## APPENDIX 2 - UNPUBLISHED DATA

## IDE Studies

### 1. Biomet *TRAC* PS Mobile Bearing Knee

| **Device Brand Name** | Biomet *TRAC*® PS Mobile Bearing Knee | | | |
|---|---|---|---|---|
| **Bearing Type** | RP= rotating platform | | | |
| **Total N** | 130 | | | |
| Cement N | 130 | | | |
| Uncemented N | 0 | | | |
| Hybrid N | 0 | | | |
| **Average Follow-Up (months, range)** | Months- 26.173; Range- 0-49.2 months | | | |
| **Demographics** | | | | |
| Average age (yrs, range) | M: 65.7 (53-81) F: 65.2 (40-87) | | | |
| Average weight (lbs, range) | M: 216.0 (165-300) F: 182.6 (123-290) | | | |
| Sex (N, %) | M : 53 (40.8%) F: 77 (59.2%) | | | |
| Pre-operative diagnosis (N, %) | OA:126 RA:1 PTA:0 Other:3 | | | |
| **Effectiveness (KSS, HSS or other score )** | Knee Society Score | | | |
| Excellent (N, %) 85-100 | 4yr. 12 (66.7) | 3yr. 13 (56.5) | 2yr. 64 (71.9) | 1yr. 84 (81.6) |
| Good (N, %) 70-84 | 4 (22.2) | 4 (17.4) | 12 (13.5) | 10 ( 9.7) |
| Fair (N, %) 55-69 | 2 (11.1) | 4 (17.4) | 8 ( 9.0) | 5 ( 4.9) |
| Poor (N, %) <55 | 0 ( 0.0) | 2 (8.7) | 5 ( 5.6) | 4 ( 3.9) |
| Pain Scores | | | | |
| **Patient Satisfaction (% satisfied)** | Currently Not Calculated | | | |
| Other Scoring Methods (SF-12, 36, etc.) | Currently Not Calculated | | | |
| **Survivorship (% @ X no. of years)** | Currently Not Calculated | | | |
| Using revision surgery for any reason as endpoint | Currently Not Calculated | | | |
| Survivorship related to other endpoint | Currently Not Calculated | | | |
| **Reason for Revision Surgery** | | | | |
| Infection | 0 | | | |
| Deep | 0 | | | |
| Superficial | 0 | | | |
| Aseptic Loosening | 0 | | | |
| of Femur | 0 | | | |
| of Tibia | 0 | | | |
| Implant Subsidence | 0 | | | |
| Polyethylene Wear | 0 | | | |
| Insert Dislocation- Fall=1, Trauma=2 | 5 | | | |
| Insert Breakage | 0 | | | |
| Insert Subluxation | 1 | | | |
| Osteolysis | 0 | | | |
| Patella Complication | 0 | | | |
| DVT | 0 | | | |
| Other: Pt. didn't like said it made noise | 1 | | | |
| **Comments:** | The aforementioned information is just on revision information, it is not indicative of all complications. | | | |

**Materials and Methods**

The Prosthesis

- **Briefly discuss the theory and design rationale of the mobile-bearing knee**

  When the *TRAC* Mobile Bearing Knee System was being developed several objectives help mold the design to what it is today.

  - Minimize bearing stresses to reduce the potential for polyethylene wear
  - Minimize interface stresses to reduce the potential for implant loosening
  - Maximize quadriceps efficiency to optimize patient mobility
  - Enhance anterior and posterior stability for patient confidence
  - Return normal rotational motion
  - Use existing instrumentation

- **How is the device categorized**

  RP= rotating platform

- **Discuss design elements such as: conformity, rotation, constraint, etc.**

  - Conformity - Large contact areas are one way to lower resulting contact stress in polyethylene articular surfaces. Tulp has identified seven types of wear mechanisms: Surface deformation, pitting, scratching, burnishing, abrasion, three-body abrasion, and delamination.

    Total knees in general are susceptible to delamination, wear caused by fatigue because the mismatch in radii of curvature of the femoral component radius and bearing sagittal radius results in small contact area in flexion. Because the small area patch produces higher stresses and the contact area moves posteriorly in flexion, subsurface cracks can develop. Within the area of contact the maximum tensile stress is located at the edge of the contact area. The maximum compressive stress is located at the center of the contact area. Therefore, as the area patch moves with knee flexion the polyethylene goes through a full stress reversal, potentially resulting in subsurface cracking and delamination.

    The larger, more centrally located (inner) distal femoral condyles maintain a congruent relationship with the inner tracks of the bearing from 5º of hyperextension to 8º of flexion. The smaller posterior femoral condyles maintain a congruent relationship with the outer tracks of the bearing at flexion angle of 8º to more that 120º of flexion. In addition, the interior, anterior surface of the closed PS box articulates with the posterior surface of the PS post from 8º thru 120º. Tibiofemoral articulation transfers from the distal to the posterior radii at 8º.

  - Rotation - The *TRAC* Mobile Bearing Knee System incorporates axial rotation in the tibial component to prevent overconstraint. There are no mechanical rotational stops with the *TRAC* Knee design. Properly balanced collateral ligaments, surrounding soft tissue and joint capsule are relied upon for rotational constraint. Rotation with the *TRAC* Mobile Bearing Knee occurs around the bearing pivot stem that engages a tapered hole in the tibial base plate stem. The *TRAC* Knee was designed so that the tibial plate stem would be centered over the long axis of the

tibia anterior to the center of the tibial plate. The reason was to reduce the likelihood of impingement on the posterior cortex of the tibia, as could happen if the pivot stem is centrally located. Since the stem of the bearing rotates within the tibial plate stem, the internal external rotation center point is anterior to the center for the tibial plate as well. Placement of the stem in the *TRAC* Knee is the same as that of the Finn Rotating Hinge Knee, Maxim, and AGC Knee.

- Constraint - When the posterior cruciate ligament is removed, more constraint must be added to the tibiofemoral articulation in the anterior-posterior direction. Two methods used in contemporary total knee design to build posterior substituting constraint into tibiofemoral articulation is anterior/posterior lipped bearings and a posterior stabilized post built into the tibial bearing. The *TRAC* Mobile Bearing Knee System has both.

  Lipped bearings discourage subluxation since the femur must climb up the lip distracting the joint and tightening the surrounding soft tissue and joint capsule before dislocation can occur. However, in the absence of the PCL, dished-type articulation force the contact point to the center or deepest portion of the dish. Lipped bearings do not facilitate rollback. In fact, in other knee systems the posterior lip inhibits normal posterior movement of the femur in flexion. Although ordinarily the A/P lipped bearing add limited constraint, they are not posterior cruciate substituting since they do nothing to restore normal join kinematics. However, in the *TRAC* Mobile Bearing Knee System a posterior shift (rollback) in tibiofemoral contact occurs as articulation is transferred from the distal to posterior radii. Thus, the A/P lips of the *TRAC* act to discourage subluxation but do not interfere with rollback. The posterior lip on the *TRAC* bearing also adds anterior stability by resisting anterior tibial subluxation.

  The *TRAC* meniscal bearing also has a P/S post, the gold standard in terms of long-term clinical success. The P/S post resists anterior subluxation of the femur by acting as a mechanical stop. The P/S post also shares the same radius with the posterior articulation of the bearing. When the tibiofemoral articulation shifts from the distal to the posterior radii at approximately 8º, the P/S post and femoral cam also engage to force rollback. This provides the quadriceps muscles with the mechanical efficiency to climb stairs normally.

- Other design features - The *TRAC* femoral component is manufactured from cobalt-chromium-molybdenum alloy (ASTM F-75) and is universal in design. The component has a highly polished articulating surface. The *TRAC* PS femoral has two radii of curvature in the sagittal plane, one for the distal femoral condyles and one for the posterior femoral condyles. The distal and posterior femoral condyles articulate congruently in the inner tracks or outer tracks, respectively, of the polyethylene intermediate bearing. Separating the medial and lateral condyles is a closed PS box.

  The *TRAC* meniscal bearing is made of ultra high molecular weight polyethylene, ArCom (ASTM F-648) and is universal and posterior stabilized in design. The bearing has a central spine that separates the medial and lateral surfaces of the implant. The medial and lateral edges of the articulation surface of the femoral component condyles is cut out providing clearance for the posterior articulating surface of the bearing. These cut outs allow the posterior radii of the tibial bearing and the femoral component to match in full flexion. Elevated posterior lips on the bearing act as anterior stabilizers.

The *TRAC* tibial component is manufactured from cobalt-chromium-molybdenum alloy (ASTM F-75) and is universal in design. Rotation with the *TRAC* Mobile Bearing Knee System occurs around the bearing pivot stem that engages a tapered hole in the tibial base plate stem. The *TRAC* system was designed so that the tibial plate stem would be centered over the long axis of the tibia anterior to the center of the tibial plate. The reason was to reduce the likelihood of impingement on the posterior cortex of the tibia, as could happen if the pivot stem is centrally located. Since the stem of the bearing rotates within the tibial plate stem, the internal/external rotation center point is anterior to the center of the tibial plate as well.

- **Discuss the indications for use of the device**

  - The *TRAC* Mobile Bearing Knee System was designed to be used in primary applications where the posterior cruciate ligament has been sacrificed. These implants are recommended for use as primary knee system. The following criteria has been developed to help optimize the use of the *TRAC* Mobile Bearing Knee System:

    1. Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, and traumatic arthritis.
    2. Rheumatoid arthritis
    3. Correction of functional deformity when bone stock is adequate
    4. Patient has failed to respond to conservative treatment modalities

    For use with bone cement.

- **Diagrams/pictures of device**

Study Design:

- **Describe the design and methods used for the study**

  This investigation is a multi-center, prospective, clinical study of the *TRAC* Total Knee System. The following safety and efficacy endpoints will be used to compare data collected on *TRAC* knee (investigational treatment) patients with control data collected on AGC and Maxim knee (control treatment) patients.

  The primary safety endpoint for this study is defined as all complications (device related or not) and device revision/removal.

  The primary effectiveness endpoints are defined as follows:

  The Knee Society Rating System (200 points total) which include (a) the knee assessment (pain, motion, stability, 100 points) and (b) functional assessment (walking, stairs, 100 points). Radiographic evaluation for progressive radiolucencies.

  Patients in both the investigational and control treatment groups will be evaluated preoperatively, at 3, 6, 12, and 24 months postoperatively, and biennially after their 24 month visit until the last enrolled subject has had a 24 month examination. The estimated duration of this study is 5-6 years.

- **Describe the randomization procedure if applicable**

  Concurrent; Non-randomized study

- **Describe blinding procedure if applicable**

  N/A

- **What was the hypothesis for the study?**

  - This study is to be conducted to investigate the safety and effectiveness of a new total knee system. The main objective of this investigation is to determine if the safety and effectiveness of the *TRAC* Total Knee is equivalent to that of the control devices (AGC and Maxim Total Knee Systems).

  - The Knee Society Score, comprised of knee and function scores, will all be compared between the two treatment groups using the t-test at each time point. Radiolucency and complications are discrete variables (i.e. yes/no) in which the chi square test will be used for comparison. Pain and other variables of results in a natural order (i.e. mild, moderate, severe) will be examined using the Wilcoxon Rank-Sum test. A survival analysis will be done to compare the revision/removal rates between the two groups.

  - The results of the above analyses will be confirmed using longitudinal analysis such as the Generalized Estimating Equations (GEE). GEE is used to adjust data collected from multivariate responses arising from this study. This will allow for measurement of the average change in the response and not the change of response averages.

- **Is the study "complete" or "in progress" and what is progress status?**

  "In Progress". One more *TRAC* knee to implant and several more controls.

- **Please insert any special materials and methods you used in this section**

  - Individual patient success**:**

    1. Patients with a total Knee Society Score ≥ 140 points; and
    2. Patients not exhibiting progressive radiolucencies increasing more than 2mm in two or more zones in the femoral or tibial implants and
    3. Patients having no device revision/removal.

  - Study success:

    1. No significant difference (delta of 10%) in complication rates at 24 months postoperative for the investigational group compared to the control group
    2. The mean Knee Society Score (200 points) at 24 months postoperative is no worse (delta to 15 points) for the investigational group compared to the control group
    3. The number of patients exhibiting progressive radiolucencies at 24 months postoperative increasing more than 2mm in two or more zones in the femoral or tibial implants is no worse (delta of 10%) for the investigational group compared to the control group

- **Selection Criteria**

  - Inclusion Criteria

    1. Patients having primary procedures with any of the following diagnoses are included.
       a) Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, and traumatic arthritis
       b) Rheumatoid arthritis
       c) Correction of functional deformity when bone stock is adequate
    2. Patient has failed to respond to conservative treatment modalities and there is a likelihood of obtaining relief of pain and improved function. Patients should have exhausted other therapies, such as, a trial of analgesics, non-steroidal anti-inflammatories, physical therapy and activity modification to be included in the study.
    3. Preoperative level of function and pain that is equal to a total knee score in the Knee Society Scale (knee + function) of 139 or below out of 200 possible points.
    4. Radiographic evidence of bone on bone articulation and collateral ligament intact.
    5. Full skeletal maturity.
    6. Ability to follow instructions.
    7. Willing to return for follow-up evaluation.
    8. Patients of either sex.
    9. Patient has signed consent form.

- **General Exclusion Criteria**

1. Infection, local or systemic, that the physician feels would compromise the clinical outcome.
2. Osteoporosis, or marked bone loss which would preclude proper fixation of the prosthesis.
3. Uncooperative patient, predictably unable to get long-term follow-up.
4. Vascular insufficiency, muscular atrophy, or neuromuscular disease in the affected limb.
5. Severe instability or deformity of the ligaments and or surrounding soft tissue which would preclude stability of the device.
6. Has a knee condition other than those identified by the inclusion diagnostic categories.
7. Has a known sensitivity to device materials.
8. Pregnancy.

- **Specific Exclusion Criteria**

1. Severe valgus or varus knees (where collateral ligament, iliotibial band, or popliteal release is required).
2. Knees where proper collateral ligament balance cannot be achieved.
3. Knees where restoration of the anatomic axis cannot be achieved.
4. Surgical techniques that include a proximal tibial "ligament strip" for exposure.
5. Surgical techniques that require a tibia cut with more than 3° of posterior slope.
6. Revision.

- **Medication Exclusions**

1. Insulin dependent diabetic.
2. Patient on more than 10mg of prednisone in the past year.
3. Methyltrexate.

- **Medical Conditions Exclusions**

1. Severe diabetes.
2. Severe pulmonary disease.
3. Congestive heart failure.
4. Senility/Alzheimer's.

<u>Follow-Up Evaluation</u>

- Patients were monitored clinically and radiographically and had preoperative, intraoperative, and follow-up ratings obtained using the Knee Society Score.

- Patients in both the investigational and control treatment groups will be evaluated preoperatively, at 3, 6, 12, and 24 months postoperatively, and biennially after their 24 month visit until the last enrolled subject has had a 24 month examination.

- The average final follow-up interval was 26.173 months; Range- 0-49.2 months.

- **Study compliance statistics**

  The Knee Society Score, comprised of knee and function scores, will all be compared between the two treatment groups using the t-test at each time point. Radiolucency and complications are discrete variables (i.e. yes/no) in which the chi square test will be used for comparison. Pain and other variables of results in a natural order (i.e. mild, moderate, severe) will be examined using the Wilcoxon Rank-Sum test. A survival analysis will be done to compare the revision/removal rates between the two groups.

  The results of the above analyses will be confirmed using longitudinal analysis such as the Generalized Estimating Equations (GEE). GEE is used to adjust data collected from multivariate responses arising from this study. This will allow for measurement of the average change in the response and not the change of response averages.

  - No significant difference (delta of 10%) in complication rates at 24 months postoperative for the investigational group compared to the control group.
  - The mean Knee Society Score (200 points) at 24 months postoperative is no worse (delta to 15 points) for the investigational group compared to the control group the number of patients exhibiting progressive radiolucencies at 24 months postoperative increasing more than 2mm in two or more zones in the femoral or tibial implants is no worse (delta of 10%) for the investigational group compared to the control group.

<u>Radiographic Assessment</u>

- Patients in both the investigational and control treatment groups will be evaluated preoperatively, at 3, 6, 12, and 24 months postoperatively, and biennially after their 24 month visit until the last enrolled subject has had a 24 month examination. Radiographic evaluation will take place at every follow-up.

- Briefly describe the radiographic method used to capture image of the knee - Used Knee Society scoring system for x-ray evaluation. Therefore, used all views found there.

- The following were recorded at the follow-up examination:

  Individual patient success**:**

  1. patients with a total Knee Society Score ≥ 140 points; and
  2. patients not exhibiting progressive radiolucencies increasing more than 2mm in two or more zones in the femoral or tibial implants and
  3. patients having no device revision/removal

  Study success:

  1. no significant difference (delta of 10%) in complication rates at 24 months postoperative for the investigational group compared to the control group.
  2. the mean Knee Society Score (200 points) at 24 months postoperative is no worse (delta to 15 points) for the investigational group compared to the control group the number of patients exhibiting progressive radiolucencies at 24 months postoperative increasing more than 2mm in

two or more zones in the femoral or tibial implants is no worse (delta of 10%) for the investigational group compared to the control group

**Results**

The Patients

- Between 10/21/97 and 11/27/01, 130 primary total knee arthroplasties with the *TRAC* Mobile Bearing Knees were implanted in 106 patients
- 65 patients (77 knees) were female, and 41 patients (53 knees) were male.
- The average age of the patients at the time of surgery was 65.4 (range, 40 to 87 years).
- The pre-operative diagnosis was osteoarthritis in 126 knees, rheumatoid arthritis in 1 knee and post-traumatic arthritis in 0 knees and 3 were in other category.
- The pre-operative diagnosis was osteoarthritis.

Outcomes

- Discuss and provide values for the effectiveness of the device using the health status questionnaire administered to the patients (KSS, HSS, Oxford, etc.) - We have not calculated this information at this time.
- Discuss and provide values for the pre and post ROM (extension and flexion) results of the study.

| **Preop Extension** | **1 Yr. Extension** | **2 Yr. Extension** | **3 Yr. Extension** |
|---|---|---|---|
| 2.864<br>std. dev. 7.865 | 0.610<br>std. dev. 3.465 | 0.360<br>std. dev. 1.727 | 0.212<br>std. dev. 1.219 |
| **Preop Flexion** | **1 Yr. Flexion** | **2 Yr. Flexion** | **3 Yr. Flexion** |
| 107.328<br>std. dev. 12.509 | 116.886<br>std. dev. 12.776 | 119.899<br>std. dev. 10.864 | 120.576<br>std. dev. 10.155 |

- Discuss and provide values for the patient's final follow-up relief of symptoms (pain, limp, stairs, walking distance, etc.) - Information is based on Knee Society Score by surgeon and not by patient questionnaire.

## Stairs

| | Preop | 3 Mos. | 6 Mos. | 1 Year | 2 Year | 3 Year | 4 Year |
|---|---|---|---|---|---|---|---|
| **Population** | 127 | 124 | 107 | 106 | 90 | 33 | 6 |
| **Normal up & dn.** | 0 (0%) | 17 (13.7%) | 36 (33.6%) | 44 (41.5%) | 38 (42.2%) | 13 (39.4%) | 5 (83.3%) |
| **Normal up, down w/ rail** | 6 (4.7%) | 14 (11.3%) | 30 (28.0%) | 21 (19.8%) | 14 (15.6%) | 4 (12.1%) | 1 (16.7%) |
| **Up & down w/ rail** | 79 (62.2%) | 78 (62.9%) | 33 (30.8%) | 36 (34.0%) | 37 (41.1%) | 16 (48.5%) | 0 (0.0%) |
| **Up w/ rail, Unable down** | 14 (11.0%) | 9 (7.3%) | 6 (5.6%) | 1 (0.9%) | 1 (1.1%) | 0 (0.0%) | 0 (0.0%) |
| **Unable** | 28 (22.0%) | 6 (4.8%) | 2 (1.9%) | 4 (3.8%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

## Pain

| | Preop | 3 Mos. | 6 Mos. | 1 Year | 2 Year | 3 Year | 4 Year |
|---|---|---|---|---|---|---|---|
| **Population** | 93 | 126 | 107 | 106 | 89 | 33 | 6 |
| **None** | 0 (0.0%) | 21 (16.7%) | 38 (35.5%) | 39 (36.8%) | 43 (44.9%) | 25 (75.8) | 5 (83.3%) |
| **Mild/ Occasional** | 0 (0.0%) | 68 (54.0%) | 57 (53.3%) | 59 (55.7%) | 40 (44.9%) | 6 (18.2%) | 1 (16.7%) |
| **Mild- Stairs Only** | 0 (0.0%) | 15 (11.9%) | 5 (4.7%) | 2 (1.9%) | 4 (4.5%) | 2 (6.1%) | 0 (0.0%) |
| **Mild & Walking** | 0 (0.0%) | 9 (7.1%) | 4 (3.7%) | 3 (2.8%) | 1 (1.1%) | 0 (0.0%) | 0 (0.0%) |
| **Moderate Occasional** | 0 (0.0%) | 9 (7.1%) | 3 (2.8%) | 1 (0.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| **Moderate Continual** | 54 (58.1%) | 4 (3.2%) | 0 (0.0%) | 2 (1.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| **Severe** | 39 (41.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) | 0 (0.0%) | 0 (0.0%) |

## Walking

| | Preop | 3 Mos. | 6 Mos. | 1 Year | 2 Year | 3 Year |
|---|---|---|---|---|---|---|
| **Population** | 127 | 124 | 107 | 106 | 89 | 33 |
| **Unlimited** | 0 (0.0%) | 29 (23.4%) | 51 (47.7%) | 67 (63.2%) | 65 (73.0%) | 28 (84.8%) |
| **>10 Blocks** | 5 (3.9%) | 19 (15.3%) | 22 (20.6%) | 17 (16.0%) | 12 (13.5%) | 3 (9.1%) |
| **5-10 Blocks** | 20 (15.7%) | 51 (41.1%) | 24 (22.4%) | 12 (11.3%) | 10 (11.2%) | 2 (6.1%) |
| **<5 Blocks** | 84 (66.1%) | 21 (16.9%) | 10 (9.3%) | 9 (8.5%) | 1 (1.1%) | 0 (0.0%) |
| **Housebound** | 14 (11.0%) | 2 (1.6%) | 0 (0.0%) | 1 (0.9%) | 1 (1.1%) | 0 (0.0%) |
| **Unable** | 4 (3.1%) | 2 (1.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

- Discuss and provide values for patient satisfaction results if applicable - N/A at this time
- Discuss and provide values for the survival analysis results if applicable - N/A at this time

Radiographic Appearances

- Currently there are no *TRAC* Knee Implants that appear radiographically loose.
- Currently there are no radiolucent lines greater than 2mm around the *TRAC* Knee Implant

Complications

Note a person may have more than one complication (i.e. some people had multiple dislocations). Time of occurrence has not yet been completed by Biomet.

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Any Fracture | 0 | |
| Femoral component loosening | 0 | |
| Tibial component loosening | 0 | |
| Patellar component loosening | 0 | |
| Bearing dislocation | 11 | N/A |
| Bearing subluxation | 1 | N/A |
| Mobile bearing wear | 0 | |
| Patellar bearing wear | 0 | |
| Ligamentous instability | 1 | N/A |
| Deep infection | 0 | |
| Fibroarthrosis | 1 | N/A |
| Other: Numbness | 1 | N/A |
| Other: Swelling | 4 | N/A |
| Other: Clicking | 2 | N/A |
| Other: Patella Dislocation | 1 | N/A |
| Other: Death | 1 | N/A |
| Other: Pulmonary | 1 | N/A |
| Other: Back Pain | 2 | N/A |
| Other: Manipulation for tight knee | 4 | N/A |
| Other: Embolism | 1 | N/A |
| Other: Soft tissue entrapment | 1 | N/A |
| Other: Strain/Contusion | 2 | N/A |

## 2. *Oxford* Meniscal Unicompartmental Knee

| **Device Brand Name** | *Oxford*™ Meniscal Unicompartmental Knee | |
|---|---|---|
| **Bearing Type** | MB= meniscal bearing | |
| **Total N** | 104 | |
| Cement N | 104 | |
| Uncemented N | 0 | |
| Hybrid N | 0 | |
| **Average Follow-Up (yrs, range)** | 4.8 (1.8 – 8.1 ) | |
| **Demographics** | | |
| Average age (yrs, range) | M-61.7 (34-84) | F-63.9 (40-85) |
| Average weight (lbs, range) | M-207.7 (140-256) | F-166.4 (105-250) |
| Sex (N, %) | M-50 (48.1%) | F-54 (51.9%) |
| Pre-operative diagnosis (N, %) | OA-95 (91%) | PTA-9 (9%) |
| **Effectiveness (KSS, HSS or other score )** | HSS (2+ year follow-up data) | |
| Excellent (N, %) | 79 (75.96%) | |
| Good (N, %) | 20 (19.23%) | |
| Fair (N, %) | 2 (1.92%) | |
| Poor (N, %) | 3 (2.88%) | |
| **Pain Scores** | At Rest (2+ yrs) | Walking (2+ yrs) |
| No Pain (N, %) | 82 (78.9%) | 66 (63.4%) |
| Mild (N, %) | 18 (17.3%) | 30 (28.9%) |
| Moderate (N, %) | 4 (3.8%) | 6 (5.8%) |
| Severe (N, %) | 0 (0.0%) | 2 (1.9%) |
| **Patient Satisfaction (% satisfied)** | | |
| Other Scoring Methods (SF-12, 36, QOL, etc.) | None | |
| **Survivorship (% @ X no. of years)** | | |
| Using component removal for any reason as endpoint | 94% at 6 years | |
| **Reason for Revision Surgery** | | |
| Deep Infection | 1 | |
| Aseptic Loosening of Femur | 3 | |
| Aseptic Loosening of Tibia | 1 | |
| Implant Subsidence | 0 | |
| Polyethylene Wear | 1 (caused by osteophyte) | |
| Insert Dislocation | 2 | |
| Insert Breakage | 0 | |
| Insert Subluxation | 0 | |
| Osteolysis | 0 | |
| Patella Complication | 1 | |
| DVT | 0 | |
| Other: Lateral Compartment Degeneration | 4 | |
| Other: On-set of Rheumatoid Arthritis | 1 | |
| Other: Automobile Accident | 1 | |
| Other: Improper Alignment | 1 | |

## Material And Methods

The Prosthesis

Osteoarthritic knees with disease limited to one compartment (usually the medial) have been treated by unicompartmental replacement for many years. Traditional unicompartmental implants use a metal femoral condyle, with polycentric surfaces, articulating on a thin, flattened polyethylene plateau (with or without metal backing).

The medium term results of these procedures were often good but in the longer term the survival rates of unicompartmental arthroplasties have not matched those of modern Total Knee Replacement (TKR). The causes of failure include catastrophic wear of the thin polyethylene tibial component; loosening, perhaps due to the effect of wear products on the bone/cement interfaces and inappropriate patient selection.

The natural menisci of the human knee are shaped to fit between the polycentric femoral and tibial condyles to make them congruous. Their effect is to double (approximately) the area of contact at the tibiofemoral interface, reducing by half the average pressure experienced at its surfaces[156]. To fulfil this function, the natural menisci are mobile so that they follow the femoral condyles as they slide and roll on the tibia, and compliant so their shapes can change during flexion/extension to fit the different contours presented during flexion/extension by the polycentric femoral condyles.

Goodfellow and O'Connor[54] introduced meniscal bearings, analogues of the menisci, into knee arthroplasty in 1974. Polyethylene is not compliant, so rigid bearings cannot articulate congruously with polycentric components. The only shapes that can remain congruous in all relative positions are a sphere in a spherical socket and a flat on a flat. The *Oxford* Knee, therefore, employed spherical femoral condyles articulating with a spherical concave bearing surface and a flat back articulating with a flat tibial plateau (Figure A). Although these shapes only roughly approximate those of the natural surfaces, the curvature of the human femoral condyles only varies by about 10% from the spherical[127].

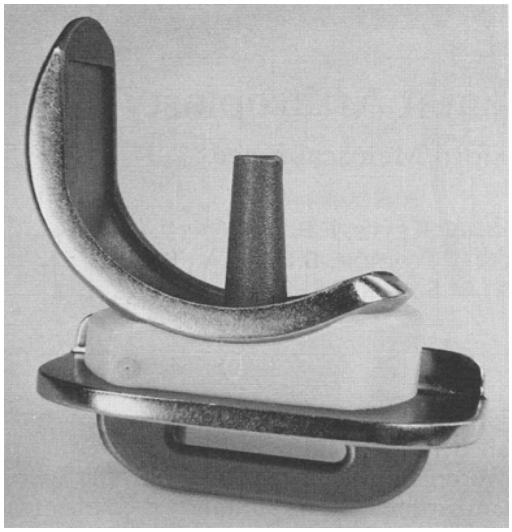

Figure A Oxford™ Meniscal Unicompartmental Knee

Early experience with bicompartmental *Oxford* knees showed that the kinematics of the knee does not depend upon the polycentric form of the femoral condyles. If natural tension in the ligaments is restored, spherical prosthetic condyles articulating on freely mobile bearings can reproduce physiological movement[56]. Additionally, congruity greatly increases the contact areas[160], diminishing the rate of polyethylene wear in knee arthroplasty by an order of magnitude[5,136]. The average penetration rate, measured on retrieved *Oxford* knee bearings, was 0.03mm per annum and did not vary with polyethylene thickness (to as thin as 3.5mm). Clinical failure from wear through of the bearings has not occurred.

The importance of the ACL in unconstrained arthroplasty had not been demonstrated statistically before the initial experience with the *Oxford* Knee[53], nor was the status of that ligament an accepted criterion for patient selection for unicompartmental replacement. "Anteromedial Osteoarthritis" describes the clinicopathological entity having the following features:

1. ACL functionally intact.
2. Cartilage and bone erosions limited to the anterior and middle parts of the medial compartment; the posterior part of the medial compartment and the whole of the lateral have cartilage of normal thickness.
3. Medial collateral ligament not structurally shortened; therefore, varus deformity is passively correctable.
4. Patellofemoral joint damage always greatest on (and usually limited to) its medial facets; correction of the varus deformity by unicompartmental arthroplasty therefore unloads the affected patellofemoral facets.

Anteromedial osteoarthritis has become the indication for *Oxford* Meniscal Unicompartmental Knee arthroplasty.

Joint stability and bearing retention both depend upon restoring normal tension to the retained ligaments throughout the range of movement. Precise location of the implants is therefore necessary. Thus, sophisticated instrumentation for the *Oxford* Meniscal Unicompartmental Knee was developed allowing location with the required accuracy (plus or minus 1mm).

Study Design

An Investigation Device Exemption (IDE) (G880193) for the study of the *Oxford* Meniscal Unicompartmental Knee Phase 2 was requested and obtained from the Food and Drug Administration (FDA) on June 9, 1989. The longitudinal study was conducted under a common protocol with defined inclusion/exclusion criteria and monitoring for compliance at eight investigational sites. The study was not randomized or blinded. The study is complete.

- **Selection Criteria**

Skeletally mature patients with a primary diagnosis of osteoarthritis, traumatic arthritis, correction of functional varus, valgus, or post-traumatic deformity and/or unsuccessful osteotomy could be included in the study.

Patients were excluded from the clinical investigation if one or more of the following exclusion criteria were met: presence of infection; a primary diagnosis of rheumatoid arthritis or revision of a failed prosthesis; fixed varus or valgus deformity due to shortening of a collateral ligament; absence or damage to the anterior or posterior cruciate ligament which would preclude stability of the device; uncooperative patient, predictably unable to get long-term follow-up; osteoporosis; metabolic disorders which may impair bone formation; vascular insufficiency, muscular atrophy, or neuromuscular disease in the affected limb; incomplete or deficient soft tissue surrounding the knee.

- **Follow-up Evaluation**

  The protocol stipulated for patient clinical and radiographic follow-up pre-operatively, and at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years post-operatively. Clinical effectiveness was determined by the results for pain, function, range of motion and overall functional score by the use of the Hospital for Special Surgery (HSS) scoring system. All general and operative site complications as well as device removal events were documented for analysis of safety. The average follow-up, for all patients enrolled in the study was 52 months.

- **Radiographic Assessment**

  Radiographs were evaluated as to the degree of tibial inclination in both the anterior-posterior and lateral planes. Femoral inclination was evaluated on lateral films. Radiolucencies surrounding the implant were recorded by width (none, <1mm, 1-2mm, >2mm) in 6 distinct tibial zones and 4 distinct femoral zones. Cement fracture was also to be noted.

**Results**

The Patients

- One hundred twenty-five unicompartmental *Oxford* Meniscal Unicompartmental Knee Phase 2 devices were implanted under the clinical investigation in 107 patients between June 26, 1989 and June 1, 1994 at eight investigational sites.

- For the entire study population (n=125), there were 60 males (48%) and 65 were females (52%). The average age at the time of surgery was 63 years (range: 29-85 years). The pre-operative diagnosis was osteoarthritis in 114 knees, post-traumatic arthritis in 10 knees and avascular necrosis in 1 knee.

- Two patients who received *Oxford* Meniscal Unicompartmental Knee Phase 2 devices were found to not meet the inclusion and exclusion criteria set forth in the protocol and were removed from further analysis. One patient received bi-compartmental *Oxford* Meniscal Unicompartmental Knee Phase 2 devices as a deviation from the protocol and was removed from the study. One patient died and seven knees were revised prior to reaching 2 years post-operative. This left a possible 115 cases available for follow-up at 2 years. Of these, 104 (90%) had sufficient data recorded at 2 years or beyond to permit clinical evaluation.

- For the analysis group of 104 knees, the last available follow-up used for analysis was 2 years in 10 knees, 3 years in 14 knees, 4 years in 8 knees, 5 years in 45 knees, 6 years in 22 knees and greater than 6 years in 5 knees.

Outcomes

- At 2 years or greater follow-up, 95% of the knees had achieved a HSS knee rating of Excellent or Good. 96% of the knees were pain free or experienced only mild pain post-operatively. 88% of the knees had mild or no impairment of function with only 14% of the patients requiring walking supports. All of the patients (100%) were able to climb stairs following *Oxford* Knee replacement. Mean pre-operative flexion was 118° and mean post-operative flexion was 122°.

- The following Kaplan-Meir Life Table presents survival for the entire (n=125) *Oxford* Knee IDE population with any component removal as the end point.

| Interval Since Operation | No. In Place at beginning of interval | No. Withdrawn | No. at risk | No. Revisions at end of Interval | % Revised - Interval | % Survival Interval | % Cumulative Survival | Std. Error Cumulative Survival | 95% CI Cumulative Survival - Minimum | 95% CI Cumulative Survival - Maximum |
|---|---|---|---|---|---|---|---|---|---|---|
| 0-1 | 125 | 5 | 122.5 | 4 | 0.0327 | 0.9673 | 1.0000 | 0.0000 | 1.0000 | 1.0000 |
| 1-2 | 116 | 5 | 113.5 | 5 | 0.0441 | 0.9559 | 0.9754 | 0.0162 | 0.9437 | 1.0071 |
| 2-3 | 106 | 8 | 102 | 1 | 0.0098 | 0.9902 | 0.9324 | 0.0243 | 0.8847 | 0.9801 |
| 3-4 | 97 | 13 | 90.5 | 2 | 0.0221 | 0.9779 | 0.9233 | 0.0258 | 0.8728 | 0.9738 |
| 4-5 | 82 | 7 | 78.5 | 2 | 0.0255 | 0.9745 | 0.9029 | 0.0290 | 0.8461 | 0.9596 |
| 5-6 | 73 | 32 | 57 | 0 | 0.0000 | 1.0000 | 0.8799 | 0.0325 | 0.8163 | 0.9435 |
| 6-7 | 41 | 19 | 31.5 | 1 | 0.0317 | 0.9683 | 0.8799 | 0.0325 | 0.8163 | 0.9435 |
| 7-8 | 21 | 9 | 16.5 | 1 | 0.0606 | 0.9394 | 0.8519 | 0.0393 | 0.7749 | 0.9290 |
| 8-9 | 11 | 7 | 7.5 | 0 | 0.0000 | 1.0000 | 0.8003 | 0.0601 | 0.6826 | 0.9180 |
| 9-10 | 4 | 4 | 2 | 0 | 0.0000 | 1.0000 | 0.8003 | 0.0595 | 0.6836 | 0.9170 |

Radiographic Appearance

One hundred and five knees were available for radiographic review at 2 years or greater post-operative. Only one zone of one tibial component and two zones of one femoral component displayed radiolucent lines greater than 2mm. No devices displayed complete radiolucent lines of any width around either the tibial or femoral components. There was no report of cement fracture and no device was deemed radiologically loose.

Complications

Nineteen complications were seen in this study but only six (4.8 %) could truly be considered device related complications. No systemic complications were reported. Complications occurring during the course of this study are listed on the following table.

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Fracture | 0 (0.0%) | |
| Femoral Component Loosening | 3 (2.4%) | 0.3, 3.7, and 5.1 years |
| Tibial Component Loosening | 1 (0.8%) | 4.1 years |
| Patellar Component Loosening | N/A | |
| Bearing Dislocation | 2 (1.6%) | 1.5 and 1.6 years |
| Bearing Subluxation | 0 (0.0%) | |
| Mobile Bearing Wear | 1 (on edge caused by osteophyte) | 5.2 years |
| Patellar Bearing Wear | N/A | |
| Ligamentous Instability | 0 (0.0%) | |
| Deep Infection | 1 (0.8%) | 1.5 years |
| Fibroarthrosis | 0 (0.0%) | |

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Patella Dislocation | 1 (0.8%) | 1.5 years |
| Degeneration of the Lateral Compartment | 4 (3.2%) | 4.1, 4.2, 7.3, and 8 years |
| On-set of Rheumatoid Arthritis | 1 (0.8%) | 1.0 years |
| Automobile Accident | 1 (0.8%) | 0.3 years |
| Improper Alignment | 1 (0.8%) (converted to bicompartmental) | 0.2 years |
| Effusion | 1 (0.8%) | 0.9 years |
| Meniscal Cyst | 1 (0.8%) | 1.6 years |
| Arthroscopic Examination | 1 (0.8%) | 0.8 years |

Additional Information

In addition to the clinical information generated in the IDE study, the *Oxford* Meniscal Unicompartmental Knee has been used extensively in Europe. The following is a review of published articles pertinent to the clinical outcome of the *Oxford* Meniscal Unicompartmental Knee prosthesis.

Use of the *Oxford* knee prosthesis began with the first case performed in November 1974 at the Nuffield Orthopaedic Centre by John Goodfellow[54,56]. One hundred and twenty-five bicompartmental implants were followed for two to six years. Pain was relieved in 90%; mean flexion limit was 99 degrees and mean flexion deformity 7 degrees. Stability and alignment were recovered in nearly all joints. Six knees failed. Two were successfully arthrodesed and four were converted to another prosthesis. Five knees required revision to replace a dislocated bearing and three to re-cement a loose component. In knees with an intact anterior cruciate ligament, there was a 4.8% revision rate.

Tibrewal, et al.[176] assessed radiolucent lines at the bone cement interface beneath the tibial components in 91 consecutive bicompartmental *Oxford* Meniscal Knee replacements in 78 patients. Of 80 knees in which radio-opaque cement was used, a radiolucent line was observed in 77, with a radio-dense line in the bone immediately adjoining. Histological examination of the interface obtained from secure tibial components suggested that the living bone under a rigid prosthesis requires a layer of relatively compliant fibrocartilaginous material at its interface to accommodate load bearing. Absence of the radiodense line at a mature interface may indicate disequilibrium and impending failure.

Goodfellow and O'Connor[53] followed three hundred and one unconstrained meniscal arthroplasties (bicompartmental and unicompartmental) for as long as nine years, during which time 25 (8.3%) failed. Risk factors were sought by studying preoperative variables. Age, weight, the magnitude or direction of preoperative deformity, and the presence of postoperative mal-alignment had no effect on the outcome. Knees with rheumatoid arthritis had a 95% survival rate at six years. Knees with osteoarthrosis had a survival rate of 83%. Knees with a normal anterior cruciate ligament (ACL) had a survival rate of 95% at six years; those with a damaged or absent ACL had a survival rate of 81%. The authors concluded that a successful knee reconstruction with an unconstrained meniscal implant requires the presence and preservation of an intact ACL.

Argenson and O'Connor[5] reported in 1992 the retrieval of 23 meniscal bearings from 18 failed bicompartmental *Oxford* knee prostheses. They had been implanted for one to nine years. The minimum thickness of the retrieved bearings was measured and compared to the thickness of 25 unused bearings. The mean penetration rate, calculated by two methods, was either 0.043 or 0.026 mm per annum. This

compares with 0.19 mm per annum reported for the Charnley hip. They found that the use of a fully congruous meniscal bearing prosthesis could reduce wear in knee arthroplasty to a very low rate. In 6 retrievals which had been implanted for 10 to 15 years, the linear wear rate in the absence of impingement was approximately 0.01mm/year[14].

No further discussion of bicompartmental use of the *Oxford* Meniscal Unicompartmental Knee will be presented, as the developers and the manufacturer have discouraged this method of implantation since the early 1970's.

Bradley, et al.[14] performed a radiographic study of bearing movement in unicompartmental *Oxford* Knee replacements. Radiographs of 20 knees were studied; with the patient supine and the muscles relaxed views with the knee at full extension and at 90º of flexion were obtained, and the movement of meniscal bearings was measured. During flexion the bearings were found to move backwards on the tibia through an average distance of 4.4mm (range 0.0-13.5mm) in the medial compartment and 6.0mm (range 1.6-13.0mm) in the lateral compartment. These movements were in the same direction as that observed in cadaver specimens, but smaller in magnitude. The bearings moved, reciprocally, backwards and forwards during internal and external rotation of the tibia on the femur.

Goodfellow, et al.[55] 1988 reported the results of the first 103 unicompartmental *Oxford* Knees at mean time since operation of 36 months (range 21-56 months). In those cases with surviving arthroplasties, pain was relieved in 96%. The full range of preoperative flexion was maintained and flexion deformity was improved from a mean of 6.7-5.4 degrees. Stability and alignment were restored to normal in nearly all knees. Six failures occurred in 37 knees lacking a normal anterior cruciate ligament (16.2%); three occurred in 63 knees with a normal anterior cruciate ligament (4.8%) ($p<0.02$).

Carr, et al.[31-32] in 1993 reported on 121 knees with medial compartment osteoarthrosis and intact anterior cruciate ligaments, treated by unicompartmental arthroplasty with the *Oxford* Knee. The mean elapsed time from surgery was 44.4 months. One knee required revision for a loose tibial component. They found with a strict selection criterion of (1) the presence of a functioning anterior cruciate ligament, (2) fully correctable deformity, and (3) full thickness of articular cartilage in the lateral compartment that the results were better than those for high tibial osteotomy.

Gunther, et al.[63] in 1996 reported the results of 53 knees with lateral compartment osteoarthritis treated by unicompartmental arthroplasty with the *Oxford* knee prosthesis. The mean follow-up was 5 years. Eleven knees required further surgery. Six of the revisions were for early dislocation of the meniscal bearing, three because of late infection, one because of loosening of the tibial component, and one because of stress fracture in the tibial plateau. They found the risk of bearing dislocation in the lateral compartment with the *Oxford* Unicompartmental Knee was greater than in the medial compartment.

Murray, O'Connor and Goodfellow[122] in 1998 reported a ten-year survival study of the *Oxford* Meniscal Unicompartmental Knee in the medial compartment. All patients who had a medial unicompartmental knee replacement under the care of a single surgeon, in knees with an intact anterior cruciate ligament, a correctable varus deformity, and full thickness cartilage in the lateral compartment, were contacted. 143 knees fit the inclusion criteria and were followed for up to 14 years. One patient was lost to follow-up and five had revisions; none for polyethylene wear. The survival rate at ten years,
when there were 44 patients at risk, was 98%. This data was further analyzed based on patient age and no significant difference was found for the survival rates of patients younger than 60 as compared with patients 60 or greater[109,133].

In 1998, Psychoyios, et al.[136] reported on polyethylene wear in unicompartmental *Oxford* Knee replacements. Sixteen bearings were examined, 0.8-12.8 years after implantation. The included effect of both upper and lower surfaces was 0.036 mm penetration per year (max. 0.08). Bearings as thin as 3.5 mm wore no faster than thicker models, but 10 with evidence of impingement had greater wear. Those with no impingement showed a mean rate of penetration of 0.01 mm per year.

In 1994, Knutson, et al.[91] reported on a nation wide study of 30,003 primary knee arthroplasties and their revisions from 1976-1992 from the Swedish Orthopaedic Society. Outcomes for medial unicompartmental arthroplasties were defined as cumulative revision rate (percent). Numbers of cases were PCA Uni 921, Marmor 2354, St. George 1345, Link Uni 1407, *Oxford* 833, and Brigham 389. Percent revised at or near 8 years was PCA Uni 17%, Marmor, Link and St. George 7%, *Oxford* 12%, and Brigham 7% at six years.

In 1995, Lewold et al.[100] compared the outcome of the *Oxford* Meniscal Unicompartmental Knee (medial and lateral; Phase 1 and 2) and Marmor Knee (medial and lateral) arthroplasties using data from the Swedish Arthroplasty Register. They reported cumulative failure rates at 7 years of 12.69% and 6.33% respectively. The *Oxford* device cohort consisted of "all primary *Oxford* Unicompartmental prostheses inserted for arthrosis from September 1983", the date that the implant was introduced into that country; and the data came from 19 centres. It reflects, therefore, the first attempts of (at least) 19 surgeons to perform this novel procedure. The Marmor implant, on the other hand, had been widely used in Sweden since 1975 and it is unlikely the contributing surgeons were in the "learning curve" phase of use. Technical failures are usually revealed early. Of the 50 *Oxford* component revisions, 37 were undertaken in the first two years, at which stage the cumulative failure rate was almost five times that of the Marmor device. The authors concluded: "It is still unclear if the design with the sliding menisci will, in the long term, reduce wear and loosening, thereby compensating for the initially inferior results."

By 2000, when the updated survival graphs for the two prostheses, at about 10 years, were published on the Swedish Arthroplasty Study web-site101, the cumulative failure rates of the two implants were not significantly different (see Figure B).

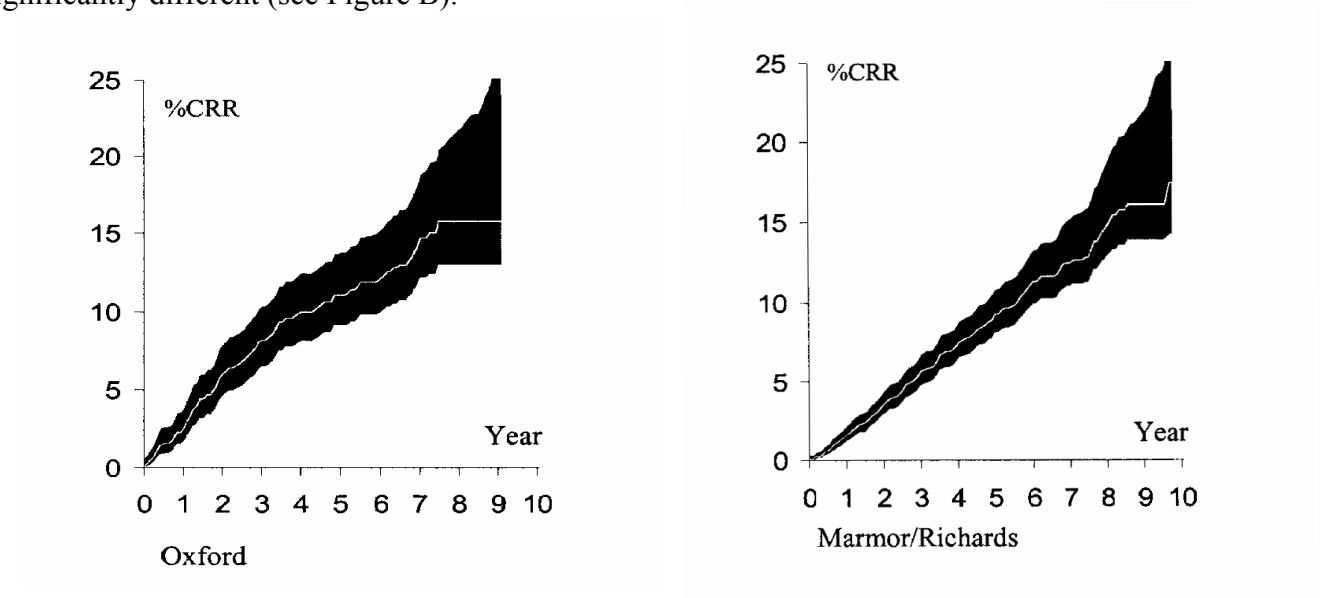


Figure B - Swedish Arthroplasty Study Results

In 2001, a comparison was published of the survival rates of three unicompartmental implants, the PCA, the *Oxford* (Phase 1 and 2) and the St. George, employed in Sweden between 1986 and 1995[29]. This study took into account the variability of surgical experience both categorically (by dividing the 78 departments from which the data came into two groups (A), those in which more than 23 unicompartmental replacements were done each year and (B), the rest) (Figure C) and numerically (by considering the mean number of operations per year in each department).

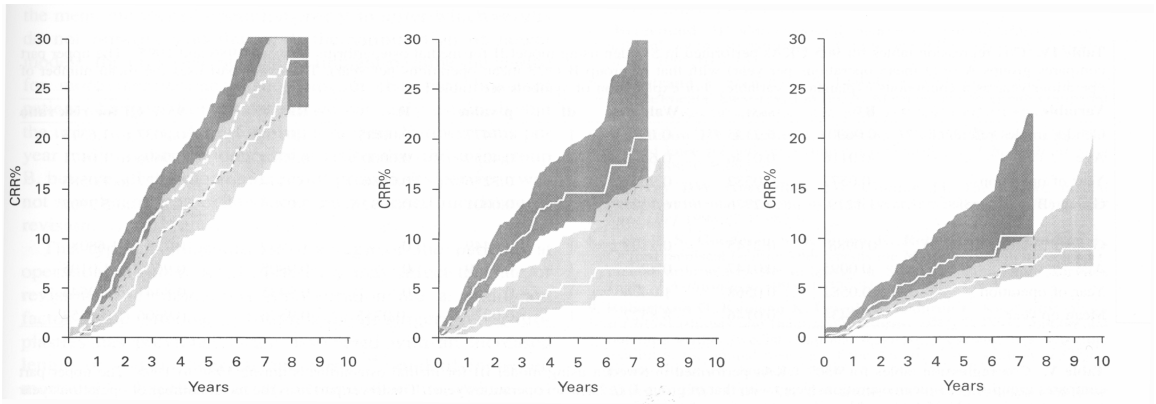


Figure C. Survival graphs of the PCA, Oxford and St Georg prostheses [29].

The PCA device had the worst results, and with this prosthesis the results in group A were no better than in B. The St. George implant, the most widely used of the three in Sweden, achieved an 8-year failure rate of about 8% in Group A and was only a little worse in Group B (about 10%).

The *Oxford* Knee showed the biggest difference between groups. In group A, it achieved the lowest 8-year failure rate (about **7%)** but in group B its failure rate was much worse (about 20%). For the *Oxford* device, there was a significant (p=0.003) reduction in the revision rate with increase in the number of operations; for the St George, there was not.

The authors concluded: "The effect of the mean number of operations per year on the risk of revision varied. The technically demanding implant (the *Oxford* device) was most affected, that most commonly used (the St. George) less so, and the number of operations performed did not influence the outcome of the unfavourable design (the PCA™). For unicompartmental arthroplasty, the long-term results are related to the number performed by the unit, probably expressing the standards of management in selecting the patients and performing the operation."

In 1997, Goodfellow, O'Connor and Murray[54] discussed their clinical results in both medial compartment replacement and lateral compartment replacement. In addition, results from other centers are discussed. Results of the first 103 cases in 1988[55] had convinced the authors that the state of the anterior cruciate ligament was a major determinant of the outcome, and after 1986, no unicompartmental arthroplasty was performed if that ligament was damaged or absent.

In 1993, Argenson, et al.[4] reported the survival rates of 552 *Oxford* unicompartmental arthroplasties performed at 4 centers in Europe (including 192 medial and 80 lateral). The cumulative success rate at five years for the medial arthroplasties (when the number at risk was 200) was 93%, and for lateral arthroplasties at five years (when the number at risk was 50) was 80%.

Kumar and Fidian[93] reported in 1999 on 100 *Oxford* Unicompartmental Knee arthroplasties. The follow-up period ranged from 1-11 years (mean 5.6 years). Eleven patients had died and six were lost to follow-up. Seven knees required revision, 4 for loosening, 2 for progressive arthritis, and 1 for fracture of the medial tibial plateau. At mean follow-up of 5.5 years, 76 arthroplasties were assessed according to the Knee Society Rating System and patient satisfaction (86% were pleased with the result, 12% satisfied, 1% unsure, and 1% unsatisfied).

In 1999, Weale, et al.[187] reported the clinical status, at a minimum of 10 years after operation, of 56 *Oxford* medial unicompartmental replacements performed between 1982 and 1987 on knees with anteromedial osteoarthritis. Of these, 24 were in patients who had died without revision, 1 was lost to follow-up, and 2 had been revised. Of the remaining 29 knees, 26 were examined clinically and radiologically, 2 were only examined clinically, and 1 was contacted by telephone. The mean age was 80.3 years. At a mean follow-up of 11.4 years (10-14) the measurements of the knee score, range of motion, and degree of deformity were not significantly different from those made at 1 and 2 years, except that range of flexion had improved. Comparison of radiographs at a similar interval of time showed no change in appearance of the lateral compartments. The retained articular cartilage continued to function for 10 or more years which suggested that anteromedial arthritis may be considered as a focal disorder of the knee and that timely unicompartmental arthroplasty can delay its spread to other compartments of the joint.

In March 2001, a survival study from an independent center was published[173]. It reports a continuous series of 124 knees with anteromedial osteoarthritis operated by three surgeons in Skovde district hospital, Sweden, between 1983 and 1989 (Phase 1 and 2 devices). None have been lost to follow up. All cases have been followed for a minimum of 10 years (mean 12.5 years: range 10 to 16 years). Six knees had been revised. The cumulative prosthetic survival rate at 10 years was 95% (CI 90.8% to 99.3%). The figures also represent the worst case. No failures had occurred between the 10$^{th}$ and the 16$^{th}$ years. This series along with those of Keys, Kanabar, and Das[16] and Harding, Ullah and Birtwhistle[13] confirms that with careful patient selection, an independent site can achieve the results of the designing surgeon.

Recently, the entire series of 420 *Oxford* Meniscal Unicompartmental Knee medial arthroplasties performed in Skovde, from 1983 to 2000, have been reviewed. None were lost to follow up. Seventeen knees have been revised (lateral compartment arthrosis 7; component loosening 4; bearing dislocation 4; infection 2). The cumulative prosthetic survival rate at 15 years is 94.3% (CI 90.5% to 98.1%). No failures occurred between the 10$^{th}$ and the 16$^{th}$ years. No knee had failed from polyethylene wear.

In 1999, Keys[87] described 10 knees treated with the *Oxford* Knee implants (Phase 2) through a limited incision and compared them with 10 done through the open approach with dislocation of the patella. He reported much more rapid recovery in the former group. Precision of implantation was not prejudiced, as shown by the postoperative radiographs.

In 2001, a comparison of a group of 40 *Oxford* arthroplasties, done through a small incision, with a group of 20 done by the open approach was published[135]. Both groups are compared with 40 TKR performed by the same surgeon during the same time period. The average rate of recovery of the first group (measured by the time to straight leg raise, flexion to 70 degrees and the ability to mount and descend stairs independently) was twice compared to the second and three times faster than the TKR group. Accuracy of implantation, measured on fluoroscopically centered radiographs was not diminished by the use of the small incision.

In 2002, the one-year clinical results of 88 knees treated through a small incision and a Phase 3 implant were reported[140]. The mean 1-year Knee Society Knee and Function scores were 95 and 93 respectively, and the average flexion at 1 year was 132°. One knee had been revised for infection and one dislocated bearing had needed to be relocated.

In 2000, the in vivo kinematics of Phase 3 *Oxford* arthroplasties were compared fluoroscopically with 1) those of normal knees and 2) knees with fixed bearing TKR[134]. The dynamic change in the patellar tendon/tibial shaft angle with changing flexion angle was recorded. The patterns in the normal knees and those with *Oxford* arthroplasties were the same. The TKR exhibited grossly abnormal kinematics. The results imply that after joint replacement with the *Oxford* Meniscal Unicompartmental Knee there is normal loading of the patellofemoral joint throughout the range of flexion. This may, in part, explain the excellent AKS and pain scores, and the large flexion range reported for the Phase 3 device.

**Conclusions**

The *Oxford* Meniscal Unicompartmental Knee IDE results are as good as those of other cemented unicompartmental implants, and the longer-term results are as good as (or better) than those for other cemented unicompartmental devices especially when patient selection is limited to those cases meeting the definition of "Anteromedial Osteoarthritis".

### 3. Smith and Nephew Genesis II Mobile Bearing Knee

| **Device Brand Name** | **Smith & Nephew**<br>**Genesis II Mobile Bearing Knee** |
|---|---|
| **Bearing Type** | RP= Rotating Platform (when Peg is inserted)<br>MP= Multidirectional Platform (without insertion of Peg) |
| **Total N** | 109 patients, 119 knees |
| Cement N | 94 patients, 104 knees |
| Uncemented N | 15 patients, 15 knees |
| Hybrid N | None |
| **Average Follow-Up (yrs, range)** | Average Follow Up = 12 months<br>Range = 3 months - 2years |
| **Demographics** | |
| Average age (yrs, range) | **M** 64 yrs. old (26-80) **F** 65 yrs. old (33-79) |
| Average weight (yrs, range) | **M** 202 lbs**.** **F** 160 lbs. |
| Sex (N, %) | **M** 48 knees (40.3%) **F** 71knees (59.6%) |
| Pre-operative diagnosis (N, %) | **OA** 104 pts. (95.4%)<br>**RA** 5 pts (4.5%)<br>**PTA** none<br>**Other** none |
| **Effectiveness (KSS, HSS or other score )** | KSS Total Score ranges from 0-100<br>Average KSS Total score preop = 29<br>Average KSS Total score at 1 year = 89 |
| Excellent (N, %) | NA |
| Good (N, %) | NA |
| Fair (N, %) | NA |
| Poor (N, %) | NA |
| Pain Scores | KSS Pain Score ranges from 0-50<br>Average KSS pain score preop = 10<br>Average KSS pain score at 1 year = 42 |
| **Patient Satisfaction (% satisfied)** | unavailable |
| Other Scoring Methods (SF-12, 36, QOL, etc.) | **Non-Inflammatory Arthritis:**<br>**Physical Score**<br>Preop score = 30.8<br>12 months score = 44.1<br><br>**Mental Score**<br>Preop score = 53.5<br>12 months score = 54.6<br>**Inflammatory Arthritis:**<br>**Physical Score**<br>Preop score = 28.6<br>12 months score = 39.0<br><br>**Mental Score**<br>Preop score = 48.3<br>12 months score = 52.0 |

| **Device Brand Name** | **Smith & Nephew<br>Genesis II Mobile Bearing Knee** |
|---|---|
| **Survivorship (% @ X no. of years)** | 117 knees out of 119 knees at 1 year |
| Using revision surgery for any reason as endpoint | Yes |
| Survivorship related to other endpoint | Pt success based on revision, x-ray, KSS Total and function scores. Percent not available at this stage of the study. |
| **Reason for Revision Surgery** | |
| Infection | |
| Deep | 1 patient at one year |
| Superficial | 0 |
| Aseptic Loosening | 0 |
| of Femur | 0 |
| of Tibia | 0 |
| Implant Subsidence | 0 |
| Polyethylene Wear | 0 |
| Insert Dislocation | 0 |
| Insert Breakage | 0 |
| Insert Subluxation | 1 patient at 3 months |
| Osteolysis | 0 |
| Patella Complication | 0 |
| DVT | 0 |
| Other: _____ | |
| **Comments:** | None |

## Materials And Methods

The Prosthesis

- **Briefly discuss the theory and design rationale of the mobile-bearing knee**

  The Genesis II Mobile Bearing construct consists of a standard commercially available femoral component, a mobile bearing (M/B) tibial insert and a M/B tibial base. The mobile bearing insert allows articulation of the femoral component on the polyethylene insert as well as movement between the polyethylene tibial insert and the metal tibial base.

  It is generally accepted that implantation of a Total Knee prosthesis requires excision of the anterior cruciate ligament. Biomechanically, this breaking of this linkage causes a disruption of the natural kinematics of the knee. Furthermore, studies indicate that the kinematics of total knees varies from normal, intact knee kinematics.

  The posterior cruciate ligament is thought to aid in femoral rollback as the knee is flexed. While some surgeons believe this adds some clinical benefit, numerous clinical studies reveal no difference in the outcomes of cruciate retaining or sacrificing designs. This is also true for cruciate retaining or sacrificing mobile bearing designs.

  Hence cruciate retaining mobile bearing designs allow anteroposterior translations to provide the conforming bearing the ability to translate as the knee is flexed. In cases where the posterior cruciate is excised, the ligaments do not impose femoral rollback and femoral rollback does not occur. Mobile bearing designs account for this fact by constraining anteroposterior motion of the bearing, in other words, locking it in to a rotation-only mode. By eliminating translation, the bearing maintains the stability usually supplied by the cruciate ligaments.

  The overwhelming clinical data supporting the similarity of outcomes between cruciate sparing and sacrificing designs support the use of either design as surgeon preference or as dictated by the anatomy. Based on biomechanical and kinematic data from fluoroscopic and clinical outcomes studies, similar mobile bearing designs can be expected to perform equally as well in cruciate sacrificing or retaining applications.

  By allowing the options of Rotation only and Rotation and Translation, the device allows the surgeon to intra-operatively determine which device is appropriate for each patient.

- **How is the device categorized**

  - A cruciate retaining Genesis II Mobile Bearing Knee is classed as MP or Multidirectional Platform.
  - A cruciate sacrificing Genesis II Mobile Bearing Knee is classed as RP or Rotating Platform.

- **Discuss design elements such as conformity, rotation, constraint, etc.**

  The mobile bearing tibial base is designed with a central metal T-post that mates with a slot in the M/B tibial insert. (Figure 1) The T-post and slot allow the insert to rotate and translate. If only rotation of the tibial insert is desired, a Rotation Peg is inserted through the hole in the tibial insert, threaded and locked onto the metal post on the tibial base. Once the Rotation Peg is in place, the insert is allowed to rotate but not allowed to translate. The Rotation Peg provides additional A/P constraint similar to the Dished or Posterior Stabilized Tibial Insert for the Fixed Bearing Knee

System. Intraoperatively, a surgeon may determine that the patient's ligaments would not provide adequate stabilization for a Rotating and Translating device. At that point, the surgeon could insert the Rotation Peg to provide additional A/P constraint.

Since the articular surface does not have a flexion or extension stop, the design relies on the patient's soft tissues to limit flexion and extension.

The Genesis II mobile bearing design does not constrain internal or external rotation; however, less than 1mm of polyethylene overhang exists between 10 degrees of external or internal rotation.

The cross-sectional (Coronal Plane) view of the femoral and tibial components show the same radius of curvature on each condylar portion of the components. There is no limiting component of the geometry that will prevent varus/valgus rotation. The patient's soft tissues, such as the collateral ligaments, will provide limits to varus/valgus rotation.

The intercondylar eminence of the tibial insert provides medial/lateral stability. The medial/lateral constraint is increased in this new design due to a higher intercondylar eminence.

There is little possibility of Proximal/Distal Translation since the components will be in contact at all times.

The anterior and posterior lips of the tibial insert provide stability. The T-post/T-slot design allows the insert to translate in the AP direction an average of 7 mm.

The Genesis II mobile bearing knee replacement is a rotation/translation, semi-constrained, posterior-cruciate retaining design. The articulation it will provide will be based off of the patient's normal gait pattern. This gait pattern will be dictated by the soft tissues and muscle forces present. Normal kinematics have gliding and rolling as part of flexion. Also normal femorotibial rotation can occur in the T-post-in-T-slot design. Translation can occur, despite the highly congruent articular surfaces, because of the T-slot/T-post design. The insert translates posteriorly as the knee goes into flexion until the T-slot stops at the T-post at which point the femoral component will roll back posteriorly as flexion increases. Clinical experience suggests that this will reduce stress at the fixation interfaces and avoid excessive polyethylene stress when rotation and translation occur.

- **Other design features**

Genesis II M/B Tibial Inserts are manufactured from UHMWPE (ASTM F 648) and are available in left and right sizes. Genesis II M/B Inserts have a proximal design that mate with the corresponding system femoral component. The minimum polyethylene thickness for the inserts is 6.3 mm.

The M/B Tibial Base is available in Nonporous (Figure 2) and Porous (Figure 3) designs. Both tibial bases are manufactured from cobalt chromium alloy material (Co-Cr-Mo, ASTM F-75 and ISO 5832/4) and are available in a variety of left and right sizes. The proximal design is the same for both tibial bases. Mobile Bearing Porous Tibial Bases are coated with Co-Cr-Mo beads that conform to ASTM F-75 and ISO 5832/4. The porous coating on the Mobile Bearing Porous Tibial Base is the same as the porous coating on the Genesis II Femoral Component (K933958).

The Genesis II M/B Tibial Insert can be used with either of the M/B Tibial Bases (Nonporous or Porous). The Nonporous and Porous M/B Tibial Base have the same polished proximal design with a T-post.

- **Discuss the indications for use of the device**

  Patients requiring primary total knee replacement who have been diagnosed with non-inflammatory arthritis (osteoarthritis) or inflammatory arthritis (rheumatoid arthritis) of the involved knee will be enrolled in the study.

  Osteoarthritis involves degenerative changes in the joint including subchondral bony sclerosis, loss of articular cartilage, and proliferation of bone and cartilage in the joint, forming osteophytes. Symptoms of osteoarthritis include but are not limited to pain, stiffness, and tenderness especially after exercise or use of the joint. Crepitus, deformity, subluxation, and synovial effusion may occur as the disease progresses.

  Rheumatoid arthritis is characterized by symmetric inflammation of the synovium and increased synovial exudate, leading to thickening of the synovium and swelling of the joint. Evidence of osteoporosis and destruction of the cartilage or subchondral bone is usually seen in later stages.

  Diagnosis for the indications is made through the clinical and radiographic examination of the patient. Chronic pain, reduction of mobility, and non-successful conservative treatment are usually determining factors, which prompt patients to seek a total knee arthroplasty. All indications can have an affect on knee pain, function, and range of motion.

- **Diagrams/pictures of device**

Study Design

- **Describe the design and methods used for the study**

  The design for the Genesis II M/B System is a prospective, multicenter, randomized, concurrently controlled study. The study is designed to assess the safety and effectiveness of the Genesis II M/B Knee System (study device) compared to the Genesis II Fixed Bearing Knee System (control device) in total knee replacement.

  The primary patient population considered for this study is unilateral, non-inflammatory arthritic patients requiring primary cemented total knee arthroplasty. The study has been designed to include the indication of inflammatory arthritis, patients requiring bilateral surgeries, patients that may need additional A/P constraint (Rotation only option), and uncemented procedures.

  This study is intended to assess the safety and effectiveness profile of the Mobile Bearing Knee System compared to a control device system in total knee arthroplasty. The revision rate by two years postoperative for both the study and control groups is an especially important adverse event measure in this study. The results will also allow evaluation of the study device performance in improving knee pain, function and range of motion. The radiographic results of the study and control implants will be reviewed to determine if proper fixation and alignment is maintained. The key study device (investigational) components of this investigation are the mobile bearing tibial insert, mobile bearing tibial base, and rotation peg.

  Patients will be screened for eligibility, and a signed and dated informed consent form will be obtained from all patients prior to enrollment in the study. Each patient enrolled will be evaluated preoperatively to document baseline status. A total of up to 362 patients will be divided between the study and control groups.

  Standardized postoperative clinical and radiographic follow-up will be collected on all patients to allow useful comparisons. Patients will be clinically and radiographically evaluated using standardized Case Report Forms preoperatively, intraoperatively, at discharge, and postoperatively at 3 months, 6 months, 12 months, and 24 months. For Postmarket Surveillance, additional patient evaluations will occur at 3 and 5-year intervals.

- **Overview of System and Study Design**

  The PDP for the Genesis II Knee System will compare the Genesis II Mobile Bearing Construct to the Genesis II Fixed Bearing Construct.

  The Genesis II M/B Construct (study) will include the components listed below.

  - Genesis II Cruciate Retaining Femoral Component,
  - Genesis II M/B Tibial Insert, and
  - Mobile Bearing Tibial Base.

The Genesis II Fixed Bearing Construct (control) will include the following components:

- Genesis II Primary Femoral Component,
- Genesis II Fixed Bearing Tibial Insert, and
- Genesis II Fixed Bearing Tibial Base.

Additional components that can be used with either system include intramedullary stems, patellar components, screws, and wedges. The Genesis II Knee System includes implants that have been previously cleared through the premarket notification [510(k)] process (K951987 and K953274). A list of the study and control implant components that are eligible for use in the PDP study is provided to the investigational sites.

- **Describe the randomization procedure if applicable**

Randomization schedules will be stratified by device type (study or control). There will be a 1:1 randomization in this study with a randomization block size of 4. Patients will be enrolled sequentially, as they become available and after the patients have read, signed, and dated the Informed Consent Document. Each patient treated will only be randomized once. If a patient is entered in the study and requires a contralateral knee replacement at some point, the patient can receive the same device configuration in the contralateral knee as was originally implanted. Therefore, bilateral patients will be randomized once. Both knees will receive the same device (study or control) depending on the randomization schedule.

Randomization schedules for assignment of treatments will be based on permutation blocks. The use of permutation blocks will assure that the assignment of treatments is balanced. Separate stratified randomization schedules will be prepared for each investigational site. Sequentially numbered envelopes containing the randomly selected treatment assignment (based on the randomization schedules) will be prepared and distributed to the sites.

- **Describe blinding procedure if applicable**

Not Applicable. This is an open label clinical trial.

- **What was the hypothesis for the study?**

The major objective of the data analysis is to evaluate device safety and device effectiveness of a total knee arthroplasty system incorporating a mobile bearing tibial insert and base compared to a fixed bearing tibial insert and base at the two year evaluation interval. The safety and effectiveness of the Mobile Bearing System will be assessed by analyzing the Patient Success Criteria, which include revision status, functional/clinical evaluation, and radiographic assessments. Additionally, the risk of mobile bearing articulation will be assessed by analyzing the revision rate by two years, applicable operative and postoperative adverse events (device related or otherwise); and comparing the events to those in the control group system. Results on knee pain, function, and range of motion will also be compared between the study and control groups.

Mobile bearing devices of similar design have been implanted in humans and used with commercially available knee devices. So the mobile bearing design concept is familiar to FDA, the Sponsor, and the Investigator. The potential benefits and disadvantages for a mobile bearing

articulation surface should be evaluated in a clinical research study. Favorable experience in the US and other countries with mobile bearing knee systems also supports the need for the mobile bearing knee systems in the U.S.

The null hypothesis to be tested is whether the success rate at 2 years postoperatively in the control device group is greater than the success rate in the study device group by at least 7.5 percent.

- **Is the study "complete" or "in progress" and what is progress status?**

  This study is in progress with of 115 fixed bearing and 109 mobile bearing patients enrolled for a total enrollment of 224. There are 106 total patients at one year out and 3 patients at two years out.

- **Please insert any special materials and methods you used in this section**

  None used.

- **Selection Criteria**

  Patient Inclusion Criteria

  1. Males and females, 21 to 80 years of age, inclusive.
  2. Diagnosis of non-inflammatory or inflammatory arthritis requiring primary total knee replacement.
  3. Patient, or his/her legal guardian, is willing to consent to participate in the study by signing and dating an approved consent form.
  4. Patient will be available for follow-up through at least two years postoperative.
  5. Patient has met an acceptable preoperative medical clearance and is free of or treated for cardiac, pulmonary, hematological, or other conditions that would pose excessive operative risk.
  6. Preoperative Knee Society Total Score (Pain, Stability and Range of Motion) of less than or equal to 60.
  7. Patient meets none of the exclusion criteria.

  Patient Exclusion Criteria

  1. Patients known to have insufficient quantity or quality of bone support resulting from conditions such as cancer, distal femoral/proximal tibial osteotomy, significant osteoporosis or metabolic disorders of calcified tissues.
  2. Patients with physical conditions tending to place extreme loads on implants such as morbid obesity ($\geq$ 100 pounds over desirable body weight as defined by IBW chart included in Appendix 5), Charcot joints, muscle deficiencies, or multiple joint disabilities;
  3. Active, local infection or systemic infection
  4. Physical or neurological conditions that would impair the patient's ability or willingness to restrict activities or follow medical advice, especially during the postoperative period (e.g.: drug or alcohol abuse), serious mental illness or retardation, or general neurologic conditions. Drug abuse is defined as the use of a drug for a non-therapeutic effects especially one for which it was not prescribed or intended. Alcohol abuse is defined as the extreme dependence and habitual use of excessive amounts of alcohol, associated with a cumulative pattern of deviant behavior-alcoholism.

5. Collateral ligament insufficiency
6. Patients with excessive biomechanical demands
7. Immunosuppressive disorders – immunosuppressive disorders are chronic conditions characterized by markedly inhibited ability to respond to antigenic stimuli. Examples of such conditions include patients who are on immunosuppressive therapy (corticosteriod hormones in large amounts, cytotoxic drugs, antilymphocytic serum or irradiation in large doses), patients receiving therapy to prevent homograft rejection, patients who have acquired immunodeficiency syndrome (AIDS), or auto-immune diseases (except rheumatoid arthritis).
8. Pregnancy
9. Participation in any other pharmaceutical, biologic or medical device clinical investigation
10. Failed total or unicondylar knee replacement on affected knee
11. Patients with known sensitivity to materials in the device.

- **Follow-Up Evaluation**

  Study and control patients are evaluated using the Knee Society Clinical Rating System. Radiographic data will be collected and evaluated using the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. Quality of life will be evaluated using the SF12 Health Survey. Both subjective (pain and SF12 Health Survey) and objective (incidence of adverse events, stability, range of motion, and width of radiolucent lines) measurements are a part of the evaluation. Knee Society Scoring Systems and the SF12 Health Survey are clinically accepted measurement tools that have been used frequently to evaluate patients since the systems were published.

  Each patient is required to be evaluated preoperatively, intraoperatively, and postoperatively at discharge from the hospital and at 3 months, 6 months, 12 months, and 24 months. For Postmarket Surveillance, additional patient evaluations will occur at 3 and 5-year intervals.

  Because the study is in progress, final follow-up interval and compliance statistics are unavailable at this time.

- **Radiographic Assessment**

  Preoperative, postoperative at discharge from the hospital and at 3 months,(6 months is optional) 12 months, and 24 months. For Postmarket Surveillance, additional patient evaluations will occur at 3 and 5-year intervals.

- **Briefly describe the radiographic method used to capture image of knee (Views)**

  The following radiographs will be taken on all patients at the defined intervals.

  - Anteroposterior (AP) View
  - Lateral View
  - Patellar Skyline/Merchant View

- **The following were recorded at the follow-up examination**

  Postoperative radiographs will be evaluated by the Investigator to determine component position, lucencies, and bone condition. Observations will be recorded on the x-ray case report form.

  If any of the following are present, the patient will be considered a radiographic failure:

  1. Radiolucencies greater than 50% of the total bone prosthesis interface
  2. Radiolucencies greater than or equal to two millimeters (2 mm) in three or more zones
  3. Progressive radiolucencies
  4. Subsidence or migration of any component greater than five millimeters (5 mm)
  5. Radiographic evidence of component failure that would result in device removal: fracture, crack, chip, flake, split, splinter, shatter, break, severe osteolysis, dislocation, subluxation, subsidence, migration, loosening, or wear-through of the implant components

**Results**

The study is in progress and the first patients enrolled are just approaching the two-year mark. The requested final values concerning patient results and outcomes are unavailable at this time.

<u>The Patients</u>

- The first patient enrolled in the Genesis II Mobile Bearing Knee Study had surgery on 3/24/2000. Patients continue to be enrolled. In April of 2002, one hundred nineteen (119) Genesis II Mobile Bearing Knees had been implanted in one hundred nine (109) patients.

- At one year following the procedure 108 patients (118 knees) were alive, one (1) patient (1 knee) had died due to a cardiac problem. No patients were known to be lost to follow up.

- Sixty-seven (67) patients (71 knees) were female and forty-two (42) patients (48 knees) were male.

- Average age at the time of surgery was 64.6 years (range, 26 to 80)

- The pre-operative diagnosis was osteoarthritis in 114 knees, rheumatoid arthritis in 5 knees and post-traumatic arthritis in 0 knees.

<u>Outcomes</u>

- Knee Society Score preoperative and 1-year average scores are provided in the chart on page one. We do not typically stratify scores based on "Excellent to Poor" criteria while the study is in progress.

- Average preoperative flexion is 100 degrees. Average flexion at the one-year interval is currently 109 degrees. Average extension is unavailable.

- Final follow-up has not been obtained. Study is ongoing.

- Patient satisfaction results are unavailable at this time.
- Survival analysis has not been calculated at this point in the study.

Radiographic Appearances

- There have been no reports, from the investigators, of radiographic looseness.
- There have been no reports, from the investigators, of radiolucent lines greater than 2 mm.

Complications

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Any fracture | 1 (1 %) | During surgery |
| Femoral component loosening | 0 | |
| Tibial component loosening | 0 | |
| Patellar component loosening | 0 | |
| Bearing dislocation | 0 | |
| Bearing subluxation | 1 (1%) | 3 months |
| Mobile bearing wear | 0 | |
| Patellar bearing wear | 0 | |
| Ligamentous instability | 0 | |
| Deep infection | 1 (1%) | 1 year |
| Fibroarthrosis | 9 (11%) | 3-6 months |
| Other: Reflex Sympathetic Dystrophy | 1 (1%) | 1 year |

- **Discuss overall complication rate**

  Eighty-two (82) complications/adverse events have been reported (discharge through 1 year follow up) in patients receiving the Genesis II Mobile Bearing Knee, which is 54% of the 152 total complications/adverse events reported in the two treatment groups collectively. Complications and adverse events reported include knee specific, general and systemic complications/adverse events.

- **Discuss overall revision rate**

  Two complete revisions have occurred in the mobile bearing group, one due to infection and one due to subluxation (1.68%). One complete revision has occurred in the fixed bearing group, due to infection (0.86%). Three (3) revisions in a total of 254 knees implanted in the treatment groups collectively is a 1.33% revision rate overall.

## Conclusions

The Genesis II Mobile Bearing Knee Study is currently in progress. The purpose of the study is to find the Genesis II Mobile Bearing Knee to be equivalent to the Genesis II Fixed Bearing Knee. Participating investigators are made aware of the most current data results on all collected data at annual investigator's meetings. Interim reports are provided as requested and as needed to keep investigators current with study results. Both participating investigators and the sponsor find no significant difference in the two study groups as the current interim data is continuously reviewed. A more intricate analysis of the data will take place as the study matures.

## 4. Smith and Nephew Profix Mobile Bearing Knee

| **Device Brand Name:** | Smith & Nephew, Inc.<br>Profix Mobile Bearing Knee System |
|---|---|
| **Bearing Type:** | RP = Rotating Platform (when Peg is inserted)<br><br>MP= Multidirectional Platform (Without insertion of Peg) |
| **Total N** | 59 |
| Cement N | 50 |
| Uncemented N | 0 |
| Hybrid N | 09 |
| **Average Follow-Up (yrs, range)** | Average Follow Up = 9 months<br>Range = 3 months - 2 years |
| **Demographics** | |
| Average age (yrs, range) | M : Avg: 64.9 Range 48-78<br>F: Avg: 63.2 Range: 48-79 |
| Average weight (yrs, range) | M: Unavailable (UA) F: UA |
| Sex (N, %) | M: 59% F: 41% |
| Pre-operative diagnosis (N, %) | OA: 59 Knees, 100%<br>RA: 0<br>PTA: 0<br>Other: 0 |
| **Effectiveness (KSS, HSS or other score )** | KSS Results[0-100] at :<br>Pre-Op: 32 points<br>One Year: 92 points |
| Excellent (N, %) | UA |
| Good (N, %) | UA |
| Fair (N, %) | UA |
| Poor (N, %) | UA |
| Pain Scores | KSS Pain Score[0-50] at:<br>Pre-Op: 09 points<br>One Year: 46 points |
| **Patient Satisfaction (% satisfied)** | UA |
| Other Scoring Methods (SF-12, 36, QOL, etc.) | SF-12<br>Physical Score Preop: 30.2<br>One year: 44.9<br><br>Mental Score Preop: 52.5<br>One year: 56.1 |
| **Survivorship (% @ X no. of years)** | 100 % at one year follow up |
| Using revision surgery for any reason as endpoint | Yes |
| Survivorship related to other endpoint<br>Define other endpoint and report % | Pt success based on revision, x-ray, KSS Total and function scores. Percent not available at this stage of the study. |

| **Device Brand Name:** | Smith & Nephew, Inc.<br>Profix Mobile Bearing Knee System |
|---|---|
| **Reason for Revision Surgery** | 0 |
| Infection | 0 |
| Deep | 0 |
| Superficial | 0 |
| Aseptic Loosening | 0 |
| of Femur | 0 |
| of Tibia | 0 |
| Implant Subsidence | 0 |
| Polyethylene Wear | 0 |
| Insert Dislocation | 0 |
| Insert Breakage | 0 |
| Insert Subluxation | 0 |
| Osteolysis | 0 |
| Patella Complication | 0 |
| DVT | 0 |
| Other: _____ | 0 |
| **Comments:** | There have been no revisions of the Mobile Bearing Knees in this study. |

**Materials And Methods**

The Prosthesis

- **Briefly discuss the theory and design rationale of the mobile-bearing knee**

The Profix Mobile Bearing construct consists of a standard commercially available femoral component, a mobile bearing (M/B) tibial insert and a M/B tibial base. The mobile bearing insert allows articulation of the femoral component on the polyethylene insert as well as movement between the polyethylene tibial insert and the metal tibial base.

It is generally accepted that implantation of a Total Knee prosthesis requires excision of the anterior cruciate ligament. Biomechanically, this breaking of this linkage causes a disruption of the natural kinematics of the knee. Furthermore, studies indicate that the kinematics of total knees varies from normal, intact knee kinematics.

The posterior cruciate ligament is thought to aid in femoral rollback as the knee is flexed. While some surgeons believe this adds some clinical benefit, numerous clinical studies reveal no difference in the outcomes of cruciate retaining or sacrificing designs. This is also true for cruciate retaining or sacrificing mobile bearing designs.

Hence cruciate retaining mobile bearing designs allow anteroposterior translations to provide the conforming bearing the ability to translate as the knee is flexed. In cases where the posterior cruciate is excised, the ligaments do not impose femoral rollback and femoral rollback does not occur. Mobile bearing designs account for this fact by constraining anteroposterior motion of the

bearing, in other words, locking it in to a rotation-only mode. By eliminating translation, the bearing maintains the stability usually supplied by the cruciate ligaments.

The overwhelming clinical data supporting the similarity of outcomes between cruciate sparing and sacrificing designs support the use of either design as surgeon preference or as dictated by the anatomy. Based on biomechanical and kinematic data from fluoroscopic and clinical outcomes studies, similar mobile bearing designs can be expected to perform equally as well in cruciate sacrificing or retaining applications.

By allowing the options of Rotation only and Rotation and Translation, the device allows the surgeon to intra-operatively determine which device is appropriate for each patient.

- **How is the device categorized**

  - A cruciate retaining Profix Mobile Bearing Knee is classed as MP or Multidirectional Platform.
  - A cruciate sacrificing Profix Mobile Bearing Knee is classed as RP or Rotating Platform.

- **Discuss design elements such as: conformity, rotation, constraint, etc.**

  The mobile bearing tibial base is designed with a central metal T-post that mates with a slot in the M/B tibial insert. (Figure 1) The T-post and slot allow the insert to rotate and translate. If only rotation of the tibial insert is desired, a Rotation Peg is inserted through the hole in the tibial insert, threaded and locked onto the metal post on the tibial base. Once the Rotation Peg is in place, the insert is allowed to rotate but not allowed to translate. The Rotation Peg provides additional A/P constraint similar to the Dished or Posterior Stabilized Tibial Insert for the Fixed Bearing Knee System. Intraoperatively, a surgeon may determine that the patient's ligaments would not provide adequate stabilization for a Rotating and Translating device. At that point, the surgeon could insert the Rotation Peg to provide additional A/P constraint.

  Since the articular surface does not have a flexion or extension stop, the design relies on the patient's soft tissues to limit flexion and extension.

  The Profix mobile bearing design does not constrain internal or external rotation; however, less than 1mm of polyethylene overhang exists between 10 degrees of external or internal rotation.

  The cross-sectional (Coronal Plane) view of the femoral and tibial components show the same radius of curvature on each condylar portion of the components. There is no limiting component of the geometry that will prevent varus/valgus rotation. The patient's soft tissues, such as the collateral ligaments, will provide limits to varus/valgus rotation.

  The intercondylar eminence of the tibial insert provides medial/lateral stability. The medial/lateral constraint is increased in this new design due to a higher intercondylar eminence.

  There is little possibility of Proximal/Distal Translation since the components will be in contact at all times.

  The anterior and posterior lips of the tibial insert provide stability. The T-post/T-slot design allows the insert to translate in the AP direction an average of 7 mm.

  The Profix mobile bearing knee replacement is a rotation/translation, semi-constrained, posterior-cruciate retaining design. The articulation it will provide will be based off of the patient's normal gait pattern. This gait pattern will be dictated by the soft tissues and muscle forces present. Normal kinematics have gliding and rolling as part of flexion. Also normal femorotibial rotation can occur

in the T-post-in-T-slot design. Translation can occur, despite the highly congruent articular surfaces, because of the T-slot/T-post design. The insert translates posteriorly as the knee goes into flexion until the T-slot stops at the T-post at which point the femoral component will roll back posteriorly as flexion increases. Clinical experience suggests that this will reduce stress at the fixation interfaces and avoid excessive polyethylene stress when rotation and translation occur.

- **Other design features**

  Profix M/B Tibial Inserts are manufactured from UHMWPE (ASTM F 648) and are available in left and right sizes. Profix M/B Inserts have a proximal design that mate with the corresponding system femoral component. The minimum polyethylene thickness for the inserts is 6.3 mm.

  The M/B Tibial Base is available in Nonporous (Figure 2) and Porous (Figure 3) designs. Both tibial bases are manufactured from cobalt chromium alloy material (Co-Cr-Mo, ASTM F-75 and ISO 5832/4) and are available in a variety of left and right sizes. The proximal design is the same for both tibial bases. Mobile Bearing Porous Tibial Bases are coated with Co-Cr-Mo beads that conform to ASTM F-75 and ISO 5832/4. The porous coating on the Mobile Bearing Porous Tibial Base is the same as the porous coating on the Profix Femoral Component (K933958).

  The Profix M/B Tibial Insert can be used with either of the M/B Tibial Bases (Nonporous or Porous). The Nonporous and Porous M/B Tibial Base have the same polished proximal design with a T-post.

- **Discuss the indications for use of the device**

  Patients requiring primary total knee replacement who have been diagnosed with non-inflammatory arthritis (osteoarthritis) or inflammatory arthritis (rheumatoid arthritis) of the involved knee will be enrolled in the study.

  Osteoarthritis involves degenerative changes in the joint including subchondral bony sclerosis, loss of articular cartilage, and proliferation of bone and cartilage in the joint, forming osteophytes. Symptoms of osteoarthritis include but are not limited to pain, stiffness, and tenderness especially after exercise or use of the joint. Crepitus, deformity, subluxation, and synovial effusion may occur as the disease progresses.

  Rheumatoid arthritis is characterized by symmetric inflammation of the synovium and increased synovial exudate, leading to thickening of the synovium and swelling of the joint. Evidence of osteoporosis and destruction of the cartilage or subchondral bone is usually seen in later stages.

  Diagnosis for the indications is made through the clinical and radiographic examination of the patient. Chronic pain, reduction of mobility, and non-successful conservative treatment are usually determining factors, which prompt patients to seek a total knee arthroplasty. All indications can have an affect on knee pain, function, and range of motion.

- **Diagrams/pictures of device**

Study Design

- **Describe the design and methods used for the study**

The PDP for the Profix M/B System is designed as a prospective, multicenter, randomized, concurrently controlled study. The study is designed to assess the safety and effectiveness of the Profix M/B Knee System (study device) compared to the Profix Fixed Bearing Knee System (control device) in total knee replacement.

The primary patient population considered for this study is unilateral, non-inflammatory arthritic patients requiring primary cemented total knee arthroplasty. The study has been designed to include the indication of inflammatory arthritis, patients requiring bilateral surgeries, patients that may need additional A/P constraint (Rotation only option), and uncemented procedures.

This study is intended to assess the safety and effectiveness profile of the Mobile Bearing Knee System compared to a control device system in total knee arthroplasty. The revision rate by two years postoperative for both the study and control groups is an especially important adverse event measure in this study. The results will also allow evaluation of the study device performance in improving knee pain, function and range of motion. The radiographic results of the study and control implants will be reviewed to determine if proper fixation and alignment is maintained. The key study device (investigational) components of this investigation are the mobile bearing tibial insert, mobile bearing tibial base, and rotation peg.

Patients will be screened for eligibility, and a signed and dated informed consent form will be obtained from all patients prior to enrollment in the study. Each patient enrolled will be evaluated preoperatively to document baseline status. A total of up to 362 patients will be divided between the study and control groups.

Standardized postoperative clinical and radiographic follow-up will be collected on all patients to allow useful comparisons. Patients will be clinically and radiographically evaluated using standardized Case Report Forms preoperatively, intraoperatively, at discharge, and postoperatively

at 3 months, 6 months, 12 months, and 24 months. For Postmarket Surveillance, additional patient evaluations will occur at 3 and 5-year intervals.

- **Overview of System and Study Design**

  The PDP for the Profix Knee System will compare the Profix Mobile Bearing Construct to the Profix Fixed Bearing Construct.

  The Profix M/B Construct (study) will include the components listed below.

  - Profix Cruciate Retaining Femoral Component,
  - Profix M/B Tibial Insert, and
  - Mobile Bearing Tibial Base.

  The Profix Fixed Bearing Construct (control) will include the following components:

  - Profix Primary Femoral Component,
  - Profix Fixed Bearing Tibial Insert, and
  - Profix Fixed Bearing Tibial Base.

  Additional components that can be used with either system include intramedullary stems, patellar components, screws, and wedges. The Profix Knee System includes implants that have been previously cleared through the premarket notification [510(k)] process (K951987 and K953274). A list of the study and control implant components that are eligible for use in the PDP study is provided to the investigational sites.

- **Describe the randomization procedure if applicable**

  Randomization schedules will be stratified by device type (study or control). There will be a 1:1 randomization in this study with a randomization block size of 4. Patients will be enrolled sequentially, as they become available and after the patients have read, signed, and dated the Informed Consent Document. Each patient treated will only be randomized once. If a patient is entered in the study and requires a contralateral knee replacement at some point, the patient can receive the same device configuration in the contralateral knee as was originally implanted. Therefore, bilateral patients will be randomized once. Both knees will receive the same device (study or control) depending on the randomization schedule.

  Randomization schedules for assignment of treatments will be based on permutation blocks. The use of permutation blocks will assure that the assignment of treatments is balanced. Separate stratified randomization schedules will be prepared for each investigational site. Sequentially numbered envelopes containing the randomly selected treatment assignment (based on the randomization schedules) will be prepared and distributed to the sites.

- **Describe blinding procedure if applicable**

  Not Applicable. This is an open label clinical trial.

- **What was the hypothesis for the study?**

  The major objective of the data analysis is to evaluate device safety and device effectiveness of a total knee arthroplasty system incorporating a mobile bearing tibial insert and base compared to a fixed bearing tibial insert and base at the two year evaluation interval. The safety and effectiveness of the Mobile Bearing System will be assessed by analyzing the Patient Success Criteria, which include revision status, functional/clinical evaluation, and radiographic assessments. Additionally, the risk of mobile bearing articulation will be assessed by analyzing the revision rate by two years, applicable operative and postoperative adverse events (device related or otherwise); and comparing the events to those in the control group system. Results on knee pain, function, and range of motion will also be compared between the study and control groups.

  Mobile bearing devices of similar design have been implanted in humans and used with commercially available knee devices. So the mobile bearing design concept is familiar to FDA, the Sponsor, and the Investigator. The potential benefits and disadvantages for a mobile bearing articulation surface should be evaluated in a clinical research study. Favorable experience in the US and other countries with mobile bearing knee systems also supports the need for the mobile bearing knee systems in the U.S.

  The null hypothesis to be tested is whether the success rate at 2 years postoperatively in the control device group is greater than the success rate in the study device group by at least 7.5 percent.

- **Is the study "complete" or "in progress" and what is progress status?**

  The study is in progress with 56 fixed bearing knees and 59 mobile bearing knees for a total enrollment of 115 knees. There are 40 total knees at one year out.

- **Please insert any special materials and methods you used in this section.**

  None Used

- **Selection Criteria**

  <u>Patient Inclusion Criteria</u>

  1. Males and females, 21 to 80 years of age, inclusive.
  2. Diagnosis of non-inflammatory or inflammatory arthritis requiring primary total knee replacement.
  3. Patient, or his/her legal guardian, is willing to consent to participate in the study by signing and dating an approved consent form.
  4. Patient will be available for follow-up through at least two years postoperative.
  5. Patient has met an acceptable preoperative medical clearance and is free of or treated for cardiac, pulmonary, hematological, or other conditions that would pose excessive operative risk.
  6. Preoperative Knee Society Total Score (Pain, Stability and Range of Motion) of less than or equal to 60.
  7. Patient meets none of the exclusion criteria

Patient Exclusion Criteria

1. Patients known to have insufficient quantity or quality of bone support resulting from conditions such as cancer, distal femoral/proximal tibial osteotomy, significant osteoporosis or metabolic disorders of calcified tissues.
2. Patients with physical conditions tending to place extreme loads on implants such as morbid obesity ($\geq$ 100 pounds over desirable body weight as defined by IBW chart included in Appendix 5), Charcot joints, muscle deficiencies, or multiple joint disabilities;
3. Active, local infection or systemic infection
4. Physical or neurological conditions that would impair the patient's ability or willingness to restrict activities or follow medical advice, especially during the postoperative period (e.g.: drug or alcohol abuse), serious mental illness or retardation, or general neurologic conditions. Drug abuse is defined as the use of a drug for a non-therapeutic effects especially one for which it was not prescribed or intended. Alcohol abuse is defined as the extreme dependence and habitual use of excessive amounts of alcohol, associated with a cumulative pattern of deviant behavior-alcoholism.
5. Collateral ligament insufficiency
6. Patients with excessive biomechanical demands
7. Immunosuppressive disorders – immunosuppressive disorders are chronic conditions characterized by markedly inhibited ability to respond to antigenic stimuli. Examples of such conditions include patients who are on immunosuppressive therapy (corticosteriod hormones in large amounts, cytotoxic drugs, antilymphocytic serum or irradiation in large doses), patients receiving therapy to prevent homograft rejection, patients who have acquired immunodeficiency syndrome (AIDS), or auto-immune diseases (except rheumatoid arthritis).
8. Pregnancy
9. Participation in any other pharmaceutical, biologic or medical device clinical investigation
10. Failed total or unicondylar knee replacement on affected knee
11. Patients with known sensitivity to materials in the device.

Follow-Up Evaluation

- Study and control patients will be evaluated using the Knee Society Clinical Rating System. Radiographic data will be collected and evaluated using the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. Quality of life will be evaluated using the SF12 Health Survey. Both subjective (pain and SF12 Health Survey) and objective (incidence of adverse events, stability, range of motion, and width of radiolucent lines) measurements are a part of the evaluation. Knee Society Scoring Systems and the SF12 Health Survey are clinically accepted measurement tools that have been used frequently to evaluate patients since the systems were published.

- Each patient is required to be evaluated preoperatively, intraoperatively, and postoperatively at discharge from the hospital and at 3 months, 6 months, 12 months, and 24 months. For Postmarket Surveillance, additional patient evaluations will occur at 3 and 5-year intervals.

- Because the study is in progress the average final follow-up interval and compliance statistics are not available.

Radiographic Assessment

- Preoperative, postoperative at discharge from the hospital and at 3 months, (6-months is optional) 12 months, and 24 months. For Postmarket Surveillance, additional patient evaluations will occur at 3 and 5-year intervals.

- The following radiographs will be taken on all patients at the defined intervals.

  - Anteroposterior (AP) View
  - Lateral View
  - Patellar Skyline/Merchant View

- Postoperative radiographs will be evaluated by the Investigator to determine component position, lucencies, and bone condition. Observations will be recorded on the x-ray case report form. If any of the following are present, the patient will be considered a radiographic failure:

  1. Radiolucencies greater than 50% of the total bone prosthesis interface
  2. Radiolucencies greater than or equal to two millimeters (2 mm) in three or more zones
  3. Progressive radiolucencies
  4. Subsidence or migration of any component greater than five millimeters (5 mm)
  5. Radiographic evidence of component failure that would result in device removal: fracture, crack, chip, flake, split, splinter, shatter, break, severe osteolysis, dislocation, subluxation, subsidence, migration, loosening, or wear-through of the implant components

**Results**

The study is in progress and the first patients enrolled are just approaching the two year mark. The requested final values concerning patient results and outcomes are unavailable at this time.

The Patients

- The first patient enrolled in the Profix Mobile Bearing Knee Study had surgery on 3/28/2000. Patients continue to be enrolled. In April of 2002, fifty-nine (59) Profix Mobile Bearing Knees had been implanted in fifty-three (53) patients.

- At one year following the procedure 20 patients (20 knees) were alive. No patients were known to be lost to follow up.

- Twenty-four (24) patients were female and thirty-five (35) patients were male.

- The Average age at the time of surgery was 65 years (range, 35 to 84).

- All fifty-nine (59) Profix Mobile Bearing Knees implanted were diagnosed as osteoarthritis knees.

Outcomes

- Knee Society Score preoperative and 1-year average scores are provided in the chart on page one. We do not typically stratify scores based on "Excellent to Poor" criteria while the study is in progress.

- Average flexion at preop is 115 degrees and the one-year interval is currently 117 degrees. Average extension at preop is seven (7) degrees and the one-year interval is currently one (1) degree.

- Final follow-up has not been obtained. Study is ongoing.

- Patient satisfaction results are unavailable at this time.

- Survival analysis has not been calculated at this point in the study.

Radiographic Appearances

- There have been no reports, from the investigators, of radiographic looseness.

- There have been no reports, from the investigators, of radiolucent lines greater than 2 mm.

Complications

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Any fracture | 0 | |
| Femoral component loosening | 0 | |
| Tibial component loosening | 0 | |
| Patellar component loosening | 0 | |
| Bearing dislocation | 0 | |
| Bearing subluxation | 0 | |
| Mobile bearing wear | 0 | |
| Patellar bearing wear | 0 | |
| Ligamentous instability | 0 | |
| Deep infection | 0 | |
| Fibroarthrosis | 0 | |
| Other: Knee specific complications | 6 | N/A |
| Other: General complications | 25 | N/A |

- **Discuss overall complication rate**

  Thirty-one adverse events have been reported in patients receiving the Profix Mobile Bearing Knee (PMBK), which is 51% of the sixty total events reported in the two treatment groups collectively.

  Six knee specific events in the (PMBK) group included echymosis, pain, arthrofibrosis, deep vein thrombosis, which represent 1% of the sixty total events reported.

Twenty-five general events in the (PMBK) group included lipoma, gastrointestinal events, urinary retention, vertigo, which represent 41% of the sixty total events reported.

- **Discuss overall revision rate**

  One revision of a Fixed Bearing Knee was performed at the 1-year interval, due to knee pain (0.86%).

**Conclusions**

The Profix Mobile Bearing Knee Study is currently in progress. The purpose of the study is to find the Profix Mobile Bearing Knee to be equivalent to the Profix Fixed Bearing Knee. Participating investigators are made aware of the most current data results on all collected data at annual investigator's meetings. Interim reports are provided as requested and as needed to keep investigators current with study results. Both participating investigators and the sponsor find no significant difference in the two study groups as the current interim data is continuously reviewed. A more intricate analysis of the data will take place as the study matures.

## 5. Howmedica Osteonics *Scorpio*+ PS Mobile Bearing Knee

| **Device Brand Name** | *Scorpio*®+ PS Mobile Bearing Knee |
|---|---|
| **Bearing Type** | RP= rotating platform |
| **Total N** | 62 |
| Cement N | N = 62 |
| Uncemented N | Not applicable to this study |
| Hybrid N | Not applicable to this study |
| **Average Follow-Up (days, range)** | 84 days (12-204 days) |
| **Demographics (N=52)** | |
| Average age (yrs, range) | M (63.2, 47-79) F (61.7, 50-77) |
| Average weight (lbs., range) | M (234.55, 178-285) F (186.34, 120-240) |
| Sex (N, %) | M (20, 38%) F (32, 62%) |
| Pre-operative diagnosis (N, %) | OA (51, 98.1%), PTA (1, 1.9%) |
| **Effectiveness (KSS Total Pain/Motion Score)** | Excellent: 85-100, Good: 70-84, Fair: 60-69, Poor: <60 |
| Excellent (N, %) | Preop (0, 0%), 7 Wk. (20, 51.28%), 6 Mos. (7, 58.33%) |
| Good (N, %) | Preop (0, 0%), 7 Wk. (7, 17.95%), 6 Mos. (2, 16.67%) |
| Fair (N, %) | Preop (0, 0%), 7 Wk. (7, 27.95%), 6 Mos. (2, 16.67%) |
| Poor (N, %) | Preop (52, 100%), 7 Wk. (5, 12.82%), 6 Mos. (1, 8.33%) |
| **Effectiveness (KSS Total Function Score)** | Excellent: 85-100, Good: 70-84, Fair: 60-69, Poor: <60 |
| Excellent (N, %) | Preop (0, 0%), 7 Wk. (9, 21.43%), 6 Mos. (7, 58.33%) |
| Good (N, %) | Preop (0, 0%), 7 Wk. (5, 11.9%), 6 Mos. (1, 8.33%) |
| Fair (N, %) | Preop (0, 0%), 7 Wk. (6, 14.29%), 6 Mos. (1, 8.33%) |
| Poor (N, %) | Preop (52, 100%), 7 Wk. (22, 52.38%), 6 Mos. (3, 25%) |
| Pain Scores | <u>KSS Total Pain/Motion Score (0-100):</u><br>Pre-Op: Mean 33.1, Range 9-56.4, N=52<br>7 Week: Mean 79.88, Range 51-100, N=39<br>6 Month: Mean 82.1, Range 49.4-99.8, N=12<br><br><u>KSS Pain Component Score (0-50):</u><br>Pre-Op Mean 7.12, Range 0-30, N=52<br>7 Week Mean 36.67, Range 10-50, N=42<br>6 Month Mean 37.5, Range 0-50, N=12 |
| **Patient Satisfaction (% satisfied)** | Not applicable to this study |
| Other Scoring Methods (SF-12, 36, QOL, etc.) | Total WOMAC (n, mean)<br>Preop (51, 186) 7 week (39, 96) 6 month (12, 87) |
| **Survivorship (% @ X no. of days)** | 100% at 204 days |
| Using revision surgery for any reason as endpoint | No revision/removal of any component of the total knee system |
| Survivorship related to other endpoint | Define other endpoint and report %:<br>• A Knee Society Pain Score >=70 at 2 years postoperative<br>• A Knee Society Function Score >=70 at 2 years postoperative<br>• Absence of progressive radiolucencies of greater that 3mm in all zones around any implant component at 2 years postoperative<br>• Absence of tibial subsidence/migration of greater than 3mm in all directions at 2 years postoperative<br>No case has reached the 2 year postoperative visit interval |

| **Device Brand Name** | *Scorpio*+ PS Mobile Bearing Knee |
|---|---|
| **Reason for Revision Surgery** | No revision/removal of any component of the total knee system |
| Infection | 0 |
| Deep | 0 |
| Superficial | 0 |
| Aseptic Loosening | 0 |
| of Femur | 0 |
| of Tibia | 0 |
| Implant Subsidence | 0 |
| Polyethylene Wear | 0 |
| Insert Dislocation | 0 |
| Insert Breakage | 0 |
| Insert Subluxation | 0 |
| Osteolysis | 0 |
| Patella Complication | 0 |
| DVT | 0 |
| Other: _____ | 0 |
| **Comments:** | |

## Materials and Methods

The Prosthesis

- **Briefly discuss the theory and design rationale of the mobile-bearing knee**

  Total knee arthroplasty has become a relatively common operation with generally successful results. There still remain some key issues, however, which can affect the outcome of this operation. Two of these issues are wear and damage of the articulating surfaces, and tibial component loosening.

  In recent years, there has been a trend toward more conforming and constrained knee prosthesis designs due to concerns about the survivorship of relatively flat bearing surfaces. Greater conformity between metal and plastic components leads to increased contact area, and is designed to produce lower contact stresses in the polyethylene. However, increased femorotibial conformity in a fixed bearing knee may lead to decreased range of motion, and possible over-constraint, which may increase the stress at the tibial component-bone interface.

  Mobile bearing knee prostheses were developed to address the issues of wear and loosening. Reports that flat, non-congruent designs with reduced contact area provide mobility at the expense of high-contact stress and potential instability have been proposed by many investigators (Bartel, Engh, Keblish, Walker et al). Therefore, congruent contact designs allowing lower contact stresses and providing stability at the expense of increased sheer stress at the bone-prosthetic interface theoretically should maximize long term implant performance and fixation. This can be achieved by combining lower constraint forces with lower contact stresses and allowing nearly normal joint articulation and loading.

  The purpose of introducing this mobile bearing prosthesis is to decrease femorotibial and patello-femoral constraint forces by allowing the polyethylene insert to rotate and/or translate about a fixed tibial axis and tibial tray. The subject device has been designed to maximize contact area between articulating surfaces by maximizing the conformity of the femoral component to the insert and the insert to the tibial tray.

- **How is the device categorized**

  - RP = rotating platform, MP=multidirectional platform, or MB=meniscal bearing.
  - The *Scorpio*+ PS mobile-bearing knee is categorized as RP (rotating platform).

- **Discuss design elements such as: conformity, rotation, constraint, etc.**

  The *Scorpio*+ PS Mobile Bearing tibial tray, 79-10xx-CS, is manufactured from cast CoCr which conforms to ASTM F-75. It features a delta-fit keel (which is also featured on our control trays) and the proximal surface friction is minimized. The subject trays are available in 6 sizes: 3,5,7,9,11, and 13 and have a waffled texture. The rotation axis on the tray is located over the center of the keel. The rotation post retains the insert by means of an all polyethylene locking ring, which limits A/P and M/L movement but allows unlimited internal/external rotation.

The *Scorpio*+ PS tibial insert, 78-3-xxxx-CS, is manufactured from UHMWPE which conforms to ASTM F-648. A chromium alloy X-ray wire is present in the tibial insert. The key features include high conformity and increased contact area such that internal polymer stresses are reduced compared to the fixed bearing PS design. The insert is highly constrained in the A/P plane to prevent rotation with respect to the femoral component but allows unlimited internal/external rotation about the tibial tray. The single M/L radius is retained and its features optimized to enhance contact with the femoral component. The internal/external rotation axis is central. The insert is available in the sizes currently offered for the *Scorpio*+ PS fixed bearing knee (sizes 3,5,7,9,11,13). Sizes 3 through 11 are available in the following thicknesses: 10, 12, 15, 18, and 21 mm. The Size 13 insert is available in the following thicknesses: 12, 15, 18 and 21 mm. The subject inserts have a tapered peripheral geometry to avoid overhang and soft tissue impingement upon internal/external rotation. Each insert has been designed to articulate with the same-sized femoral component. However, size interchangeability is accomplished through various insert-tray combinations.

- **Other design features**

  There are no additional design features.

- **Discuss the indications for use of the device**

  The tibial baseplate and tibial tray are intended for investigational use in primary reconstruction of the distal femur and bearing surface of the tibia, resulting from non-inflammatory joint disease (osteoarthritis, avascular necrosis, and traumatic arthritis).

- **Diagrams/pictures of device**

Study Design

- **Describe the design and methods used for the study**

  This study is a prospective, randomized, single blind multicenter clinical trial to determine the safety and effectiveness of the *Scorpio*+ PS Mobile Bearing Knee. Effectiveness will be determined by comparing the investigational system to the control system using the results of the Knee Society Score (KSS). Safety will be evaluated by comparing the investigational system to the control system for: revision rates, complications potentially related to the implant, radiographic loosening rates and tibial subsidence/migration rates. For each site, assignment will be randomized between the *Scorpio*+ PS Mobile Bearing Knee and the *Osteonics*® *Scorpio* Posteriorly Stabilized Total Knee System.

  If the patient is in need of a second procedure after the first study procedure, then a bilateral case will be also included in the study; contingent upon enrollment still being open. If the additional surgery is needed after the first study case and enrollment has been closed, it will be recorded that the patient is a bilateral and will be included in the correct analysis group. Therefore, staged and simultaneous bilateral cases will be included in this study. The contralateral knee will receive the same treatment as the ipsilateral knee. If a second procedure is enrolled in this study for the same patient, it is still considered a separate case and will be followed for a minimum of two years.

  Prior to enrollment each patient will be screened for eligibility according to the inclusion and exclusion criteria. Upon consent, each patient will understand their right is waived to know which device will be implanted, unless their doctor deems it medically necessary to inform them. All patients eligible for the study who give their informed consent and are randomized will be enrolled.

- **Describe the randomization procedure if applicable**

  A randomization schedule, developed by an independent biostatistician, will be kept and controlled by the Sponsor for each Investigational Site. The Investigators will not have access to the randomization schedule. When the next eligible patient signs the consent form, and meets the inclusion/exclusion criteria, an Investigational Site representative will contact the Sponsor prior to the surgery date and obtain assignment to the next study system on the randomization schedule to be implanted in that particular patient (this will also be confirmed in writing). Each of the Investigational Sites has been randomized independently. Any deviation from the assigned system by the Investigational Sites will be reported as a deviation from Protocol.

  At least 223 patients per study group will be enrolled, comprised of at least 178 unilateral patients with at least 10% of the total being bilateral patients, although the anticipated percentage of bilaterals is 20% as described in the sample size justification below. The randomization will be stratified according to study site and planned unilateral/bilateral patients. Each study site will be assigned 2 randomization lists according to whether the patient plans on having both knees replaced, either during the same surgery or delayed surgeries, or plans on having only one knee replaced. The purpose of stratifying by unilateral/bilateral as well as study site is to insure that the unilateral/ bilateral proportions will be balanced across study arms. An appropriate block size will be selected for each list.

The randomized choice of study arm will be based on patients rather than knee cases. Hence, for a planned bilateral patient the choice of knee system will come from the bilateral list for that study site, and both knees will be replaced using that randomized knee system. The choice of the knee system for a planned unilateral patient will come from the unilateral list for that study site. It may happen that within the 2 year follow-up an original (planned) unilateral patient requires the other knee to be replaced. If this knee satisfies the inclusion/exclusion requirements of the study and the patient provides consent, then the knee system used for the second knee will be the same as for the first knee, and this second knee will become part of the study. If a knee system other than the one for the first knee is used for the second knee, then this knee will not be part of the study. Such a patient will be classified as a bilateral for the 2-year analysis regardless of when the second knee was replaced (and regardless of which system was used for the second knee).

- **Describe blinding procedure if applicable**

  A patient will be identified as a subject in this clinical trial upon signing a study Informed Patient Consent and upon being randomized into the study. The randomization date will be used as the enrollment date for each subject. Subjects will be blinded as to which device he/she receives unless his/her doctor deems it medically necessary for the patient to be told. Should a patient be randomized and withdraw from the study before receiving the study device, the reason for withdrawal will be documented and no further follow-up will be obtained.

- **What was the hypothesis for the study?**

  Total Knee Arthroplasty is the surgical reconstruction of the knee joint in order to relieve pain, restore function and correct deformity. Total Knee Arthroplasty is a successful procedure for reducing pain and restoring function in severely diseased knee joints.

  It is the intention of the sponsor of the IDE application to conduct a clinical evaluation of the *Scorpio*+ PS Mobile Bearing Knee components which will provide scientifically valid data demonstrating the safety and effectiveness of this device when used for the recommended clinical indication. Only cemented primary total knee replacements will be included in this study.

  In order to obtain these data, a multi-center, randomized, single-blind study will be conducted. The performance of the *Scorpio*+ PS Mobile Bearing Knee components will be compared to the performance of the *Osteonics Scorpio* Posteriorly Stabilized Total Knee System components. Both groups will use identical femoral and patellar components. The Investigational components are the tibial tray and the tibial insert. The purpose of the clinical trial will be to show at least equivalence in terms of safety and effectiveness between the two groups.

- **Is the study "complete" or "in progress" and what is progress status?**

  The study is "in progress" and is in the enrollment phase. A total of 62 cases have been enrolled out of the expected 223 investigational device cases. Preoperative data are available for 52 cases and surgical details are available for 45 cases. Forty-one cases have returned for their 7 week postoperative follow-up and 12 cases have been seen at 6 months.

- **Selection Criteria**

  Inclusion Criteria:

  1. Patient is a male or non-pregnant female between the ages of 21-80.
  2. Patient requires cemented primary total knee replacement.
  3. Patient has a diagnosis of osteoarthritis (OA), traumatic arthritis (TA) or avascular necrosis (AVN).
  4. Patient has intact collateral ligaments.
  5. Patient has signed and dated an IRB approved study specific consent form.
  6. Patients is able and willing to participate in the study according to the protocol for the full length of the expected term of follow-up, and to follow their physician's directions.
  7. Patient has failed to respond to conservative treatment modalities.
  8. Patient has a preoperative Knee Society Pain Score of less than 60.
  9. Patient has a preoperative Knee Society Function Score of less than 60.

  Exclusion Criteria:

  1. Patient has had a prior procedure of high tibial osteotomy, cruciate ligament reconstruction or patellectomy of the surgical knee.
  2. Patient is morbidly obese, >60% over ideal body weight for frame and height (From Metropolitan height and weight tables (1983)).
  3. Patient has a deformity at the involved knee greater than 45 degrees of flexion, 45 degrees of varus or 45 degrees of valgus.
  4. Patient has an active or suspected latent infection in or about the knee joint.
  5. Patient has a malignancy in the area of the involved knee joint.
  6. Patient has a diagnosed systemic disease that would affect the subject's welfare or overall outcome of the study (i.e. moderate to severe osteoporosis, Paget's disease, renal osteodystrophy) or is immunologically suppressed, or receiving steroids in excess of physiologic dose requirements.
  7. Patient has a neurological deficit which interferes with the patient's ability to limit weightbearing or places an extreme load on the implant during the healing period.
  8. Female patient is or plans to become pregnant during the course of the study.
  9. Patient has a known sensitivity to device materials.
  10. Patient is a prisoner.
  11. Patient's bone stock is compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis.
  12. Patient has a TKA on the contralateral side less than six months post-op.

Follow-up Evaluation

- Patients were monitored clinically and radiographically and had preoperative and follow-up ratings obtained using the Knee Society questionnaire.

- The follow-up intervals for the study are at 7 weeks (+/- 2 weeks), 6 months (+/- 1 month), 12 months (+/- 2 months), 24 months (+/- 2 months), and biennially thereafter until the last patient reaches two years post-op. The average final follow-up interval was 84 days (12 - 204 days).

Study compliance statistics

Performance Table for *Scorpio*+ PS MBK Investigational Cases

| Evaluation Period | Theoretical Follow-up | Dropout | Death | Revision Removal | Expected Follow-up | Actual Follow-up | Actual Follow-up Percent |
|---|---|---|---|---|---|---|---|
| Pre-Op | 62 | 0 | 0 | 0 | 62 | 52 | 83.8 % |
| 7 Week | 51 | 0 | 0 | 0 | 51 | 41 | 80.3 % |
| 6 Months | 16 | 0 | 0 | 0 | 16 | 12 | 75.0 % |

Radiographic Assessment

All patients are examined radiographically at the preoperative visit (up to 4 months before surgery) and postoperatively at 7 weeks (+/- 2 weeks), 6 months (+/- 1 month), 12 months (+/- 2 months), 24 months (+/- 2 months), and biennially thereafter until the last patient reaches two years post-op.

The suggested radiograph technique includes general requirements and a description of each type of view captured.

General Requirements:

- The film-to-tube distance is 40" (102 cm.).
- At least a 14" x 17" sized film should be used for anteroposterior and lateral films.
- At least 8" x 10" sized film should be used for merchant view films.
- Merchant view should contain only the operative knee.

Types:

Anteroposterior - Standing Weight Bearing

- The patient should be standing with their knee fully extended and their foot pointing directly forward.
- The film cassette should be placed directly behind the patient at the level of the patient's knee and parallel to their frontal plane.
- The x-ray beam is directed perpendicular to the joint line and is aligned with the middle of the shaft in the AP plane.
- The following must be included in the x-ray: the entire knee joint, at least 15 cm (~6 in) of the femur superior to the joint line and at least 15 cm (~6 in) of tibia inferior to the joint line.

Lateral - Standing Lateral

- The patient should be standing with their knee fully extended and their foot pointing directly forward.
- The film cassette should be placed directly adjacent to the medial aspect of the knee, perpendicular to the patient's frontal plane.
- The x-ray beam is directed perpendicular to the film cassette, pointing at the lateral portion of the joint line and aligned with the middle of the shaft in the lateral plane.

- The following must be included in this x-ray: the entire knee joint, at least 15cm (~6 in) of the femur superior to the joint line and at least 15 cm (~6 in) of the tibia inferior to the joint line.

Lateral - Cross Table Lateral

- The patient should be supine (face up) with their sacrum flat against the table. The patient's affected leg should be fully extended with their foot pointing toward the ceiling.
- The film cassette should be placed directly adjacent to the medial aspect of the knee, perpendicular to the frontal plane of the patient.
- The x-ray beam is directed perpendicular to the film cassette, centered at the knee joint and aligned with the middle of the shaft in the lateral plane.
- The following must be included in the x-ray: the entire knee joint, at least 15cm (~6 in) of the femur superior to the joint line and at least 15cm (~6 in) of the tibia inferior to the joint line.

Merchant

- Patient is placed in supine position.
- Knee is flexed at 45° at the table edge.
- A device is used to keep the knee in position.
- The central beam is directed caudally through the patella at a 60° angle from the vertical.

The following were recorded at the follow-up examination:

Radiolucency, osteopenia (for all three components) and condensation (femoral, tibial component), tibial subsidence/migration, patellar problems, patellar position, patellar height and tibial coverage. The radiographic measurements are a modification of the standards set forth by the Knee Society.

**Results**

The Patients

Of the 62 enrolled cases, patient data are available for 52 cases.

- Between November 19, 2001 and September 27, 2002, 52 primary cemented total knee arthroplasties with the *Scorpio*+ PS Mobile Bearing Knee were implanted in 38 patients.
- At 7 weeks to 6 months following the procedure, 38 patients (52 knees) were alive, 0 patients (0 knees) had died, and 0 patients (0 knees) had been lost to follow-up.
- 24 patients (32 knees) were female, and 14 patients (20 knees) were male.

- The average age of the patients at the time of surgery was 63.1 (range, 47 to 79 years).
- The pre-operative diagnosis was osteoarthritis in 51 knees and post-traumatic arthritis in 1 knee.

Outcomes

With only 41 cases seen at 7 weeks postoperative and 12 cases seen at 6 months postoperative, it is too early to discuss study results. Data tables have been provided and any noteworthy mean scores will be stated in their respective section.

- **Discuss and provide values for the effectiveness of the device using the Knee Society questionnaire**

  The mean pain/motion score and function score at 6 months postoperative are 82.1 and 80.83 respectively. Although only 12 cases have returned at 6 months, the mean scores are >= 70 and show an increase in comparison to the preoperative mean scores.

**KSS Total Pain/Motion Score (0-100)**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 33.1 | 9 - 56.4 | 11.82 | 52 |
| 7 Week | 79.88 | 51 - 100 | 15.27 | 39 |
| 6 Months | 82.1 | 49.4 - 99.8 | 14.9 | 12 |

**KSS Total Function Score (0-100)**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 44.23 | 15-55 | 9.04 | 52 |
| 7 Week | 60.48 | 5-100 | 23.47 | 42 |
| 6 Months | 80.83 | 45-100 | 23.34 | 12 |

- **Discuss and provide values for the pre and post ROM (extension and flexion) results of the study**

  Preoperatively the range of motion mean scores were 102.8° actively and 106° passively. Although only 12 cases have been seen at 6 months, the mean active range of motion increased to 120.6° and the mean passive range of motion increased to 124.5°.

**KSS Range of Motion Score (0-25)**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 20.54 | 14-25 | 2.67 | 52 |
| 7 Week | 21.35 | 12-25 | 3.27 | 42 |
| 6 Months | 23.52 | 20-25 | 1.73 | 12 |

**KSS Active Range of Motion**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 102.8 | 70-130 | 13.5 | 52 |
| 7 Week | 107.5 | 60-143 | 17.5 | 42 |
| 6 Months | 120.6 | 100-143 | 12.6 | 12 |

**KSS Passive Range of Motion**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 106 | 75-130 | 13.7 | 52 |
| 7 Week | 112.2 | 65-143 | 15.8 | 42 |
| 6 Months | 124.5 | 105-150 | 14.1 | 12 |

**Active Flexion**

| Evaluation Period | Mean | Range | N |
|---|---|---|---|
| Pre-Op | 107 | 85-140 | 52 |
| 7 Week | 109.9 | 60-143 | 42 |
| 6 Months | 124 | 100-148 | 12 |

**Passive Flexion**

| Evaluation Period | Mean | Range | N |
|---|---|---|---|
| Pre-Op | 109.3 | 85-140 | 52 |
| 7 Week | 113.2 | 65-143 | 42 |
| 6 Months | 127.5 | 110-155 | 12 |

- **Discuss and provide values for the patient's final follow-up relief of symptoms (pain, limp, stairs, walking distance, etc.)**

The Knee Society mean pain, stairs and walking scores are presented below. Although only 12 cases are reported at 6 months, the mean scores increased compared to the preoperative means. The mean pain score increased from 7.12 preoperatively to 37.5 at 6 months. The mean stairs score increased from 27.79 preoperatively to 40.83 at 6 months.

The mean walking score increased from 19.42 preoperatively to 41.67 at 6 months.

**KSS Pain Score (0-50)**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 7.12 | 0-30 | 8.25 | 52 |
| 7 Week | 36.67 | 10-50 | 12.28 | 42 |
| 6 Months | 37.5 | 0-50 | 15.74 | 12 |

**KSS Stairs Score (0-50)**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 27.79 | 0-40 | 7.5 | 52 |
| 7 Week | 35.24 | 0-50 | 10.18 | 42 |
| 6 Months | 40.83 | 30-50 | 9.96 | 12 |

**KSS Walking Score (0-50)**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 19.42 | 10-30 | 3.66 | 52 |
| 7 Week | 30.95 | 10-50 | 10.78 | 42 |
| 6 Months | 41.67 | 20-50 | 12.67 | 12 |

- **Discuss and provide values for patient satisfaction results if applicable**

Although the SF-12 results are not noteworthy, the WOMAC mean scores for the 12 reported cases decreased at 6 months versus the preoperative means. The mean pain score decreased from 56.84 preoperatively to 26.1 at 6 months. The mean stiffness score decreased from 67.54 preoperatively to 31.88 at 6 months. The mean physical score decreased from 61.65 preoperatively to 29.5 at 6 months. The mean total score decreased from 186.03 preoperatively to 87.48 at 6 months.

**Summary Analysis of SF-12 Physical Component Score**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 27.8 | 17.67-40.84 | 5.28 | 51 |
| 7 Week | 35.99 | 18.83-51.04 | 9.28 | 37 |
| 6 Months | 37.78 | 19.26-58.07 | 11.6 | 12 |

**Summary Analysis of SF-12 Mental Component Score**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 50.8 | 35.37-68.66 | 11.21 | 51 |
| 7 Week | 53.99 | 34.45-65 | 8.55 | 37 |
| 6 Months | 50.23 | 35.47-63.98 | 10.04 | 12 |

**WOMAC Pain Mean Score**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 56.84 | 10.8-97.2 | 20.15 | 51 |
| 7 Week | 27.03 | 2.2-75.6 | 19.44 | 41 |
| 6 Months | 26.10 | 2.2-83.4 | 22.29 | 12 |

**WOMAC Stiffness Mean Score**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 67.54 | 7.5-98 | 19.55 | 51 |
| 7 Week | 36.95 | 2-85 | 23.63 | 41 |
| 6 Months | 31.88 | 2-89.5 | 30.97 | 12 |

**WOMAC Physical Mean Score**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 61.65 | 22.12-98 | 15.75 | 51 |
| 7 Week | 29.22 | 0.65-68.12 | 20.04 | 39 |
| 6 Months | 29.5 | 2.47-83.12 | 24.18 | 12 |

**Total WOMAC Score**

| Evaluation Period | Mean | Range | Std. Dev. | N |
|---|---|---|---|---|
| Pre-Op | 186.03 | 50.35-292.2 | 45.99 | 51 |
| 7 Week | 96.04 | 7.05-228.12 | 58.28 | 39 |
| 6 Months | 87.48 | 6.67-256.02 | 73.98 | 12 |

- **Discuss and provide values for the survival analysis results if applicable**

  Not applicable because there has been no revision/removal of any component of the total knee system and no case has reached the 2-year postoperative visit interval.

- **What survival analysis method was used?**

  Not applicable because there has been no revision/removal of any component of the total knee system and no case has reached the 2-year postoperative visit interval.

- **How is failure defined?**

  Failure to achieve each of the following will constitute an individual patient failure:

  - No revision/removal of any component of the total knee system.
  - A Knee Society Pain Score >=70 at 2 years postoperative;
  - A Knee Society Function Score >=70 at 2 years postoperative;
  - Absence of progressive radiolucencies of greater that 3mm in all zones around any implant component at 2 years postoperative;
  - Absence of tibial subsidence/migration of greater than 3mm in all directions at 2 years postoperative.
  - Failure to achieve each of the following will constitute study failure:
  - Percent of subjects meeting all individual success criteria is no worse for the *Scorpio*+ PS Mobile Bearing Knee System than for the Osteonics *Scorpio* PS Knee.
  - Complication rates are no greater for the *Scorpio*+ PS Mobile Bearing Knee System than for the Osteonics *Scorpio* PS Knee.
  - Survival of the prosthesis at 204 days was 100%.

Radiographic Appearances

- **List (N and %) and discuss any component that appeared radiographically loose**

  No component (0%) appeared radiographically loose.

- **Discuss the presence of radiolucent lines greater than 2 mm thick around any of the components**

  There is no presence of radiolucent lines greater than 2mm thick around any of the components.

Complications

| Complication | N | Time of Occurrence |
|---|---|---|
| Any fracture | 0 | |
| Femoral component loosening | 0 | |
| Tibial component loosening | 0 | |
| Patellar component loosening | 0 | |
| Bearing dislocation | 0 | |
| Bearing subluxation | 0 | |
| Mobile bearing wear | 0 | |
| Patellar bearing wear | 0 | |
| Ligamentous instability | 0 | |
| Deep infection | 0 | |
| Fibroarthrosis | 0 | |
| Other: Superficial Wound Infection | 1 (1.61%) | 2.14 weeks |
| Other: Wound Hematoma | 1 (1.61%) | 5.14 weeks |
| Other: Wound Related | 2 (3.23%) | 0.43 weeks/1.29 weeks |

| Complication | N | Time of Occurrence |
|---|---|---|
| Other: Inadequate ROM Post-Op | 1 (1.61%) | 7.86 weeks |
| Other: Tendonitis Lower Extremity | 1 (1.61%) | 22.86 weeks |
| Other: Avulsion Medial Epicondyle | 1 (1.61%) | 0 weeks |
| Other: Partial Disruption of Infrapatellar Ligament | 1 (1.61%) | 0 weeks |

- **Discuss overall complication rate**

  A total of 8 operative site complications have occurred yielding an overall operative site complication rate of 12.9%. Percent is based on total number of operative site complications divided by the total number of cases enrolled in the study (N=62).

  A total of 7 systemic complications have occurred yielding an overall systemic complication rate of 15.2%. Percent is based on total number of systemic complications divided by the total number of patients enrolled in the study (N=46).

- **Discuss overall revision rate**

  No cases have been revised yielding an overall revision rate of 0%.

**Conclusions**

With only 41 cases seen at 7 weeks postoperative and 12 cases seen at 6 months postoperative, it is too early to discuss study results and provide summary statements.

## 6. Zimmer *MBK* Mobile Bearing Knee

| **Device Brand Name** | *MBK*® Mobile Bearing Knee | |
|---|---|---|
| **Bearing Type** | MP= multidirectional platform | |
| **Total N** | 179 (81 female, 92 male, 6 unknown) | |
| Cement N | 179 | |
| Uncemented N | 0 | |
| Hybrid N | 0 | |
| **Average Follow-Up (yrs, range)** | Enrollment discontinued, patient follow-up continuing: 100% at 6 weeks, 100% at 6 months, 98% at 1 year, and 69% at 2 years | |
| **Demographics** | | |
| Average age (yrs, range) | M 65.5 | F 64.6 |
| Average weight (lbs, range) | M 206.1 | F 174.0 |
| Sex (N, %) | M 92 (51.4) | F 81 (45.3) |
| Pre-operative diagnosis (N, %) | OA =168 (94) RA =3 (2) PTA =5 (3) Other =2 (1) | |
| **Effectiveness (HSS)** | **1 Year** | **2 Year** |
| Excellent (N, %) (85-100) | 107 (73.8%) | 46 (70.8%) |
| Good (N, %) (70-84) | 23 (15.9%) | 12 (18.5%) |
| Fair (N, %) (60-69) | 8 ( 5.5%) | 5 ( 7.7%) |
| Poor (N, %) (≤ 59) | 7 ( 4.8%) | 2 ( 3.1%) |
| Pain Scores (% with no pain) | 58.7% | 65.3% |
| **SF-12** (Physical Health) | 47.9 | 48.6 |
| (Mental Health) | 56.1 | 55.9 |
| **Survivorship (% @ X no. of years)** | N/A | |
| Using revision surgery for any reason as endpoint | | |
| Revision rate | 3/179= 1.7% | |
| **Reason for Revision Surgery** | | |
| Infection | | |
| Deep | 1 | |
| Superficial | | |
| Aseptic Loosening | | |
| of Femur | | |
| of Tibia | | |
| Implant Subsidence | | |
| Polyethylene Wear | | |
| Insert Dislocation | | |
| Insert Breakage | | |
| Insert Subluxation | | |
| Osteolysis | | |
| Patella Complication | | |
| DVT | | |
| Other: Pain | 1 | |
| PCL insufficiency poly exchange | 1 | |
| **Comments:** | These results are from the 4th annual report submitted to the FDA in support of the IDE registered by Zimmer Inc. | |

**Materials And Methods**

The Prosthesis

- **Briefly discuss the theory and design rationale of the mobile-bearing knee**

  The Mobile Bearing Knee (*MBK*) design goals were four-fold:

  - Reduction of polyethylene wear
  - Improved kinematic function
  - Increased patient proprioception
  - Compatible with all NexGen instrumentation

- **How is the device categorized**

  The *MBK* design would be classified as having a multidirectional platform.

- **Discuss design elements such as: conformity, rotation, constraint, etc.**

  - Wear

    1. Wide femoral condyles with radii matched to corresponding tibial articular surfaces achieve a one-to-one ratio of conformity in both the frontal and sagittal planes throughout the full range of motion, thereby maximizing contact area and reducing contact stresses to below the yield strength of polyethylene.
    2. The highly polished tibial base plate is designed to reduce the coefficient of friction with the articular surface.
    3. Femoral "dimple" provides maximum contact area of the articular surface component.
    4. Articular surface and patellar components are machined from compression molded UHMWPE which is extensively tested and packaged in a nitrogen environment.
    5. Extended patellar groove is designed to provide full patella contact in high load areas up to 85 degrees of flexion, thus maximizing contact area and reducing contact stresses on the patella.
    6. Constant radii of curvature on the distal and posterior condyles provides full contact during the full range of knee motion.

  - Kinematics

    1. The femoral anterior chamfer has a trochlear recess to provide a deep patella groove. This is designed to decrease compressive forces on the patella, improve tracking, and provide a smooth transition from flexion to extension.
    2. Unique articular surface "saddle" design provides enhanced stability through the full range of motion. The medial wall is radiused to match the femoral component and maintains full contact in up to 10 degrees of lateral lift-off. The lateral wall prevents medial translation of the femur.
    3. Articular surface components in left and right configurations are kinematically matched to femoral components. Tibio-femoral interchangeability is achieved with no compromise in the tibio-femoral contact area.

4. Anterior rail on tibial base plate provides resistance to posterior subluxation, and enhanced stability in full extension, and permits 53 degrees of rotational freedom of the articular surface on the plate.
5. Reduced width and thickness of the anterior femoral flange is designed to relieve tension on the extensor mechanism. Theoretically, this reduced tension will provide for more normal motion and fewer lateral retinacular releases.
6. An extensive offering of up to six articular surface thicknesses enables the surgeon to balance joint tension and stability.
7. Rotational freedom plus 4.5mm of anteroposterior translation permit natural rollback and axial rotational movement of the femur on the tibia during the full range of motion.
8. *MBK* Femoral Components are designed to accept an unresurfaced patella.

- Materials/Design

1. Snap fit capture of the articulating surface onto the tibial tray D-shaped mushroom provides secure attachment and prevents dislocation.
2. Tibial articular surfaces are front loading for surgical ease.
3. NexGen Patella Components are utilized and are available in six diameters to optimize implant-to-bone fit.

- Fixation

1. The eight symmetrical perimeter profiles of the base plates are designed to optimize coverage of the proximal tibia and minimize the potential for tibial subsidence. Available in PMMA and non-coated surfaces and manufactured from Zimaloy Cobalt-Chromium-Molybdenum Alloy for increased stiffness.
2. Multiple instrumentation options are available.

- **Discuss the indications for use of the device**

The device is intended to reduce or relieve pain and restore function and motion to the knee joint. As with total knee replacement, this device is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. The device is intended for cement use only.

- **Diagrams/picture of the device**

Study Design

- **Describe the design and methods used for the study**

  The trial is an open multicenter study with a non-randomized concurrent control group drawn from an existing study of the NexGen Knee. The planned enrollment is for unilateral osteoarthritis cases to be enrolled into the study for the primary analysis of safety and efficacy. Patients with rheumatoid arthritis can be included subject to meeting all inclusion/exclusion criteria. Data on pain, function, deformity, radiographic parameters, and complications will be tracked on all investigational devices. Follow-up exams will be made at 6 weeks, 6 months, 12 months, and 24 months after surgery to include both functionality and radiographic evaluations. At two-year intervals thereafter, patients will be evaluated until the last patient enrolled reaches the two-year interval. 10 to 15 sites will participate with each site enrolled 15-40 patients each. The enrollment period will be 12 months or longer to assure an adequate number of cases at each site.

- **Describe the randomization procedure if applicable**

  Not applicable

- **Describe the blinding procedure if applicable**

  Not applicable

- **What was the hypothesis for the study**

  The *MBK* will be considered successful if the results are no worse than the results obtained in the control group or literature findings.

- **Is the study "complete" or "in progress" and what is progress status?**

  Currently, 179 patients have been enrolled. Enrollment is complete: 100% at 6 weeks, 100% at 6 months, 98% at 1 year, and 69% at 2 years.

- **Please insert any special materials and methods you used in this section**

  None

- **Selection Criteria**

  Patient Inclusion Criteria

  1. Age 21 to 80 years
  2. Male or female, no selection on gender
  3. Patients must weigh less than 250 pounds at the time of enrollment
  4. Degenerative joint disease including: OA, RA, polyarthritis, collagen disorders, AVN of the femoral condyle or pseudogout, varus, valgus or flexion deformities
  5. Patient exhibits Knee Society knee and function scores of < 60.
  6. Patient presents with unilateral disease suggesting that a knee implant on the contralateral side will not be required during the course of the study.
  7. Patient exhibits preoperative radiographic evidence of joint degeneration consistent with TKA.
  8. Patient is willing and able to cooperate in follow-up therapy.
  9. Patient is in stable health based upon physical exam and medical history.

  Patient Exclusion Criteria

  1. Patient has previous history of infection in the affected joint
  2. Patient has previous failed knee endoprosthesis of any kind
  3. Patients with either a contralateral knee implant or those with bilateral disease suggesting that a contralateral knee implant will be required during the course of the study
  4. Patients with Charcot disease or other severe neurosensory deficits
  5. Patients with previous patellectomy of the affected knee
  6. Skeletally immature individuals
  7. Patients with grossly insufficient femoral and/or tibial bone stock or previous surgery to the index joint that could affect outcome, including but not limited to high tibial osteotomy
  8. Patients with loss of musculature or absence of musculoligamentous supporting structures required for appropriate soft tissue balance
  9. Patient is pregnant
  10. Varus or valgus deformity > 20 degrees
  11. Fixed flexion deformity > 15 degrees
  12. Previous high tibial osteotomy

13. Previous femoral osteotomy
14. Patient is a poor compliance risk

- **Follow-Up Evaluation**

  Patients were monitored clinically and radiographically and had preoperative, intraoperative, and follow-up ratings obtained using the Hospital for Special Surgery score and the Knee Society score questionnaires.

  Preoperative, Immediate post-op, 6 weeks post-op, 6 months post-op, 12 months post-op, 24 months post-op. Some will be followed at 48 months post-op.

  Because the study is in progress, final follow-up interval is unavailable at this time.

- **Study compliance statistics**

| | 6 Weeks | 6 Months | 1 Year | 2 Year |
|---|---|---|---|---|
| Theoretical Follow-up | 179 | 179 | 179 | 179 |
| Cumulative Deaths | 0 | 0 | 1 | 0 |
| Cumulative Revisions | 0 | 2 | 0 | 1 |
| Not Yet at Interval | 0 | 0 | 3 | 54 |
| Expected Follow-up | 179 | 177 | 176 | 124 |
| Missed Visits | 2 | 15 | 23 | 59 |
| Lost to Follow-up | 0 | 0 | 0 | 2 |
| Withdrawals | 0 | 0 | 0 | 0 |
| Total Patient Evaluations Processed | 177 | 162 | 153 | 63 |
| Follow-up Compliance % | 98.9% | 91.5 | 86.9 | 50.8 |

Radiographic Assessment

All patients were examined radiographically at the following intervals: preoperatively, immediate post-op, 6 weeks post-op, 6 months post-op, 1 year post-op, and 2 year post-op.

Briefly describe the radiographic method used to capture image of knee (Views)

Anteroposterior and lateral X-rays will be used to detect changes in the position of the *MBK* prosthesis. Other changes including lucency at the prosthesis/bone interface, subsidence, and bone remodelling will be identified by the clinical study investigator and characterized according to location in any of the radiographic zones on the Significant Radiographic Findings forms. The primary radiographic analysis will be based on an expert review performed by an independent reviewer at completion of the study.

Radiographic endpoints

Statistics based on radiographic data are not available at this interim interval.

**Results**

The Patients

- Thirteen institutions were selected for participation in the study. All institutions have secured IRB approval, and inventory has been shipped to and returned from every site. Zimmer has received verbal notification that 181 patients have been enrolled at twelve of those sites. However, not all case report forms have been received from the investigators and entered into the database. The first study patient was enrolled on August 5, 1999.
- 81 patients are female, and 92 patients are male. 6 are unknown.
- The average age of the patients at the time of surgery was 65.1 years.
- The pre-operative diagnosis was osteoarthritis in 94.4% of patients, rheumatoid arthritis in 1.7% of patients and post-traumatic arthritis in 2.8% of patients. Another 0.6% had avascular necrosis and 0.6% osteonecrosis.

Outcomes

- **Health status questionnaire results (KSS, and HSS)**

Summary Of Knee Society Clinical Rating Scores (KSS)

| | **Knee Assessment Score (0-100)** | | | **Function Score (0-100)** | | | **Total Score (0-200)** | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | Mean | Std. Dev. | n | Mean | Std. Dev. | n | Mean | Std. Dev. |
| Preoperative | 171 | 36.0 | 14.2 | 176 | 53.3 | 16.5 | 176 | 88.3 | 24.3 |
| 6 Weeks | 173 | 76.7 | 17.6 | 176 | 59.7 | 21.7 | 176 | 135.1 | 33.0 |
| 6 Months | 163 | 85.1 | 12.1 | 164 | 80.7 | 18.9 | 164 | 165.3 | 26.0 |
| 1 Year | 145 | 87.5 | 12.4 | 149 | 83.8 | 17.0 | 149 | 169.0 | 28.1 |
| 2 Year | 65 | 87.7 | 12.4 | 71 | 85.3 | 19.2 | 71 | 165.6 | 35.5 |

Summary Of Hospital For Special Surgery (HSS) Scores

| | n | Mean | Std. Dev. | Minimum | Maximum |
|---|---|---|---|---|---|
| Preoperative | 172 | 61.5 | 8.5 | 39.4 | 81.0 |
| 6 Weeks | 176 | 74.1 | 11.2 | 28.9 | 96.0 |
| 6 Months | 164 | 84.8 | 8.4 | 58.8 | 98.3 |
| 1 Year | 145 | 87.6 | 7.5 | 65.2 | 97.9 |
| 2 Year | 70 | 88.6 | 8.1 | 65.2 | 98.7 |

- **ROM (extension and flexion) results of the study**

Summary Of Flexion And Extension

| | Flexion | | | | | Extension | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Preop | 6 Weeks | 6 Months | 1 Year | 2 Year | Preop | 6 Weeks | 6 Months | 1 Year | 2 Year |
| Mean | 110.5 | 104.7 | 112.9 | 115.1 | 115.0 | 4.7 | 3.7 | 1.0 | 0.5 | 0.3 |
| Std. Dev. | 14.1 | 13.3 | 11.0 | 11.0 | 11.6 | 5.4 | 5.2 | 2.9 | 2.0 | 1.3 |
| Minimum | 70.0 | 60.0 | 85.0 | 85.0 | 92.0 | -5.0 | -10.0 | 0.0 | -5.0 | 0.0 |
| Maximum | 145.0 | 140.0 | 140.0 | 145.0 | 137.0 | 30.0 | 25.0 | 20.0 | 15.0 | 10.0 |
| N | 175 | 177 | 165 | 151 | 72 | 175 | 177 | 165 | 151 | 72 |

- **Values for the patient's final follow-up relief of symptoms (pain, limp, stairs, walking distance, etc.)**

Summary Of Knee Pain (Assessment/HSS Item)

| Knee Pain | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | | 2 Year | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| None | 1 | 0.6 | 54 | 30.0 | 82 | 51.2 | 93 | 62.0 | 54 | 75.0 |
| Mild/Occasional | 4 | 2.3 | 68 | 39.4 | 45 | 26.0 | 32 | 21.3 | 6 | 8.2 |
| Mild/Stairs Only | 1 | 0.6 | 4 | 1.3 | 14 | 7.9 | 4 | 2.7 | 1 | 1.4 |
| Mild/Stairs and level walking | 8 | 4.5 | 12 | 6.9 | 7 | 4.7 | 8 | 5.3 | 3 | 4.2 |
| Moderate/Pain comes and goes | 27 | 15.3 | 20 | 11.3 | 9 | 5.5 | 6 | 4.0 | 4 | 5.6 |
| Moderate/Pain each day | 94 | 53.4 | 17 | 10.5 | 7 | 4.7 | 7 | 4.7 | 4 | 5.6 |
| Severe/constant | 41 | 23.3 | 1 | 0.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| TOTAL | 176 | 100 | 176 | 100 | 164 | 100 | 150 | 100 | 72 | 100 |

Summary Of Stairs Capability (Function Item)

| Stairs | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | | 2 Year | |
|---|---|---|---|---|---|---|---|---|---|---|
| | N | % | n | % | n | % | n | % | n | % |
| Normally (one foot on each step) | 10 | 5.7 | 28 | 15.9 | 71 | 43.3 | 73 | 48.6 | 40 | 55.5 |
| Normally but require rail when going down | 12 | 6.8 | 29 | 16.5 | 24 | 14.6 | 22 | 14.7 | 6 | 8.3 |
| Normally but require rail when going up | 4 | 2.3 | 7 | 4.0 | 8 | 4.9 | 6 | 4.0 | 4 | 5.6 |
| Require rail while going up & down | 143 | 81.3 | 106 | 60.2 | 58 | 35.4 | 49 | 32.7 | 21 | 29.2 |
| Up by rail but unable to go down | 5 | 2.8 | 1 | 0.6 | 2 | 1.2 | 0 | 0 | 0 | 0 |
| Unable to go up and down | 2 | 1.1 | 5 | 2.8 | 1 | 0.6 | 0 | 0 | 1 | 1.4 |
| TOTAL | 176 | 100 | 176 | 100 | 164 | 100 | 150 | 100 | 72 | 100 |

Summary Of Walking Capability With Support (Function Item)

| Walking With Support | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | | 2 Year | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Walk Without any support | 122 | 69.3 | 86 | 48.9 | 142 | 86.5 | 134 | 89.4 | 66 | 91.6 |
| Use one cane on a long walk | 24 | 13.6 | 43 | 24.4 | 16 | 9.8 | 11 | 7.3 | 4 | 5.6 |
| Use one cane most of the time | 29 | 16.5 | 27 | 15.3 | 6 | 3.7 | 5 | 3.3 | 1 | 1.4 |
| Use one crutch | 0 | 0 | 4 | 2.3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Use two canes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Use two crutches | 1 | 0.6 | 2 | 1.1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Use a walker | 0 | 0 | 14 | 8.0 | 0 | 0 | 0 | 0 | 1 | 1.4 |
| Unable to walk | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 176 | 100 | 176 | 100 | 164 | 100 | 150 | 100 | 72 | 100 |

Summary Of Distance Walking Capability (Function Item)

| Distance Walked | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | | 2 Year | |
|---|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | n | % |
| Unlimited | 19 | 10.8 | 30 | 17.0 | 90 | 54.9 | 93 | 62.0 | 50 | 69.5 |
| More than 10 blocks | 5 | 2.8 | 25 | 14.2 | 24 | 14.6 | 19 | 12.7 | 8 | 11.1 |
| 5-10 blocks | 35 | 19.9 | 45 | 25.6 | 30 | 18.3 | 26 | 17.3 | 8 | 11.1 |
| < 5 blocks | 78 | 44.3 | 58 | 33.0 | 18 | 11.0 | 11 | 7.3 | 5 | 6.9 |
| Short Distance | 39 | 22.2 | 18 | 10.2 | 2 | 1.2 | 1 | 0.7 | 1 | 1.4 |
| Wheelchair or bed | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **TOTAL** | 176 | 100 | 176 | 100 | 164 | 100 | 150 | 100 | 72 | 100 |

- **Patient satisfaction results (SF-12)**

Summary Of SF-12 Questionnaire Scores

| SF-12 SCORE | | Preoperative | 6 Weeks | 6 Months | 1 Year | 2 Year |
|---|---|---|---|---|---|---|
| Physical Health | Mean | 36.1 | 40.3 | 48.0 | 47.9 | 48.6 |
| | Std. Dev. | 8.7 | 10.2 | 8.8 | 9.1 | 8.3 |
| | Min | 20.6 | 19.4 | 22.2 | 20.4 | 26.1 |
| | Max | 56.6 | 58.4 | 59.8 | 59.4 | 62.9 |
| | N | 174 | 175 | 161 | 150 | 70 |
| Mental Health | Mean | 53.9 | 54.5 | 56.2 | 56.1 | 55.9 |
| | Std. Dev. | 11.2 | 9.5 | 7.5 | 6.5 | 6.9 |
| | Min | 17.1 | 19.8 | 18.3 | 28.8 | 30.4 |
| | Max | 72.0 | 69.0 | 67.2 | 67.3 | 65.0 |
| | N | 174 | 175 | 161 | 150 | 70 |

- **Survival analysis results**

  Not applicable.

- **Radiographic Appearances**

  Not available.

Complications

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Any fracture | 0 | |
| Femoral component loosening | 0 | |
| Tibial component loosening | 0 | |
| Patellar component loosening | 0 | |
| Bearing dislocation | 0 | |
| Bearing subluxation | 0 | |
| Mobile bearing wear | 0 | |
| Patellar bearing wear | 0 | |
| Ligamentous instability | 0 | |
| Deep infection | 0 | |
| Fibroarthrosis | 0 | |
| Other: Device clicking | 10 (5.4%) | 2 (3 mos), 1 (4 mos), 2 (6 mos), 2 (7 mos), 1 (16 mos), 1 (25 mo) and 1 (29 mos) |
| Other: Knee Pain | 9 (4.9%) | 1 (2 mos), 1 (5 mos), 1 (6 mos), 1 (7 mos), 1 (10 mos), 1 (12 mos), 1 (13 mos), 1 (20 mos) and 22 (mos) |
| Other: Stiff/tight knee | 6 (3.2%) | 4 (1 mos) and 2 (12 mos) |
| Other: Bursitis | 2 (1.1%) | 1 (22 mos) and 1 (15 mos) |
| Other: Hetrotopic ossification | 1 (0.5%) | 3 mos. |
| Other: Quad pain | 1 (0.5%) | 3 mos. |
| Other: Synovitis | 1 (0.5%) | 15 mos. |
| Other: Flexion contracture | 1 (0.5%) | 18 mos. |

- **Discuss overall complication rate**

  One hundred eighty five (185) complications/adverse events have been reported in patients receiving the *MBK* mobile bearing knee and are categorized as device related (16.6%) or general/systemic (83.2%).

- **Discuss overall revision rate**

  Two complete revisions and one articular surface revision have occurred to date. The complete revisions were due to one deep infection and one painful knee. The articular surface revision is due to a PCL insufficiency S/P injury. 3/179 revisions were reported for a 1.7 % overall revision rate.

**Conclusions**

The *MBK* mobile bearing knee study is currently in progress. The purpose of the study is to find the *MBK* mobile bearing knee to be equivalent to non-mobile NexGen total knees. Participating investigators are sent a copy of the annual report to keep them abreast of the most current data results on all collected data. Interim reports are provided as requested and as needed.

## 7. Zimmer LPS-Flex Mobile Bearing Knee

| **Device Brand Name** | LPS-Flex Mobile Bearing Knee | |
|---|---|---|
| **Bearing Type** | RP= rotational platform | |
| **Total N** | 62 controls (32 female, 32 male)<br>61 mobiles (24 female, 37 male) | |
| Cement N | 123 | |
| Uncemented N | 0 | |
| Hybrid N | 0 | |
| **Average Follow-Up (yrs, range)** | Enrollment is still continuing: 100% at 6 weeks, 85% at 6 months, and 72% at 1 year | |
| **Demographics** | **LPS-Flex fixed (Control)** | **LPS-Flex mobile (Investigational)** |
| Average age (yrs, range) | M 67 F 64 | M 62 F 62 |
| Average weight (lbs, range) | M 212 F 168 | M 208 F 180 |
| Sex (N, %) | M 30 (48) F 32 (52) | M 37 (61) F 24 (39) |
| Pre-operative diagnosis (N, %) | OA 60 (97)<br>RA 0 ( 0)<br>PTA 2 ( 3) | OA 56 (92)<br>RA 3 ( 5)<br>PTA 1 ( 2) |
| **Effectiveness (KSS) 1 Year follow-up** | **LPS-Flex fixed (Control)** | **LPS-Flex mobile (Investigational)** |
| Excellent (N, %) (85-100) | 21 (91) | 12 (67) |
| Good (N, %) (70-84) | 2 ( 9) | 3 (17) |
| Fair (N, %) (60-69) | 0 ( 0) | 2 (11) |
| Poor (N, %) (≤ 59) | 0 ( 0) | 1 ( 6) |
| Pain Scores (% with no pain) | 17 (71) | 6 (33) |
| **SF-12** (Physical Health) | 39.7 | 38.0 |
| (Mental Health) | 52.8 | 55.3 |
| **Survivorship (% @ X no. of years)** | 100% at 1 year | |
| Using revision surgery for any reason as endpoint | | |
| Revision rate | 0/123= 0% There have been no revisions. | |
| **Reason for Revision Surgery** | | |
| Infection | | |
| Deep | | |
| Superficial | | |
| Aseptic Loosening | | |
| of Femur | | |
| of Tibia | | |
| Implant Subsidence | | |
| Polyethylene Wear | | |
| Insert Dislocation | | |
| Insert Breakage | | |
| Insert Subluxation | | |
| Osteolysis | | |
| Patella Complication | | |
| DVT | | |
| Other: | | |
| **Comments:** | These results are from the 3rd annual report submitted to the FDA in support of the IDE registered by Zimmer Inc. | |

## Materials And Methods

The Prosthesis

- **Briefly discuss the theory and design rationale of the mobile bearing knee**

  The LPS-Flex (Fixed and Mobile) Knee is a posterior stabilized knee system for use without the cruciate ligaments. The LPS-Flex is designed to allow a maximum active (under load) flexion of 155 degrees and a passive (no load) flexion of 165 degrees. The femoral component geometry is an adaptation of the current *Legacy*® Knee PS Femoral with design modifications to safely accommodate high flexion activities.

  The LPS-Flex Knee is primarily designed to safely accommodate high flexion activities up to 155 degrees, for those patients who have both the flexibility and desire to perform high flexion activities. The LPS-Flex Knee is developed to work in conjunction with other factors that may improve the flexion range, such as patient selection, surgical technique, and rehabilitation protocol. A posterior stabilized implant is chosen because the design provides a predictable pathway for increased flexion and the cam/spine mechanism assists in properly controlling rollback and kinematics. To address the global market need for a high flexion knee prosthesis, the LPS-Flex Knee is available in both mobile bearing and fixed bearing versions.

- **How is the device categorized**

  The LPS-Flex mobile bearing knee design is classified as a rotational platform.

- **Discuss design elements such as conformity, rotation, constraint, etc.**

  - Extended Posterior Condyles

    1. The tibiofemoral contact area was increased to prevent "digging in" of the metal condyle into the articular surface when the knee is flexed beyond 130 degrees. This was accomplished by thickening the posterior condyles to provide an extended articulating surface on the proximal posterior condyles.
    2. The proximal posterior condyles of the LPS-Flex femoral are radiused to provide good contact between the poly and the femoral component during flexion greater than 130 degrees. An additional femoral posterior bone cut of approximately 2mm is needed to accommodate this feature. This is accomplished by using the Posterior Re-Cut Guide.
    3. The radius of curvature in the sagittal plane is designed to facilitate the natural rollback of the femur. The constraint and conformity are optimized to help prevent lift-off and subluxation of the femur without restricting motion/ flexion. It should be noted that more constraint and conformity, as seen in other designs, are not desirable for high flexion as rollback may be compromised.

  - Patellofemoral Design

    1. Like all NexGen Femoral Components, the LPS-Flex Femoral Component has a deep patellar groove that allows the patella to track as deeply, or more deeply than the normal

patella. The groove has been extended more distally/posteriorly than on traditional posterior stabilized components, to fully support the patella up to 85 degrees of flexion.

2. The articulating surface of the NexGen Patella is a modified dome configuration. It is designed to closely match the shape of the patella groove in mid-to-deep flexion. This optimizes patellofemoral contact area during high load angles of flexion. Also, the rounded lateral ridge increases the resistance to lateral subluxation. The component features a central dome, an angled flat, and a concave radius that correspond to the articulating geometry of the LPS-Flex Femoral.

- Patella Relief

1. To decrease stresses on the quadriceps mechanism during high flexion, material was removed from the anterior face of the articular surface component.
2. During deep flexion, the patella contacts the femoral component in a more distal and posterior location. More clearance was provided on the articular surface to reduce patellar tendon tension, provide relief for the inferior patellar bone, and reduce the potential for patellar impingement.

- Cam/Spine Interaction

1. To improve stability of the femoral component on the articular surface and to reduce the bending moment applied to the articular surface spine, the shape of the femoral cam was modified.
2. The LPS-Flex femoral cam design increases the subluxation resistance beyond that of the LPS design at flexion angles greater than 130 degrees.

- Bearing Surface and Plates

1. The mobile articular surface rotates about a highly polished trunnion. Posterior lift-off forces imposed on the articulating surface during deep squatting are counteracted by this trunnion and an anterior rotational stop. The rotational stop also helps prevent “spin out” of the articular surface that has been reported to occur with other mobile systems.
2. The pivot axis of the articular surface is placed in an anterior location versus a central location, to maximize polyethylene support and minimize overhang as the mobile articular surface rotates throughout the range of motion.
3. Research has shown that in the normal knee, motion is believed to occur anteriorly about the longitudinal axis of the tibia, which is approximately at the insertion of the ACL.
4. For the fixed bearing design, either the NexGen Fluted Stem Tibial Plate or the NexGen Finned Tibial Plate can be used with the LPS-Flex Components.
5. Both pegged and porous tibial plates, however, are contraindicated for use with the LPS-Flex due to the early and/or aggressive rehabilitation requirements necessary to achieve high range of motion.

- Secondary Locking Mechanism

1. A secondary locking mechanism is required on the 17 and 20mm LPS-Flex Mobile Bearing Articular Surfaces. This is required to enhance the mobile articular surface fixation during

flexion greater than 130 degrees, resist the anterior lift-off effects and prevent the disassembly of the articular surface during deep-flexion activities (data on file).

2. For the mobile bearing system, the locking screw is placed through an anterior hole on the 17 and 20mm mobile articular surfaces and threaded into the trunnion. The locking screw does not prevent freedom of rotation of the articular surface.

- **Discuss the indications for use of the device**

  Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities.

  The LPS-Flex femoral provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. It is designed for use with both cruciate ligaments excised and to provide a load bearing range of motion up to 155º. The fluted stem mobile tibial baseplate is designed to allow ± 25º of rotational movement.

  The device is intended for cement use only.

- **Diagrams/pictures of device**

Study Design

- **Describe the design and methods used for the study**

  The trial is to be an open multicenter study with a randomized concurrent control group provided by using the *NexGen* LPS Flex Fixed Bearing implant. We plan to enroll a minimum of 180 unilateral osteoarthritis cases into the LPS-Flex Mobile Bearing Knee test group. This sample size includes a provision for a 15% drop-out. Patients with a pre-existing contralateral total knee implant will not be entered into the study. We will discourage, but allow contralateral cases after the index surgery. Statistical analysis for survivorship, radiographic parameters, complications, and Knee Assessment score will utilize data from unilateral and bilateral cases. Only unilateral cases will be included in the primary assessment of Knee Society Function score. In cases where a contralateral knee implant becomes necessary during the course of the study due to unexpected worsening of contralateral symptoms, patients may be provided with a LPS-Flex Mobile Bearing Knee, a LPS-Flex Fixed Bearing Knee, or another device of the surgeon's choosing. If either the investigational or control device is used, the contralateral implant will be determined by the randomization scheme.

  Data on pain, function, deformity, radiographic parameters, and complications will be tracked on all investigational devices. Functional data from all bilateral patients will not be used as part of the primary analysis of safety and effectiveness due to the potential for confounding effects. Follow-up examinations will be made at 6 weeks, 6 months, 12 months, and 24 months after surgery to include both functional and radiographic evaluations. At two-year intervals thereafter, patients will be evaluated until the last patient enrolled has completed a two-year follow-up evaluation.

  Up to 15 sites will participate in the evaluation of the investigational LPS-Flex Mobile Bearing Knee Prosthesis. This number of centers will permit assessment of the consistency of outcomes across a variety of investigators. Each site is expected to enroll at least a minimum number of investigational cases, so that differences among sites can be examined statistically. Each site will enroll approximately 40 patients, with a maximum of 60 patients per site. The enrollment period may be 12 months or longer to assure an adequate number of cases at each site.

- **Describe the randomization procedure if applicable**

  Randomization will be to either the control group (*NexGen* LPS-Flex Fixed Bearing Knee) or the treatment group (LPS-Flex Mobile Bearing Knee). To assure temporal balance in treatment assignments, individual permuted block randomization will be supplied to each participating center. Permuted block randomization involves division of all patients within each participating center into several blocks of equal or unequal sizes. Patients will be randomized within each block for each particular center. Random permutation of numbers according to the size of the block will be generated. Given a block of size four, after a particular treatment has been assigned to first two patients, the remaining patients in that block would automatically receive the alternative treatment. This is called "Permuted Block Randomization." This method will be implemented by using SAS V8.0 procedure, PROC PLAN. This should ensure a temporal balance of treatment assignments within each center.

  Since age or sex should not make any difference in the outcome variables, stratified randomization will not be necessary.

- **Describe the blinding procedure if applicable**

  Randomization should occur after patients have satisfied all inclusion criteria. The investigator should not know which device will be assigned prior to randomization. Zimmer Clinical Affairs Department will provide each site with Screening and Randomization Forms to be used to assess patient eligibility for the study and for determination of device assignment. The completed form will be faxed to Zimmer Clinical Affairs where calculation of knee scores and patient eligibility will be determined. After eligibility is determined, Zimmer will provide a case ID number and device assignment according to the randomization scheme previously described.

- **What was the hypothesis for the study?**

  The success of the LPS-Flex Mobile Bearing Knee prosthesis will be assessed using the survivorship of the device as well as clinical, functional, radiographic, and safety evaluations. More precisely, an individual patient will be successful if the patient satisfies all of the following criteria.

  - Within 2 years post-operatively, there is no actual, intended or planned removal of any component of the knee system.
  - The patient exhibits less than 2 mm of osteolysis and less than 2 mm of subsidence in any zone and on any view for prosthesis/cement or for cement/bone or for prosthesis/bone (The time-point for radiographic success/failure determination is at 2 years post-op.).
  - Within 2 years post-operatively, the patient has a knee society assessment score of 70 or above.
  - Within 2 years post-operatively, the patient has a knee society function score of 70 or above.
  - Within 2 years post-operatively, the patient has no knee-related, severe adverse events and there is no unanticipated device effects (UADE).

  In this study, the criterion of survivorship is taken to be that the prosthesis has not been removed, nor is it scheduled for removal. This knee design will be considered successful if the results of the investigational prosthesis are no worse than the *NexGen* LPS-Flex Fixed Bearing prosthesis on any of the criteria mentioned above.

- **Is the study "complete" or "in progress" and what is progress status?**

  At the time of this report Zimmer had received notification that 123 cases have been enrolled into the study. Enrollment is still continuing: 100% at 6 weeks, 85% at 6 months, and 72% at 1 year.

- **Please insert any special materials and methods you used in this section**

  None

- **Selection Criteria**

Patient Inclusion Criteria

1. Age: 21 to 80 years.
2. Sex: Both males and females will be included, with no selection on gender.
3. Weight: Patients must weigh less than 250 pounds at the time of enrollment with a thigh/calf index of ≥ 90.
4. Based on physical examination and history, candidates will include those suffering from severe knee pain and disability due to degenerative joint disease including:
5. Osteoarthritis (OA) or Rheumatoid arthritis (RA)
6. Primary and secondary traumatic arthritis
7. Polyarthritis
8. Collagen disorders
9. Avascular necrosis of the femoral condyle or pseudogout
10. Posttraumatic arthritis
11. Varus, valgus, or flexion deformities
12. Patient exhibits Knee Society knee and function scores of ≤ 60.
13. Patient exhibits knee flexion ≥ 90 degrees.
14. Patient exhibits preoperative radiographic evidence of joint degeneration consistent with TKA, including but not limited to decreased joint space, presence of osteophytes, and/or other significant radiographic evidence of arthritic degeneration that can not be treated in a non-operative fashion.
15. Patient is willing and able to cooperate in follow-up therapy.
16. Patient is in stable health based upon physical examination and medical history.

Patient Exclusion Criteria

1. Patients with a previous history of infection in the affected joint.
2. Patients with previously failed knee endoprosthesis of any kind.
3. Patients presenting with a contralateral knee implant in place.
4. Patients requiring bilateral knee replacement under the same anesthetic.
5. Patients with Charcot joint disease or other severe neurosensory deficits.
6. Patients presenting with previous patellectomy of the index knee.
7. Skeletally immature individuals.
8. Patients with grossly insufficient femoral or tibial bone stock, e.g., due to osteoporosis, metabolic bone disease, congenital anomaly, or previous surgery to the index joint that could affect outcome, including but not limited to high tibial osteotomy or a patient requiring bone grafting.
9. Patients with loss of musculature or absence of musculoligamentous supporting structures required for appropriate soft tissue balance.
10. Patient is pregnant.
11. Varus or Valgus deformity >20 degrees.
12. Fixed flexion deformity >15 degrees.
13. Knee flexion < 90 degrees.
14. Previous high tibial osteotomy.

15. Previous femoral osteotomy.
16. Patient is a poor compliance risk, i.e., history of ethanol or drug abuse, or mental handicap that would compromise patient compliance with respect to rehabilitation or follow-up.

- **Follow-Up Evaluation**

  Patients were monitored clinically and radiographically and had preoperative, intraoperative, and follow-up ratings obtained using the Hospital for Special Surgery score and the Knee Society score questionnaires.

  Preoperative, Immediate post-op, 6 weeks post-op, 6 months post-op, 12 months post-op, 24 months post-op.

  Because the study is in progress, final follow-up interval is unavailable at this time.

- **Study compliance statistics**

| | 6 Weeks | 6 Months | 1 Year |
|---|---|---|---|
| Theoretical Follow-up | 123 | 123 | 123 |
| Cumulative Deaths | 0 | 0 | 0 |
| Cumulative Revisions | 0 | 0 | 0 |
| Not yet at Interval | 0 | 18 | 35 |
| Expected Follow-up | 123 | 105 | 88 |
| Missed Visits | 16 | 15 | 7 |
| Lost to Follow-up | 1 | 0 | 0 |
| Withdrawals | 1 | 0 | 0 |
| Total Patient Evaluations Processed | 106 | 90 | 81 |
| Follow-up Compliance % | 86 | 86 | 92 |

Radiographic Assessment

All patients were examined radiographically at the following intervals: preoperatively, immediate post-op, 6 weeks post-op, 6 months post-op, 1 year post-op, and 2 year post-op.

Briefly describe the radiographic method used to capture image of knee (Views)

Anteroposterior and lateral X-rays will be used to detect changes in the position of the LPS-Flex Mobile prosthesis. Other changes including lucency at the prosthesis/bone interface, subsidence, and bone remodeling will be identified by the clinical study investigator and characterized according to location in any of the radiographic zones on the Significant Radiographics Findings forms. The primary radiographic analysis will be based on an expert review performed by an independent reviewer at completion of the study.

Radiographic endpoints

Statistics based on radiographic data are not available at this interim interval.

## Results

The Patients

- Thirteen sites have secured IRB approval, and inventory has been shipped to all thirteen sites. Zimmer has received notification that patients have been enrolled at twelve of those sites. The first study patient was enrolled on May 18, 2001.
- Among the 62 controls, 32 are female, 30 male. For the 61 LPS-Flex Mobile patients, 24 are female and 37 are male.
- The average age of the patients at the time of surgery for controls is 65.5 years and 62.0 for mobiles.
- The pre-operative diagnosis for controls is: osteoarthritis in 96.5% of patients, rheumatoid arthritis in 0% of patients and post-traumatic arthritis in 3.2% of patients. For mobiles: 91.8% osteoarthritis, 4.9% rheumatoid arthritis, and 1.6% post-traumatic arthritis.

Outcomes

- **Health status questionnaire results (KSS, and HSS)**

Summary of Knee Society Clinical Rating Scores (KSS)

**Control Group**

| | **Knee Assessment Score (0-100)** | | | **Function Score (0-100)** | | | **Total Score (0-200)** | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | Std. Dev. | N | Mean | Std. Dev. | N | Mean | Std. Dev. |
| **Preoperative** | 59 | 35.7 | 12.2 | 59 | 49.3 | 10.0 | 59 | 85 | 17.9 |
| **6 Weeks** | 52 | 76.2 | 19.8 | 54 | 60.6 | 18.0 | 54 | 133.9 | 31.0 |
| **6 Months** | 35 | 91.3 | 9.4 | 36 | 82.2 | 16.5 | 36.1 | 171.0 | 25.7 |
| **1 Year** | 23 | 90.9 | 7.4 | 24 | 80.0 | 18.4 | 24 | 169.1 | 32.9 |

**Treatment Group**

| | Knee Assessment Score (0-100) | | | Function Score (0-100) | | | Total Score (0-200) | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | Std. Dev. | N | Mean | Std. Dev. | N | Mean | Std. Dev. |
| **Preoperative** | 56 | 38.6 | 14.1 | 57 | 50.8 | 13.2 | 57 | 88.7 | 23.0 |
| **6 Weeks** | 44 | 74.8 | 21.3 | 47 | 61.2 | 20.4 | 47 | 131.2 | 37.1 |
| **6 Months** | 35 | 88.9 | 14.7 | 36 | 82.5 | 17.7 | 36 | 169.0 | 32.0 |
| **1 Year** | 18 | 85.7 | 13.4 | 18 | 82.5 | 19.3 | 18 | 168.2 | 29.8 |

Summary of Hospital For Special Surgery (HSS) Scores

**Control Group**

| | N | Mean | Std. Dev. | Minimum | Maximum |
|---|---|---|---|---|---|
| **Preoperative** | 56 | 62.0 | 8.6 | 38.3 | 79.2 |
| **6 Weeks** | 50 | 72.5 | 12.0 | 36.2 | 96.9 |
| **6 Months** | 36 | 87.4 | 6.0 | 73.7 | 97.9 |
| **1 Year** | 24 | 88.7 | 5.5 | 77.5 | 97.5 |

**Treatment Group**

| | N | Mean | Std. Dev. | Minimum | Maximum |
|---|---|---|---|---|---|
| **Preoperative** | 56 | 61.9 | 9.5 | 39.4 | 84.7 |
| **6 Weeks** | 47 | 72.4 | 12.1 | 31.4 | 93.3 |
| **6 Months** | 35 | 86.1 | 9.3 | 55.0 | 97.9 |
| **1 Year** | 18 | 85.5 | 9.0 | 68.4 | 98.4 |

- **ROM (extension and flexion) results of the study**

Summary of Flexion And Extension

**Control Group**

| | Flexion | | | | Extension | | | |
|---|---|---|---|---|---|---|---|---|
| | Preop | 6 weeks | 6 months | 1 Year | Preop | 6 weeks | 6 months | 1 Year |
| N | 62 | 57 | 37 | 24 | 62 | 57 | 37 | 24 |
| Mean | 119.6 | 112.4 | 128.4 | 129.9 | 2.7 | 4.4 | 0.5 | 0.2 |
| Std. Dev. | 9.1 | 19.8 | 10.2 | 7.8 | 5.5 | 16.3 | 1.1 | 1.4 |
| Minimum | 95 | 120.0 | 105.0 | 115.0 | -10.0 | -10.0 | 0.0 | -3.0 |
| Maximum | 140.0 | 160.0 | 150.0 | 150.0 | 15.0 | 3.0 | 5.5 | 5.0 |

**Treatment Group**

| | **Flexion** | | | | **Extension** | | | |
|---|---|---|---|---|---|---|---|---|
| | **Preop** | **6 Weeks** | **6 Months** | **1 Year** | **Preop** | **6 Weeks** | **6 Months** | **1 Year** |
| N | 58 | 49 | 37 | 20 | 58 | 49 | 37 | 20 |
| Mean | 116.4 | 109.6 | 125.6 | 127.4 | 4.1 | 3.6 | 0.8 | 0.2 |
| Std. Dev. | 10.8 | 18.2 | 10.4 | 9.5 | 5.5 | 5.5 | 1.8 | 1.1 |
| Minimum | 95.0 | 40.0 | 100.0 | 110.0 | -10.0 | -5.0 | -2.0 | -2.0 |
| Maximum | 140.0 | 140.0 | 145.0 | 145.0 | 15.0 | 30.0 | 5.0 | 3.0 |

- **Values for the patient's final follow-up relief of symptoms (pain, limp, stairs, walking distance, etc.)**

Summary of Knee Pain (Assessment/HSS Item)

**Control Group**

| Knee Pain | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| None | 0 | 0.0 | 13 | 24.1 | 16 | 44.5 | 15 | 60.0 |
| Mild/Occasional | 0 | 0.0 | 18 | 33.2 | 13 | 36.1 | 4 | 16.0 |
| Mild/Stairs Only | 0 | 0.0 | 3 | 5.6 | 3 | 8.3 | 4 | 16.0 |
| Mild/Stairs and level walking | 4 | 6.8 | 2 | 5.6 | 1 | 2.8 | 1 | 4.0 |
| Moderate/Pain comes and goes | 2 | 3.4 | 7 | 13.0 | 3 | 8.3 | 1 | 4.0 |
| Moderate/Pain each day | 34 | 57.6 | 10 | 18.5 | 0 | 0.0 | 0 | 0.0 |
| Severe/constant | 19 | 32.2 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| **TOTAL** | 59 | 100 | 53 | 100 | 36 | 100 | 25 | 100 |

**Treatment Group**

| Knee Pain | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| None | 0 | 0.0 | 12 | 22.3 | 21 | 58.2 | 7 | 38.8 |
| Mild/Occasional | 2 | 3.4 | 22 | 40.7 | 9 | 25.0 | 6 | 33.3 |
| Mild/Stairs Only | 0 | 0.0 | 2 | 3.7 | 0 | 0.0 | 0 | 0.0 |
| Mild/Stairs and level walking | 1 | 1.7 | 8 | 14.8 | 2 | 5.6 | 1 | 5.6 |
| Moderate/Pain comes and goes | 4 | 6.8 | 2 | 3.7 | 2 | 5.6 | 3 | 16.7 |
| Moderate/Pain each day | 35 | 59.3 | 8 | 14.8 | 1 | 2.8 | 1 | 5.6 |
| Severe/constant | 17 | 28.8 | 0 | 0.0 | 1 | 2.8 | 0 | 0.0 |
| **TOTAL** | 59 | 100 | 54 | 100 | 36 | 100 | 18 | 100 |

Summary of Stairs Capability (Function Item)

**Control Group**

| Stairs | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| Normally (one foot on each step) | 0 | 0.0 | 8 | 14.8 | 19 | 52.8 | 10 | 40.0 |
| Normally but require rail when going down | 3 | 5.1 | 15 | 27.8 | 4 | 11.1 | 7 | 28.0 |
| Normally but require rail when going up | 1 | 1.7 | 2 | 3.7 | 1 | 2.8 | 1 | 4.0 |
| Require rail while going up & down | 54 | 91.5 | 26 | 48.1 | 12 | 33.3 | 7 | 28.0 |
| Up by rail but unable to go down | 0 | 0.0 | 3 | 5.6 | 0 | 0.0 | 0 | 0.0 |
| Unable to go up or down stairs | 1 | 1.7 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| **TOTAL** | 59 | 100 | 54 | 100 | 36 | 100 | 25 | 100 |

**Treatment Group**

| Stairs | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| Normally (one foot on each step) | 1 | 1.7 | 9 | 17.6 | 20 | 55.5 | 11 | 61.1 |
| Normally but require rail when going down | 2 | 3.4 | 9 | 19.6 | 4 | 11.1 | 0 | 0.0 |
| Normally but require rail when going up | 3 | 5.1 | 3 | 5.9 | 0 | 0.0 | 0 | 0.0 |
| Require rail while going up & down | 50 | 84.7 | 26 | 51.0 | 11 | 30.6 | 7 | 38.9 |
| Up by rail but unable to go down | 1 | 1.7 | 2 | 3.9 | 1 | 2.8 | 0 | 0.0 |
| Unable to go up or down stairs | 2 | 3.4 | 1 | 2.0 | 0 | 0.0 | 0 | 0.0 |
| **TOTAL** | 59 | 100 | 50 | 100 | 36 | 100 | 18 | 100 |

Summary of Walking Capability With Support (Function Item)

**Control Group**

| Walking With Support | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| Walk Without any support | 46 | 77.9 | 32 | 59.2 | 30 | 83.3 | 21 | 84.0 |
| Use one cane on a long walk | 4 | 6.8 | 10 | 18.5 | 5 | 13.9 | 3 | 12.0 |
| Use one cane most of the time | 6 | 10.2 | 11 | 20.4 | 1 | 2.8 | 1 | 4.0 |
| Use one crutch | 2 | 3.4 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Use a walker | 1 | 1.7 | 1 | 1.9 | 0 | 0.0 | 0 | 0.0 |
| **TOTAL** | 59 | 100 | 54 | 100 | 36 | 100 | 25 | 100 |

**Treatment Group**

| Walking With Support | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| Walk Without any support | 48 | 77.5 | 28 | 51.8 | 33 | 91.7 | 15 | 83.3 |
| Use one cane on a long walk | 3 | 4.8 | 12 | 22.2 | 3 | 8.3 | 2 | 11.1 |
| Use one cane most of the time | 5 | 8.1 | 6 | 11.1 | 0 | 0.0 | 1 | 5.6 |
| Use one crutch | 1 | 1.6 | 1 | 1.9 | 0 | 0.0 | 0 | 0.0 |
| Use two canes | 1 | 1.6 | 1 | 1.9 | 0 | 0.0 | 0 | 0.0 |
| Use two crutches | 1 | 1.6 | 2 | 3.7 | 0 | 0.0 | 0 | 0.0 |
| Use a walker | 2 | 3.2 | 4 | 7.4 | 0 | 0.0 | 0 | 0.0 |
| Unable to walk | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| **TOTAL** | 62 | 100 | 54 | 100 | 36 | 100 | 18 | 100 |

Summary of Distance Walking Capability (Function Item)

**Control Group**

| Distance Walked | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| Unlimited | 1 | 1.7 | 5 | 9.3 | 15 | 41.7 | 12 | 48.0 |
| More than 10 blocks | 0 | 0.0 | 9 | 16.7 | 13 | 36.1 | 5 | 20.0 |
| 5-10 blocks | 14 | 23.8 | 14 | 25.9 | 5 | 13.9 | 5 | 20.0 |
| < 5 blocks | 31 | 52.5 | 20 | 37.0 | 3 | 8.3 | 1 | 4.0 |
| Short Distance | 13 | 22.0 | 6 | 11.1 | 0 | 0.0 | 2 | 8.0 |
| **TOTAL** | 59 | 100 | 54 | 100 | 36 | 100 | 25 | 100 |

**Treatment Group**

| Distance Walked | Preoperative | | 6 Weeks | | 6 Months | | 1 Year | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| Unlimited | 1 | 1.7 | 5 | 9.8 | 20 | 55.6 | 10 | 55.6 |
| More than 10 blocks | 3 | 5.1 | 9 | 17.6 | 5 | 13.9 | 2 | 11.1 |
| 5-10 blocks | 14 | 23.7 | 18 | 35.4 | 7 | 19.4 | 4 | 22.2 |
| < 5 blocks | 34 | 57.6 | 15 | 29.4 | 3 | 8.3 | 2 | 11.1 |
| Short Distance | 7 | 11.9 | 4 | 7.8 | 1 | 2.8 | 0 | 0.0 |
| **TOTAL** | 59 | 100 | 50 | 100 | 36 | 100 | 18 | 100 |

- **Patient satisfaction results (SF-12)**

Summary of SF-12 Questionnaire Scores

**Control Group**

| SF-12 SCORE | | Preoperative | 6 Weeks | 6 Months | 1 Year |
|---|---|---|---|---|---|
| Physical Health | Mean | 31.5 | 38.7 | 48.9 | 49.2 |
| | Std. Dev. | 5.3 | 8.3 | 9.6 | 8.7 |
| | Min | 19.8 | 22.8 | 26.4 | 27.9 |
| | Max | 45.8 | 56.6 | 65.7 | 59.4 |
| | N | 60 | 53 | 36 | 23 |
| Mental Health | Mean | 51.5 | 51.4 | 54.5 | 56.8 |
| | Std. Dev. | 11.1 | 11.7 | 10.6 | 6.4 |
| | Min | 24.0 | 25.3 | 18.3 | 38.0 |
| | Max | 71.4 | 71.3 | 67.1 | 66.0 |
| | N | 60 | 53 | 36 | 23 |

**Treatment Group**

| SF-12 SCORE | | Preoperative | 6 Weeks | 6 Months | 1 Year |
|---|---|---|---|---|---|
| Physical Health | Mean | 32.5 | 36.9 | 46.6 | 42.9 |
| | Std. Dev. | 8.0 | 10.1 | 8.7 | 10.5 |
| | Min | 18.8 | 17.1 | 24.4 | 24.9 |
| | Max | 53.1 | 56.6 | 61.2 | 56.9 |
| | N | 58 | 52 | 33 | 17 |
| Mental Health | Mean | 55.8 | 54.3 | 56.3 | 54.6 |
| | Std. Dev. | 10.8 | 9.7 | 7.4 | 10.7 |
| | Min | 26.4 | 22.2 | 35.9 | 21.2 |
| | Max | 71.3 | 68.1 | 66.9 | 67.4 |
| | N | 58 | 52 | 33 | 17 |

- **Survival analysis results**

  Not applicable (enrollment ongoing)

- **Radiographic Appearances**

  Not available.

Complications

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Any fracture | 0 | |
| Femoral component loosening | 0 | |
| Tibial component loosening | 0 | |
| Patellar component loosening | 0 | |
| Bearing dislocation | 0 | |
| Bearing subluxation | 0 | |
| Mobile bearing wear | 0 | |
| Patellar bearing wear | 0 | |
| Ligamentous instability | 0 | |
| Deep infection | 0 | |
| Fibroarthrosis | 0 | |
| Other: Occasional device clicking | 1 (0.8%) | 4 mos |
| Other: DVT | 2 (1.7%) | 1 unknown and 1 immediate post-op |
| Other: Stiff/tight knee | 4 (3.4%) | 3 (2 mos) and 1 (4 mos) |
| Other: Effusion | 1 (0.8%) | 17 mos |
| Other: Aggravated Spondylolisthesis | 1 (0.8%) | 7 mos |

- **Discuss overall complication rate**

  Fifty four (54) complications/adverse events have been reported in patients receiving the LPS-Flex mobile bearing knee. These are categorized as device related (7.5%) or general/systemic (92.5%). Fifty seven (57) complications/adverse events have been reported in patients receiving the LPS-Flex fixed bearing knee.

- **Discuss overall revision rate**

  There have been no revisions for this study.

**Conclusions**

The LPS-Flex mobile bearing knee study is currently in progress. The purpose of the study is to find the LPS-Flex mobile bearing knee to be equivalent to the non-mobile LPS-Flex fixed bearing knee. Participating investigators are sent a copy of the annual report to keep them abreast of the most current data results on all collected data. Interim reports are provided as requested and as needed.

## Outcomes Studies

### 1. Zimmer *MBK* Mobile Bearing Knee:

| **Device Brand Name** | *MBK* Mobile Bearing Knee |
|---|---|
| **Bearing Type** | MP= multidirectional platform |
| **Total N** | 1254 |
| Cement N | 1254 |
| Uncemented N | 0 |
| Hybrid N | 0 |
| **Average Follow-Up (yrs, range)** | Year – Number (Compliance%)<br>1 year – 813 (64.8%)<br>2 year – 414 (33.0%)<br>3 year – 14 ( 1.1%)<br>5 year – 5 ( 0.4%) |
| **Demographics** | |
| Average age (yrs, range) | M 66.77 (31-85) F 68.16 (35-89) |
| Average weight (kg, range) | M 85.06 (51-193) F 76.32 (37-180) |
| Sex (N, %) | M 358 (28.55%) F 891 (71.05%) |
| Pre-operative diagnosis (N, %) | OA 1170 (93.30%)<br>RA 51 ( 4.07%)<br>PTA 18 ( 1.44%)<br>Other 15 ( 1.19%) |
| Effectiveness (KSS) | See Table for KSS results. |
| Excellent (N, %) | |
| Good (N, %) | |
| Fair (N, %) | |
| Poor (N, %) | |
| Good-Excellent Results (%) | 1 Yr (A=81%, B=87%, C=67%)<br>2 Yr (A=86%, B=84%, C=74%) |
| **Patient Satisfaction (% satisfied)** | Overall : 91.84%<br>1 Year : 91.76%<br>2 Year : 92.17% |
| Other Scoring Methods (SF-12, 36, QOL, etc.) | |
| **Survivorship (% @ X no. of years)** | N/A |
| Using revision surgery for any reason as endpoint | |
| Survivorship related to other endpoint | |
| **Reason for Revision Surgery** | |
| Infection | |
| Deep | |
| Superficial | |
| Aseptic Loosening | |
| of Femur | |
| of Tibia | |
| Implant Subsidence | |
| Polyethylene Wear | |
| Insert Dislocation | |
| Insert Breakage | |

| **Device Brand Name** | *MBK* Mobile Bearing Knee |
|---|---|
| Insert Subluxation | |
| Osteolysis | |
| Patella Complication | 2 |
| DVT | |
| Other: Stiffness or fixed flexion deformity | 4 |
| Other: Under investigation or no details | 2 |
| **Comments:** | Total of 8 revisions (Revision rate: 0.6%) |

**Knee Society Score Results**

- **Knee Society Knee Scores**

One year results

| Effectiveness (KSS) | A* | B* | C* |
|---|---|---|---|
| Excellent (85-100) (N, %) | 282 (63.1%) | 143 (64.1%) | 58 (40.6%) |
| Good (70-84) (N, %) | 80 (17.9%) | 51 (22.9%) | 38 (26.6%) |
| Fair (60-69) (N, %) | 17 (3.8%) | 13 (5.8%) | 15 (10.5%) |
| Poor (< 60) (N,%) | 68 (15.2%) | 16 (7.2%) | 32 (22.4%) |

N=813

Two year results

| Effectiveness (KSS) | A* | B* | C* |
|---|---|---|---|
| Excellent (85-100) (N, %) | 156 (70.0%) | 73 (62.4%) | 40 (54.1%) |
| Good (70-84) (N, %) | 35 (15.7%) | 25 (21.4%) | 15 (20.3%) |
| Fair (60-69) (N, %) | 13 (5.8%) | 6 (5.1%) | 9 (12.2%) |
| Poor (< 60) (N,%) | 19 (8.5%) | 13 (11.1%) | 10 (13.5%) |

N=414

- **Knee Society Function Scores**

One year results

| Effectiveness (KSS) | A | B | C |
|---|---|---|---|
| Excellent (85-100) (N, %) | 261 (58.4%) | 74 (33.2%) | 36 (25.2%) |
| Good (70-84) (N, %) | 123 (27.5%) | 71 (31.8%) | 30 (21.0%) |
| Fair (60-69) (N, %) | 32 (7.2%) | 33 (14.8%) | 21 (14.7%) |
| Poor (< 59) (N,%) | 31 (6.9%) | 45 (20.2%) | 56 (39.2%) |

N=813

Two year results

| Effectiveness (KSS) | A | B | C |
|---|---|---|---|
| Excellent (85-100) (N, %) | 135 (60.5%) | 32 (15.5%) | 19 (25.7%) |
| Good (70-84) (N, %) | 56 (25.1%) | 36 (17.4%) | 15 (20.3%) |
| Fair (60-69) (N, %) | 20 (9.0%) | 21 (10.2%) | 14 (18.9%) |
| Poor (< 59) (N,%) | 12 (5.4%) | 28 (14.0%) | 26 (35.1%) |

N=414

*Patient categories (Insall et al., 1989):

A. Unilateral or bilateral (opposite knee successfully replaced)
B. Unilateral, other knee symptomatic
C. Multiple arthritis or medical infirmity

## Materials And Methods

### The Prosthesis

The Zimmer Mobile Bearing Knee (*MBK*) is designed specifically to maximise congruency between the femoral and tibial articulating surfaces over the entire range of motion, while providing movement of the tibial surface to maintain optimum kinematics. Congruency is important over the entire range of motion because the highest contact pressures are often encountered at significant flexion angles during stair climbing and descending and rising out of a chair. It is anticipated that the increased congruency will reduce contact pressures at the articulating surfaces, and thereby lead to reduced wear. The *MBK* is a modular, anatomical, tricompartmental total knee replacement, designed to accommodate posterior cruciate ligament recession or resection.

The device is categorized as a multidirectional platform (MP)

Study Design

The study is a prospective open trial of all patients who receive the Zimmer *MBK* prosthesis, conducted by Orthopaedic Surgeons experienced in total knee replacement surgery and familiar with the use of the *MBK* design. The study will incorporate 12 International centres. Patients will be selected according to the criteria set out in Section 4. All patients will be assessed physically and radiographically both pre- and post-operatively using Study Data Forms provided. Follow up assessments will be conducted during the early post-operative period (within 10 days of surgery), and at 1, 3, and 5 years post-operatively. Patients will be scored using the Knee Society system for clinical and functional parameters, and the Knee Society Roentgenographic Evaluation for radiographic assessment. In addition, all surgical, clinical or device-related complications will be recorded.

- **Selection Criteria**

  Patient Inclusion Criteria

  - Sex: Male and Female
  - Weight: No limit
  - Indications: Severe knee pain and disability requiring total knee replacement
  - Diagnosis: Degenerative Joint Disease, including but not limited to:
    1. Osteoarthritis
    2. Rheumatoid Arthritis
    3. Post-traumatic Arthritis
  - Health: In stable health, suitable for surgery, and able to participate in follow-up program

  Patient Exclusion Criteria

  - History of infection in the affected joint Skeletal immaturity
  - Previous joint replacement surgery in the affected joint
  - Neuropathic Arthropathies, e.g. Charcot Joint Disease
  - Severe knee instability due to loss of musculoligamentous support
  - Severe muscle weakness, e.g. post poliomyelitis
  - Fixed Flexion Contracture of over 45°
  - Grossly insufficient femoral or tibial bone stock

**Results**

The Patients

- Between November 1996 and June 2002, 1254 primary total knee arthroplasties with the *MBK* were implanted.

- At 1 to 5 years following the procedure, 1249 patients (1254 knees) were alive, 13 patients had died, and no patients had been lost to follow-up.

- 891 patients (71%) were female, and 358 patients (29%) were male.

- The average age of the patients at the time of surgery was 68 (range, 31 to 89 years).

- The pre-operative diagnosis was osteoarthritis (93%), rheumatoid arthritis (4%), post-traumatic arthritis (2%) and other (1%).

Outcomes

- Patients reported their level of post-operative knee pain as follows:

  - No pain (20.5%)
  - Decreased pain (72.0%)
  - Same pain as pre-op (5.4%)
  - Increased pain (2.0%)

- Patients reported their satisfaction with the procedure as follows:

  - Satisfied (91.8%)
  - Not satisfied (8.2%)

- Patients reported their knee status as follows:

  - Better than pre-op (81.3%)
  - Same as pre-op (15.3%)
  - Worse than pre-op (3.4%)

- Mean pre-op ROM was 105 degrees. Two year follow-up ROM was 106 degrees.

Radiographic Appearances

Not available

Complications

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| Ligamentous instability | 1 (0.25%) | 2 years |
| Deep infection | 1 (0.13%) | 1 year |
| Deep infection | 1 (0.25%) | 2 years |
| DVT | 16 (2.02%) | 1 year |
| DVT | 3 (0.74%) | 2 years |
| Manipulation under anaesthesia | 9 (1.14%) | 1 year |
| Major wound discharge | 5 (0.63%) | 1 year |
| Minor wound discharge | 6 (0.76%) | 1 year |
| Pulmonary embolism | 1 (0.13%) | 1 year |
| Patellofemoral pain | 1 (0.13%) | 1 year |
| Patella maltracking | 1 (0.13%) | 1 year |
| Patella maltracking | 1 (0.25%) | 2 years |
| Dislocation | 1 (0.13%) | 1 year |
| Knee locking | 1 (0.13%) | 1 year |

- **Discuss overall complication rate**

  Overall complication rate is 3.6%.

- **Discuss overall revision rate**

  Overall revision rate is 0.6%.

**Conclusions**

In an international outcome study of the *MBK* Mobile Bearing Knee design, there were 1254 cases implanted by 22 surgeons from 7 countries (Australia, Canada, France, Germany, Italy, Spain, and the United Kingdom). The mobile bearing knee could be implanted according to general criteria provided by the sponsor in conjunction with the orthopaedic surgeon's judgment (inclusion/exclusion criteria were not as strictly controlled as an U.S. IDE). At one year, among patients who had a unilateral or bilateral replacement (N=447) KSS good to excellent results were found for 81% of patients. At two years, these patients (N=223) reported good to excellent results of 85.7%. For patients who had one knee replaced but the other remained symptomatic at 1 year (N=223) good to excellent KSS scores were reported for 87% of patients. At two years, these patients (N=117) had good to excellent results of 83.8%. A total of 8 revisions have occurred (revision rate: 0.6%) for the following reasons: 2 for patellar complications, 4 for fixed flexion deformity or stiffness, and 2 for some other unspecified reason. These outcomes data provide wider generalizability concerning effectiveness and safety for this mobile bearing knee design.

## 2. Zimmer LPS-Flex Mobile Bearing Knee:

| **Device Brand Name** | LPS-Flex MB |
|---|---|
| **Bearing Type** | RP = Rotating platform |
| **Total N** | 390 |
| Cement N | 390 |
| Uncemented N | 0 |
| Hybrid N | 0 |
| **Average Follow-Up (yrs, range)** | Review Number<br>3 months 190<br>6 months 135<br>1 year 159<br>2 year 22 |
| **Demographics** | |
| Average age (yrs, range) | M 66.43 (30-87) F 63.24 (28-82) |
| Average weight (yrs, range) | M 77.27 (45-160) F 77.34 (36-115) |
| Sex (N, %) | M 163 (41.79%) F 225 (58.00%) |
| Pre-operative diagnosis (N, %) | OA 363 (93.08%)<br>RA 21 (5.38%)<br>PTA 5 (1.28%)<br>Other 1 (0.26%) |
| **Effectiveness (KSS)** | See Table for KSS results. |
| Excellent (N, %) | |
| Good (N, %) | |
| Fair (N, %) | |
| Poor (N, %) | |
| Good-Excellent Results (%) | 1 Yr (A=93%, B=79%, C=91%)<br>2 Yr (A=100%, B=67%, C=100%) |
| **Patient Satisfaction (% satisfied) (Yes/No)** | Overall : 92.02% satisfied<br>3 Months : 92.06% satisfied<br>6 Months : 94.07% satisfied<br>1 Year : 90.08% satisfied<br>2 Year : 90.48% satisfied |
| Other Scoring Methods (SF-12, 36, QOL, etc.) | |
| **Survivorship (% @ X no. of years)** | |
| Using revision surgery for any reason as endpoint | 3 Months: 1 case – (99.95% survived)<br>6 Months: 1 case – (99.26% survived)<br>1 Year: 0 cases – (100% survived)<br>2 Year: 0 cases – (100% survived) |
| Survivorship related to other endpoint | 0 Died (100% survived) |
| **Reason for Revision Surgery** | |
| Infection | 1 (3 Months) |
| Deep | |
| Superficial | |
| Aseptic Loosening | |
| of Femur | |
| of Tibia | |
| Implant Subsidence | |
| Polyethylene Wear | |
| Insert Dislocation | |
| Insert Breakage | |

| **Device Brand Name** | LPS-Flex MB |
|---|---|
| Insert Subluxation | |
| Osteolysis | |
| Patella Complication | |
| DVT | |
| Instability | 1 (6 Months) |
| **Comments:** | Total of 2 revisions (Revision rate 0.5%) |

**Knee Society Score Results**

- **Knee Society Knee Scores**

One year Results

| **Effectiveness (KSS)** | **A*** | **B*** | **C*** |
|---|---|---|---|
| Excellent (85-100) (N, %) | 69 (86.3%) | 13 (54.2%) | 31 (56.4%) |
| Good (70-84) (N, %) | 5 (6.3%) | 6 (25%) | 19 (34.5%) |
| Fair (60-69) (N, %) | 1 (1.1%) | 2 (8.3%) | 1 (1.8%) |
| Poor (< 60) (N,%) | 5 (6.3%) | 3 (12.5%) | 4 (7.3%) |

N=159

Two year Results

| **Effectiveness (KSS)** | **A*** | **B*** | **C*** |
|---|---|---|---|
| Excellent (85-100) (N, %) | 15 (100%) | 2 (66.7%) | 3 (75%) |
| Good (70-84) (N, %) | 0 (0%) | 0 (0%) | 1 (25%) |
| Fair (60-69) (N, %) | 0 (0%) | 0 (0%) | 0 (0%) |
| Poor (< 60) (N,%) | 0 (0%) | 1 (33.3%) | 0 (0%) |

N=22

- **Knee Society Function Scores**

One year Results

| **Effectiveness (KSS)** | **A** | **B** | **C** |
|---|---|---|---|
| Excellent (85-100) (N, %) | 31 (38.8%) | 12 (50.0%) | 17 (30.9%) |
| Good (70-84) (N, %) | 27 (33.8%) | 3 (12.5%) | 25 (45.5%) |
| Fair (60-69) (N, %) | 10 (12.5%) | 2 (8.3%) | 1 (1.8%) |
| Poor (< 59) (N,%) | 12 (15.0%) | 7 (29.2%) | 12 (21.8%) |

N=159

Two year Results

| Effectiveness (KSS) | A | B | C |
|---|---|---|---|
| Excellent (85-100) (N, %) | 11 (73.3%) | 1 (33.3%) | 2 (50%) |
| Good (70-84) (N, %) | 1 (6.7%) | 0 (0%) | 2 (50%) |
| Fair (60-69) (N, %) | 0 (0%) | 0 (0%) | 0 (0%) |
| Poor (< 59) (N,%) | 3 (20%) | 2 (67.3%) | 0 (0%) |

N=22

*Patient categories (Insall et al., 1989):

A. Unilateral or bilateral (opposite knee successfully replaced)
B. Unilateral, other knee symptomatic
C. Multiple arthritis or medical infirmity

## Materials And Methods

The Prosthesis

Clinical experience has highlighted the need to develop a knee to safely accommodate high flexions for patients who have both the flexibility and desire to perform deep flexion activities.

In areas of the world high flexion activities such as sitting and praying on the floor are a normal part of life and high flexion is considered to be greater than 140 degrees. Research has shown that during these activities internal rotation of the tibia of up to 25 degrees is expected. Therefore a mobile bearing design was selected to accommodate the range of movement and rotation as described above (25 degrees internal to 25 degrees external rotation). In this way tibial/femoral conformity is maximised throughout the entire range of movement.

The NexGen LPS Flex Mobile prosthesis is a posterior stabilised, modular, anatomical, tricompartmental total knee replacement, designed to accommodate a range of high flexion patient activities.

The device is categorized as a rotational platform (RP)

Study Design

The study is a prospective open trial of all patients who receive the NexGen LPS Flex Mobile prosthesis, conducted by Orthopaedic Surgeons experienced in total knee replacement surgery and familiar with the use of this implant design. The study will incorporate multiple International centres. Patients will be selected according to the criteria set out in Section 4. All patients will be assessed physically and radiographically both pre- and post-operatively using Study Data Forms provided. Follow up assessments will be conducted during the early post-operative period (within 10 days of surgery), and at 3 months, 6 months, 1yr, 2yrs, and 5 years post-operatively. Patients will be scored using the Knee Society system for clinical and functional parameters, and the Knee Society Roentgenographic Evaluation for radiographic assessment. In addition, all surgical, clinical or device-related complications will be recorded.

- **Selection Criteria**

  Patient Inclusion Criteria

  - Age: 21years to no upper limit
  - Sex: Male and Female
  - Weight: No limit
  - Indications: Severe knee pain and disability requiring total knee replacement
  - Knee: Minimum of 120 degrees of flexion preoperatively. Stable and functional collateral ligaments preoperatively. Angular deformity less than 20 degrees varus or 20 degrees valgus.
  - Diagnosis: Degenerative Joint Disease, including but not limited to:
    1. Osteoarthritis
    2. Rheumatoid Arthritis
    3. Post-traumatic Arthritis

- Lifestyle: Patient has potential to perform higher than average ROM's offered by a standard prosthesis.
- Health: In stable health, suitable for surgery, and able to participate in follow-up program.

Patient Exclusion Criteria

- History of infection in the affected joint
- Skeletal Immaturity
- Previous joint replacement surgery in the affected joint
- Neuropathic Arthropathies, e.g. Charcot Joint Disease
- Severe knee instability due to loss of musculoligamentous support
- Severe muscle weakness, e.g. post poliomyelitis
- Grossly insufficient femoral or tibial bone stock
- No flexion contracture greater that 45 degrees

**Results**

The Patients

- Between August 1999 and June 2002 primary total knee arthroplasties with the NexGen® LPS Flex Mobile were implanted in 390 patients.

- At 3 months to 2 years following the procedure, 388 patients (390 knees) were alive, no patients had died, and no patients had been lost to follow-up.

- 225 patients (58%) were female, and 163 patients (42%) were male.

- The average age of the patients at the time of surgery was 65 (range, 28 to 87 years).

- The pre-operative diagnosis was osteoarthritis (93%), rheumatoid arthritis (5%), post-traumatic arthritis (1.5%), and other (0.5%).

Outcomes

Patients reported their satisfaction (% satisfied) as follows:

- Overall: 92.02%
- 3 months: 92.06%
- 6 months: 94.07%
- 1 year: 90.08%
- 2 years: 90.48%

Radiographic Appearances

Not available.

Complications

| Complication | N (%) | Time of Occurrence |
|---|---|---|
| DVT | 1 (0.53%) | 3 months |
| Manipulation under anaesthesia | 1 (0.74%) | 1 year |
| Minor wound discharge | 1 (0.53%) | 3 months |
| Dislocation | 1 (0.53%) | 3 months |

- **Discuss overall complication rate**

  Overall complication rate is 1.0%.

- **Discuss overall revision rate**

  Overall revision rate is 0.5%.

**Conclusions**

In an international outcomes study initiated in 1999 using the NexGen LPS Flex Mobile, there have been 390 implantations by 19 surgeons from 17 centers from Europe, the United Arab Emirates, and Japan. At 1 year (N=159), KSS good to excellent results were 92.6%. At two years (N=22), good to excellent results were found for 100% of patients. Two revisions (revision rate: 0.5%) have occurred: 1 for deep infection and 1 for instability. These outcomes data provide wider generalizability concerning effectiveness and safety for this mobile bearing knee design.