003 on ASA and clopidogrel. On 7/16/2006 the patient was admitted to the hospital with asymmetry of the mouth and problems with speech. A summary of the neurological examination noted dysarthric speech, anisocoria and slight central facial paresis on the left. A Discharge Summary reported that a head CT revealed a lacunar lesion and several hypodensities and a diagnosis of a right hemisphere infarction was made. The patient was discharged in stable condition on 7/19/2006 with permanent residual deficits. |
| | | DRIVER | **Stroke 133 days post-procedure**<br>The patient is a 67 year-old woman with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class IV unstable angina. On 12/22/2003 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/22/2003 on ASA and clopidogrel. On 5/3/2004 the patient was rehospitalized with an acute onset of apathy, a decreased level of consciousness and “disordered language.” A neurology exam revealed global aphasia and a positive right-sided Babinski. The site reported that a MRI showed a large left temporal ischemic lesion and an EEG revealed a slow focus of the left temporal lobe. The site also reported that patient’s upper and lower body motor defects and speech deficits were judged to be permanent. The patient’s aphasia subsequently improved and she was discharged. Rehabilitation was planned on an out-patient basis. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | **DRIVER** | **Stroke 999 days post-procedure** |
| | | | The patient is a 47 year-old man with a history of dyslipidemia, hypertension, and former smoking who presented with CCS Class II angina. On 11/7/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. A second assigned stent was placed distal and overlapping to the first stent for stabilization. There were no clinical sequelae. The Angiographic Core Lab reported a 7% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/8/2003 on ASA and clopidogrel. According to a Discharge Summary the patient was admitted on 8/2/2006 with aphasia and temporary weakness of the right hand with onset reported an hour prior to admission. The patient was treated with Actilyse thrombolytic therapy and the site reported an improvement in the aphasia later that evening. The initial head CT with angiogram on 8/2/2006 showed an occlusion of the left internal carotid artery due to thrombus. A follow-up CT on 8/3/2006 revealed a left median infarction. The aphasia was present at time of discharge on 8/8/2006. The patient was discharged with permanent deficits and referred for outpatient speech therapy. |
| | | **ENDEAVOR DES** | **Stroke 479 days post-procedure** |
| | | | The patient is a 75 year-old man with a history of dyslipidemia and hypertension who presented without angina or a positive functional ischemia study. On 9/12/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 9/13/2003 on ASA and clopidogrel. On 1/3/2005 the patient was rehospitalized for an acute onset of right-sided hemiplegia and hypertensive crisis. The Discharge Summary reported a cerebral hemorrhage was ruled out by computer tomography and confirmed in a query response that the report is not available. The patient was discharged on 1/13/2005 with improvement of the symptoms; however the right arm motor deficit was judged to be permanent. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | **DRIVER** | **Stroke 1027 days post-procedure** |
| | | | The patient is a 48 year-old man with a history of dyslipidemia, hypertension, and former smoking who presented with CCS Class III angina. On 11/20/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal LAD with a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/21/2003 on ASA and clopidogrel. A Discharge Report noted the patient was hospitalized on 9/12/2006 for neurological deficits and symptoms of "ACI stenosis on the left." A query response confirmed the onset of symptoms is unknown/SEP/2006. The Report further noted the patient experienced numbness in the right half of the face and alternating loss of strength in the limbs, right greater than left. A severe stenosis of the right ACI was also reported. The site reported diagnostic testing was performed; however a query response indicates "no tests" were done. A re-query for an explanation reported "diagnostic test is physical examination of patient neurological status." The patient underwent left carotid endarterectomy and the report further states the post-operative course was free of "neurological sensations." The patient was discharged on 9/16/2006 with permanent residual deficits according to a query response. |

| Site | Pt | Treatment Group | Case Summary |
|---|---|---|---|
| | | ENDEAVOR DES | **Stroke 788 days post-procedure**<br>The patient is 69 year-old man with a history of current smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, and a MI in 1995 who presented with CCS Class III unstable angina. On 11/18/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the R-PDA. A second assigned stent was placed distal to and overlapping the first stent for a site reported sub-optimal distal edge result. The stent was post-dilated and there were no clinical sequelae reported. The Angiographic Core Lab reported abrupt closure with a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/20/2003 on ASA and clopidogrel. A monitored Neurological Event Form reported on 1/14/2006 the patient experienced an onset of speech, motor (arms and legs), sensory, cranial and facial neurological deficits. A Discharge Summary reported the patient was rehospitalized on 1/15/2006 after the patient felt a sudden [word illegible] and some hours later noted right-sided weakness. He fell and was not injured; however Emergency Medical Support transported him to a hospital and he was diagnosed with right hemiparesis. A brain CT revealed "massive hemorrhage" in the left thalamus and ASA was stopped. The site reported a neurological exam found the patient conscious with dysarthria, weakness, and right hemiparesis. Follow-up CT showed resolution of the hemorrhage and the patient was transferred to another hospital for neurological rehabilitation on 1/30/2006 with permanent residual deficits. |
| | | ENDEAVOR DES | **Stroke 419 days post-procedure**<br>The patient is a 59 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class I stable angina. On 12/11/2003 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 29% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/15/2003 on ASA and clopidogrel. On 2/2/2005 the patient was rehospitalized with motor neurological deficits of the arms and legs. Neurological testing was performed and a query response indicates a head MRI revealed small ischemic changes in both hemispheres and similar focal changes in the pons with the notation "no recent ischemic lesions found." The site reported a stroke with permanent deficits. |

# Listing 1. Detailed Patient Listing

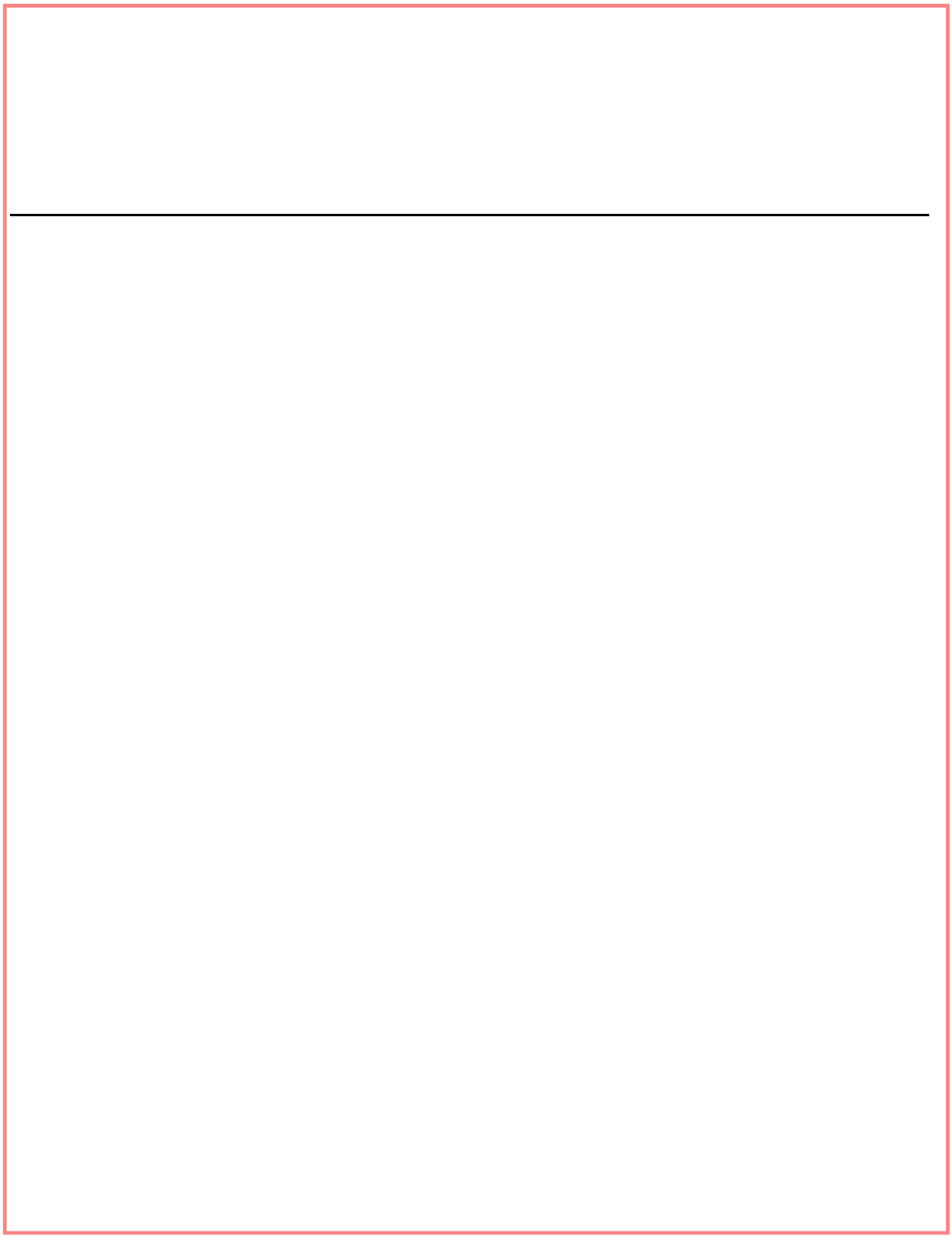
**Listing 2. Minor Protocol Deviation Type – Other**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**



**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

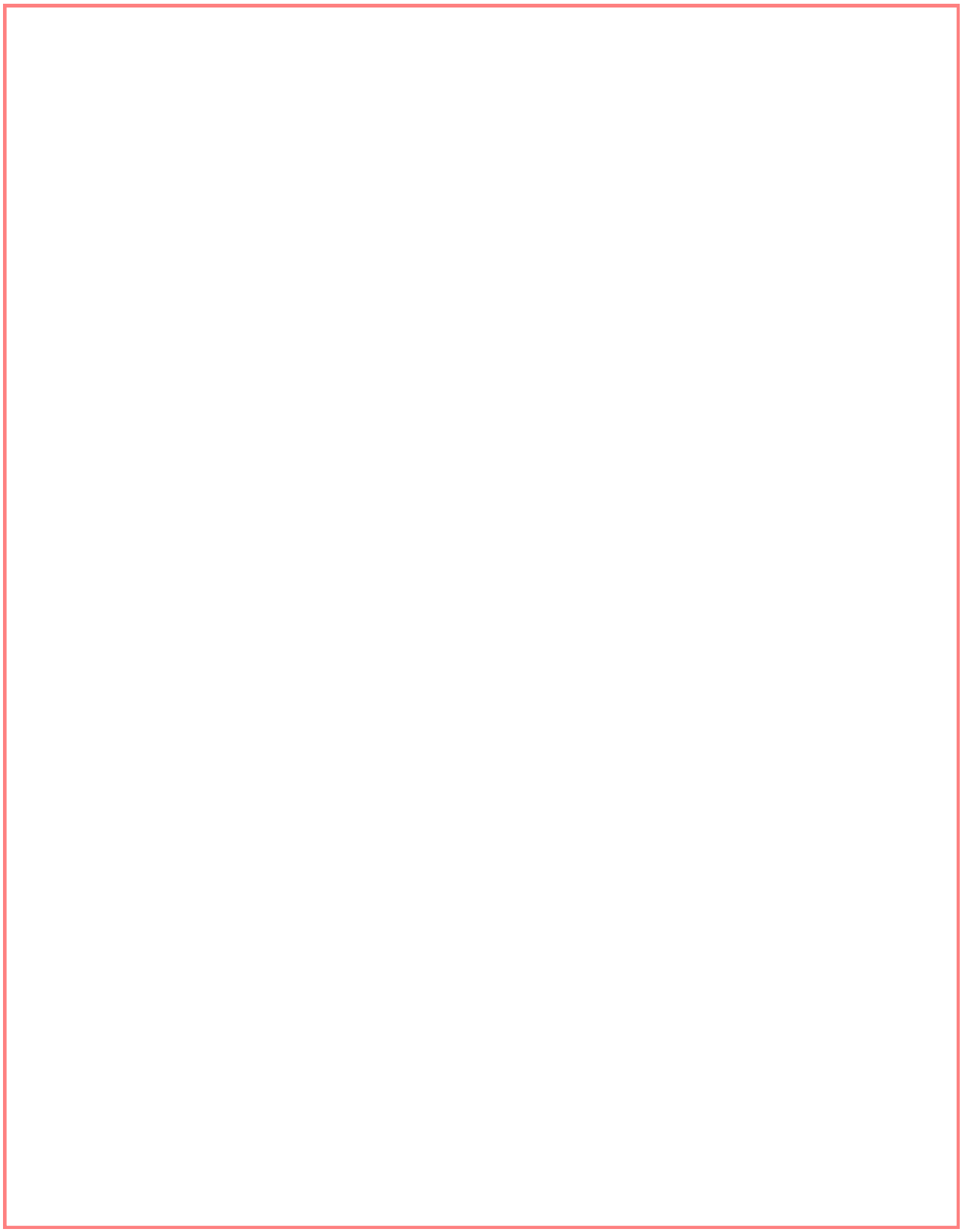
**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**



**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

**Listing 2. Minor Protocol Deviation Type – Other (Continued)**

# Appendix A: Additional Analyses

## Appendix Table 1a. Region Listing

| Site | Clinical Site | Region |
|---|---|---|
| 503 | Universitaetsklinikum | 1 |
| 504 | Allgemeines Krankenhaus St. Georg | 1 |
| 512 | Universitaetskliniken des Saarlandes | 1 |
| 513 | Universitaetsklinik Hamburg | 1 |
| 511 | Herzzentrum Leipzig GmbH | 2 |
| 514 | Klinikum Benjamin Franklin Medizinische Klinik II | 2 |
| 515 | Humboldt Universitaetsklinikum Charite Berlin | 2 |
| 508 | Krankenhaus der Barmherzigen Brueder | 3 |
| 509 | Universitaet Aachen | 3 |
| 505 | Herzzentrum Bad Krozingen | 4 |
| 506 | Kerckhoff-Klinik | 4 |
| 540 | Klinikum der Johann W. Goethe-Universitaet | 5 |
| 507 | Krankenhaus und Herzzentrum | 6 |
| 501 | Allgemeines Krankenhaus d. Stadt | 7 |
| 502 | Universitaetsklinik Innsbruck | 7 |
| 543 | Klinik Dr. Mueller | 7 |
| 510 | St. Johannes Hospital | 8 |
| 531 | Klinika Kardiologii | 9 |
| 532 | Szpital Specjalistyczny im. Jana Pawla II | 10 |
| 533 | I Klinika Kardiologii Slaskiej Akademii Medycznej | 10 |
| 534 | Slaskie Centrum Chorob Serca | 11 |
| 407 | Rigshopsital | 12 |
| 408 | Skejby Hospital | 12 |
| 428 | Hosp. de Santa Marta | 12 |
| 516 | University Hospital of Ioannina | 12 |
| 422 | Catharina Ziekenhuis | 13 |
| 423 | Leids Universitair Medisch Centrum | 13 |
| 425 | Stichting Sint Antonius Ziekenhuis | 13 |
| 424 | Onze Lieve Vrouwe Gasthuis | 14 |
| 426 | Academisch Ziekenhuis Vrije | 14 |
| 301 | Monash Medical Centre | 15 |
| 302 | St. Vincent's Hospital | 15 |
| 313 | St. Vincent's Hospital | 15 |
| 307 | Grantham Hospital | 16 |
| 308 | Prince of Wales Hospital | 16 |
| 309 | National Heart Center/Singapore General Hospital | 17 |
| 310 | National University Hospital/The Heart Institute | 17 |
| 314 | Greenlane Hospital | 18 |
| 315 | Dunedin Hospital | 18 |
| 317 | Mercy Hospital | 18 |

## Appendix Table 1a. Region Listing (Continued)

| Site | Clinical Site | Region |
|---|---|---|
| 401 | A.Z. Middelheim | 19 |
| 402 | C.H.U. Sart | 19 |
| 403 | C.H.R de la Citadelle | 19 |
| 404 | Onze-Lieve Vrouw Ziekenhuis | 19 |
| 405 | U.Z. Gasthuisberg | 19 |
| 406 | Z.O.L Campus St-Jan | 19 |
| 409 | Hopital Bichat Claude Bernard | 20 |
| 410 | Centre Hospitalier prive Saint Martin | 20 |
| 411 | CHU de Caen | 20 |
| 412 | Hopital Jean Minjoz | 20 |
| 413 | Clinique Pasteur | 20 |
| 414 | Clinique Saint Augustin | 20 |
| 417 | Hopital Cardiologique du Haut Leveque, CHU de Bordeaux | 20 |
| 418 | CHU Rangueil | 20 |
| 419 | Hopital Laennec, CHU Nord | 20 |
| 420 | Institut Hospitalier Jacques Cartier | 20 |
| 444 | Hopital Lariboisiere | 20 |
| 437 | Derriford Hospital | 21 |
| 438 | Freeman Hospital | 21 |
| 439 | Glenfield Hospital | 21 |
| 440 | John Radcliffe Hospital | 21 |
| 441 | Royal Infirmary of Edinburgh | 21 |
| 442 | Southampton General Hospital | 21 |
| 517 | Rabin Medical Center | 22 |
| 518 | Hadassah Medical Center- Ein Kerem | 22 |
| 519 | Carmel Medical Center | 22 |
| 520 | Rambam Medical Center | 22 |
| 541 | Rabin Medical Center | 22 |
| 542 | Chaim Sheba Medical Center | 22 |
| 537 | Hopitaux Universitaires de Geneve- HUG | 23 |
| 538 | Universitatsspital Zurich | 23 |
| 539 | Herzzentrum Bodensee | 23 |

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# Appendix Table 1b. Pooled Site Listing

| Site | Clinical Site | Enrolled | Pooled Site |
|---|---|---|---|
| 301 | Monash Medical Centre | 13 | 1 |
| 302 | St. Vincent's Hospital | 21 | 2 |
| 307 | Grantham Hospital | 7 | 3 |
| 308 | Prince of Wales Hospital | 16 | 3 |
| 309 | National Heart Center/Singapore General Hospital | 20 | 4 |
| 310 | National University Hospital/The Heart Institute | 7 | 5 |
| 313 | St. Vincent's Hospital | 14 | 5 |
| 314 | Greenlane Hospital | 36 | 6 |
| 315 | Dunedin Hospital | 17 | 7 |
| 317 | Mercy Hospital | 2 | 8 |
| 401 | A.Z. Middelheim | 12 | 8 |
| 402 | C.H.U. Sart | 1 | 9 |
| 403 | C.H.R de la Citadelle | 6 | 9 |
| 404 | Onze-Lieve Vrouw Ziekenhuis | 16 | 9 |
| 405 | U.Z. Gasthuisberg | 8 | 10 |
| 406 | Z.O.L Campus St-Jan | 13 | 10 |
| 407 | Rigshopsital | 2 | 11 |
| 408 | Skejby Hospital | 11 | 11 |
| 409 | Hopital Bichat Claude Bernard | 5 | 12 |
| 410 | Centre Hospitalier prive Saint Martin | 5 | 12 |
| 411 | CHU de Caen | 6 | 13 |
| 412 | Hopital Jean Minjoz | 17 | 13 |
| 413 | Clinique Pasteur | 10 | 14 |
| 414 | Clinique Saint Augustin | 13 | 15 |
| 417 | Hopital Cardiologique du Haut Leveque, CHU de Bordeaux | 3 | 16 |
| 418 | CHU Rangueil | 10 | 16 |
| 419 | Hopital Laennec, CHU Nord | 3 | 17 |
| 420 | Institut Hospitalier Jacques Cartier | 2 | 17 |
| 422 | Catharina Ziekenhuis | 28 | 17 |
| 423 | Leids Universitair Medisch Centrum | 12 | 18 |
| 424 | Onze Lieve Vrouwe Gasthuis | 66 | 19 |
| 425 | Stichting Sint Antonius Ziekenhuis | 41 | 20 |
| 426 | Academisch Ziekenhuis Vrije | 8 | 21 |
| 428 | Hosp. de Santa Marta | 8 | 21 |
| 437 | Derriford Hospital | 14 | 22 |

## Appendix Table 1b. Pooled Site Listing (Continued)

| Site | Clinical Site | Enrolled | Pooled Site |
|---|---|---|---|
| 438 | Freeman Hospital | 7 | 23 |
| 439 | Glenfield Hospital | 2 | 23 |
| 440 | John Radcliffe Hospital | 2 | 23 |
| 441 | Royal Infirmary of Edinburgh | 8 | 24 |
| 442 | Southampton General Hospital | 2 | 24 |
| 444 | Hopital Lariboisiere | 5 | 25 |
| 501 | Allgemeines Krankenhaus d. Stadt | 15 | 25 |
| 502 | Universitaetsklinik Innsbruck | 5 | 26 |
| 503 | Universitaetsklinikum | 16 | 26 |
| 504 | Allgemeines Krankenhaus St. Georg | 54 | 27 |
| 505 | Herzzentrum Bad Krozingen | 6 | 28 |
| 506 | Kerckhoff-Klinik | 20 | 28 |
| 507 | Krankenhaus und Herzzentrum | 32 | 29 |
| 508 | Krankenhaus der Barmherzigen Brueder | 42 | 30 |
| 509 | Universitaet Aachen | 11 | 31 |
| 510 | St. Johannes Hospital | 32 | 32 |
| 511 | Herzzentrum Leipzig GmbH | 16 | 33 |
| 512 | Universitaetskliniken des Saarlandes | 29 | 34 |
| 513 | Universitaetsklinik Hamburg | 47 | 35 |
| 514 | Klinikum Benjamin Franklin Medizinische Klinik II | 37 | 36 |
| 515 | Humboldt Universitaetsklinikum Charite Berlin | 18 | 37 |
| 516 | University Hospital of Ioannina | 11 | 38 |
| 517 | Rabin Medical Center | 24 | 39 |
| 518 | Hadassah Medical Center- Ein Kerem | 18 | 40 |
| 519 | Carmel Medical Center | 16 | 41 |
| 520 | Rambam Medical Center | 15 | 42 |
| 531 | Klinika Kardiologii | 33 | 43 |
| 532 | Szpital Specjalistyczny im. Jana Pawla II | 33 | 44 |
| 533 | I Klinika Kardiologii Slaskiej Akademii Medycznej | 41 | 45 |
| 534 | Slaskie Centrum Chorob Serca | 19 | 46 |
| 537 | Hopitaux Universitaires de Geneve- HUG | 25 | 47 |
| 538 | Universitatsspital Zurich | 9 | 48 |
| 539 | Herzzentrum Bodensee | 37 | 48 |
| 540 | Klinikum der Johann W. Goethe-Universitaet | 27 | 49 |
| 541 | Rabin Medical Center | 4 | 50 |
| 542 | Chaim Sheba Medical Center | 2 | 50 |
| 543 | Klinik Dr. Mueller | 4 | 50 |

Sites with enrollment less than 10 patients were pooled with the next numerically adjacent site until the pooled enrollment reached at least 10 patients.

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# Appendix Table 2a. Baseline Characteristics by Region

| | Region 1 | Region 2 | Region 3 | Region 4 | Region 5 | Region 6 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.69±5.38 (143) | 14.93±6.28 (69) | 14.84±5.25 (52) | 14.92±6.92 (26) | 12.10±5.49 (27) | 13.70±5.59 (31) |
| Range (Min,Max) | (2.71,33.35) | (6.06,31.89) | (7.09,31.67) | (6.74,38.50) | (6.19,28.01) | (5.31,28.11) |
| Median | 12.59 | 12.96 | 13.56 | 14.36 | 10.41 | 13.13 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.84±0.32 (143) | 0.90±0.40 (71) | 0.96±0.32 (52) | 0.87±0.40 (26) | 0.96±0.46 (27) | 0.87±0.35 (31) |
| Range (Min,Max) | (0.13,1.65) | (0.00,1.74) | (0.44,1.70) | (0.00,1.64) | (0.47,2.15) | (0.29,1.63) |
| Median | 0.80 | 0.85 | 0.91 | 0.89 | 0.87 | 0.91 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.79±0.50 (143) | 2.78±0.54 (71) | 2.77±0.40 (52) | 2.79±0.61 (26) | 2.66±0.53 (27) | 2.86±0.48 (31) |
| Range (Min,Max) | (1.77,4.19) | (1.75,4.51) | (1.88,3.65) | (2.01,4.14) | (2.01,4.23) | (2.06,3.82) |
| Median | 2.78 | 2.75 | 2.73 | 2.82 | 2.57 | 2.84 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 22.2% (32/144) | 19.7% (14/71) | 18.9% (10/53) | 30.8% (8/26) | 25.9% (7/27) | 16.1% (5/31) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 57.5% (84/146) | 43.7% (31/71) | 67.9% (36/53) | 80.8% (21/26) | 18.5% (5/27) | 67.7% (21/31) |
| Double | 30.8% (45/146) | 36.6% (26/71) | 26.4% (14/53) | 7.7% (2/26) | 40.7% (11/27) | 22.6% (7/31) |
| Triple | 11.6% (17/146) | 19.7% (14/71) | 5.7% (3/53) | 11.5% (3/26) | 40.7% (11/27) | 9.7% (3/31) |
| LAD | 53.8% (77/143) | 56.3% (40/71) | 36.5% (19/52) | 46.2% (12/26) | 44.4% (12/27) | 45.2% (14/31) |

## Appendix Table 2a. Baseline Characteristics by Region (Continued)

| | Region 7 | Region 8 | Region 9 | Region 10 | Region 11 | Region 12 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.12±4.36 (24) | 15.36±4.63 (32) | 18.96±8.07 (31) | 17.44±4.85 (73) | 14.70±5.05 (19) | 13.55±4.87 (32) |
| Range (Min,Max) | (4.78,23.77) | (6.63,24.81) | (7.57,39.53) | (5.87,28.66) | (6.21,24.13) | (5.39,23.87) |
| Median | 11.35 | 15.47 | 18.31 | 17.03 | 13.81 | 13.67 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.79±0.24 (24) | 0.73±0.30 (32) | 0.87±0.38 (32) | 0.96±0.33 (73) | 0.83±0.31 (19) | 0.81±0.29 (32) |
| Range (Min,Max) | (0.43,1.35) | (0.24,1.38) | (0.19,1.99) | (0.38,1.83) | (0.33,1.44) | (0.26,1.61) |
| Median | 0.80 | 0.66 | 0.82 | 0.92 | 0.92 | 0.78 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.66±0.53 (24) | 2.53±0.41 (32) | 2.85±0.44 (32) | 2.71±0.38 (73) | 2.70±0.42 (19) | 2.85±0.44 (32) |
| Range (Min,Max) | (1.96,3.74) | (1.85,3.54) | (1.86,4.10) | (2.04,3.59) | (2.09,3.48) | (1.86,3.69) |
| Median | 2.55 | 2.58 | 2.82 | 2.69 | 2.75 | 2.84 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 16.7% (4/24) | 21.9% (7/32) | 24.2% (8/33) | 20.5% (15/73) | 26.3% (5/19) | 9.4% (3/32) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 41.7% (10/24) | 46.9% (15/32) | 69.7% (23/33) | 52.1% (38/73) | 57.9% (11/19) | 84.4% (27/32) |
| Double | 41.7% (10/24) | 21.9% (7/32) | 24.2% (8/33) | 34.2% (25/73) | 26.3% (5/19) | 15.6% (5/32) |
| Triple | 16.7% (4/24) | 31.3% (10/32) | 6.1% (2/33) | 13.7% (10/73) | 15.8% (3/19) | 0.0% (0/32) |
| LAD | 37.5% (9/24) | 59.4% (19/32) | 37.5% (12/32) | 50.7% (37/73) | 63.2% (12/19) | 62.5% (20/32) |

## Appendix Table 2a. Baseline Characteristics by Region (Continued)

| | Region 13 | Region 14 | Region 15 | Region 16 | Region 17 | Region 18 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.62±4.36 (79) | 12.97±6.00 (74) | 13.24±5.42 (46) | 12.90±4.01 (23) | 16.35±4.78 (26) | 14.14±5.63 (54) |
| Range (Min,Max) | (5.48,24.28) | (5.12,34.61) | (6.50,27.16) | (7.84,19.26) | (8.48,25.79) | (4.81,27.42) |
| Median | 11.87 | 11.37 | 11.73 | 11.88 | 15.63 | 13.63 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.83±0.35 (81) | 0.79±0.31 (74) | 0.76±0.29 (47) | 0.74±0.35 (23) | 0.77±0.35 (26) | 0.84±0.35 (54) |
| Range (Min,Max) | (0.12,2.34) | (0.13,1.76) | (0.12,1.49) | (0.12,1.45) | (0.14,1.61) | (0.29,1.67) |
| Median | 0.76 | 0.75 | 0.72 | 0.73 | 0.72 | 0.82 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.82±0.52 (81) | 2.71±0.40 (74) | 2.76±0.49 (47) | 2.62±0.32 (23) | 2.59±0.31 (26) | 2.92±0.50 (54) |
| Range (Min,Max) | (1.72,4.28) | (1.92,3.93) | (1.83,4.15) | (2.13,3.26) | (1.97,3.24) | (1.98,4.07) |
| Median | 2.82 | 2.69 | 2.69 | 2.55 | 2.56 | 2.81 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 12.5% (10/80) | 18.9% (14/74) | 22.9% (11/48) | 43.5% (10/23) | 29.6% (8/27) | 14.8% (8/54) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 81.5% (66/81) | 79.7% (59/74) | 81.3% (39/48) | 47.8% (11/23) | 66.7% (18/27) | 70.4% (38/54) |
| Double | 14.8% (12/81) | 12.2% (9/74) | 16.7% (8/48) | 47.8% (11/23) | 18.5% (5/27) | 20.4% (11/54) |
| Triple | 3.7% (3/81) | 8.1% (6/74) | 2.1% (1/48) | 4.3% (1/23) | 14.8% (4/27) | 9.3% (5/54) |
| LAD | 43.2% (35/81) | 36.5% (27/74) | 27.7% (13/47) | 34.8% (8/23) | 65.4% (17/26) | 35.2% (19/54) |

## Appendix Table 2a. Baseline Characteristics by Region (Continued)

| | Region 19 | Region 20 | Region 21 | Region 22 | Region 23 |
|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | |
| Lesion Length (mm) | | | | | |
| Mean±SD (n) | 14.57±4.74 (53) | 13.16±5.61 (75) | 13.91±6.20 (34) | 15.66±5.67 (77) | 12.56±5.52 (70) |
| Range (Min,Max) | (5.81,25.57) | (3.16,32.20) | (6.05,31.65) | (5.66,42.07) | (4.15,30.46) |
| Median | 14.36 | 12.04 | 12.42 | 15.50 | 10.66 |
| In-Segment MLD (mm) | | | | | |
| Mean±SD (n) | 0.79±0.38 (55) | 0.82±0.29 (75) | 0.87±0.33 (35) | 0.76±0.35 (78) | 0.78±0.37 (71) |
| Range (Min,Max) | (0.11,1.88) | (0.26,1.72) | (0.11,1.44) | (0.13,1.67) | (0.11,2.04) |
| Median | 0.73 | 0.76 | 0.89 | 0.70 | 0.73 |
| Reference Vessel Diameter (mm) | | | | | |
| Mean±SD (n) | 2.74±0.52 (55) | 2.66±0.48 (75) | 2.78±0.48 (35) | 2.77±0.52 (78) | 2.64±0.50 (71) |
| Range (Min,Max) | (1.72,3.95) | (1.66,4.06) | (1.92,3.96) | (1.66,4.41) | (1.61,3.93) |
| Median | 2.77 | 2.58 | 2.86 | 2.78 | 2.69 |
| **Patient Characteristic** | | | | | |
| Diabetes Mellitus | 10.7% (6/56) | 26.9% (21/78) | 14.3% (5/35) | 30.4% (24/79) | 7.0% (5/71) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | |
| Single | 76.8% (43/56) | 71.8% (56/78) | 62.9% (22/35) | 59.5% (47/79) | 57.7% (41/71) |
| Double | 19.6% (11/56) | 23.1% (18/78) | 20.0% (7/35) | 32.9% (26/79) | 19.7% (14/71) |
| Triple | 3.6% (2/56) | 5.1% (4/78) | 17.1% (6/35) | 7.6% (6/79) | 22.5% (16/71) |
| LAD | 34.5% (19/55) | 44.0% (33/75) | 28.6% (10/35) | 48.7% (38/78) | 47.9% (34/71) |

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# Appendix Table 2a. Baseline Characteristics by Pooled Site

| | Pooled Site 1 | Pooled Site 2 | Pooled Site 3 | Pooled Site 4 | Pooled Site 5 | Pooled Site 6 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 10.61±3.05 (13) | 15.34±5.79 (19) | 12.90±4.01 (23) | 16.65±5.42 (19) | 13.74±5.00 (21) | 14.89±5.91 (35) |
| Range (Min,Max) | (7.17,15.85) | (6.98,27.16) | (7.84,19.26) | (8.48,25.79) | (6.50,22.50) | (4.81,27.42) |
| Median | 10.27 | 15.37 | 11.88 | 16.90 | 14.12 | 14.41 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.76±0.23 (13) | 0.70±0.29 (20) | 0.74±0.35 (23) | 0.75±0.34 (19) | 0.83±0.35 (21) | 0.89±0.36 (35) |
| Range (Min,Max) | (0.41,1.12) | (0.12,1.28) | (0.12,1.45) | (0.14,1.36) | (0.34,1.61) | (0.29,1.67) |
| Median | 0.82 | 0.70 | 0.73 | 0.69 | 0.75 | 0.85 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.60±0.57 (13) | 2.71±0.49 (20) | 2.62±0.32 (23) | 2.61±0.33 (19) | 2.83±0.38 (21) | 3.02±0.53 (35) |
| Range (Min,Max) | (1.83,3.81) | (1.90,4.15) | (2.13,3.26) | (1.97,3.24) | (2.23,3.56) | (2.08,4.07) |
| Median | 2.53 | 2.65 | 2.55 | 2.64 | 2.88 | 2.95 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 30.8% (4/13) | 28.6% (6/21) | 43.5% (10/23) | 30.0% (6/20) | 14.3% (3/21) | 20.0% (7/35) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 84.6% (11/13) | 85.7% (18/21) | 47.8% (11/23) | 65.0% (13/20) | 71.4% (15/21) | 62.9% (22/35) |
| Double | 15.4% (2/13) | 14.3% (3/21) | 47.8% (11/23) | 20.0% (4/20) | 19.0% (4/21) | 25.7% (9/35) |
| Triple | 0.0% (0/13) | 0.0% (0/21) | 4.3% (1/23) | 15.0% (3/20) | 9.5% (2/21) | 11.4% (4/35) |
| LAD | 30.8% (4/13) | 35.0% (7/20) | 34.8% (8/23) | 68.4% (13/19) | 28.6% (6/21) | 40.0% (14/35) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 7 | Pooled Site 8 | Pooled Site 9 | Pooled Site 10 | Pooled Site 11 | Pooled Site 12 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.92±4.90 (17) | 14.75±5.03 (14) | 13.90±4.32 (22) | 14.88±5.30 (19) | 11.80±4.68 (13) | 12.57±3.97 (10) |
| Range (Min,Max) | (6.59,22.28) | (5.81,23.22) | (6.18,25.57) | (7.20,24.12) | (6.84,23.87) | (6.15,16.31) |
| Median | 12.45 | 14.96 | 13.56 | 14.39 | 10.94 | 14.18 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.75±0.32 (17) | 0.83±0.36 (14) | 0.76±0.33 (23) | 0.81±0.45 (20) | 0.73±0.30 (13) | 0.83±0.20 (10) |
| Range (Min,Max) | (0.30,1.25) | (0.34,1.58) | (0.14,1.36) | (0.11,1.88) | (0.28,1.24) | (0.59,1.18) |
| Median | 0.73 | 0.73 | 0.73 | 0.74 | 0.78 | 0.78 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.69±0.38 (17) | 2.82±0.53 (14) | 2.60±0.47 (23) | 2.87±0.53 (20) | 2.93±0.39 (13) | 2.55±0.45 (10) |
| Range (Min,Max) | (1.98,3.40) | (2.01,3.95) | (1.72,3.33) | (1.96,3.71) | (2.34,3.67) | (2.09,3.67) |
| Median | 2.69 | 2.91 | 2.59 | 2.84 | 2.97 | 2.45 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 5.9% (1/17) | 0.0% (0/14) | 21.7% (5/23) | 4.8% (1/21) | 0.0% (0/13) | 40.0% (4/10) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 88.2% (15/17) | 50.0% (7/14) | 78.3% (18/23) | 90.5% (19/21) | 100.0% (13/13) | 90.0% (9/10) |
| Double | 5.9% (1/17) | 50.0% (7/14) | 13.0% (3/23) | 9.5% (2/21) | 0.0% (0/13) | 0.0% (0/10) |
| Triple | 5.9% (1/17) | 0.0% (0/14) | 8.7% (2/23) | 0.0% (0/21) | 0.0% (0/13) | 10.0% (1/10) |
| LAD | 23.5% (4/17) | 42.9% (6/14) | 39.1% (9/23) | 25.0% (5/20) | 61.5% (8/13) | 70.0% (7/10) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 13 | Pooled Site 14 | Pooled Site 15 | Pooled Site 16 | Pooled Site 17 | Pooled Site 18 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.03±4.94 (21) | 15.26±6.98 (9) | 11.45±5.48 (13) | 12.14±6.03 (13) | 12.28±4.39 (31) | 14.25±3.93 (11) |
| Range (Min,Max) | (5.73,22.28) | (4.49,24.07) | (3.16,22.05) | (4.64,25.85) | (6.06,22.50) | (9.49,22.31) |
| Median | 10.99 | 16.07 | 10.63 | 10.42 | 11.56 | 13.12 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.79±0.28 (21) | 0.84±0.41 (9) | 0.81±0.25 (13) | 0.83±0.31 (13) | 0.80±0.35 (32) | 0.85±0.31 (12) |
| Range (Min,Max) | (0.44,1.23) | (0.29,1.45) | (0.52,1.55) | (0.26,1.56) | (0.12,1.72) | (0.15,1.44) |
| Median | 0.72 | 0.67 | 0.77 | 0.81 | 0.75 | 0.85 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.96±0.46 (21) | 2.55±0.32 (9) | 2.44±0.31 (13) | 2.61±0.54 (13) | 2.57±0.47 (32) | 2.66±0.52 (12) |
| Range (Min,Max) | (2.19,4.06) | (2.20,3.06) | (1.85,2.94) | (1.66,3.66) | (1.72,3.66) | (1.85,3.40) |
| Median | 2.99 | 2.57 | 2.55 | 2.48 | 2.46 | 2.68 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 8.7% (2/23) | 0.0% (0/9) | 30.8% (4/13) | 46.2% (6/13) | 15.2% (5/33) | 16.7% (2/12) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 69.6% (16/23) | 77.8% (7/9) | 76.9% (10/13) | 46.2% (6/13) | 72.7% (24/33) | 75.0% (9/12) |
| Double | 30.4% (7/23) | 11.1% (1/9) | 23.1% (3/13) | 38.5% (5/13) | 24.2% (8/33) | 25.0% (3/12) |
| Triple | 0.0% (0/23) | 11.1% (1/9) | 0.0% (0/13) | 15.4% (2/13) | 3.0% (1/33) | 0.0% (0/12) |
| LAD | 33.3% (7/21) | 66.7% (6/9) | 30.8% (4/13) | 38.5% (5/13) | 43.8% (14/32) | 33.3% (4/12) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 19 | Pooled Site 20 | Pooled Site 21 | Pooled Site 22 | Pooled Site 23 | Pooled Site 24 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.95±5.72 (66) | 12.57±4.33 (41) | 13.26±6.53 (16) | 12.77±6.22 (13) | 12.66±4.27 (11) | 16.75±7.51 (10) |
| Range (Min,Max) | (5.12,34.61) | (5.48,24.28) | (5.91,33.00) | (6.05,23.74) | (7.31,22.02) | (8.06,31.65) |
| Median | 11.55 | 11.87 | 13.01 | 12.26 | 12.00 | 16.90 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.80±0.31 (66) | 0.86±0.39 (41) | 0.79±0.37 (16) | 1.00±0.34 (14) | 0.84±0.32 (11) | 0.72±0.29 (10) |
| Range (Min,Max) | (0.25,1.76) | (0.17,2.34) | (0.13,1.61) | (0.12,1.44) | (0.11,1.39) | (0.13,1.06) |
| Median | 0.76 | 0.77 | 0.75 | 1.04 | 0.92 | 0.83 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.71±0.41 (66) | 3.08±0.46 (41) | 2.70±0.39 (16) | 2.76±0.50 (14) | 2.81±0.38 (11) | 2.78±0.57 (10) |
| Range (Min,Max) | (1.92,3.93) | (2.38,4.28) | (1.86,3.25) | (1.92,3.96) | (2.13,3.28) | (1.92,3.78) |
| Median | 2.69 | 2.96 | 2.73 | 2.74 | 2.97 | 2.73 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 18.2% (12/66) | 12.5% (5/40) | 12.5% (2/16) | 21.4% (3/14) | 18.2% (2/11) | 0.0% (0/10) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 77.3% (51/66) | 90.2% (37/41) | 100.0% (16/16) | 42.9% (6/14) | 72.7% (8/11) | 80.0% (8/10) |
| Double | 13.6% (9/66) | 4.9% (2/41) | 0.0% (0/16) | 28.6% (4/14) | 9.1% (1/11) | 20.0% (2/10) |
| Triple | 9.1% (6/66) | 4.9% (2/41) | 0.0% (0/16) | 28.6% (4/14) | 18.2% (2/11) | 0.0% (0/10) |
| LAD | 37.9% (25/66) | 46.3% (19/41) | 37.5% (6/16) | 28.6% (4/14) | 18.2% (2/11) | 40.0% (4/10) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 25 | Pooled Site 26 | Pooled Site 27 | Pooled Site 28 | Pooled Site 29 | Pooled Site 30 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.40±5.74 (20) | 14.98±6.09 (21) | 14.58±5.48 (52) | 14.92±6.92 (26) | 13.70±5.59 (31) | 14.76±5.14 (42) |
| Range (Min,Max) | (4.78,32.20) | (7.93,26.56) | (5.41,33.35) | (6.74,38.50) | (5.31,28.11) | (7.86,31.67) |
| Median | 12.06 | 13.20 | 14.42 | 14.36 | 13.13 | 13.56 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.81±0.24 (20) | 0.87±0.31 (21) | 0.90±0.31 (52) | 0.87±0.40 (26) | 0.87±0.35 (31) | 0.97±0.34 (42) |
| Range (Min,Max) | (0.45,1.35) | (0.42,1.57) | (0.46,1.61) | (0.00,1.64) | (0.29,1.63) | (0.44,1.70) |
| Median | 0.79 | 0.88 | 0.87 | 0.89 | 0.91 | 0.98 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.59±0.49 (20) | 2.98±0.54 (21) | 2.89±0.52 (52) | 2.79±0.61 (26) | 2.86±0.48 (31) | 2.80±0.36 (42) |
| Range (Min,Max) | (1.83,3.67) | (1.98,3.91) | (1.77,3.79) | (2.01,4.14) | (2.06,3.82) | (2.18,3.65) |
| Median | 2.46 | 3.08 | 2.92 | 2.82 | 2.84 | 2.73 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 25.0% (5/20) | 15.0% (3/20) | 24.1% (13/54) | 30.8% (8/26) | 16.1% (5/31) | 19.0% (8/42) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 45.0% (9/20) | 81.0% (17/21) | 57.4% (31/54) | 80.8% (21/26) | 67.7% (21/31) | 66.7% (28/42) |
| Double | 40.0% (8/20) | 19.0% (4/21) | 35.2% (19/54) | 7.7% (2/26) | 22.6% (7/31) | 26.2% (11/42) |
| Triple | 15.0% (3/20) | 0.0% (0/21) | 7.4% (4/54) | 11.5% (3/26) | 9.7% (3/31) | 7.1% (3/42) |
| LAD | 35.0% (7/20) | 52.4% (11/21) | 51.9% (27/52) | 46.2% (12/26) | 45.2% (14/31) | 35.7% (15/42) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 31 | Pooled Site 32 | Pooled Site 33 | Pooled Site 34 | Pooled Site 35 | Pooled Site 36 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 15.19±5.97 (10) | 15.36±4.63 (32) | 14.87±6.29 (16) | 12.26±5.97 (29) | 12.80±4.37 (46) | 14.83±6.40 (35) |
| Range (Min,Max) | (7.09,26.02) | (6.63,24.81) | (6.20,27.74) | (2.71,25.72) | (5.69,28.10) | (6.06,31.89) |
| Median | 13.71 | 15.47 | 13.70 | 10.99 | 11.94 | 13.06 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.90±0.22 (10) | 0.73±0.30 (32) | 0.69±0.29 (16) | 0.77±0.33 (29) | 0.79±0.30 (46) | 0.98±0.47 (37) |
| Range (Min,Max) | (0.68,1.27) | (0.24,1.38) | (0.12,1.14) | (0.37,1.65) | (0.13,1.53) | (0.00,1.74) |
| Median | 0.83 | 0.66 | 0.73 | 0.65 | 0.76 | 1.00 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.66±0.54 (10) | 2.53±0.41 (32) | 2.90±0.49 (16) | 2.66±0.48 (29) | 2.63±0.43 (46) | 2.65±0.54 (37) |
| Range (Min,Max) | (1.88,3.46) | (1.85,3.54) | (2.15,3.77) | (1.86,4.19) | (1.78,3.53) | (1.75,4.51) |
| Median | 2.65 | 2.58 | 2.94 | 2.59 | 2.68 | 2.70 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 18.2% (2/11) | 21.9% (7/32) | 18.8% (3/16) | 25.0% (7/28) | 23.4% (11/47) | 24.3% (9/37) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 72.7% (8/11) | 46.9% (15/32) | 75.0% (12/16) | 75.9% (22/29) | 38.3% (18/47) | 29.7% (11/37) |
| Double | 27.3% (3/11) | 21.9% (7/32) | 25.0% (4/16) | 20.7% (6/29) | 36.2% (17/47) | 37.8% (14/37) |
| Triple | 0.0% (0/11) | 31.3% (10/32) | 0.0% (0/16) | 3.4% (1/29) | 25.5% (12/47) | 32.4% (12/37) |
| LAD | 40.0% (4/10) | 59.4% (19/32) | 43.8% (7/16) | 44.8% (13/29) | 60.9% (28/46) | 56.8% (21/37) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 37 | Pooled Site 38 | Pooled Site 39 | Pooled Site 40 | Pooled Site 41 | Pooled Site 42 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 15.20±6.37 (18) | 15.69±4.95 (11) | 15.24±5.37 (23) | 16.20±5.07 (18) | 14.55±4.43 (16) | 16.84±8.11 (15) |
| Range (Min,Max) | (7.67,30.09) | (5.39,22.23) | (5.66,27.00) | (7.92,26.51) | (9.50,24.40) | (9.53,42.07) |
| Median | 12.94 | 14.29 | 15.87 | 15.99 | 13.74 | 14.79 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.94±0.29 (18) | 0.82±0.15 (11) | 0.70±0.33 (24) | 0.82±0.39 (18) | 0.72±0.33 (16) | 0.86±0.39 (15) |
| Range (Min,Max) | (0.48,1.36) | (0.64,1.12) | (0.13,1.33) | (0.28,1.63) | (0.24,1.58) | (0.38,1.67) |
| Median | 0.84 | 0.76 | 0.76 | 0.74 | 0.67 | 0.72 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.95±0.54 (18) | 2.90±0.45 (11) | 2.67±0.44 (24) | 2.69±0.46 (18) | 2.89±0.57 (16) | 2.96±0.67 (15) |
| Range (Min,Max) | (1.78,4.13) | (2.32,3.69) | (1.66,3.72) | (2.05,3.51) | (1.92,3.79) | (2.00,4.41) |
| Median | 2.88 | 2.79 | 2.66 | 2.69 | 2.95 | 2.87 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 11.1% (2/18) | 27.3% (3/11) | 29.2% (7/24) | 38.9% (7/18) | 25.0% (4/16) | 33.3% (5/15) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 44.4% (8/18) | 54.5% (6/11) | 58.3% (14/24) | 61.1% (11/18) | 62.5% (10/16) | 60.0% (9/15) |
| Double | 44.4% (8/18) | 45.5% (5/11) | 33.3% (8/24) | 27.8% (5/18) | 31.3% (5/16) | 33.3% (5/15) |
| Triple | 11.1% (2/18) | 0.0% (0/11) | 8.3% (2/24) | 11.1% (2/18) | 6.3% (1/16) | 6.7% (1/15) |
| LAD | 66.7% (12/18) | 72.7% (8/11) | 37.5% (9/24) | 55.6% (10/18) | 56.3% (9/16) | 46.7% (7/15) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 43 | Pooled Site 44 | Pooled Site 45 | Pooled Site 46 | Pooled Site 47 | Pooled Site 48 |
|---|---|---|---|---|---|---|
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 18.96±8.07 (31) | 18.12±5.12 (33) | 16.88±4.61 (40) | 14.70±5.05 (19) | 15.92±5.87 (25) | 10.70±4.36 (45) |
| Range (Min,Max) | (7.57,39.53) | (5.87,27.76) | (10.73,28.66) | (6.21,24.13) | (7.42,27.29) | (4.15,30.46) |
| Median | 18.31 | 18.61 | 15.96 | 13.81 | 14.42 | 9.88 |
| In-Segment MLD (mm) | | | | | | |
| Mean±SD (n) | 0.87±0.38 (32) | 0.91±0.30 (33) | 1.01±0.35 (40) | 0.83±0.31 (19) | 0.80±0.33 (25) | 0.77±0.39 (46) |
| Range (Min,Max) | (0.19,1.99) | (0.38,1.62) | (0.52,1.83) | (0.33,1.44) | (0.33,1.61) | (0.11,2.04) |
| Median | 0.82 | 0.86 | 1.01 | 0.92 | 0.72 | 0.75 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.85±0.44 (32) | 2.66±0.37 (33) | 2.76±0.40 (40) | 2.70±0.42 (19) | 2.76±0.45 (25) | 2.58±0.52 (46) |
| Range (Min,Max) | (1.86,4.10) | (2.22,3.59) | (2.04,3.52) | (2.09,3.48) | (1.92,3.93) | (1.61,3.84) |
| Median | 2.82 | 2.61 | 2.75 | 2.75 | 2.85 | 2.54 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 24.2% (8/33) | 21.2% (7/33) | 20.0% (8/40) | 26.3% (5/19) | 4.0% (1/25) | 8.7% (4/46) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 69.7% (23/33) | 72.7% (24/33) | 35.0% (14/40) | 57.9% (11/19) | 72.0% (18/25) | 50.0% (23/46) |
| Double | 24.2% (8/33) | 21.2% (7/33) | 45.0% (18/40) | 26.3% (5/19) | 24.0% (6/25) | 17.4% (8/46) |
| Triple | 6.1% (2/33) | 6.1% (2/33) | 20.0% (8/40) | 15.8% (3/19) | 4.0% (1/25) | 32.6% (15/46) |
| LAD | 37.5% (12/32) | 48.5% (16/33) | 52.5% (21/40) | 63.2% (12/19) | 40.0% (10/25) | 52.2% (24/46) |

## Appendix Table 2a. Baseline Characteristics by Pooled Site (Continued)

| | Pooled Site 49 | Pooled Site 50 |
|---|---|---|
| **Lesion Characteristic** | | |
| Lesion Length (mm) | | |
| Mean±SD (n) | 12.10±5.49 (27) | 14.46±4.57 (9) |
| Range (Min,Max) | (6.19,28.01) | (7.80,22.85) |
| Median | 10.41 | 14.74 |
| In-Segment MLD (mm) | | |
| Mean±SD (n) | 0.96±0.46 (27) | 0.68±0.20 (9) |
| Range (Min,Max) | (0.47,2.15) | (0.43,0.99) |
| Median | 0.87 | 0.58 |
| Reference Vessel Diameter (mm) | | |
| Mean±SD (n) | 2.66±0.53 (27) | 2.72±0.53 (9) |
| Range (Min,Max) | (2.01,4.23) | (1.96,3.74) |
| Median | 2.57 | 2.76 |
| **Patient Characteristic** | | |
| Diabetes Mellitus | 25.9% (7/27) | 10.0% (1/10) |
| Major Coronary Stenosis (>50% Stenosed) | | |
| Single | 18.5% (5/27) | 40.0% (4/10) |
| Double | 40.7% (11/27) | 50.0% (5/10) |
| Triple | 40.7% (11/27) | 10.0% (1/10) |
| LAD | 44.4% (12/27) | 55.6% (5/9) |

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## Appendix Table 2b. Assessment of Differences in Baseline Characteristics Across Region

| Measure | P-value |
|---|---|
| Diabetes Mellitus | 0.0153 |
| Major Coronary Stenosis (>50% Stenosed) | <.0001 |
| Lesion Length | <.0001 |
| Reference Vessel Diameter | 0.0373 |
| MLD | 0.0069 |
| LAD | 0.0043 |

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## Appendix Table 2c. Assessment of Differences in Baseline Characteristics Across Pooled Sites

| Measure | P-value |
|---|---|
| Diabetes Mellitus | 0.0706 |
| Major Coronary Stenosis (>50% Stenosed) | <.0001 |
| Lesion Length | <.0001 |
| Reference Vessel Diameter | <.0001 |
| MLD | 0.0393 |
| LAD | 0.1368 |

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## Appendix Table 3a. Baseline Characteristics by Region and Treatment

| | Region 1 | | Region 2 | | Region 3 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.98±5.69 (70) | 13.41±5.10 (73) | 15.24±5.68 (35) | 14.62±6.91 (34) | 14.48±4.09 (26) | 15.20±6.27 (26) |
| Range (Min,Max) | (5.72,33.35) | (2.71,28.10) | (6.06,30.09) | (6.51,31.89) | (8.21,26.02) | (7.09,31.67) |
| Median | 12.34 | 12.88 | 14.46 | 12.22 | 13.61 | 13.56 |
| MLD | | | | | | |
| Mean±SD (n) | 0.85±0.29 (70) | 0.83±0.34 (73) | 0.88±0.43 (36) | 0.92±0.38 (35) | 0.97±0.33 (26) | 0.94±0.32 (26) |
| Range (Min,Max) | (0.43,1.65) | (0.13,1.61) | (0.00,1.66) | (0.00,1.74) | (0.44,1.70) | (0.45,1.62) |
| Median | 0.84 | 0.78 | 0.83 | 0.92 | 0.92 | 0.91 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.74±0.49 (70) | 2.83±0.50 (73) | 2.82±0.56 (36) | 2.74±0.52 (35) | 2.72±0.42 (26) | 2.82±0.38 (26) |
| Range (Min,Max) | (1.77,3.69) | (1.80,4.19) | (1.75,4.51) | (1.77,4.13) | (1.88,3.65) | (2.18,3.51) |
| Median | 2.73 | 2.79 | 2.81 | 2.74 | 2.61 | 2.75 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 22.5% (16/71) | 21.9% (16/73) | 25.0% (9/36) | 14.3% (5/35) | 18.5% (5/27) | 19.2% (5/26) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 52.8% (38/72) | 62.2% (46/74) | 44.4% (16/36) | 42.9% (15/35) | 66.7% (18/27) | 69.2% (18/26) |
| Double | 33.3% (24/72) | 28.4% (21/74) | 36.1% (13/36) | 37.1% (13/35) | 25.9% (7/27) | 26.9% (7/26) |
| Triple | 13.9% (10/72) | 9.5% (7/74) | 19.4% (7/36) | 20.0% (7/35) | 7.4% (2/27) | 3.8% (1/26) |
| LAD | 52.9% (37/70) | 54.8% (40/73) | 50.0% (18/36) | 62.9% (22/35) | 26.9% (7/26) | 46.2% (12/26) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 4 | | Region 5 | | Region 6 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.62±3.72 (12) | 16.03±8.80 (14) | 11.63±5.86 (13) | 12.54±5.32 (14) | 14.47±6.15 (14) | 13.06±5.19 (17) |
| Range (Min,Max) | (7.40,19.10) | (6.74,38.50) | (6.19,26.00) | (7.11,28.01) | (6.72,28.11) | (5.31,24.11) |
| Median | 14.36 | 14.28 | 9.81 | 10.49 | 12.95 | 13.80 |
| MLD | | | | | | |
| Mean±SD (n) | 0.99±0.42 (12) | 0.77±0.36 (14) | 1.00±0.37 (13) | 0.92±0.53 (14) | 0.79±0.32 (14) | 0.93±0.37 (17) |
| Range (Min,Max) | (0.00,1.55) | (0.31,1.64) | (0.52,1.88) | (0.47,2.15) | (0.29,1.25) | (0.31,1.63) |
| Median | 1.02 | 0.62 | 0.95 | 0.79 | 0.83 | 0.91 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.93±0.66 (12) | 2.67±0.56 (14) | 2.47±0.37 (13) | 2.83±0.60 (14) | 2.60±0.32 (14) | 3.08±0.50 (17) |
| Range (Min,Max) | (2.01,4.14) | (2.06,3.59) | (2.01,3.25) | (2.09,4.23) | (2.06,3.21) | (2.26,3.82) |
| Median | 2.92 | 2.54 | 2.43 | 2.81 | 2.58 | 3.11 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 33.3% (4/12) | 28.6% (4/14) | 23.1% (3/13) | 28.6% (4/14) | 7.1% (1/14) | 23.5% (4/17) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 83.3% (10/12) | 78.6% (11/14) | 23.1% (3/13) | 14.3% (2/14) | 64.3% (9/14) | 70.6% (12/17) |
| Double | 8.3% (1/12) | 7.1% (1/14) | 46.2% (6/13) | 35.7% (5/14) | 21.4% (3/14) | 23.5% (4/17) |
| Triple | 8.3% (1/12) | 14.3% (2/14) | 30.8% (4/13) | 50.0% (7/14) | 14.3% (2/14) | 5.9% (1/17) |
| LAD | 50.0% (6/12) | 42.9% (6/14) | 46.2% (6/13) | 42.9% (6/14) | 50.0% (7/14) | 41.2% (7/17) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 7 | | Region 8 | | Region 9 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 11.28±4.04 (12) | 12.96±4.68 (12) | 15.36±5.00 (16) | 15.36±4.39 (16) | 18.25±6.15 (15) | 19.63±9.69 (16) |
| Range (Min,Max) | (4.78,18.22) | (7.80,23.77) | (6.63,24.81) | (9.03,23.00) | (9.14,29.00) | (7.57,39.53) |
| Median | 9.69 | 12.63 | 15.06 | 15.47 | 17.38 | 19.09 |
| MLD | | | | | | |
| Mean±SD (n) | 0.80±0.22 (12) | 0.78±0.27 (12) | 0.72±0.34 (16) | 0.74±0.26 (16) | 0.76±0.24 (16) | 0.99±0.46 (16) |
| Range (Min,Max) | (0.48,1.25) | (0.43,1.35) | (0.24,1.38) | (0.37,1.23) | (0.19,1.16) | (0.32,1.99) |
| Median | 0.81 | 0.80 | 0.68 | 0.64 | 0.80 | 0.84 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.78±0.52 (12) | 2.54±0.54 (12) | 2.49±0.40 (16) | 2.57±0.43 (16) | 2.81±0.41 (16) | 2.89±0.48 (16) |
| Range (Min,Max) | (1.98,3.74) | (1.96,3.67) | (1.85,3.22) | (2.01,3.54) | (1.86,3.84) | (1.99,4.10) |
| Median | 2.74 | 2.41 | 2.60 | 2.52 | 2.78 | 2.87 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 16.7% (2/12) | 16.7% (2/12) | 18.8% (3/16) | 25.0% (4/16) | 25.0% (4/16) | 23.5% (4/17) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 50.0% (6/12) | 33.3% (4/12) | 31.3% (5/16) | 62.5% (10/16) | 68.8% (11/16) | 70.6% (12/17) |
| Double | 41.7% (5/12) | 41.7% (5/12) | 31.3% (5/16) | 12.5% (2/16) | 18.8% (3/16) | 29.4% (5/17) |
| Triple | 8.3% (1/12) | 25.0% (3/12) | 37.5% (6/16) | 25.0% (4/16) | 12.5% (2/16) | 0.0% (0/17) |
| LAD | 50.0% (6/12) | 25.0% (3/12) | 50.0% (8/16) | 68.8% (11/16) | 37.5% (6/16) | 37.5% (6/16) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 10 | | Region 11 | | Region 12 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 17.70±5.30 (37) | 17.18±4.41 (36) | 12.75±4.35 (10) | 16.87±5.10 (9) | 13.04±5.09 (16) | 14.05±4.76 (16) |
| Range (Min,Max) | (5.87,28.66) | (9.66,28.34) | (6.21,18.13) | (12.01,24.13) | (5.91,23.87) | (5.39,22.23) |
| Median | 17.03 | 17.13 | 13.84 | 13.81 | 13.33 | 14.91 |
| MLD | | | | | | |
| Mean±SD (n) | 0.93±0.31 (37) | 1.00±0.35 (36) | 0.89±0.30 (10) | 0.76±0.32 (9) | 0.79±0.31 (16) | 0.82±0.28 (16) |
| Range (Min,Max) | (0.38,1.62) | (0.41,1.83) | (0.49,1.44) | (0.33,1.19) | (0.26,1.28) | (0.47,1.61) |
| Median | 0.88 | 0.99 | 0.95 | 0.82 | 0.78 | 0.81 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.74±0.37 (37) | 2.68±0.40 (36) | 2.74±0.39 (10) | 2.66±0.47 (9) | 3.04±0.40 (16) | 2.66±0.39 (16) |
| Range (Min,Max) | (2.15,3.59) | (2.04,3.52) | (2.09,3.30) | (2.12,3.48) | (2.44,3.69) | (1.86,3.25) |
| Median | 2.70 | 2.67 | 2.82 | 2.58 | 3.02 | 2.65 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 18.9% (7/37) | 22.2% (8/36) | 40.0% (4/10) | 11.1% (1/9) | 6.3% (1/16) | 12.5% (2/16) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 56.8% (21/37) | 47.2% (17/36) | 50.0% (5/10) | 66.7% (6/9) | 93.8% (15/16) | 75.0% (12/16) |
| Double | 32.4% (12/37) | 36.1% (13/36) | 30.0% (3/10) | 22.2% (2/9) | 6.3% (1/16) | 25.0% (4/16) |
| Triple | 10.8% (4/37) | 16.7% (6/36) | 20.0% (2/10) | 11.1% (1/9) | 0.0% (0/16) | 0.0% (0/16) |
| LAD | 45.9% (17/37) | 55.6% (20/36) | 60.0% (6/10) | 66.7% (6/9) | 56.3% (9/16) | 68.8% (11/16) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 13 | | Region 14 | | Region 15 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.13±4.59 (41) | 13.16±4.09 (38) | 12.75±6.02 (36) | 13.17±6.05 (38) | 12.57±4.55 (24) | 13.98±6.26 (22) |
| Range (Min,Max) | (6.06,22.50) | (5.48,24.28) | (5.12,34.61) | (5.54,33.00) | (6.50,22.50) | (6.96,27.16) |
| Median | 11.19 | 13.13 | 11.37 | 11.25 | 11.91 | 11.46 |
| MLD | | | | | | |
| Mean±SD (n) | 0.84±0.36 (42) | 0.81±0.35 (39) | 0.80±0.31 (36) | 0.78±0.31 (38) | 0.77±0.29 (25) | 0.75±0.30 (22) |
| Range (Min,Max) | (0.12,2.34) | (0.15,1.44) | (0.31,1.76) | (0.13,1.52) | (0.12,1.36) | (0.42,1.49) |
| Median | 0.78 | 0.76 | 0.73 | 0.81 | 0.81 | 0.70 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.79±0.56 (42) | 2.85±0.49 (39) | 2.72±0.31 (36) | 2.71±0.47 (38) | 2.75±0.47 (25) | 2.77±0.53 (22) |
| Range (Min,Max) | (1.81,4.28) | (1.72,4.04) | (2.25,3.57) | (1.92,3.93) | (1.90,3.81) | (1.83,4.15) |
| Median | 2.68 | 2.87 | 2.70 | 2.60 | 2.77 | 2.65 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 9.8% (4/41) | 15.4% (6/39) | 22.2% (8/36) | 15.8% (6/38) | 15.4% (4/26) | 31.8% (7/22) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 81.0% (34/42) | 82.1% (32/39) | 83.3% (30/36) | 76.3% (29/38) | 84.6% (22/26) | 77.3% (17/22) |
| Double | 16.7% (7/42) | 12.8% (5/39) | 11.1% (4/36) | 13.2% (5/38) | 11.5% (3/26) | 22.7% (5/22) |
| Triple | 2.4% (1/42) | 5.1% (2/39) | 5.6% (2/36) | 10.5% (4/38) | 3.8% (1/26) | 0.0% (0/22) |
| LAD | 45.2% (19/42) | 41.0% (16/39) | 38.9% (14/36) | 34.2% (13/38) | 24.0% (6/25) | 31.8% (7/22) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 16 | | Region 17 | | Region 18 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.33±3.84 (11) | 13.42±4.26 (12) | 15.78±4.27 (13) | 16.91±5.35 (13) | 13.66±5.63 (28) | 14.67±5.70 (26) |
| Range (Min,Max) | (8.20,18.34) | (7.84,19.26) | (10.60,23.95) | (8.48,25.79) | (6.20,27.42) | (4.81,23.02) |
| Median | 11.51 | 12.65 | 15.24 | 17.40 | 13.05 | 15.72 |
| MLD | | | | | | |
| Mean±SD (n) | 0.74±0.39 (11) | 0.73±0.33 (12) | 0.76±0.37 (13) | 0.78±0.33 (13) | 0.76±0.29 (28) | 0.93±0.39 (26) |
| Range (Min,Max) | (0.12,1.45) | (0.29,1.29) | (0.42,1.61) | (0.14,1.36) | (0.29,1.30) | (0.36,1.67) |
| Median | 0.73 | 0.73 | 0.63 | 0.75 | 0.76 | 0.87 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.59±0.35 (11) | 2.65±0.30 (12) | 2.50±0.27 (13) | 2.69±0.33 (13) | 2.95±0.46 (28) | 2.88±0.54 (26) |
| Range (Min,Max) | (2.25,3.19) | (2.13,3.26) | (2.08,2.97) | (1.97,3.24) | (1.98,3.91) | (2.08,4.07) |
| Median | 2.40 | 2.65 | 2.45 | 2.72 | 2.85 | 2.75 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 27.3% (3/11) | 58.3% (7/12) | 21.4% (3/14) | 38.5% (5/13) | 10.7% (3/28) | 19.2% (5/26) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 63.6% (7/11) | 33.3% (4/12) | 78.6% (11/14) | 53.8% (7/13) | 71.4% (20/28) | 69.2% (18/26) |
| Double | 27.3% (3/11) | 66.7% (8/12) | 14.3% (2/14) | 23.1% (3/13) | 14.3% (4/28) | 26.9% (7/26) |
| Triple | 9.1% (1/11) | 0.0% (0/12) | 7.1% (1/14) | 23.1% (3/13) | 14.3% (4/28) | 3.8% (1/26) |
| LAD | 27.3% (3/11) | 41.7% (5/12) | 69.2% (9/13) | 61.5% (8/13) | 35.7% (10/28) | 34.6% (9/26) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 19 | | Region 20 | | Region 21 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.96±5.35 (25) | 15.11±4.14 (28) | 13.41±5.29 (39) | 12.89±6.01 (36) | 14.16±6.68 (16) | 13.68±5.93 (18) |
| Range (Min,Max) | (5.81,24.12) | (8.22,25.57) | (5.26,25.85) | (3.16,32.20) | (6.96,31.65) | (6.05,23.74) |
| Median | 14.29 | 14.38 | 11.89 | 12.12 | 12.42 | 12.48 |
| MLD | | | | | | |
| Mean±SD (n) | 0.73±0.40 (27) | 0.85±0.36 (28) | 0.88±0.31 (39) | 0.75±0.26 (36) | 0.86±0.32 (17) | 0.88±0.36 (18) |
| Range (Min,Max) | (0.11,1.88) | (0.32,1.78) | (0.44,1.72) | (0.26,1.55) | (0.12,1.44) | (0.11,1.39) |
| Median | 0.73 | 0.73 | 0.80 | 0.74 | 0.85 | 0.92 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.68±0.44 (27) | 2.81±0.59 (28) | 2.69±0.54 (39) | 2.63±0.42 (36) | 2.73±0.58 (17) | 2.83±0.37 (18) |
| Range (Min,Max) | (1.72,3.71) | (1.72,3.95) | (1.83,4.06) | (1.66,3.67) | (1.92,3.96) | (2.22,3.78) |
| Median | 2.62 | 2.84 | 2.58 | 2.56 | 2.71 | 2.89 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 0.0% (0/28) | 21.4% (6/28) | 25.0% (10/40) | 28.9% (11/38) | 11.8% (2/17) | 16.7% (3/18) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 78.6% (22/28) | 75.0% (21/28) | 72.5% (29/40) | 71.1% (27/38) | 64.7% (11/17) | 61.1% (11/18) |
| Double | 17.9% (5/28) | 21.4% (6/28) | 20.0% (8/40) | 26.3% (10/38) | 17.6% (3/17) | 22.2% (4/18) |
| Triple | 3.6% (1/28) | 3.6% (1/28) | 7.5% (3/40) | 2.6% (1/38) | 17.6% (3/17) | 16.7% (3/18) |
| LAD | 18.5% (5/27) | 50.0% (14/28) | 48.7% (19/39) | 38.9% (14/36) | 23.5% (4/17) | 33.3% (6/18) |

## Appendix Table 3a. Baseline Characteristics by Region and Treatment (Continued)

| | Region 22 | | Region 23 | |
|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | |
| Lesion Length (mm) | | | | |
| Mean±SD (n) | 16.44±6.41 (39) | 14.87±4.74 (38) | 11.70±5.21 (34) | 13.38±5.74 (36) |
| Range (Min,Max) | (5.66,42.07) | (6.51,26.51) | (4.15,26.76) | (8.01,30.46) |
| Median | 15.97 | 14.72 | 10.30 | 10.81 |
| MLD | | | | |
| Mean±SD (n) | 0.73±0.30 (39) | 0.78±0.40 (39) | 0.78±0.42 (35) | 0.78±0.32 (36) |
| Range (Min,Max) | (0.14,1.53) | (0.13,1.67) | (0.19,2.04) | (0.11,1.61) |
| Median | 0.69 | 0.72 | 0.70 | 0.75 |
| Reference Vessel Diameter (mm) | | | | |
| Mean±SD (n) | 2.77±0.53 (39) | 2.77±0.52 (39) | 2.59±0.47 (35) | 2.69±0.54 (36) |
| Range (Min,Max) | (1.66,4.41) | (1.92,3.79) | (1.61,3.65) | (1.64,3.93) |
| Median | 2.83 | 2.76 | 2.54 | 2.71 |
| **Patient Characteristic** | | | | |
| Diabetes Mellitus | 25.6% (10/39) | 35.0% (14/40) | 5.7% (2/35) | 8.3% (3/36) |
| Major Coronary Stenosis (>50% Stenosed) | | | | |
| Single | 59.0% (23/39) | 60.0% (24/40) | 60.0% (21/35) | 55.6% (20/36) |
| Double | 33.3% (13/39) | 32.5% (13/40) | 14.3% (5/35) | 25.0% (9/36) |
| Triple | 7.7% (3/39) | 7.5% (3/40) | 25.7% (9/35) | 19.4% (7/36) |
| LAD | 48.7% (19/39) | 48.7% (19/39) | 40.0% (14/35) | 55.6% (20/36) |

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## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment

| | Pooled Site 1 | | Pooled Site 2 | | Pooled Site 3 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 10.32±2.92 (7) | 10.94±3.44 (6) | 14.30±3.97 (9) | 16.28±7.13 (10) | 12.33±3.84 (11) | 13.42±4.26 (12) |
| Range (Min,Max) | (7.90,14.89) | (7.17,15.85) | (8.03,20.00) | (6.98,27.16) | (8.20,18.34) | (7.84,19.26) |
| Median | 8.62 | 10.61 | 15.37 | 15.44 | 11.51 | 12.65 |
| MLD | | | | | | |
| Mean±SD (n) | 0.85±0.24 (7) | 0.65±0.17 (6) | 0.65±0.28 (10) | 0.76±0.31 (10) | 0.74±0.39 (11) | 0.73±0.33 (12) |
| Range (Min,Max) | (0.41,1.12) | (0.49,0.91) | (0.12,1.06) | (0.42,1.28) | (0.12,1.45) | (0.29,1.29) |
| Median | 0.91 | 0.57 | 0.65 | 0.71 | 0.73 | 0.73 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.85±0.63 (7) | 2.30±0.35 (6) | 2.55±0.35 (10) | 2.88±0.57 (10) | 2.59±0.35 (11) | 2.65±0.30 (12) |
| Range (Min,Max) | (2.15,3.81) | (1.83,2.61) | (1.90,2.94) | (2.36,4.15) | (2.25,3.19) | (2.13,3.26) |
| Median | 2.58 | 2.43 | 2.52 | 2.71 | 2.40 | 2.65 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 0.0% (0/7) | 66.7% (4/6) | 27.3% (3/11) | 30.0% (3/10) | 27.3% (3/11) | 58.3% (7/12) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 85.7% (6/7) | 83.3% (5/6) | 90.9% (10/11) | 80.0% (8/10) | 63.6% (7/11) | 33.3% (4/12) |
| Double | 14.3% (1/7) | 16.7% (1/6) | 9.1% (1/11) | 20.0% (2/10) | 27.3% (3/11) | 66.7% (8/12) |
| Triple | 0.0% (0/7) | 0.0% (0/6) | 0.0% (0/11) | 0.0% (0/10) | 9.1% (1/11) | 0.0% (0/12) |
| LAD | 14.3% (1/7) | 50.0% (3/6) | 40.0% (4/10) | 30.0% (3/10) | 27.3% (3/11) | 41.7% (5/12) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 4 | | Pooled Site 5 | | Pooled Site 6 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 16.41±5.02 (9) | 16.86±6.03 (10) | 13.19±4.77 (12) | 14.49±5.49 (9) | 14.25±6.02 (18) | 15.56±5.90 (17) |
| Range (Min,Max) | (10.60,23.95) | (8.48,25.79) | (6.50,22.50) | (6.96,21.91) | (6.20,27.42) | (4.81,23.02) |
| Median | 16.90 | 17.31 | 13.41 | 14.12 | 13.41 | 16.98 |
| MLD | | | | | | |
| Mean±SD (n) | 0.72±0.32 (9) | 0.78±0.37 (10) | 0.84±0.37 (12) | 0.81±0.33 (9) | 0.82±0.28 (18) | 0.96±0.43 (17) |
| Range (Min,Max) | (0.42,1.25) | (0.14,1.36) | (0.34,1.61) | (0.49,1.49) | (0.29,1.30) | (0.36,1.67) |
| Median | 0.63 | 0.81 | 0.78 | 0.75 | 0.83 | 0.85 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.48±0.30 (9) | 2.73±0.34 (10) | 2.80±0.38 (12) | 2.88±0.40 (9) | 3.08±0.47 (18) | 2.97±0.59 (17) |
| Range (Min,Max) | (2.08,2.97) | (1.97,3.24) | (2.23,3.35) | (2.25,3.56) | (2.40,3.91) | (2.08,4.07) |
| Median | 2.45 | 2.76 | 2.82 | 2.89 | 2.96 | 2.95 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 20.0% (2/10) | 40.0% (4/10) | 16.7% (2/12) | 11.1% (1/9) | 11.1% (2/18) | 29.4% (5/17) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 70.0% (7/10) | 60.0% (6/10) | 83.3% (10/12) | 55.6% (5/9) | 66.7% (12/18) | 58.8% (10/17) |
| Double | 20.0% (2/10) | 20.0% (2/10) | 8.3% (1/12) | 33.3% (3/9) | 16.7% (3/18) | 35.3% (6/17) |
| Triple | 10.0% (1/10) | 20.0% (2/10) | 8.3% (1/12) | 11.1% (1/9) | 16.7% (3/18) | 5.9% (1/17) |
| LAD | 66.7% (6/9) | 70.0% (7/10) | 33.3% (4/12) | 22.2% (2/9) | 44.4% (8/18) | 35.3% (6/17) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 7 | | Pooled Site 8 | | Pooled Site 9 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.28±4.74 (9) | 12.51±5.36 (8) | 13.19±5.23 (7) | 16.32±4.67 (7) | 12.69±4.68 (11) | 15.11±3.74 (11) |
| Range (Min,Max) | (7.77,22.28) | (6.59,21.32) | (5.81,20.29) | (9.82,23.22) | (6.18,22.41) | (11.94,25.57) |
| Median | 12.83 | 11.02 | 14.63 | 16.67 | 12.08 | 13.96 |
| MLD | | | | | | |
| Mean±SD (n) | 0.65±0.30 (9) | 0.86±0.32 (8) | 0.69±0.32 (7) | 0.96±0.37 (7) | 0.71±0.37 (12) | 0.81±0.29 (11) |
| Range (Min,Max) | (0.30,1.17) | (0.38,1.25) | (0.34,1.21) | (0.64,1.58) | (0.14,1.36) | (0.39,1.30) |
| Median | 0.68 | 0.89 | 0.68 | 0.74 | 0.72 | 0.80 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.68±0.34 (9) | 2.71±0.45 (8) | 2.77±0.44 (7) | 2.87±0.64 (7) | 2.58±0.40 (12) | 2.62±0.56 (11) |
| Range (Min,Max) | (1.98,3.18) | (2.12,3.40) | (2.12,3.21) | (2.01,3.95) | (1.72,3.27) | (1.72,3.33) |
| Median | 2.77 | 2.65 | 3.01 | 2.82 | 2.58 | 2.73 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 11.1% (1/9) | 0.0% (0/8) | 0.0% (0/7) | 0.0% (0/7) | 0.0% (0/12) | 45.5% (5/11) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 77.8% (7/9) | 100.0% (8/8) | 57.1% (4/7) | 42.9% (3/7) | 75.0% (9/12) | 81.8% (9/11) |
| Double | 11.1% (1/9) | 0.0% (0/8) | 42.9% (3/7) | 57.1% (4/7) | 16.7% (2/12) | 9.1% (1/11) |
| Triple | 11.1% (1/9) | 0.0% (0/8) | 0.0% (0/7) | 0.0% (0/7) | 8.3% (1/12) | 9.1% (1/11) |
| LAD | 22.2% (2/9) | 25.0% (2/8) | 28.6% (2/7) | 57.1% (4/7) | 16.7% (2/12) | 63.6% (7/11) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 10 | | Pooled Site 11 | | Pooled Site 12 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 15.43±6.77 (8) | 14.49±4.25 (11) | 12.25±5.70 (7) | 11.28±3.59 (6) | 14.48±1.75 (5) | 10.65±4.82 (5) |
| Range (Min,Max) | (7.20,24.12) | (8.22,22.09) | (6.84,23.87) | (7.76,17.19) | (11.89,16.31) | (6.15,16.19) |
| Median | 15.46 | 14.39 | 11.21 | 10.48 | 14.53 | 8.82 |
| MLD | | | | | | |
| Mean±SD (n) | 0.78±0.51 (9) | 0.83±0.41 (11) | 0.73±0.33 (7) | 0.74±0.28 (6) | 0.86±0.18 (5) | 0.80±0.24 (5) |
| Range (Min,Max) | (0.11,1.88) | (0.32,1.78) | (0.28,1.24) | (0.47,1.18) | (0.71,1.16) | (0.59,1.18) |
| Median | 0.76 | 0.71 | 0.78 | 0.72 | 0.82 | 0.69 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.78±0.51 (9) | 2.95±0.56 (11) | 2.98±0.46 (7) | 2.87±0.32 (6) | 2.46±0.26 (5) | 2.64±0.61 (5) |
| Range (Min,Max) | (1.96,3.71) | (2.02,3.71) | (2.44,3.67) | (2.34,3.25) | (2.09,2.73) | (2.17,3.67) |
| Median | 2.80 | 3.07 | 2.97 | 2.96 | 2.43 | 2.47 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 0.0% (0/10) | 9.1% (1/11) | 0.0% (0/7) | 0.0% (0/6) | 40.0% (2/5) | 40.0% (2/5) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 100.0% (10/10) | 81.8% (9/11) | 100.0% (7/7) | 100.0% (6/6) | 80.0% (4/5) | 100.0% (5/5) |
| Double | 0.0% (0/10) | 18.2% (2/11) | 0.0% (0/7) | 0.0% (0/6) | 0.0% (0/5) | 0.0% (0/5) |
| Triple | 0.0% (0/10) | 0.0% (0/11) | 0.0% (0/7) | 0.0% (0/6) | 20.0% (1/5) | 0.0% (0/5) |
| LAD | 11.1% (1/9) | 36.4% (4/11) | 57.1% (4/7) | 66.7% (4/6) | 100.0% (5/5) | 40.0% (2/5) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 13 | | Pooled Site 14 | | Pooled Site 15 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.09±5.53 (11) | 12.96±4.51 (10) | 16.76±7.01 (4) | 14.06±7.51 (5) | 10.29±4.22 (6) | 12.45±6.53 (7) |
| Range (Min,Max) | (7.00,22.11) | (5.73,22.28) | (7.43,23.98) | (4.49,24.07) | (5.40,18.11) | (3.16,22.05) |
| Median | 10.66 | 12.27 | 17.82 | 12.49 | 9.31 | 11.95 |
| MLD | | | | | | |
| Mean±SD (n) | 0.89±0.30 (11) | 0.67±0.22 (10) | 1.06±0.38 (4) | 0.67±0.38 (5) | 0.72±0.17 (6) | 0.89±0.29 (7) |
| Range (Min,Max) | (0.44,1.23) | (0.46,1.11) | (0.56,1.45) | (0.29,1.30) | (0.52,0.97) | (0.73,1.55) |
| Median | 1.05 | 0.59 | 1.12 | 0.59 | 0.74 | 0.80 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 3.06±0.52 (11) | 2.85±0.38 (10) | 2.69±0.38 (4) | 2.44±0.26 (5) | 2.27±0.35 (6) | 2.59±0.18 (7) |
| Range (Min,Max) | (2.28,4.06) | (2.19,3.53) | (2.22,3.06) | (2.20,2.81) | (1.85,2.71) | (2.33,2.94) |
| Median | 3.12 | 2.84 | 2.75 | 2.34 | 2.28 | 2.58 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 8.3% (1/12) | 9.1% (1/11) | 0.0% (0/4) | 0.0% (0/5) | 33.3% (2/6) | 28.6% (2/7) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 66.7% (8/12) | 72.7% (8/11) | 100.0% (4/4) | 60.0% (3/5) | 66.7% (4/6) | 85.7% (6/7) |
| Double | 33.3% (4/12) | 27.3% (3/11) | 0.0% (0/4) | 20.0% (1/5) | 33.3% (2/6) | 14.3% (1/7) |
| Triple | 0.0% (0/12) | 0.0% (0/11) | 0.0% (0/4) | 20.0% (1/5) | 0.0% (0/6) | 0.0% (0/7) |
| LAD | 27.3% (3/11) | 40.0% (4/10) | 75.0% (3/4) | 60.0% (3/5) | 33.3% (2/6) | 28.6% (2/7) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 16 | | Pooled Site 17 | | Pooled Site 18 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.02±7.57 (7) | 11.10±4.02 (6) | 12.22±4.73 (17) | 12.35±4.13 (14) | 15.70±4.73 (6) | 12.51±1.93 (5) |
| Range (Min,Max) | (5.26,25.85) | (4.64,14.84) | (6.06,22.50) | (6.50,20.22) | (11.64,22.31) | (9.49,14.67) |
| Median | 9.82 | 12.12 | 10.60 | 11.60 | 13.35 | 13.12 |
| MLD | | | | | | |
| Mean±SD (n) | 0.92±0.32 (7) | 0.72±0.27 (6) | 0.78±0.34 (18) | 0.84±0.36 (14) | 0.94±0.30 (6) | 0.75±0.31 (6) |
| Range (Min,Max) | (0.63,1.56) | (0.26,1.01) | (0.12,1.72) | (0.27,1.42) | (0.58,1.44) | (0.15,1.01) |
| Median | 0.81 | 0.79 | 0.75 | 0.75 | 0.92 | 0.82 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.74±0.52 (7) | 2.46±0.58 (6) | 2.54±0.50 (18) | 2.60±0.45 (14) | 2.53±0.44 (6) | 2.80±0.60 (6) |
| Range (Min,Max) | (2.27,3.66) | (1.66,3.45) | (1.81,3.66) | (1.72,3.30) | (1.85,3.12) | (1.95,3.40) |
| Median | 2.53 | 2.43 | 2.42 | 2.56 | 2.66 | 2.99 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 42.9% (3/7) | 50.0% (3/6) | 11.1% (2/18) | 20.0% (3/15) | 16.7% (1/6) | 16.7% (1/6) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 57.1% (4/7) | 33.3% (2/6) | 72.2% (13/18) | 73.3% (11/15) | 66.7% (4/6) | 83.3% (5/6) |
| Double | 14.3% (1/7) | 66.7% (4/6) | 22.2% (4/18) | 26.7% (4/15) | 33.3% (2/6) | 16.7% (1/6) |
| Triple | 28.6% (2/7) | 0.0% (0/6) | 5.6% (1/18) | 0.0% (0/15) | 0.0% (0/6) | 0.0% (0/6) |
| LAD | 42.9% (3/7) | 33.3% (2/6) | 38.9% (7/18) | 50.0% (7/14) | 50.0% (3/6) | 16.7% (1/6) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 19 | | Pooled Site 20 | | Pooled Site 21 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.15±6.24 (32) | 12.76±5.28 (34) | 11.32±4.01 (21) | 13.88±4.36 (20) | 10.20±3.87 (8) | 16.32±7.41 (8) |
| Range (Min,Max) | (5.12,34.61) | (5.54,23.40) | (6.37,21.98) | (5.48,24.28) | (5.91,16.54) | (9.02,33.00) |
| Median | 11.64 | 11.25 | 10.75 | 14.06 | 10.09 | 15.56 |
| MLD | | | | | | |
| Mean±SD (n) | 0.81±0.32 (32) | 0.80±0.30 (34) | 0.90±0.42 (21) | 0.81±0.35 (20) | 0.76±0.33 (8) | 0.82±0.43 (8) |
| Range (Min,Max) | (0.31,1.76) | (0.25,1.52) | (0.35,2.34) | (0.17,1.44) | (0.26,1.28) | (0.13,1.61) |
| Median | 0.74 | 0.82 | 0.90 | 0.77 | 0.69 | 0.84 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.73±0.32 (32) | 2.70±0.48 (34) | 3.08±0.52 (21) | 3.07±0.40 (20) | 2.80±0.22 (8) | 2.60±0.51 (8) |
| Range (Min,Max) | (2.25,3.57) | (1.92,3.93) | (2.50,4.28) | (2.38,4.04) | (2.46,3.09) | (1.86,3.25) |
| Median | 2.70 | 2.58 | 2.92 | 2.99 | 2.81 | 2.57 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 21.9% (7/32) | 14.7% (5/34) | 10.0% (2/20) | 15.0% (3/20) | 12.5% (1/8) | 12.5% (1/8) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 81.3% (26/32) | 73.5% (25/34) | 95.2% (20/21) | 85.0% (17/20) | 100.0% (8/8) | 100.0% (8/8) |
| Double | 12.5% (4/32) | 14.7% (5/34) | 4.8% (1/21) | 5.0% (1/20) | 0.0% (0/8) | 0.0% (0/8) |
| Triple | 6.3% (2/32) | 11.8% (4/34) | 0.0% (0/21) | 10.0% (2/20) | 0.0% (0/8) | 0.0% (0/8) |
| LAD | 40.6% (13/32) | 35.3% (12/34) | 52.4% (11/21) | 40.0% (8/20) | 37.5% (3/8) | 37.5% (3/8) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 22 | | Pooled Site 23 | | Pooled Site 24 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 14.29±6.15 (6) | 11.47±6.45 (7) | 11.80±3.01 (5) | 13.39±5.28 (6) | 16.37±9.88 (5) | 17.12±5.37 (5) |
| Range (Min,Max) | (6.96,21.22) | (6.05,23.74) | (7.56,15.96) | (7.31,22.02) | (8.06,31.65) | (8.71,22.69) |
| Median | 14.62 | 9.00 | 12.00 | 12.26 | 12.41 | 18.10 |
| MLD | | | | | | |
| Mean±SD (n) | 0.93±0.44 (7) | 1.08±0.21 (7) | 0.81±0.21 (5) | 0.87±0.42 (6) | 0.81±0.25 (5) | 0.63±0.33 (5) |
| Range (Min,Max) | (0.12,1.44) | (0.71,1.30) | (0.58,1.09) | (0.11,1.39) | (0.46,1.06) | (0.13,0.89) |
| Median | 0.88 | 1.15 | 0.74 | 0.92 | 0.85 | 0.82 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.75±0.70 (7) | 2.77±0.24 (7) | 2.82±0.47 (5) | 2.81±0.33 (6) | 2.63±0.60 (5) | 2.93±0.57 (5) |
| Range (Min,Max) | (1.92,3.96) | (2.42,3.06) | (2.13,3.28) | (2.22,3.12) | (1.92,3.46) | (2.36,3.78) |
| Median | 2.56 | 2.89 | 3.04 | 2.96 | 2.71 | 2.75 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 14.3% (1/7) | 28.6% (2/7) | 20.0% (1/5) | 16.7% (1/6) | 0.0% (0/5) | 0.0% (0/5) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 42.9% (3/7) | 42.9% (3/7) | 100.0% (5/5) | 50.0% (3/6) | 60.0% (3/5) | 100.0% (5/5) |
| Double | 14.3% (1/7) | 42.9% (3/7) | 0.0% (0/5) | 16.7% (1/6) | 40.0% (2/5) | 0.0% (0/5) |
| Triple | 42.9% (3/7) | 14.3% (1/7) | 0.0% (0/5) | 33.3% (2/6) | 0.0% (0/5) | 0.0% (0/5) |
| LAD | 28.6% (2/7) | 28.6% (2/7) | 0.0% (0/5) | 33.3% (2/6) | 40.0% (2/5) | 40.0% (2/5) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment

| | Pooled Site 25 | | Pooled Site 26 | | Pooled Site 27 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.24±4.52 (10) | 14.55±6.79 (10) | 15.23±7.14 (11) | 14.71±5.05 (10) | 15.73±6.12 (26) | 13.43±4.59 (26) |
| Range (Min,Max) | (4.78,18.22) | (8.53,32.20) | (8.40,26.56) | (7.93,23.77) | (6.11,33.35) | (5.41,27.45) |
| Median | 11.35 | 12.63 | 11.94 | 13.57 | 15.97 | 13.31 |
| MLD | | | | | | |
| Mean±SD (n) | 0.78±0.24 (10) | 0.84±0.24 (10) | 0.88±0.30 (11) | 0.86±0.33 (10) | 0.90±0.30 (26) | 0.90±0.33 (26) |
| Range (Min,Max) | (0.45,1.25) | (0.46,1.35) | (0.45,1.28) | (0.42,1.57) | (0.46,1.50) | (0.47,1.61) |
| Median | 0.79 | 0.81 | 0.98 | 0.84 | 0.88 | 0.78 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.56±0.49 (10) | 2.63±0.52 (10) | 3.06±0.49 (11) | 2.89±0.61 (10) | 2.84±0.54 (26) | 2.94±0.50 (26) |
| Range (Min,Max) | (1.83,3.24) | (2.01,3.67) | (1.98,3.63) | (2.07,3.91) | (1.77,3.69) | (1.80,3.79) |
| Median | 2.46 | 2.47 | 3.12 | 3.06 | 2.94 | 2.92 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 20.0% (2/10) | 30.0% (3/10) | 18.2% (2/11) | 11.1% (1/9) | 22.2% (6/27) | 25.9% (7/27) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 40.0% (4/10) | 50.0% (5/10) | 90.9% (10/11) | 70.0% (7/10) | 48.1% (13/27) | 66.7% (18/27) |
| Double | 50.0% (5/10) | 30.0% (3/10) | 9.1% (1/11) | 30.0% (3/10) | 40.7% (11/27) | 29.6% (8/27) |
| Triple | 10.0% (1/10) | 20.0% (2/10) | 0.0% (0/11) | 0.0% (0/10) | 11.1% (3/27) | 3.7% (1/27) |
| LAD | 50.0% (5/10) | 20.0% (2/10) | 45.5% (5/11) | 60.0% (6/10) | 53.8% (14/26) | 50.0% (13/26) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 28 | | Pooled Site 29 | | Pooled Site 30 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 13.62±3.72 (12) | 16.03±8.80 (14) | 14.47±6.15 (14) | 13.06±5.19 (17) | 14.19±3.65 (21) | 15.33±6.34 (21) |
| Range (Min,Max) | (7.40,19.10) | (6.74,38.50) | (6.72,28.11) | (5.31,24.11) | (8.21,23.04) | (7.86,31.67) |
| Median | 14.36 | 14.28 | 12.95 | 13.80 | 13.31 | 13.70 |
| MLD | | | | | | |
| Mean±SD (n) | 0.99±0.42 (12) | 0.77±0.36 (14) | 0.79±0.32 (14) | 0.93±0.37 (17) | 1.00±0.35 (21) | 0.95±0.35 (21) |
| Range (Min,Max) | (0.00,1.55) | (0.31,1.64) | (0.29,1.25) | (0.31,1.63) | (0.44,1.70) | (0.45,1.62) |
| Median | 1.02 | 0.62 | 0.83 | 0.91 | 1.02 | 0.91 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.93±0.66 (12) | 2.67±0.56 (14) | 2.60±0.32 (14) | 3.08±0.50 (17) | 2.82±0.37 (21) | 2.78±0.36 (21) |
| Range (Min,Max) | (2.01,4.14) | (2.06,3.59) | (2.06,3.21) | (2.26,3.82) | (2.38,3.65) | (2.18,3.51) |
| Median | 2.92 | 2.54 | 2.58 | 3.11 | 2.73 | 2.75 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 33.3% (4/12) | 28.6% (4/14) | 7.1% (1/14) | 23.5% (4/17) | 19.0% (4/21) | 19.0% (4/21) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 83.3% (10/12) | 78.6% (11/14) | 64.3% (9/14) | 70.6% (12/17) | 71.4% (15/21) | 61.9% (13/21) |
| Double | 8.3% (1/12) | 7.1% (1/14) | 21.4% (3/14) | 23.5% (4/17) | 19.0% (4/21) | 33.3% (7/21) |
| Triple | 8.3% (1/12) | 14.3% (2/14) | 14.3% (2/14) | 5.9% (1/17) | 9.5% (2/21) | 4.8% (1/21) |
| LAD | 50.0% (6/12) | 42.9% (6/14) | 50.0% (7/14) | 41.2% (7/17) | 23.8% (5/21) | 47.6% (10/21) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 31 | | Pooled Site 32 | | Pooled Site 33 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 15.72±5.97 (5) | 14.66±6.61 (5) | 15.36±5.00 (16) | 15.36±4.39 (16) | 16.66±6.02 (8) | 13.08±6.43 (8) |
| Range (Min,Max) | (11.12,26.02) | (7.09,25.19) | (6.63,24.81) | (9.03,23.00) | (6.20,25.00) | (7.62,27.74) |
| Median | 14.42 | 13.00 | 15.06 | 15.47 | 15.97 | 11.12 |
| MLD | | | | | | |
| Mean±SD (n) | 0.87±0.23 (5) | 0.92±0.24 (5) | 0.72±0.34 (16) | 0.74±0.26 (16) | 0.65±0.35 (8) | 0.72±0.23 (8) |
| Range (Min,Max) | (0.68,1.27) | (0.69,1.27) | (0.24,1.38) | (0.37,1.23) | (0.12,1.14) | (0.32,1.00) |
| Median | 0.80 | 0.85 | 0.68 | 0.64 | 0.63 | 0.74 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.31±0.40 (5) | 3.00±0.45 (5) | 2.49±0.40 (16) | 2.57±0.43 (16) | 2.86±0.37 (8) | 2.93±0.60 (8) |
| Range (Min,Max) | (1.88,2.81) | (2.32,3.46) | (1.85,3.22) | (2.01,3.54) | (2.44,3.55) | (2.15,3.77) |
| Median | 2.47 | 3.12 | 2.60 | 2.52 | 2.94 | 2.89 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 16.7% (1/6) | 20.0% (1/5) | 18.8% (3/16) | 25.0% (4/16) | 37.5% (3/8) | 0.0% (0/8) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 50.0% (3/6) | 100.0% (5/5) | 31.3% (5/16) | 62.5% (10/16) | 75.0% (6/8) | 75.0% (6/8) |
| Double | 50.0% (3/6) | 0.0% (0/5) | 31.3% (5/16) | 12.5% (2/16) | 25.0% (2/8) | 25.0% (2/8) |
| Triple | 0.0% (0/6) | 0.0% (0/5) | 37.5% (6/16) | 25.0% (4/16) | 0.0% (0/8) | 0.0% (0/8) |
| LAD | 40.0% (2/5) | 40.0% (2/5) | 50.0% (8/16) | 68.8% (11/16) | 37.5% (3/8) | 50.0% (4/8) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 34 | | Pooled Site 35 | | Pooled Site 36 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 11.95±4.73 (14) | 12.55±7.10 (15) | 11.94±3.85 (22) | 13.59±4.74 (24) | 14.31±5.46 (18) | 15.37±7.40 (17) |
| Range (Min,Max) | (5.72,22.00) | (2.71,25.72) | (6.89,24.30) | (5.69,28.10) | (6.06,25.38) | (6.51,31.89) |
| Median | 9.74 | 11.17 | 11.45 | 12.74 | 13.31 | 13.06 |
| MLD | | | | | | |
| Mean±SD (n) | 0.73±0.34 (14) | 0.82±0.33 (15) | 0.83±0.24 (22) | 0.75±0.34 (24) | 0.95±0.50 (19) | 1.00±0.44 (18) |
| Range (Min,Max) | (0.47,1.65) | (0.37,1.46) | (0.43,1.22) | (0.13,1.53) | (0.00,1.66) | (0.00,1.74) |
| Median | 0.58 | 0.69 | 0.79 | 0.65 | 1.06 | 0.99 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.64±0.37 (14) | 2.67±0.58 (15) | 2.52±0.42 (22) | 2.74±0.42 (24) | 2.73±0.65 (19) | 2.58±0.39 (18) |
| Range (Min,Max) | (1.92,3.33) | (1.86,4.19) | (1.78,3.29) | (2.09,3.53) | (1.75,4.51) | (1.77,3.03) |
| Median | 2.57 | 2.61 | 2.48 | 2.78 | 2.66 | 2.71 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 23.1% (3/13) | 26.7% (4/15) | 26.1% (6/23) | 20.8% (5/24) | 26.3% (5/19) | 22.2% (4/18) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 71.4% (10/14) | 80.0% (12/15) | 34.8% (8/23) | 41.7% (10/24) | 31.6% (6/19) | 27.8% (5/18) |
| Double | 21.4% (3/14) | 20.0% (3/15) | 39.1% (9/23) | 33.3% (8/24) | 36.8% (7/19) | 38.9% (7/18) |
| Triple | 7.1% (1/14) | 0.0% (0/15) | 26.1% (6/23) | 25.0% (6/24) | 31.6% (6/19) | 33.3% (6/18) |
| LAD | 42.9% (6/14) | 46.7% (7/15) | 59.1% (13/22) | 62.5% (15/24) | 42.1% (8/19) | 72.2% (13/18) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 37 | | Pooled Site 38 | | Pooled Site 39 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 15.83±6.16 (9) | 14.57±6.89 (9) | 15.88±3.38 (5) | 15.53±6.31 (6) | 15.83±5.53 (12) | 14.60±5.38 (11) |
| Range (Min,Max) | (7.67,30.09) | (8.86,29.70) | (12.59,20.11) | (5.39,22.23) | (5.66,27.00) | (6.51,24.40) |
| Median | 15.81 | 12.02 | 14.09 | 16.78 | 16.09 | 15.31 |
| MLD | | | | | | |
| Mean±SD (n) | 0.93±0.26 (9) | 0.94±0.34 (9) | 0.87±0.18 (5) | 0.77±0.11 (6) | 0.67±0.37 (12) | 0.73±0.30 (12) |
| Range (Min,Max) | (0.70,1.31) | (0.48,1.36) | (0.68,1.12) | (0.64,0.92) | (0.14,1.33) | (0.13,1.15) |
| Median | 0.79 | 0.92 | 0.90 | 0.75 | 0.62 | 0.83 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.99±0.49 (9) | 2.91±0.61 (9) | 3.24±0.43 (5) | 2.62±0.22 (6) | 2.73±0.53 (12) | 2.61±0.35 (12) |
| Range (Min,Max) | (2.14,3.80) | (1.78,4.13) | (2.71,3.69) | (2.32,2.93) | (1.66,3.72) | (2.02,3.37) |
| Median | 2.82 | 2.93 | 3.36 | 2.59 | 2.73 | 2.66 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 11.1% (1/9) | 11.1% (1/9) | 20.0% (1/5) | 33.3% (2/6) | 8.3% (1/12) | 50.0% (6/12) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 44.4% (4/9) | 44.4% (4/9) | 80.0% (4/5) | 33.3% (2/6) | 66.7% (8/12) | 50.0% (6/12) |
| Double | 44.4% (4/9) | 44.4% (4/9) | 20.0% (1/5) | 66.7% (4/6) | 25.0% (3/12) | 41.7% (5/12) |
| Triple | 11.1% (1/9) | 11.1% (1/9) | 0.0% (0/5) | 0.0% (0/6) | 8.3% (1/12) | 8.3% (1/12) |
| LAD | 77.8% (7/9) | 55.6% (5/9) | 60.0% (3/5) | 83.3% (5/6) | 33.3% (4/12) | 41.7% (5/12) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 40 | | Pooled Site 41 | | Pooled Site 42 | |
|---|---|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 15.85±4.06 (9) | 16.55±6.16 (9) | 15.59±5.44 (8) | 13.51±3.16 (8) | 18.96±11.16 (7) | 14.99±4.06 (8) |
| Range (Min,Max) | (8.91,22.96) | (7.92,26.51) | (9.99,24.40) | (9.50,18.68) | (9.53,42.07) | (9.91,23.11) |
| Median | 15.97 | 16.46 | 13.52 | 13.74 | 16.51 | 14.58 |
| MLD | | | | | | |
| Mean±SD (n) | 0.78±0.35 (9) | 0.86±0.45 (9) | 0.75±0.28 (8) | 0.70±0.39 (8) | 0.79±0.20 (7) | 0.93±0.50 (8) |
| Range (Min,Max) | (0.32,1.53) | (0.28,1.63) | (0.30,1.21) | (0.24,1.58) | (0.59,1.19) | (0.38,1.67) |
| Median | 0.74 | 0.75 | 0.68 | 0.64 | 0.72 | 0.83 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.48±0.44 (9) | 2.89±0.40 (9) | 2.86±0.42 (8) | 2.91±0.72 (8) | 3.10±0.72 (7) | 2.84±0.65 (8) |
| Range (Min,Max) | (2.05,3.23) | (2.25,3.51) | (2.14,3.42) | (1.92,3.79) | (2.18,4.41) | (2.00,3.74) |
| Median | 2.29 | 2.90 | 2.92 | 3.14 | 3.05 | 2.83 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 44.4% (4/9) | 33.3% (3/9) | 25.0% (2/8) | 25.0% (2/8) | 42.9% (3/7) | 25.0% (2/8) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 66.7% (6/9) | 55.6% (5/9) | 50.0% (4/8) | 75.0% (6/8) | 57.1% (4/7) | 62.5% (5/8) |
| Double | 22.2% (2/9) | 33.3% (3/9) | 37.5% (3/8) | 25.0% (2/8) | 42.9% (3/7) | 25.0% (2/8) |
| Triple | 11.1% (1/9) | 11.1% (1/9) | 12.5% (1/8) | 0.0% (0/8) | 0.0% (0/7) | 12.5% (1/8) |
| LAD | 55.6% (5/9) | 55.6% (5/9) | 50.0% (4/8) | 62.5% (5/8) | 57.1% (4/7) | 37.5% (3/8) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 43 | | Pooled Site 44 | | Pooled Site 45 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 18.25±6.15 (15) | 19.63±9.69 (16) | 18.81±5.83 (16) | 17.47±4.44 (17) | 16.85±4.83 (21) | 16.92±4.49 (19) |
| Range (Min,Max) | (9.14,29.00) | (7.57,39.53) | (5.87,27.76) | (9.66,24.51) | (10.94,28.66) | (10.73,28.34) |
| Median | 17.38 | 19.09 | 19.10 | 18.38 | 15.21 | 16.50 |
| MLD | | | | | | |
| Mean±SD (n) | 0.76±0.24 (16) | 0.99±0.46 (16) | 0.92±0.32 (16) | 0.89±0.29 (17) | 0.93±0.31 (21) | 1.09±0.39 (19) |
| Range (Min,Max) | (0.19,1.16) | (0.32,1.99) | (0.38,1.62) | (0.41,1.50) | (0.54,1.48) | (0.52,1.83) |
| Median | 0.80 | 0.84 | 0.89 | 0.83 | 0.88 | 1.03 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.81±0.41 (16) | 2.89±0.48 (16) | 2.72±0.42 (16) | 2.60±0.31 (17) | 2.76±0.34 (21) | 2.76±0.46 (19) |
| Range (Min,Max) | (1.86,3.84) | (1.99,4.10) | (2.23,3.59) | (2.22,3.06) | (2.15,3.31) | (2.04,3.52) |
| Median | 2.78 | 2.87 | 2.61 | 2.61 | 2.76 | 2.69 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 25.0% (4/16) | 23.5% (4/17) | 31.3% (5/16) | 11.8% (2/17) | 9.5% (2/21) | 31.6% (6/19) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 68.8% (11/16) | 70.6% (12/17) | 81.3% (13/16) | 64.7% (11/17) | 38.1% (8/21) | 31.6% (6/19) |
| Double | 18.8% (3/16) | 29.4% (5/17) | 18.8% (3/16) | 23.5% (4/17) | 42.9% (9/21) | 47.4% (9/19) |
| Triple | 12.5% (2/16) | 0.0% (0/17) | 0.0% (0/16) | 11.8% (2/17) | 19.0% (4/21) | 21.1% (4/19) |
| LAD | 37.5% (6/16) | 37.5% (6/16) | 37.5% (6/16) | 58.8% (10/17) | 52.4% (11/21) | 52.6% (10/19) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 46 | | Pooled Site 47 | | Pooled Site 48 | |
|---|---|---|---|---|---|---|
| | Endeavor | Driver | Endeavor | Driver | Endeavor | Driver |
| **Lesion Characteristic** | | | | | | |
| Lesion Length (mm) | | | | | | |
| Mean±SD (n) | 12.75±4.35 (10) | 16.87±5.10 (9) | 14.07±6.15 (12) | 17.64±5.25 (13) | 10.41±4.23 (22) | 10.98±4.55 (23) |
| Range (Min,Max) | (6.21,18.13) | (12.01,24.13) | (7.42,26.76) | (9.81,27.29) | (4.15,18.57) | (8.01,30.46) |
| Median | 13.84 | 13.81 | 11.77 | 16.79 | 9.04 | 10.38 |
| MLD | | | | | | |
| Mean±SD (n) | 0.89±0.30 (10) | 0.76±0.32 (9) | 0.86±0.36 (12) | 0.75±0.31 (13) | 0.74±0.45 (23) | 0.80±0.33 (23) |
| Range (Min,Max) | (0.49,1.44) | (0.33,1.19) | (0.33,1.44) | (0.46,1.61) | (0.19,2.04) | (0.11,1.52) |
| Median | 0.95 | 0.82 | 0.82 | 0.68 | 0.56 | 0.84 |
| Reference Vessel Diameter (mm) | | | | | | |
| Mean±SD (n) | 2.74±0.39 (10) | 2.66±0.47 (9) | 2.67±0.35 (12) | 2.85±0.53 (13) | 2.55±0.53 (23) | 2.60±0.53 (23) |
| Range (Min,Max) | (2.09,3.30) | (2.12,3.48) | (2.18,3.09) | (1.92,3.93) | (1.61,3.65) | (1.64,3.84) |
| Median | 2.82 | 2.58 | 2.83 | 2.95 | 2.52 | 2.62 |
| **Patient Characteristic** | | | | | | |
| Diabetes Mellitus | 40.0% (4/10) | 11.1% (1/9) | 0.0% (0/12) | 7.7% (1/13) | 8.7% (2/23) | 8.7% (2/23) |
| Major Coronary Stenosis (>50% Stenosed) | | | | | | |
| Single | 50.0% (5/10) | 66.7% (6/9) | 75.0% (9/12) | 69.2% (9/13) | 52.2% (12/23) | 47.8% (11/23) |
| Double | 30.0% (3/10) | 22.2% (2/9) | 25.0% (3/12) | 23.1% (3/13) | 8.7% (2/23) | 26.1% (6/23) |
| Triple | 20.0% (2/10) | 11.1% (1/9) | 0.0% (0/12) | 7.7% (1/13) | 39.1% (9/23) | 26.1% (6/23) |
| LAD | 60.0% (6/10) | 66.7% (6/9) | 33.3% (4/12) | 46.2% (6/13) | 43.5% (10/23) | 60.9% (14/23) |

## Appendix Table 3a. Baseline Characteristics by Pooled Site and Treatment (Continued)

| | Pooled Site 49 | | Pooled Site 50 | |
|---|---|---|---|---|
| | **Endeavor** | **Driver** | **Endeavor** | **Driver** |
| **Lesion Characteristic** | | | | |
| Lesion Length (mm) | | | | |
| Mean±SD (n) | 11.63±5.86 (13) | 12.54±5.32 (14) | 16.04±4.96 (5) | 12.50±3.67 (4) |
| Range (Min,Max) | (6.19,26.00) | (7.11,28.01) | (10.28,22.85) | (7.80,16.00) |
| Median | 9.81 | 10.49 | 16.83 | 13.09 |
| MLD | | | | |
| Mean±SD (n) | 1.00±0.37 (13) | 0.92±0.53 (14) | 0.77±0.20 (5) | 0.57±0.17 (4) |
| Range (Min,Max) | (0.52,1.88) | (0.47,2.15) | (0.55,0.99) | (0.43,0.80) |
| Median | 0.95 | 0.79 | 0.84 | 0.52 |
| Reference Vessel Diameter (mm) | | | | |
| Mean±SD (n) | 2.47±0.37 (13) | 2.83±0.60 (14) | 3.01±0.47 (5) | 2.36±0.39 (4) |
| Range (Min,Max) | (2.01,3.25) | (2.09,4.23) | (2.50,3.74) | (1.96,2.89) |
| Median | 2.43 | 2.81 | 2.94 | 2.30 |
| **Patient Characteristic** | | | | |
| Diabetes Mellitus | 23.1% (3/13) | 28.6% (4/14) | 0.0% (0/5) | 20.0% (1/5) |
| Major Coronary Stenosis (>50% Stenosed) | | | | |
| Single | 23.1% (3/13) | 14.3% (2/14) | 40.0% (2/5) | 40.0% (2/5) |
| Double | 46.2% (6/13) | 35.7% (5/14) | 60.0% (3/5) | 40.0% (2/5) |
| Triple | 30.8% (4/13) | 50.0% (7/14) | 0.0% (0/5) | 20.0% (1/5) |
| LAD | 46.2% (6/13) | 42.9% (6/14) | 60.0% (3/5) | 50.0% (2/4) |

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## Appendix Table 3b. Assessment of Differences in Baseline Characteristics Across Region by Treatment

| Measure | Endeavor | Driver |
|---|---|---|
| Diabetes Mellitus | 0.1807 | 0.1976 |
| Major Coronary Stenosis (>50% Stenosed) | <.0001 | <.0001 |
| Lesion Length | <.0001 | 0.0048 |
| Reference Vessel Diameter | 0.0374 | 0.2349 |
| MLD | 0.1446 | 0.1044 |
| LAD | 0.1245 | 0.1591 |

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## Appendix Table 3c. Assessment of Differences in Baseline Characteristics Across Pooled Site by Treatment

| Measure | Endeavor | Driver |
|---|---|---|
| Diabetes Mellitus | 0.4431 | 0.1643 |
| Major Coronary Stenosis (>50% Stenosed) | <.0001 | <.0001 |
| Lesion Length | 0.0003 | 0.0160 |
| Reference Vessel Diameter | <.0001 | 0.0540 |
| MLD | 0.5235 | 0.3406 |
| LAD | 0.4660 | 0.6983 |

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# Appendix Table 4a. Predictors Of TVF

| Predictors of TVF<br>Simple Logistic Regression | Coefficient | Standard Error | Odds Ratio | P-Value |
|---|---|---|---|---|
| Number of Total Stents Implanted | 0.831 | 0.181 | 2.295 | <0.001 |
| Post-Procedure In-Stent Minimal Lumen Diameter (per mm) | -0.889 | 0.217 | 0.411 | <0.001 |
| Treatment Group (Endeavor vs Driver) | 0.721 | 0.191 | 2.056 | <0.001 |
| Lesion Length (per mm) | 0.053 | 0.015 | 1.054 | <0.001 |
| ACC/AHA Lesion Morphology Class (C vs all others) | 0.539 | 0.193 | 1.714 | 0.005 |
| Post-Procedure Reference Vessel Diameter (per mm) | -0.551 | 0.200 | 0.576 | 0.006 |
| Pre-Procedure Reference Vessel Diameter (per mm) | -0.434 | 0.197 | 0.648 | 0.027 |
| History of Hypertension | 0.448 | 0.207 | 1.565 | 0.030 |
| Age (years) | 0.019 | 0.009 | 1.019 | 0.031 |
| History of Diabetes | 0.437 | 0.208 | 1.548 | 0.036 |
| Post-Procedure In-Stent Diameter Stenosis (%) | 0.017 | 0.009 | 1.017 | 0.052 |
| LAD(vs all others) | 0.311 | 0.183 | 1.365 | 0.088 |
| History of Prior MI | -0.320 | 0.192 | 0.727 | 0.096 |
| Pre-Procedure Thrombus | 0.706 | 0.434 | 2.026 | 0.104 |
| Pre-Procedure Minimal Lumen Diameter (per mm) | -0.380 | 0.274 | 0.684 | 0.165 |
| Region | -0.013 | 0.012 | 0.987 | 0.280 |
| Post-Procedure Thrombus | 1.022 | 1.049 | 2.779 | 0.330 |
| History of Hyperlipidemia | -0.202 | 0.214 | 0.817 | 0.345 |
| Calcification (Moderate/Severe vs Mild) | 0.124 | 0.204 | 1.132 | 0.542 |
| Canadian Cardiovascular Society Class III or IV | -0.123 | 0.205 | 0.884 | 0.548 |
| Gender (Male) | -0.115 | 0.209 | 0.891 | 0.581 |
| History of Smoking | 0.072 | 0.191 | 1.074 | 0.707 |
| Angulation (>45 degrees) | -0.086 | 0.231 | 0.918 | 0.710 |
| History of Prior CABG | 0.100 | 0.415 | 1.105 | 0.809 |

| Predictors of TVF<br>Multiple Logistic Regression | Coefficient | Standard Error | Odds Ratio | P-Value |
|---|---|---|---|---|
| Intercept | -1.519 | 0.786 | 3.735 | 0.053 |
| Number of Total Stents Implanted | 0.613 | 0.214 | 8.218 | 0.004 |
| Post-Procedure In-Stent Minimal Lumen Diameter (per mm) | -0.776 | 0.273 | 8.081 | 0.004 |
| ACC/AHA Lesion Morphology Class (C vs all others) | 0.466 | 0.234 | 3.973 | 0.046 |
| LAD (vs all others) | 0.386 | 0.221 | 3.050 | 0.081 |
| Treatment Group (Endeavor vs Driver) | 0.594 | 0.223 | 7.074 | 0.008 |
| Pre-Procedure Thrombus | 0.957 | 0.536 | 3.186 | 0.074 |

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Predictors were chosen by stepwise logistic regression using an entry criterion of 0.2 with a stay criterion of 0.1.

# Appendix Table 4b. Predictors Of TVF

| Predictors of TVF<br>Simple Logistic Regression | Coefficient | Standard Error | Odds Ratio | P-Value |
|---|---|---|---|---|
| Number of Total Stents Implanted | 0.831 | 0.181 | 2.295 | <0.001 |
| Post-Procedure In-Stent Minimal Lumen Diameter (per mm) | -0.889 | 0.217 | 0.411 | <0.001 |
| Treatment Group (Endeavor vs Driver) | 0.721 | 0.191 | 2.056 | <0.001 |
| Lesion Length (per mm) | 0.053 | 0.015 | 1.054 | <0.001 |
| ACC/AHA Lesion Morphology Class (C vs all others) | 0.539 | 0.193 | 1.714 | 0.005 |
| Post-Procedure Reference Vessel Diameter (per mm) | -0.551 | 0.200 | 0.576 | 0.006 |
| Pre-Procedure Reference Vessel Diameter (per mm) | -0.434 | 0.197 | 0.648 | 0.027 |
| History of Hypertension | 0.448 | 0.207 | 1.565 | 0.030 |
| Age (years) | 0.019 | 0.009 | 1.019 | 0.031 |
| History of Diabetes | 0.437 | 0.208 | 1.548 | 0.036 |
| Post-Procedure In-Stent Diameter Stenosis (%) | 0.017 | 0.009 | 1.017 | 0.052 |
| LAD(vs all others) | 0.311 | 0.183 | 1.365 | 0.088 |
| History of Prior MI | -0.320 | 0.192 | 0.727 | 0.096 |
| Pre-Procedure Thrombus | 0.706 | 0.434 | 2.026 | 0.104 |
| Pre-Procedure Minimal Lumen Diameter (per mm) | -0.380 | 0.274 | 0.684 | 0.165 |
| Post-Procedure Thrombus | 1.022 | 1.049 | 2.779 | 0.330 |
| History of Hyperlipidemia | -0.202 | 0.214 | 0.817 | 0.345 |
| Calcification (Moderate/Severe vs Mild) | 0.124 | 0.204 | 1.132 | 0.542 |
| Canadian Cardiovascular Society Class III or IV | -0.123 | 0.205 | 0.884 | 0.548 |
| Gender (Male) | -0.115 | 0.209 | 0.891 | 0.581 |
| History of Smoking | 0.072 | 0.191 | 1.074 | 0.707 |
| Angulation (>45 degrees) | -0.086 | 0.231 | 0.918 | 0.710 |
| History of Prior CABG | 0.100 | 0.415 | 1.105 | 0.809 |

| Predictors of TVF<br>Multiple Logistic Regression | Coefficient | Standard Error | Odds Ratio | P-Value |
|---|---|---|---|---|
| Intercept | -1.519 | 0.786 | . | 0.053 |
| LAD (vs all others) | 0.386 | 0.221 | 1.472 | 0.081 |
| Pre-Procedure Thrombus | 0.957 | 0.536 | 2.605 | 0.074 |
| ACC/AHA Lesion Morphology Class (C vs all others) | 0.466 | 0.234 | 1.594 | 0.046 |
| Treatment Group (Endeavor vs Driver) | 0.594 | 0.223 | 1.811 | 0.008 |
| Number of Total Stents Implanted | 0.613 | 0.214 | 1.846 | 0.004 |
| Post-Procedure In-Stent Minimal Lumen Diameter (per mm) | -0.776 | 0.273 | 0.460 | 0.004 |

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Predictors were chosen by stepwise logistic regression using an entry criterion of 0.2 with a stay criterion of 0.1.

# Appendix Table 5a. TVF at 270 Days by Region

| Region | TVF |
|---|---|
| 1 | 14.6% (21/144) |
| 2 | 13.2% (9/68) |
| 3 | 7.5% (4/53) |
| 4 | 15.4% (4/26) |
| 5 | 29.6% (8/27) |
| 6 | 16.7% (5/30) |
| 7 | 8.3% (2/24) |
| 8 | 21.9% (7/32) |
| 9 | 6.1% (2/33) |
| 10 | 8.2% (6/73) |
| 11 | 10.5% (2/19) |
| 12 | 6.3% (2/32) |
| 13 | 6.2% (5/81) |
| 14 | 13.5% (10/74) |
| 15 | 2.1% (1/48) |
| 16 | 4.3% (1/23) |
| 17 | 11.1% (3/27) |
| 18 | 5.7% (3/53) |
| 19 | 16.1% (9/56) |
| 20 | 10.5% (8/76) |
| 21 | 2.9% (1/35) |
| 22 | 16.7% (13/78) |
| 23 | 14.1% (10/71) |

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## Appendix Table 5b. TVF at 270 Days by Pooled Site

| Pooled Site | TVF |
|---|---|
| 1 | 7.7% (1/13) |
| 2 | 0.0% (0/21) |
| 3 | 4.3% (1/23) |
| 4 | 10.0% (2/20) |
| 5 | 4.8% (1/21) |
| 6 | 8.8% (3/34) |
| 7 | 0.0% (0/17) |
| 8 | 14.3% (2/14) |
| 9 | 26.1% (6/23) |
| 10 | 4.8% (1/21) |
| 11 | 15.4% (2/13) |
| 12 | 10.0% (1/10) |
| 13 | 8.7% (2/23) |
| 14 | 12.5% (1/8) |
| 15 | 7.7% (1/13) |
| 16 | 7.7% (1/13) |
| 17 | 12.1% (4/33) |
| 18 | 0.0% (0/12) |
| 19 | 15.2% (10/66) |
| 20 | 2.4% (1/41) |
| 21 | 0.0% (0/16) |
| 22 | 0.0% (0/14) |
| 23 | 9.1% (1/11) |
| 24 | 0.0% (0/10) |
| 25 | 15.8% (3/19) |

## Appendix Table 5b. TVF at 270 Days by Pooled Site (Continued)

| Pooled Site | TVF |
|---|---|
| 26 | 19.0% (4/21) |
| 27 | 11.3% (6/53) |
| 28 | 15.4% (4/26) |
| 29 | 16.7% (5/30) |
| 30 | 9.5% (4/42) |
| 31 | 0.0% (0/11) |
| 32 | 21.9% (7/32) |
| 33 | 12.5% (2/16) |
| 34 | 6.9% (2/29) |
| 35 | 21.7% (10/46) |
| 36 | 14.7% (5/34) |
| 37 | 11.1% (2/18) |
| 38 | 0.0% (0/11) |
| 39 | 16.7% (4/24) |
| 40 | 23.5% (4/17) |
| 41 | 18.8% (3/16) |
| 42 | 6.7% (1/15) |
| 43 | 6.1% (2/33) |
| 44 | 9.1% (3/33) |
| 45 | 7.5% (3/40) |
| 46 | 10.5% (2/19) |
| 47 | 16.0% (4/25) |
| 48 | 13.0% (6/46) |
| 49 | 29.6% (8/27) |
| 50 | 10.0% (1/10) |

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## Appendix Table 6a. Assessment of the Treatment Effect Adjusting for Region and Baseline Characteristics

| | C-Statistic | P-Value |
|---|---|---|
| Treatment (adjusting for region) | 0.681 | 0.0002 |
| Treatment (adjusting for region and baseline predictors) | 0.733 | <.0001 |

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## Appendix Table 6b. Assessment of the Treatment Effect Adjusting for Pooled Site and Baseline Characteristics

| | C-Statistic | P-Value |
|---|---|---|
| Treatment (adjusting for region) | 0.716 | 0.0001 |
| Treatment (adjusting for region and baseline predictors) | 0.759 | <.0001 |

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## Appendix Table 7a. TVF at 270 Days by Region and Treatment

| | TVF | |
|---|---|---|
| **Region** | **Endeavor** | **Driver** |
| 1 | 7.0% (5/71) | 21.9% (16/73) |
| 2 | 8.6% (3/35) | 18.2% (6/33) |
| 3 | 7.4% (2/27) | 7.7% (2/26) |
| 4 | 8.3% (1/12) | 21.4% (3/14) |
| 5 | 30.8% (4/13) | 28.6% (4/14) |
| 6 | 21.4% (3/14) | 12.5% (2/16) |
| 7 | 8.3% (1/12) | 8.3% (1/12) |
| 8 | 18.8% (3/16) | 25.0% (4/16) |
| 9 | 6.3% (1/16) | 5.9% (1/17) |
| 10 | 8.1% (3/37) | 8.3% (3/36) |
| 11 | 10.0% (1/10) | 11.1% (1/9) |
| 12 | 0.0% (0/16) | 12.5% (2/16) |
| 13 | 4.8% (2/42) | 7.7% (3/39) |
| 14 | 5.6% (2/36) | 21.1% (8/38) |
| 15 | 0.0% (0/26) | 4.5% (1/22) |
| 16 | 0.0% (0/11) | 8.3% (1/12) |
| 17 | 7.1% (1/14) | 15.4% (2/13) |
| 18 | 3.6% (1/28) | 8.0% (2/25) |
| 19 | 10.7% (3/28) | 21.4% (6/28) |
| 20 | 7.9% (3/38) | 13.2% (5/38) |
| 21 | 5.9% (1/17) | 0.0% (0/18) |
| 22 | 10.5% (4/38) | 22.5% (9/40) |
| 23 | 8.6% (3/35) | 19.4% (7/36) |

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## Appendix Table 7b. TVF at 270 Days by Pooled Site and Treatment

| | TVF | |
|---|---|---|
| **Pooled Site** | **Endeavor** | **Driver** |
| 1 | 0.0% (0/7) | 16.7% (1/6) |
| 2 | 0.0% (0/11) | 0.0% (0/10) |
| 3 | 0.0% (0/11) | 8.3% (1/12) |
| 4 | 10.0% (1/10) | 10.0% (1/10) |
| 5 | 0.0% (0/12) | 11.1% (1/9) |
| 6 | 5.6% (1/18) | 12.5% (2/16) |
| 7 | 0.0% (0/9) | 0.0% (0/8) |
| 8 | 0.0% (0/7) | 28.6% (2/7) |
| 9 | 25.0% (3/12) | 27.3% (3/11) |
| 10 | 0.0% (0/10) | 9.1% (1/11) |
| 11 | 0.0% (0/7) | 33.3% (2/6) |
| 12 | 20.0% (1/5) | 0.0% (0/5) |
| 13 | 0.0% (0/12) | 18.2% (2/11) |
| 14 | 0.0% (0/3) | 20.0% (1/5) |
| 15 | 16.7% (1/6) | 0.0% (0/7) |
| 16 | 0.0% (0/7) | 16.7% (1/6) |
| 17 | 11.1% (2/18) | 13.3% (2/15) |
| 18 | 0.0% (0/6) | 0.0% (0/6) |
| 19 | 6.3% (2/32) | 23.5% (8/34) |
| 20 | 0.0% (0/21) | 5.0% (1/20) |
| 21 | 0.0% (0/8) | 0.0% (0/8) |
| 22 | 0.0% (0/7) | 0.0% (0/7) |
| 23 | 20.0% (1/5) | 0.0% (0/6) |
| 24 | 0.0% (0/5) | 0.0% (0/5) |
| 25 | 22.2% (2/9) | 10.0% (1/10) |

## Appendix Table 7b. TVF at 270 Days by Pooled Site and Treatment (Continued)

| | TVF | |
|---|---|---|
| **Pooled Site** | **Endeavor** | **Driver** |
| 26 | 0.0% (0/11) | 40.0% (4/10) |
| 27 | 11.5% (3/26) | 11.1% (3/27) |
| 28 | 8.3% (1/12) | 21.4% (3/14) |
| 29 | 21.4% (3/14) | 12.5% (2/16) |
| 30 | 9.5% (2/21) | 9.5% (2/21) |
| 31 | 0.0% (0/6) | 0.0% (0/5) |
| 32 | 18.8% (3/16) | 25.0% (4/16) |
| 33 | 12.5% (1/8) | 12.5% (1/8) |
| 34 | 7.1% (1/14) | 6.7% (1/15) |
| 35 | 4.3% (1/23) | 39.1% (9/23) |
| 36 | 5.6% (1/18) | 25.0% (4/16) |
| 37 | 11.1% (1/9) | 11.1% (1/9) |
| 38 | 0.0% (0/5) | 0.0% (0/6) |
| 39 | 8.3% (1/12) | 25.0% (3/12) |
| 40 | 12.5% (1/8) | 33.3% (3/9) |
| 41 | 12.5% (1/8) | 25.0% (2/8) |
| 42 | 14.3% (1/7) | 0.0% (0/8) |
| 43 | 6.3% (1/16) | 5.9% (1/17) |
| 44 | 6.3% (1/16) | 11.8% (2/17) |
| 45 | 9.5% (2/21) | 5.3% (1/19) |
| 46 | 10.0% (1/10) | 11.1% (1/9) |
| 47 | 8.3% (1/12) | 23.1% (3/13) |
| 48 | 8.7% (2/23) | 17.4% (4/23) |
| 49 | 30.8% (4/13) | 28.6% (4/14) |
| 50 | 0.0% (0/5) | 20.0% (1/5) |

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# Appendix B: Methods for Qualifying Angiograms

**Ascertainment of Qualifying Angiograms**

1. Identify patients in the angiographic subset.
2. Identify experimental lesions in the angiographic subset; discard non-experimental lesions:
    a. Compare post and pre films to see if the CASS numbers match;
    b. Compare the FU with baseline. If any CASS numbers do not match, then issue query and await resolution.
3. Reconcile duplicate QCA readings or inappropriate QCA readings (e.g., follow-up reads on baseline CRF's). The angiographic core laboratory will receive queries regarding duplicate or inappropriate QCA readings. Once the readings are reconciled, the duplicate or inappropriate readings will be discarded.
4. Perform all analyses as lesion-based, NOT patient or vessel-based.
5. Exemptions from Angiographic F/U:
    a. Intent to Treat analyses:
        i. Peri-procedural CABG (within 14 days);
        ii. Death before F/U QCA due in the absence of a qualifying angiogram.
    b. Per-protocol analyses:
        i. Patients who withdraw consent for further follow-up, including angiograms;
        ii. Lesion never successfully treated with assigned device strategy.
6. Define the upper window that will be acceptable for qualifying angiograms. Three Hundred Sixty (360) days is the upper window for 8-month follow-up.
7. All QCA ≤ 14 days post-procedure and instances of subacute closure will not be included for analysis of restenosis.
8. All QCA after any TVR (clinically indicated or NOT) that occurs >14 days post-procedure are censored; TVR changes natural history of the lesion. TVRs occurring within the first 14 days post-procedure should NOT be used for excluding subsequent QCA's (unless it's a CABG, which exempts the patient).
9. Define a date cut-off as the earliest acceptable date for qualifying angiograms:
    a. One Hundred Fifty (150) days is the cut-off for 8-month follow-up.
    b. If QCA between days 15-150 and in-segment QCADS ≥70%, angiogram qualifies as restenosis.
    c. If QCA between days 15-150 and in-segment QCADS <50% and NO clinically-driven TLR occurred within a reasonable time window (vide infra), the angiogram is censored.
    d. If QCA between days 15-150 and in-segment QCADS <50% but is associated with a TLR that the CEC has deemed clinically-driven (despite the fact that the QCADS <50%), then this angiogram should be considered *qualified* and should NOT be censored. This lesion will have undergone a clinically-driven TLR in the absence of angiographic restenosis.
    e. If QCA between days 15-150 and in-segment QCADS 50-69.9% and a TVR (clinically indicated or NOT) occurs within a reasonable time window (e.g., 30 days after the QCA), the angiogram qualifies as restenosis.
    f. If QCA between days 15-150 and QCADS 50-69.9% and NO TVR occurs within a reasonable time window, the angiogram is censored.
10. In case of multiple qualifying angiograms, first take the one associated with TVR and/or TLR, whichever occurs first, then use the one closest to the follow-up date, and then take the latest one (to allow for vessel remodeling).
11. If a QCA has an in-lesion diameter stenosis which qualifies (e.g., in-lesion DS 53% with TVR at day 60), then the entire angiogram should qualify, even if the in-stent diameter stenosis <50%.
12. If the in-lesion MLD is 0 (total occlusion) upstream (proximal to) the experimental stent, then the in-stent MLD should be set to zero. The two situations where in-stent MLD is not zero (even if in-lesion MLD is zero) are in cases where no stent was deployed during the index procedure or where the total occlusion is distal to the stent (in which case the in-stent MLD should be available and >0).