VI. CLINICAL RESULTS OF CONSTRAINED HIP ARTHROPLASTY

A. J & J - S-ROM Polv-Dial Constrained Acetabular Liner

Two published constrained hip case series describe the use of the S-ROM Poly-Dial Acetabular Liner **(Series 1:** (16) Lombardi AV, Mallory TH, Kraus TJ, and Vaughn BK, Preliminary Report on the S-ROM Constraining Acetabular Insert: A Retrospective Clinical Experience, ***Orthopedics*** 1991 March; 14(3): 297-303; and **Series 2: (10)** Anderson MJ, Murray WR, Skinner HB, Constrained Acetabular Components, ***Journal of Arthroplasty*** 1994 February, 9(1): 17-23).

Series 1 describes the experience with 57 arthroplasties using the S-ROM constrained Poly-Dial Liner in 55 patients (30 female and 25 male) The mean age was 69 (range 39-91 years of age). Six primary procedures were performed (4 for trauma, and 2 for osteoarthritis complicated by poliomyelitis and myositis ossificans) and 5 1 revisions of previous surgeries; the mean number of previous revisions in these patients was 2.3 (range 1-6). Thirty-one revisions were for dislocation, 7 for femoral fracture, 6 for aseptic loosening, 4 for flail hip, and 3 for conversion of arthrodesis. Thirteen of the 3 1 patients had multiple dislocations (mean 2.7, range 2-5). In Series 1, the average follow-up period was 28 months (range 24-35). Five of the 55 patients subsequently dislocated their hip a total of 8 times at a mean of 2.5 months (range l-9).

Series 2 describes 22 consecutive patients receiving the S-ROM Poly-Dial constrained acetabular liner. One patient did not meet the inclusion criteria and was excluded from further analysis. Eighteen patients had chronic dislocation of their previous hip prosthesis, and three were treated for intraoperative joint instability during a revision procedure. Patients were followed for an average of 3 1 months (range 24-64 months). Six of the patients (29%) dislocated their hips at a mean of 10 months (range l-30). Two of these six had additional dislocations of their prosthetic hips. One dislocation was due to trauma, the others occurred during normal activities. The average final Harris Hip Score was 76. In addition, their Hospital for Special Surgery (HSS) hip rating scores were 7 excellent, 2 good, 2 fair, and 10 poor. Six of the poor results were due to the dislocations, and the remaining 4 were due to continuing use of analgesics.

In addition, other published results (11,12, & 15) using the S-ROM constrained hip are included herein.

B. Osteonics Omnifit Constrained Acetabular Liner

Published clinical results (13) Goetz, et al in JBJS and (14) Goetz, et al in Clinical Orthopaedics using the Omnifit Constrained Liner manufactured by Osteonics are included herein.

C. Information on Another Design – Biomet Ringloc Constrained Acetabular Liner

Information concerning clinical experience and laboratory testing of the Biomet Ringloc Constrained Liner is attached to this section.

J & J S-ROM

LITERATURE REVIEW TABLE

	Anderson, et al (10) Journal Arthop	
	J & J S-ROM May 1987 – Oct. 1990 2 1 Consecutive Cases (one tumor patient excluded)	
Follow-Up	Ave. 3 1 months Range 24-64 months	
Demographic Data		
Average Age	65.5 years Range 37.5 – 88.5 years	
Average Weight		
Sex	10 male – 11 female	
Indications	Revision Total Hip (8 had liner change only) 3 Intraoper, ve Instability 18 Chronically Dislocating	
Primary Diagnosis	Osteoarthrosis 10 patients Post-Traumatic Arthritis 4 patients Avascular Necrosis 3 patients Congenital Dislocation 2 patients Rheumatoid Arthritis 1 patient Postsepsis 1 patient	
Safety Data		
Infection (Deep and Superficial)	Deep sepsis	1 patient
	Peroneal nerve palsy	2 patients
Implant Malposition		
Implant Failure		
Dislocation		
Recurrent Dislocation	6 patients (29%) dislocated - time from implantation to dislocation averaged 10 months	
Effectiveness		
HHS Excellent 90-100 points	7 patients	
HHS Good 80-90 points	2 patients	
HHS Fair 70-80 points	2 patients	
HHS Poor < 70 points	10 patients	
Recurrent dislocation or progressive loosening suggestive of impending failure	15 patients (71%) experienced no subsequent dislocation	

Discussion –

Of the 10 outcomes considered poor, 6 were due to dislocations, and 4 were due to low HHS scores due to analgesic use. Of the 4, 2 suffered from severe chronic lower back pain due to multiple back surgeries (no hip pain), and 2 had multiple revisions. All were pleased with the constrained device due to freedom from recurrent dislocations.

Comments

No acetabular migration was seen in any patient. Of the two patients with cemented cups, one died of unrelated caused, and one suffered recurrent dislocation 6 months after implantation with no evidence of loosening, radiographically or clinically. Of the remaining 19 patients with porous ingrowth acetabular components, only 3 developed any evidence of lucent lines (with no progression).

LITERATURE REVIEW TABLE

	Cameron, Hugh U. (11) Contemporary Orthop J&J S-ROM . 1991 6 Revision Cases Performed Over 4 years 1 Case Report Described
Follow-Up	2 years
Demographic Data	
Average Age	58 years
Average Weight	
Sex	1 male
Indications	Patient had 12 previous hip surgeries and a semi-constrained hip was used for revision of 7 year old Girdlestone (allografts used) followed by recurrent dislocation
Primary Diagnosis	Recurrent Dislocation – following multiple hip surgeries
Discussion	Postoperative dislocation followed by closed reduction, and then redislocation. Allografts were allowed to heal 6 mos. and hip was revised with constrained socket.

Safety Data and Effectiveness

At two years follow-up, the hip remained stable and pain free. Patient wore a hip abduction brace for 6 mos. post op.

LITERATURE REVIEW TABLE

	Fisher, D.A. and Kiley, K. (12) Journal Arthrop J & J S-ROM 1994 2 Case Reports Described
Follow-Up	Case 1 10 years approx.(revision of THR with a constrained hip followed by revision with a second constrained hip) Case 2 3 years approx.(THR for severe degenerative arthritis, 5 dislocations and infected 4 mos. post op, cup revised to constrained, 5 mos. later cup again revised due to trauma)
Demographic Data	
Age	Case 1 76 years Case 2 79 years
Average Weight	
Sex	2 females
Indications	Case 1 Revision of previous THR involving femoral fracture using constrained hip, subsequent dislocation and revision with 2nd constrained hip Case 2 Recurrent dislocation, loose metal shell, trauma (fell down stairs) causing need for 2nd cup revision with constrained hip
Primary Diagnosis	Case 1 Recurrent Dislocation following multiple hip surgeries Case 2 Recurrent dislocation following THR, and trauma
Discussion	Case 1 Revision THR using a constrained cup with joint instability due to fracture of femur, dislocation required 2nd revision with constrained cup Case 2 Falling down stairs caused constrained liner to disassociate fi-om metal shell. She had previous sepsis and cultures had no growth at revision,

Safety Data and Effectiveness	Case 1 18 month follow-up from latest revision with sequential radiographs showing no evidence of wear or deformity of polyethylene. No further problems with the hip. Ambulates with a walker. Case 2 18 months following her second revision, she continues to have a useful hip and is ambulatory with a cane. Radiographically, she has no evidence of interface demarcation, polyethylene failure, or separation.
Discussion	
The author reports that the constrained liner has been used in other patients with few adverse consequences. In the senior author's private practice, 51 patients have received a constrained liner for either recurrent dislocations or extensive revisions with sufficient intraoperative instability to require additional constraint. Five of the 51 patients (10%), including these two cases, have suffered an additional dislocation (3 patients) or disassociation (2 patients). All five of these cases required open reduction or revision of the component.	

LITERATURE REVIEW TABLE

	Kaper, B.P., et al (15) JBJS
	J & J S-ROM 1989/1996 4 Cases (2 Illustrative Case Reports Discussed)
Follow-Up	Case 1 Patient followed for approx. 10 years (patient had semi-constrained THR in 1989). Apr. 1993 cup revised with semi-constrained followed by recurrent dislocation Nov. 1993 revised with semi-constrained cup followed by recurrent dislocation Mar. 1994 revised with semi-constrained cup followed by dislocation 2 yrs. postop Feb. 1996 revised with constrained cup and asymptomatic at latest follow-up Case 2 Patient followed for approx. 3 years (patient had cornminuted fracture of right acetabulum in 1993) Mar. 1995 semi-constrained right THR followed by recurrent dislocation Oct. 1996 revised with semi-constrained prosthesis followed by recurrent dislocation Dec. 1996 revised cup with constrained S-ROM followed by dislocation and open reduction
Demographic Data	
Age	Case 1 67 years Case 2 35 years
Average Weight	
Sex	2 Females
Indications	Case 1 Revision of previous THR with subsequent recurrent dislocation Case 2 Revision of previous THR with subsequent recurrent dislocation
Primary Diagnosis	Case 1 Degenerative Osteoarthrosis Case 2 Post-Traumatic Osteoarthrosis

Discussion

The author reported on 4 failures by describing 2 illustrative case histories. The author states that 9 additional patients were treated successfully.

Complications	
	2 failures due to fracture of the constraining ring (only 1 resulted in dislocation or instability) 2 revisions resulted from dislocation of the femoral head from the constrained socket

	Lombardi, A.V., et al (16) Orthopedics
	J & J S-ROM 1991 55 Patients (57 Hips)
Follow-Up	Ave. 27.7 Months Range 24-35 Months
Demographic Data	
Average Age	**69.1** Years Range 39-91 Years
Sex	25 Males 30 Females
Indications	55 Patients with multiply revised THR , unstable hips, and neuromuscular and/or neurological conditions associated with THR were treated with the S-ROM constrained hip Indications for 5 1 revision cases were: 3 1 Dislocations 7 Femoral Fractures 6 Aseptic Loosening 4 Resection Arthroplasty w/Flail Hip 3 Conversion Arthrodesis Indications for 6 primary cases were 4 Post Trauma Hip Arthrodesis 2 Osteoarthritis Complicated by Neuromuscular Disease
Primary Diagnosis	Six Primary Cases 1 Post Trauma Hip Arthrodesis 3 Post Trauma Hip Fractures with Intraoperative Instability 2 Osteoarthritis Complicated by Poliomyelitis & Myositis Ossificans Fifty-One Revision Cases 46 Osteoarthristis 2 Rheumatoid Arthritis 2 Avascular Necrosis 1 Congenital Hip Dysplasia

Discussion

Among the 31 patients who presented with dislocation, the average length of time from previous arthroplasty to dislocation was 3.2 months (range 4 days – 24

months).
Thirteen of these patients had multiple dislocations (average 2.7). Five of these patients were treated with closed reduction, but dislocation occurred again in an average of 2 months.

Safety Data and Effectiveness

Five of 55 patients redislocated a total of 8 times in an average time of 2.5 months from operative procedure to dislocation. Fifty patients have not experienced dislocation after the constrained hip procedure at an average of 30.2 months. The authors historical dislocation rate in 176 revision THR arthroplasties was 19%, but has been lowered to 4.5% (p<.001) by use of the constrained hip.

Harris Hio Scores	Preop	Postop(Ave. 30.2 months)
Total	**36.3**	**67.3**
Pain	**19.6**	**37.2**
Function	**13.9**	**23.5**
Deformity	**0.1**	**3.2**
Range of Motion	**2.7**	**3.4**

Complications

The five patients who dislocated are reported as case histories.

Case 1 72 year old female with 2 previous revision surgeries dislocated 1 month after insertion of the S-ROM constrained cup. After an open reduction with neck length increase and a cup angle adjustment, patient was fitted with a hip cast brace for 6 mos. and at 24 mos. is ambulatory without redislocation.

Case 2 59 year old man dislocated 2 mos. after insertion of the S-ROM constrained cup resulting from the constraining ring disengaging at 2 weeks postop. Ring and liner were replaced during open reduction. Patient was fitted with hip cast brace for 6 weeks, and at 24 mos. is ambulatory without redislocation.

Case 3 73 year old man with Parkinson's disease experienced recurrent dislocation at 1 and 2 mos. after insertion of the S-ROM constrained cup. Parkinsonism caused chronic positional dislocations, necessitating open reduction and constraining insert change with both dislocations. After the second dislocation, patient was fitted with hip cast brace for 6 weeks and at 22 mos. is ambulatory without redislocation.

Case 4 70 year old woman experienced 2 dislocations at 1 month and 9 months following insertion of the S-ROM constrained cup. The first open reduction showed the insert had rotated. and the insert was changed and

new acetabular angles established. The second open reduction showed extensive wear and dislocation. Again, the insert was changed and patient was fitted with hip cast brace for 6 weeks. Patient is ambulatory at 14 mos. without redislocation.

Case 5 66 year old man experienced 2 posterior dislocations at 2 and 3 mos. postop. After first dislocation, patient underwent adductor tenotomy but dislocation recurred. Because he had an above the knee amputation, a hip cast brace could not be used. Presently, the patient is girdlestoned secondary to hematogenous infectious spread from decubitous ulcer.

Discussion

Constraint has been an adjunct in the management of patients with the difficult problem of chronic dislocations or unstable and/or multiply revised hips. It provides most patients with a viable alternative to repeated dislocations, instability, and loss of mobility.

OSTEONICS OMNIFIT

LITERATURE REVIEW TABLE

	Goetz D.D., et al (13) JBJS
	Osteonics Omnifit April 1988 -Feb. 1993 55 Patients (56 components -1 female biiateral) (one patient lost to follow-up)
Follow-Up	Ave. 64 months Range 37-97 months
Demographic Data	
Average Age	**71** years Range 3 1 – 92 years
Operative Hip	31 Right **25** Left
Sex	19 male – 36 female
Indications	Recurrent Dislocation 56 hips had an average of 6 dislocations each Range 2 – 2) dislocations
Primary Diagnosis	Osteoarthrosis 34 patients Post-Traumatic Arthrosis 10 patients Osteonecrosis 3 patients Congenital Dislocation 2 patients Rheumatoid Arthritis 8 patient Postsepsis 1 patient

Discussion

An average of 3 previous procedures (range l-12 procedures) had been performed on these 56 hips. 7 hips (all with a history of infection) had had a Girdlestone arthroplasty, 6 had a bulk femoral or acetabular allograft, 3 a protrusio cage, 2 an arthrodesis, 2 a periprosthetic fracture, and 1 a proximal femoral replacement prosthesis. In addition, 2 patients were mentally retarded, and another 8 had severe confusion or Alzheimer disease.

Safety Data and Effectiveness

At latest follow-up: 38 patients (39 hips) were alive, 16 had died, 1 was lost. 55 hips (98%) were followed. Living patients had 64 mos. average follow-up (range 37-97 mos.), and deceased patients had 27 mos. average follow-up (range 1-81 mos.).

38 living patients (39 hips)

Pain	Function	Walking Aids*
28 (72%) No Pain	19 No Limp	12 No Support
7 (18%) Mild Pain	12 Mild Limp	14 Cane
3 (8%) Moderate Pain	6 Moderate Limp	11 Crutches/Walker
1 (3%) Severe Pain	2 Unable to Walk	2 Wheelchair

***wheelchair, walker, & crutches patients had factors not related to the hip contributing to their disability**

16 hips in patients who had died

2 patients needed reoperation for infection debridement
1 patient was revised for recurrent dislocation

Complications

38 Living Patients (39 Hips)	16 Hips in Patients Who Died
1 (3%) Recurrent Dislocation	1 Recurrent Dislocation
5 (13%) Reoperation	2 Infection
2 infection	
1 allograft failure	
1 periprosthetic fracture	
1 aseptic cup loosening	

In addition to complications requiring reoperation, these complications not related to the device occurred: 10 patients had trochanteric nonunion, 1 deep venous thrombosis, 2 intraoperative fractures, 1 incomplete sciatic nerve palsy, and 1 severe heterotopic ossification.

Discussion

The constrained acetabular component successfully prevented instability in 38 (97%) of 39 hips in the living patients after an average duration of follow-up of 5 years. It is important to realize that the primary goal was a stable hip with no additional dislocations. The clinical results in terms of pain, limp and walking ability were difficult to interpret due to the patient population. 27 (49%) of the 55 patients were more than 75 years old, 20 (36%) had severe mental impairment, and several had severe physical disability unrelated to the hip. Due to the limited indications for this device, a homogenous population of patients is not available.

LITERATURE REVIEW TABLE

	Goetz, D.D. et al (14) Clinical Orthop.
	Osteonics Omnifit Apr. 1988 – Feb. 1993 98 Patients (101 Hips) (one patient lost to follow-up)
Follow-Up	Average 61 months for 74 living patients (77hips) Range 24-97 months Average 19 months for 23 deceased patients (23 hips) Range l-8 1 months One patient lost to follow-up at 8 months
Average Age	71 Years Range 3 l-92 years
Operative Hip	**54** Right 47 Left
Sex	6 Males 65 Females
Indications	56 Cases for Recurrent Dislocation (average of 6 dislocations, range 2-20 months) 38 Cases for Intraoperative Instability 7 Cases for Neurologic Impairment
Primary Diagnosis	5 1 Hips – Osteoarthritis 28 Hips – Post Traumatic Osteoarthritis 9 Hips – Inflammatory Arthritis 6 Hips – Congenital Hip Dysplasia 4 Hips – Infection 2 Hips – Osteonecrosis 1 Hip – Inflammatory Arthritis & Osteonecrosis
Complications	Cumulative to the time of latest follow-up <u>Deceased Patients</u> 2 of 23 (9%) had Recurrent Dislocation 2 of 23 (9%) had Reoperation for debridement of infection with no removal of components <u>Living Patients</u> 2 of 77 (3%) had Recurrent Dislocation 10 of 77 (13%) had reoperation for reasons other than dislocation or instability (5 infection, 2 allograft failure, 1 internal fixation of fracture, 1 debridement of heterotopic bone)

Other Complications Reported	Trochanteric Nonunion	16 Cases
	Venous Thrombosis	2 Cases
	Intraoperative Fracture	5 Cases
	Incomplete Nerve Palsy	3 Cases
	Intraoperative Hemorrhage	2 Cases
	Decubitis Ulcer	1 Case
	Severe Heterotopic Ossific.	1 Case
	Prostate Resection	1 Case
	Postop Cardiac Death	1 Case
	Postop Lower Gastrointestinal Complications/ Death	1 Case

Results At latest follow-up

Pain	68 patients – No pain
	16 patients – Mild
	8 patients – Moderate
	4 patients – Severe
	R ainder Unknown
	96 patients with known pain status
Limp	35 patients – No limp
	3 5 patients – Mild
	16 patients – Moderate
	6 patients – Severe
	5 patients – Unable to ambulate
	97 patients with known gait status
Walking Aids	23 patients – No support required
	29 patients – Cane
	35 patients – Crutches / walker
	10 patients – Wheelchair confined
	97 patients with known ambulatory status

Discussion

At latest follow-up, 90 (92%) of the 98 patients (or family members) reported that the operation had improved their quality of life. Only 6 of the 16 patients who required reoperation during the follow-up period thought the placement of the constrained implant had not improved their quality of life. In all cases, patients who had used crutches, a walker, or a wheelchair had factors unrelated to the hip that contributed to their disability. 48 (49%) of the 98 patients were more than 75 years old, and 3 1 (32%) had mental impairment from mental retardation , or dementia.

BIOMET RINGLOC

INFORMATION ON THE BIOMET CONSTRAINED LINER

SUMMARY OF CLINICAL DATA FOR BIOMET RINGLOC

Retrospective data was collected for patients receiving the Biomet, Inc. Ringloc Constrained Liner. The data has been separated into two groups identified as Group 1 and Group 2. Group 1 includes patients with surgery dates prior to December 26, 1996. Group 2 includes patients with surgery dates after December 26, 1996. All pertinent safety and efficacy data were collected for patients in both Groups 1 and 2. Data collected includes demographic data, preoperative and postoperative Harris Hip Scores, radiographic information, and safety data defined as complication rates.

A total of 53 liner procedures were identified at five sites as Group 1 patients. Demographic and clinical data were collected retrospectively on these patients having the Biomet Ringloc Constrained Liner implanted during hip surgery between May 22, 1995 - December 26, 1996. In addition, data was collected on 84 liner procedures comprising Group 2 with surgery dates after December 26, 1996. In total, safety and efficacy data was collected on 137 liner procedures with follow-up ranging from 0.26 – 41.1 months (mean 8.9 months).

TABLE 1 - Baseline Patient Characteristics

	BIOMET RINGLOC		
	Growl Group 1 n =	Group 2 n =	Groups 1& 2 n =
Sex: males	26 (49%)	31 (37%)	57 (42%)
females	27 (51%)	53 (63%)	80 (58%)
Age: mean	65	68	68
(years) range	34-88	23-89	23-89
Weight: mean	166	171	169
(pounds) range	100-251	99-319	99-319
Mean Preop HHS	**45.6**	52.5	46.6
Range	10-94	19-90	10-94

Table 1 provides baseline data for age, sex, weight, and preop Harris Hip Scores (HHS) collected for the Biomet Group 1, Group 2, and Groups 1 and 2 combined. The baseline data for sex, age, and weight are comparable for Groups 1, 2, and combined.

RESULTS

Group 1

Of the 53 liner procedures in Group 1 with follow-up, 47 Ringloc liners (88.7%) have proveded stability with no recurrent dislocations reported. Five patients (liners) suffered six recurrent dislocations, four liners were revised, one patient was converted to a bipolar device, and one non-complaint patient with a previous liner revision was not revised again. The recurrent dislocations occurred at 2, 5, 10, 16, 20, and 24 months postoperative. The average time from the operative procedure to dislocation was 12.8 months. The recurrent dislocation rate for this group is 11.3% (95% C.I. 4.3% - 23.0%). The one year dislocation-free survival probability is 95.6% (95% C.I. 89.5% - 100%)

Radiographic data was available for 41 (77%) of the 53 liners. Of these 41 liners, one patient (2.4%; 95% C.I. 0.1% - 12.9%) was radiographically unstable.

Eight liners total (15.1%; 95% C.I. 6.7% - 27.6%), including the four liners revised for recurrent dislocation, were revised in this group. The remaining four liner revisions were due to infection (two), aseptic loosening (1), . .nd broken cement (1). The one year revision-free survival probability is 93.0% (95% C.I. 85.2% - 100.0%).

Group 2

Recurrent dislocation was found in three patients in this group at 4, 5, and 6 weeks. The average time from the operative procedure to dislocation was 5 weeks. Two patients had their liner revised at the time of dislocation and one had their femoral head only replaced and the ring was re-inserted. These three patients represent a 3.6% (95% C.I. 0.7% - 10.1%) recurrent dislocation rate for this group. The one year dislocation-free survival probability was 96.4% (95% C.I. 9 1.5 – 100.0%).

Radiographic data was available for 58 (69%) of the 84 patients in this group and all were found to be radiographically stable. One patient's x-rays showed a lmm radiolucency, where she was allografted and cemented. There was no sign of loosening and the surgeon stated this lucency is seen "all the time and is not always progressive".

Six liners (7.1%; 95% C.I. 2.7% - 14.9%), including the three due to recurrent dislocation, were revised in this group. Of the remaining three liner revisions, one each was revised due to infection, pelvic diastases, and poor bone quality. The one year revision-free survival probability is 86.5% (95% C.I. 73.9 – 99.1). The one year revision-free survival probability is 86.5% (95% C.I. 73.9% - 991.1%).

Clinical outcomes for both groups are defined as primary outcomes (recurrent dislocation, radiographic stability) and secondary outcomes (revision, infection, Harris Hip Score). The following **Table** 2 summarizes the primary and secondary outcomes for Group 1, Group 2, and Groups 1 & 2 combined.

TABLE 2 - OUTCOMES SUMMARY			
	Group 1	**Group 2**	**Groups 1&2**
	n=53	n=84	n=137
	n %	n %	n %
Primary Outcomes: Recurrent dislocation	6 (11.3)	3 (3.6)	9 (6.6)
	n=41	n=58	n=99
Radiographic data: Radiolucent lines – yes	1 (2.4)	1 (1.2)	1 (1.0)
Loosening – yes	1 (2.4)	0 (0.0)	1 (1.0)
Osteolysis – yes	0 (0.0)	0 (0.0)	0 (0.0)
Stable – yes	41 (97.4)	58 (100.0)	98 (99.0)
	n=53	n=84	n=137
Secondary Outcomes: Liner revision	8 (15.1)	6 (7.1)	14 (10.2)
Other revision	1 (1.9)	8 (9.5)	9 (6.6)
Infection (deep)	2 (3.8)	3 (3.6)	5 (3.6)
Infection (superficial)	1 (1.9)	1 (1.1)	2 (1.5)
	n=39	n=6	n=45
Post-op HHS (points)	69	76	70
Range	O-100	62-100	O-100

Nine recurrent dislocations were reported on a total of seven patients (5.1%; 95% C.I. 2.1% - 10.2%) receiving the Biomet constrained liner between May 1995 - November 1998.

Nine revisions were reported in Group 1, which includes 8 liner revisions and one revision to a bipolar device. Group 2 had 14 revisions including 6 liner revisions, one femoral head revision, four stem revisions, and three patients where all the components were removed. A total of 23 (16.8%; 95% C.I. 11 .O% - 24.1%) revisions were found in the 137 patient population, which includes 14 (10.2%; 95 C.I. 5.7 – 16.6%) liner revisions. The one year revision-free survival probability (liner revision) is 90.0% (95% C.I. 83.0% - 96.5%).

TABLE 3 - CLINICAL OUTCOMES

	BIOMET RINGLOC		
	Group 1	**Group 2**	**Groups 1 & 2**
	n (%)	**n (%)**	**n (%)**
Number of liners	53	a4	**137**
Males	26 (49)	31 (37)	57 (42)
Females	27 (51)	53 (63)	80 (58)
Mean age (years)	65	66	66
Revision cases	45 (87)	63 (75)	108 (79)
Mean Follow-up (mo.)	14.8	4.9	8.9
Follow-up range	0.59-4 1	0.26-18	0.26-4 1
Harris Hip Scores (HHS)			
Mean Preop HHS	45.6	52.5	46.6
Range	1 o-94	19-90	1 o-94
Mean Postop HHS	67.6	75.7	68.7
Range	O-100	6?-100	O-100
Recurrent Dislocations			
	6/53	**3/84**	**9/137**
(%)	**(11.3)**	**(3.6)**	**(6.6)**

POTENTIAL ADVERSE EFFECTS

The following is the primary potential adverse events specific to the device.

a. Re-operation for dislocation of the hip joint (reported in B. 1 of the following complications table)

The following are complications noted during the retrospective review of clinical data collected for patients receiving the Biomet, Inc. Ringloc Constrained Liner. This retrospective study is included in "IX. SUMMARY OF CLINICAL INVESTIGATIONS"

COMPLICATIONS

Summary of Recurrent Dislocations

1. Patient #41 & #1 10 - two recurrent dislocations
   Age: 52 years Sex: Male Side: Right
   DOS: 5/6/96 & 10/6/96 Weight: 165 lbs.
   Primary diagnosis: avascular necrosis
   Number of previous revisions - 3, 4
   Patient dislocated hip at 5 months postoperative and was revised for the fourth time on 10/6/96. Patient broke ring on constrained liner and dislocated again 10 months postoperative. He is non-compliant and was not revised. At 27 months postoperative, no recurrent dislocation was reported.

2. Patient #12
   Age: 44 years Sex: Female Side: Left
   DOS: 4/23/96 Weight: 205 lbs.
   Primary diagnosis: rheumatoid arthritis
   Primary Procedure
   Patient dislocated hip at 16 months postoperative with complete avulsion of the acetabulum from the pelvic side with suspect infection. This severe destruction of the hip was caused by rheumatoid arthritis. The dislocation was due to poor bone quality and the liner did not fail. This patient was converted to a bipolar device.

3. Patient #97 & #152 - two recurrent dislocations
   Age: 78 years Sex: Female Side: Right
   DOS: 10/30/96 Weight: 145 lbs.
   Primary diagnosis: markedly con-minuted supracondylar and intracondylar fracture.
   Number of previous revisions: 3, 4
   Patient dislocated hip at 24 months postoperative and was revised 1 l/l 1/98 to another constrained liner, but did not include the poly locking ring this time. After 6 weeks postoperative this patient dislocated again and was revised for the fourth time on 2/1/99. Intraoperative inspection revealed a fracture of the liner of the cup causing this dislocation.

4. Patient #101
   Age: 56 years Sex: Male Side: Left
   DOS: 1 0/28/97 Weight: 225 lbs.
   Primary diagnosis: congenital deformity
   Number of previous revisions: 2
   Patient dislocated 6 weeks postoperative (12/11/97), the femoral head only was replaced and the ring was re-inserted. Patient has had no further hip problems as of 14 months postoperative.

5. Patient #28

Age: 75 years Sex: Female Side: Right
DOS: 12/24/96 Weight: 120 lbs.
Primary diagnosis: traumatic arthritis
Patient dislocated 20 months postoperative and was revised on 8/24/98. Her O-ring was fractured and was floating free.

6. Patient #141

Age: 63 years Sex: Female Side: Right
DOS: 8/2 1/98 Weight: 120 lbs. ,
Number of previous revisions: 1
Patient dislocated at 5 weeks postoperative and was revised on 9/30/98. Intraoperatively it was noted that the stem and cup showed no signs of loosening. The femoral head had dislodged out of the constrained liner. The liner demonstrated fracturing of the polyethylene along the inferior and posterior segments. The ring was intact. This patient had a history of sepsis and on 1 i/9/98 all the components were removed due to infection.

7. Patient #67

Age: 72 years Sex: Female Side: Right
DOS: 10/31/96 Weight: 134 lbs.
Revision for infection
Patient dislocated at 2 months postoperative and her liner was revised on 12/31/96. At 12 months postoperative with her second liner, her x-rays look fine and she has had no recurrence of drainage or dislocation.

COMPLICATIONS (Retrospective Data)	Biomet Ringloc Constrained Liner Patients	Group 1	Group 2	Groups 1 & 2
		n=53	n=84	n=137
		n %	n %	n %
A. Recurrent dislocation		6 (11.3%)	3 (3.6%)	9 (6.6%)
B. Revisions (of liner) due to:				
	1. recurrent dislocation	4 (7.5%)	2 (2.4%)	6 (4.4%)
	2. infection	2 (3.8%)	21.2%) 0	3 (2.2%)
	3. aseptic loosening	1 (1.9%)	(.0%) 1	1 (0.7%)
	4. pelvic diastases	(00%)	(1.2%)	1 (0.7%)
	5. broken cement	21.9%)	(00%)	1 (0.7%)
	6. cup pulled out of pelvis (due to poor bone quality)	0 (.0%)	11.2%)	1 (0.7%)
	7. fractured stem	0 (.0%)	1 (1.2%)	(1 0 . 7 %)
	TOTAL NUMBER OF LINER REVTSIONS	8 (15.1%)	6 (7.1%)	14 (10.2%)
C. Other Revisions				
	1. femoral head only due tc recurrent dislocation	0 (0%)	11.2%)	1 (0.7%)
	2. femoral component revised	0 (.0%)	4 (4.8%)	4 (2.9%)
	3. loose painful hip, possibly infected (removed components)	0 (. 0%)	11.2%)	1 (0.7%)
	4. complete avulsion of acetabulum converted to bipolar device	1 (119%)	0 (.0%)	1 (0.7%)
	5. infected, removed components	0 (.0%)	2.4%)	2 (1.5%)
D. Other Complications				
	1. hematoma	1 (1.9%)	1 (1.2%)	2 (1.5%)
	2. infected hip wound	11.9%)	11.2%)	2 (1.5%)
	3. trochonteric bursitis	0	1	1 (0.7%)

	(.0%)	(1.2%)	
4. heterotopic ossification (secondary to fall)	0 (.0%)	21.2%)	1 (0.7%)
5. excision of trochanteric fragment from previous surgery (non union)	1 (1.9%)	0 (.0%)	1 (0.7%)
6. protruding hardware removal	0 (.0%)	1 (1.2%)	1 (0.7%)
7. tendonitis in foot (cause limp)	1 (1.9%)	0 (.0%)	1 (0.7%)
1. posterior tibia1 blood clot	0 (.0%)	1 (1.2%)	1 (0.7%)
2. supracondylar femur fracture (fell out of bed while in nursing home)	1 (1.9%)	0 (.0%)	1 (0.7%)
10. liver problems	0 (.0%)	1 (1.2%)	1 (0.7%)
11. heart problems	0 (.0%)	2 (2.4%)	2 (1.5%)
TOTAL	20 (37.7%)	25 (29.8%)	45 (32.9%)

SUMMARY OF LABORATORY TESTING OF BIOMET RINGLOC

The primary objective of the pre-clinical studies was to define the mechanical characteristics of the device. Testing was conducted to determine the lever-out force, and pull-out resistance, and push-out resistance of the device.

a. Lever-out Resistance – Liner/Shell

Femoral head and constrained acetabular cup were tested to determine the lever-out force necessary to separate the two components. The force necessary for separation of the components ranged from an average of 1630 lbs. for initial lever-out to an average of 1398 lbs. on the second lever-out. These results indicate that the device should withstand physiologic loading.

b. Push-out Resistance – Liner/Shell

This test was conducted to measure the push-out force necessary to separate the acetabular liner from the metal shell. The force required to push the liner from the shell ranged from an average of 740 lbs. for the initial push to an average of 450 lbs. on the fourth push, These results indicate that the device is expected to survive physiologic loading.

c. Femoral Head Push-in and Pull-out - Cup/Head

This test measures the force necessary to push a 32 MM femoral prosthesis head into the assembled constrained liner, and the tensile force required to pull a 32 MM femoral prosthesis head from the assembled constrained acetabular cup. The mean maximum load required to push the femoral head into the assembled cup is 40.4 lbs. The mean maximum load required to pull the femoral head from the assembled cup is 36 1.4 lbs.

d. Femoral Head Toggle-Out – Cup/Head

This test was performed to determine the torque necessary to toggle the femoral head out of the socket after impingement of the femoral neck on the rim of the liner. The mean maximum torque to failure was 622 inch pounds.

e. Cup / Liner Conformity (congruency)

Benjamin I. Rosner, B.S.; Paul D Posta ., B.S.; and Seth A. Greenwald, D.Phil.(Oxon); ***Cup Liner Conformity Of Acetabular Designs,*** AAOS 1995, Orthopaedic Research Laboratories, The Mt. Sinai Medical Center.

f. Characterization of UHMWPE / Titanium 6Al-4V Alloy

The UHMWPE used in the construction of this device conforms to the voluntary consensus standard published by the American Society of Testing and Materials (ASTM) F-648-98 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants recognized by the FDA. Chemical and mechanical properties of the material are detailed in a. master file (MAF-434) submitted to and residing with the Agency. This material is similar to the UHMWPE used to manufacture Biomet class II commercially available total joint prostheses, including semi-constrained total hip prostheses.

The titanium 6Al-4v alloy used in the construction of the locking ring conforms to the voluntary consensus standard published by the American Society for Testing and Materials (ASTM) F- 136-98 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications.

COMPARISON BETWEEN CONSTRAINED AND SEMI-CONSTRAINED HIPS – CHRONIC DISLOCATIONS

A. Comparison between constrained liners and semi-constrained liners

1. Chronic Dislocations
   a. Comparative Summary of dislocations, pain, function, radiographic

B. Dislocation studies chosen to summarize for comparison

1. (7)Schulte KR, et al, The outcome of Charnley total hip arthroplasty with cement after a minimum twenty-year follow-up. The results of one surgeon. JBJS 1993 July 75(7): 1418
2. (8)Turner RS, Postoperative Total Hip Prosthetic Femoral Head Dislocations. Incidence, etiologic Factors, and Management. Clinical Otthopaedics, 1994 April, (30 1):196-204.
3. (6)Paterno SA, et al, The influence of patient related factors and the position of the acetabular component on the rate of dislocation after total hip replacement. JBJS Vol 79-A, No 8, August 1997

C. Constrained hip studies chosen to summarize for comparison

1. (10)Anderson MJ, et al, Constrained Acetabular Components, Journal of Arthroplasty, Vol 9 No 1: 1994: 17-23
2. (16)Lombardi AV, et al, Preliminary report on the S-ROM constraining acetabular insert: a retrospective clinical experience. Orthopedics, March 1991, Vol 14 No 3: 297-03
3. (14)Goetz DD, et al, Salvage of Total Hip Instability with a Constrained Acetabular Component, Clinical Orthopaedics, 1998 October, (355): 17 l-8 1.
4. (13)Goetz DD, et al, Salvage of a Recurrently Dislocating Total Hip Prosthesis with Use of a Constrained Acetabular Component. A Retrospective Analysis of Fifty-Six Cases. Journal of Bone and Joint Surgery, 1998 April; 80(40): 561-5.
5. Biomet retrospective study on the Ringloc constrained acetabular liner, unpublished, 1999.

BASELINE COMPARISONS OF ANDERSON, ET AL, (10); LOMBARDI, ET AL, (16); GOETZ, ET AL (14) (13); AND BIOMET RINGLOC - CONSTRAINED HIPS

STUDY	Anderson et al (10)	Lombardi et al (16)	Goetz et al (14)	Goetz et al (13)	Biomet Ringloc
DEVICE	Constrained S-ROM	Constrained S-ROM	Constrained Osteonics	Constrained Osteonics	Constrained Ringloc
NUMBER OF CASES	N=21	N=57 55 patients	N=101 98 patients	N=56 55 patients	N=137
SEX	10 males 11 females	25 males 30 females	36 males 65 females	19 males 36 females	57 males 80 females
TYPE OF SURGERY	2 1 revision	6 primary 51 revision	38 primary 56 revision	56 revision	29 primary 108 revision
FOLLOW-UP	Avg. 31 months Range 24-64 months	Avg. 27.7 months Range 24-35 months	Living patients avg. 61 months Range 24-97 months Deceased avg. 19 mos.	Avg. 64 months Range 37-97 months	Avg. 9 months Range 1-41 months
RESULTS					
Dislocations Following Surgery	6 of21 (29%)	8 of 55 (14.5%)	2 of27 (9%) in deceased patients 2 of 77 (3%) in living patients	2 of 55 (3.6%) deceased patients 1 of 16 (6%) living patients 1 of 38 (2.6%)	9 of 137 (6.6%)
HSS or other evaluation at most recent follow-up	7 excellent 2 good 2 fair 10 poor	67.26 HSS average 29.25-93.25 range	68 no pain 16 mild 8 moderate 4 severe	38 living 35/38 no to mild pain 31/38 no to mild limp 26/38 no aid to cane	68.7 HSS average 0- 100 range
Time to dislocation	10 months average (l-30 mos. range)	2.5 months average (l-9 mos. Range)	4 & 17 mos. in deceased 53 & 64 mos. in living patients	Both hips dislocated repeatedly post surgery	9 months average range 1-24 months

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ACETABULUM RADIOGRAPHICALLY STABLE	21/21 (100%)	48/50 (96%)	97/101 (96%)	49/56 (88%)	98/99 (99%) EVALUATED
PAIN AND FUNCTION					
Pain	N/A	37.2 HSS	87% none to mild	35/38 (90%) none to mild	
Function	N/A	23.5 HSS	72% no to mild limp	37/39 (95%) no/mod limp	
Deformity	N/A	3.2 HSS	54% no aid to cane	26/38 (68%) no aid/cane	
ROM	Avg. 102"	3.4 HSS	N/A	N/A	
Total	76 (32-100)	67 (29-94)	N/A	N/A	

STUDY	Schulte et al (7)	Turner (8)	Paterno et al (6)		
DEVICE	Semi-Constrained	Semi-Constrained	Semi-Constrained		
NUMBER OF CASES	N=322	N=561	N=446		
SEX	159 males 171 females	215 males 346 females	208 males 349 females		
TYPE OF SURGERY	254 primary 68 revision	477 primary 84 revision	391 primary 169 revision		
FOLLOW-UP	20 years minimum	2 – 20 years	6 years avg. range 2-12 for primary 5 years avg. range 2-10 for revision		
RESULTS					
Dislocations Following Surgery	3 /322 (1%) 1/98 (1%) alive at 20 years post surgery	25/561 (4.5%) 9125 recurrent	32/560 (6%) 17/391 (4%) for primary 15/169 (9%) for revision		
HSS or other evaluation at most recent follow-up	Outcomes at 20+ years 83 (85%) no revision 9 (9%) 1 rev 4 (4%) 2+ rv 2 (2%) resection	Not reported	Study found no effects of age, gender, obesity, diagnosis on dislocation after primary or revision		
Time to dislocation	Not reported	1-9 year range reported	Avg. 4 months Range O-38 months (7 occurred while in the hospital)		

Acetabulum Radiographically Stable	2791322 (87%)	Not reported	Not reported		
PAIN AND FUNCTION					
Pain Function Deformity ROM Total	90% none to mild 78% wlk 30 min.-no Imt. 98% no aid to cane N/A N/A	Dislocation Rates Only	Dislocation Rates Only		