

SECTION VII

**PUBLISHED/UNPUBLISHED
CLINICAL RESULTS**

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A. Unpublished Clinical Studies

Device Descriptions

The metal/metal (experimental) and metal/polyethylene (control) devices in this clinical summary report are all semi-constrained total hip prostheses from three orthopaedic device manufacturers.

The metal/metal acetabular components are two-piece modular components consisting of 28 mm, 32mm and 36mm inner diameter cobalt chromium molybdenum (Co-Cr-Mo) alloy bearing inserts fitted to the outer shells by means of a taper fit mechanism. The outer rims of the bearing inserts are either neutral or have extended lips to provide for additional coverage of the modular femoral heads. The metal outer shells are manufactured from either commercially pure (CP) titanium or titanium alloy (Ti-6Al-4V). The outer surfaces of the acetabular components have either sintered or plasma sprayed porous coatings to provide for biological ingrowth as a means for primary fixation. The porous coatings are manufactured from either CP titanium or titanium alloy. Some acetabular components have screw holes located on the outer shells to allow for adjunctive fixation with bone screws.

The metal/polyethylene acetabular components are two-piece modular components consisting of 28mm inner diameter ultrahigh molecular weight polyethylene (UHMWPE) bearing insert liners fitted to the outer shells by means of snap-fit locking mechanisms. The metal outer shells were manufactured from either commercially pure (CP) titanium or titanium alloy (Ti-6Al-4V). The outer surfaces of the acetabular components all have either sintered or plasma sprayed porous coatings to provide for biological ingrowth as a means for primary fixation. The porous coatings are manufactured from either CP titanium or titanium alloy. The acetabular components have screw holes located on the outer shells to allow for adjunctive fixation with bone screws.

The femoral prostheses components for both the experimental and control device configurations are manufactured from either titanium or cobalt chrome alloys. The femoral components have proximal tapers to receive the modular ball heads having diameters that match the inner diameters of the acetabular prostheses. Both cemented and uncemented femoral prostheses were implanted in these studies.

Methods

The results from three prospective, multicenter regulated clinical trials conducted in the U.S. and one prospective, multicenter regulated trial conducted in Europe of metal/metal

semi-constrained total hip prostheses are presented. A total of 45 centers, 40 U.S. centers and five European centers, participated. The results reported for the patients in this summary cover surgeries that were performed between December 1995 and February 2000. The results from randomized, concurrent control populations of metal/polymer (polyethylene) semi-constrained total hip prostheses from two of the U.S. multicenter trials are also reported.

All patients underwent primary total hip replacement, cemented or uncemented, for noninflammatory degenerative joint disease (NIDJD). NIDJD is a composite of diagnoses that includes osteoarthritis, traumatic arthritis, avascular necrosis, acute traumatic fracture of the femoral head or neck, and diastrophic variant. Due to the similar prognostic indicators for these diagnostic categories, pooling them under the heading of NIDJD is appropriate.

Patients were followed longitudinally preoperatively and at six weeks, six months, and annually following their surgeries. The results from their primary total hip replacement surgeries were recorded on case report forms for compilation into electronic databases. The Harris Hip Evaluation score (HHS) was the primary instrument employed for recording the clinical results.¹ Radiographic observations recorded for the femoral and acetabular components utilized the radiographic zones described by Gruen, et al.,² and by DeLee and Charnley³ respectively. Complications observed during the surgery and postoperatively were also recorded and submitted to the study sponsors for compilation into the database.

Tabulations of the compiled data from three of the multicenter trials are provided as display tables attached to this summary report and as Appendix 1. The display tables stratify the compiled data according to device type, i.e., metal/metal versus polyethylene. Summary tables display the mean total scores and scores from selected parameters comprising the HHS for the preoperative baseline and 24 month or greater follow-up time intervals. Frequency distributions of the observations for selected radiographic parameters are also displayed by device type. Operative and postoperative complications for all of the metal/metal and metal/polymer hip cases were categorized by type, i.e., operative site or systemic, and the frequencies of their occurrences tabulated. Details, where available, of complications thought to be device related are reported.

Results

Patient demographics are displayed in table 1. A total of 873 patients (927 hip cases) from the four multicenter clinical trials are included in this report. There were 54 patients with bilateral hip replacements. Of these 927 cases, 624 cases received metal/metal total hip replacement prostheses and 303 cases received metal/polyethylene total hip replacement prostheses. The mean age for the metal/metal cases was close to that for the metal/polyethylene cases (54.4 yrs vs. 54.9 yrs). The ratio of males to females was higher for males for both the metal/metal hip cases (1.47 male: 1 female) and metal/polyethylene hip cases (1.91 male:1 female). The frequency distributions across the diagnostic

categories comprising NIDJD displayed in table 1 show osteoarthritis as the most common diagnosis followed by avascular necrosis.

Table 2 displays the number of metal/metal hips and metal/polyethylene hips evaluated at or beyond the 24 month time interval. Only the latest evaluations were counted; therefore cases with evaluations beyond 24 months were rolled into the 24 month interval, thereby establishing an interval termed the 24(+) months time interval. The average follow-up was 27.1 months for the metal/metal hip cases and 27.3 months for the metal/polyethylene hip cases.

Table 3 displays the preoperative baseline, 12 and 24(+) months HHS mean total scores by device type. This table also displays the pain and function parameters mean scores for these same intervals. (Note: The function parameter includes the scores for range of motion and deformity for 56 points possible.) The mean total HHS score for the metal/metal hip cases at 24(+) months follow-up was 95.5 points. The mean HHS score for the metal/polyethylene cases at 24(+) months follow-up was 92.5 points. The mean HHS scores for each parameter for each time interval are provided in the summary tables in Appendix 1. (Note: Data from one of the U.S. multicenter trials were not available for inclusion in the summary tables in Appendix 1.)

The radiographic observations from three of the multicenter trials were compiled from the 24 month or later time interval and included in the 24(+) months interval. Only the latest evaluations were counted. The number of observations recorded for seven radiographic parameters from the 24(+) months radiographic evaluations appear in table 4. For each parameter in table 4, the numerator represents the frequency of occurrence and the denominator is the number of evaluations for which the parameter was completed. The frequencies of observations for each parameter for each time interval are provided in the summary tables in Appendix 1. (Note: Data from one of the U.S. multicenter trials were not available for inclusion in the radiographic summary tables in Appendix 1.)

Notable differences appear in table 4 for the number of radiolucencies observed surrounding the acetabulum and the AP views of the femoral components. None of these metal/metal hip cases with observed radiolucencies in the acetabulum had them in all three radiographic zones. There were two cases with radiolucencies in two x-ray zones and 12 cases had lucency in one of the zones. While the number of radiolucencies is slightly higher for the metal/metal acetabulum components, the reverse is true for AP radiographs of the metal/polyethylene device femoral components.

Tables 5-7 display the reported operative and postoperative complications for all metal/metal and metal/polyethylene hip cases. Postoperative complications were classified as either operative site or systemic.

There were no operative complications reported for any of the 303 metal/polyethylene hip cases. (Table 5) Of the four metal/metal hip operative dislocations, all were resolved; however one of these cases suffered a second dislocation two weeks postoperatively.

One case suffered a disassociation of the metal insert component intraoperatively. The disassociation was believed to be the result of improper alignment of the metal insert prior to seating in the outer shell of the acetabular component. Both the insert and outer shell components were removed and replaced with a metal/polyethylene acetabular prosthesis and the patient was withdrawn from further follow-up. No further complications were noted for this case.

There were three deep infections reported for three metal/metal hip cases. (Table 6) The first case became infected five months postoperatively and following further infection-related complications was subsequently revised nine months after the initial surgery. The second case had a confirmed deep infection 29 days postoperatively. This patient was treated with debridement and medications. The hip prosthesis has not been removed to date. The third case was a suspected deep infection 19 months postoperatively. No other information was available for this case.

A total of 11 postoperative dislocations/subluxations were reported for seven metal/metal hip cases. (Table 6) One case suffered three hip dislocations and two cases each suffered two dislocations. Two of these seven cases were treated with closed reductions, two cases were reduced, but the type of reduction (closed or open) was not specified. One of the cases with the reduction not specified was the patient who also suffered an intraoperative dislocation. One case had no treatment specified, but it was noted that a revision of the prosthesis was believed necessary. The remaining two cases required that their metal/metal hip prostheses be revised as a result of their dislocations.

There were three deaths reported for four hip cases. (Table 7) One patient had a metal/metal hip, one patient had a metal/polyethylene hip and the third patient was a bilateral case having both metal/metal and metal/polyethylene prostheses. The first patient expired from cardiovascular complications, the second patient died after a cerebral aneurysm and the third patient was reported to have died from natural causes. None of these deaths are considered to be related to the hip replacement prostheses.

There have been eight metal/metal hip prostheses and one metal/polyethylene hip prostheses revised. (Table 6) Three of the metal/metal hip revisions were considered to be attributable to the device and five were not device related. The three device related revisions were discussed previously as those cases having an intraoperative disassociation of the device and two cases suffering postoperative dislocations. The fourth revision, also discussed previously, was the result of a postoperative deep infection. The four remaining metal/metal hip revisions consist of two cases revised because of loosening and two cases revised due to cement failure. These four revisions were believed to be the result of poor cement fixation of the femoral prostheses and were not caused by the metal/metal device.

Conclusions

The results from four multicenter regulated clinical trials of metal/metal semi-constrained total hip prostheses were pooled for evaluation of the clinical and radiographic outcomes

of patients undergoing primary total hip replacement surgeries with these devices. The metal/metal hip HHS scores at two or more years follow-up were slightly higher than those from a patient group with metal/polyethylene hip prostheses. The radiographic outcomes at two or more years were comparable. While the number of observed radiolucencies around the metal/metal acetabulum devices was slightly above the metal/polyethylene group of devices, the reverse was true for the number of radiolucencies around the femoral components for the AP radiographs. Dislocations/subluxations, both operative and postoperative, were higher for the metal/metal hip prostheses, and the disassociation of a third device may indicate that implantation of these devices is a technically demanding procedure.

The results from the studies demonstrate that metal/metal semi-constrained total hip prostheses pose no increased risks to patients and function in an equivalent manner to metal/polyethylene semi-constrained total hip prostheses provided that the surgeon is fully informed about and proficient with the surgical technique for their implantation.

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1. Harris, W.H. "Traumatic Arthritis of the Hip After Dislocation and Acetabular Fractures: Treatment by Mold Arthroplasty."; *J. Bone and Joint Surg.* 51A (1969): 737-55.
 2. Gruen, T.A., G.M. McNeice and H.C. Amstutz. "Modes of Failure" of Cemented Stem-type Femoral Components: A Radiographic Analysis of Loosening."; *Clin. Orthop.* No. 141 (1979): 17-27.

PATIENT DEMOGRAPHICS

| | METAL/METAL | | METAL/POLYETHYLENE | |
|---------------|-------------|-------------|--------------------|-------------|
| | N | MEAN | N | MEAN |
| AGE | 624 | 54.4 | 303 | 54.9 |
| GENDER | FEMALES | MALES | FEMALES | MALES |
| | 253 (40.5%) | 371 (59.5%) | 104 (34.3%) | 199 (65.7%) |

| NIDJD DIAGNOSIS | METAL/METAL | | METAL/POLYETHYLENE | |
|---------------------------------|-------------|---------|--------------------|---------|
| | N | PERCENT | N | PERCENT |
| OSTEOARTHRITIS | 487 | 78.00 | 224 | 73.90 |
| AVASCULAR NECROSIS | 75 | 12.00 | 47 | 15.50 |
| POSTTRAUMATIC | 25 | 4.00 | 17 | 5.60 |
| CONGENITAL HIP DYSPLASIA | 18 | 3.00 | 8 | 2.60 |
| OTHER | 19 | 3.00 | 7 | 2.30 |
| TOTAL | 624 | 100.00 | 303 | 100.00 |

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TABLE 2

FOLLOW UP

FOR HIPS EVALUATED AT LAST EVALUATION AT/AFTER 24 MONTH (24+)

| INTERVAL | METAL/METAL N | METAL/POLYETHYLENE N |
|--------------------------|--------------------|-------------------------|
| 24 | 97 | 66 |
| 36 | 30 | 20 |
| 48 | 2 | 2 |
| TOTAL | 129 | 108 |
| AVERAGE FOLLOW-UP | 27.1 MONTHS | 27.3 MONTHS |

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TABLE 3**HARRIS HIP TOTAL SCORE (MAX = 100)**

| INTERVAL | METAL/METAL | | METAL/POLYETHYLENE | |
|------------|-------------|------|--------------------|------|
| | N | MEAN | N | MEAN |
| PREOP | 598 | 47.0 | 289 | 46.8 |
| 12 MONTH | 293 | 92.7 | 153 | 94.0 |
| 24 + MONTH | 96 | 95.5 | 73 | 92.5 |

HARRIS HIP PAIN SCORE (MAX = 44)

| INTERVAL | METAL/METAL | | METAL/POLYETHYLENE | |
|------------|-------------|------|--------------------|------|
| | N | MEAN | N | MEAN |
| PREOP | 611 | 13.7 | 296 | 14.1 |
| 12 MONTH | 314 | 40.8 | 156 | 41.7 |
| 24 + MONTH | 125 | 42.1 | 85 | 40.5 |

HARRIS HIP FUNCTION SCORE (MAX = 56)

| INTERVAL | METAL/METAL | | METAL/POLYETHYLENE | |
|------------|-------------|------|--------------------|------|
| | N | MEAN | N | MEAN |
| PREOP | 598 | 32.9 | 289 | 32.8 |
| 12 MONTH | 294 | 51.9 | 153 | 52.2 |
| 24 + MONTH | 96 | 53.4 | 74 | 52.2 |

TABLE 4

RADIOGRAPHIC OBSERVATIONS AT 24 (+) MONTHS

| PARAMETER | METAL/METAL | | METAL/POLYETHYLENE | |
|--|-------------|------------|--------------------|------------|
| | # OBSERVED | PERCENTAGE | # OBSERVED | PERCENTAGE |
| FEMORAL STEM SUBSIDENCE | 2/112 | 1.8 | 2/80 | 2.5 |
| FEMORAL RADIOLUCENCY (AP VIEW) | 7/110 | 6.4 | 10/81 | 12.3 |
| FEMORAL RADIOLUCENCY (LATERAL VIEW) | 3/73 | 4.1 | 2/79 | 2.5 |
| RESORPTION OF SHAFT (AP VIEW) | 3/111 | 2.7 | 0/81 | 0.0 |
| RESORPTION OF SHAFT (LATERAL VIEW) | 0/73 | 0.0 | 0/79 - | 0.0 |
| LYSIS, FEMORAL STEM | 2/112 | 1.8 | 3/82 | 3.7 |
| CUP RADIOLUCENCY | 14/111 | 12.6 | 6/82 | 7.3 |

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INTRAOPERATIVE COMPLICATIONS

| COMPLICATIONS | METAL/METAL (N=624) | METAL/POLYETHYLENE (N= 303) |
|-----------------------------|------------------------|--------------------------------|
| COMPONENT DISASSOCIATION | 1 (.2%) | 0 (0%) |
| DIFFICULT FEMORAL INSERTION | 1 (.2%) | 0 (0%) |
| DISLOCATION | 4 (.6%) | 0 (0%) |
| FEMUR FRACTURED | 2 (.3%) | 0 (0%) |
| FEMUR PERFORATED | 3 (.5%) | 0 (0%) |
| TROCHANTERIC FRACTURE | 1 (.2%) | 0 (0%) |

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**POSTOPERATIVE COMPLICATIONS
OPERATIVE SITE COMPLICATIONS**

| COMPLICATIONS | POLYETHYLENE LINER (N=303) | METAL LINER (N= 624) |
|-----------------------------|----------------------------|----------------------|
| DEEP INFECTION | 0 (0%) | 3 (.5%) |
| *DISLOCATION/SUBLUXATION | 3 (1.0%) | 11 (1.8%) |
| FRACTURE OF FEMUR | 1 (.3%) | 2 (.3%) |
| HEMATOMA | 1 (.3%) | 0 (0%) |
| HETEROTOPIC OSSIFICATION | 1 (.3%) | 1 (.2%) |
| NERVE PALSY | 1 (.3%) | 0 (0%) |
| PAIN | 1 (.3%) | 7 (1.1%) |
| PATIENT FELL | 1 (.3%) | 0 (0%) |
| SUPERFICIAL WOUND INFECTION | 2 (.7%) | 1 (.2%) |
| TROCHANTERIC BURSITIS | 3 (1.0%) | 2 (.3%) |
| WOUND PROBLEM | 2 (.7%) | 2 (.3%) |

*Includes 1 metal/metal hip patient with 3 dislocations and 2 metal/metal hip patients with 2 dislocations/subluxations

| | | |
|--------------------|---------|----------|
| **REMOVAL/REVISION | 1 (.3%) | 8 (1.3%) |
|--------------------|---------|----------|

**Includes 2 patients revised due to cement fracture/failure; 2 patients revised for loosening due to poor cement technique; and 1 patient revised for intraoperative component disassociation.

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POSTOPERATIVE COMPLICATIONS SYSTEMIC COMPLICATIONS

| COMPLICATIONS | POLYETHYLENE LINER (N=303) | METAL LINER (N= 624) |
|------------------------|----------------------------|----------------------|
| CANCER | 1 (.3%) | 0 (0%) |
| CARDIOVASCULAR | 4 (1.3%) | 2 (.3%) |
| CENTRAL NERVOUS SYSTEM | 0 (0%) | 1 (.2%) |
| DEEP VEIN THROMBOSIS | 3 (1.0%) | 5 (.8%) |
| DERMATOLOGICAL | 0 (0%) | 1 (.2%) |
| EENT | 2 (.7%) | 0 (0%) |
| ENDOCRINE/METABOLIC | 1 (.3%) | 1 (.2%) |
| GASTROINTESTINAL | 4 (1.3%) | 3 (.5%) |
| GENITOURINARY | 7 (2.3%) | 0 (0%) |
| HEMATOLOGICAL | 2 (.7%) | 0 (0%) |
| MUSCULOSKELETAL | 15 (4.9%) | 16 (2.6%) |
| NEUROLOGICAL | 4 (1.3%) | 2 (.3%) |
| OTHER | 1 (.3%) | 4 (.6%) |
| PULMONARY EMBOLUS | 3 (1.0%) | 2 (.3%) |

| | |
|---------|---------|
| * DEATH | 3 (.4%) |
|---------|---------|

*Includes 1 patient with bilateral metal/metal and metal/polyethylene hip prostheses.

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B. Published Reports

The following is a summation of several significant articles found in published literature using a search of various medical databases. A tabular presentation of the clinical results (Table 8) and complications/adverse safety information (Table 9) from all publications identified in the bibliography is included at the end of this summary.

Albrecht-Olsen et al.¹ reviewed 238 Ring prostheses implanted during the period 1968-1979. Of those cases, 127 with a median follow-up of 9 years were available for evaluation with 90% of those patients demonstrating excellent/good results upon self assessment. Using the Charnley scale, 87% had a pain score of 4 or greater (score of 6 = no pain), 76% had a motion score of 4 or greater, and 57% had a walking score of 4 or greater. The author cites an infection rate of 2.5% (6 deep infections, 16 superficial infections). Four dislocations were also encountered. At the time of this evaluation, 17% (n=40) of the patients had been revised, mainly due to pain. Overall results predicted an 81% survival rate at 12 years, comparable to outcomes seen with metal-on-polyethylene articulation

Almby² reported on 93 patients receiving the Muller device, 57% of which had been followed for more than 10 years. Using the Charnley scale (6 possible points in each category), 90% had pain rating of 4 or better or a range of motion greater than 100°. Nine deep infections were reported. Thirty patients died (26 unrelated to device, 1 embolus, 1 ileus, 1 renal failure, 1 septic). Twenty-nine patients were revised (19 aseptically loose, 7 septic loose, 4 stem fractures, 1 fracture). Twenty-three acetabular and 16 femoral components showed signs of loosening. Femoral loosening was secondary to calcar resorption and cement settling in most cases. Survivorship in this series was calculated to be approximately 80% at 5 years and 57% at 10 years.

Andrew³ presented his results of 116 Ring patients followed for 8 years. Using the Harris scoring system (100 points possible), 33% of the patients had 80 points or greater with another 13% exhibiting total scores of 70-80. Using the Ring evaluation, 49% of the patients rated excellent or good. Two deep infections and 4 dislocations were encountered. Other complications included grade IV heterotopic ossification (5), fracture (4), embolic event (7), and sciatic palsy (1).

Results of 175 patients with the McKee-Farrar device at an average 13.9 years of follow-up are presented by August⁴. Using the Harris evaluation, the average total score was 76.4, with 48.9% having excellent/good outcomes. On self assessment, 90% of the patients rated themselves as having a satisfactory outcome. Sixty-four patients were revised, mainly for loosening, stem fracture and bone fracture. Over 50% of the stems and cups showed signs of looseness radiographically. Additionally, the cup showed signs of protrusion in 62.5% of rheumatoid patients. Heterotopic ossification (grade IV) was reported in 2.7% of the cases. August calculated survival at 84.3% at 14 years and 27.5% at 20 years.

Djerf⁴ presents results on 107 McKee-Farrar and 70 Charnley devices with 5 years followup. Analysis revealed 94% of patients to have no pain and 78% to have improved

flexion. Unrelated death occurred in 12% of the patients. Six infections (3.4%) and 4 dislocations (2.3%) were reported. Other complications included trochanteric problems (2.8%), nerve injury (1.7%), deep venous thrombosis (1.7%), pulmonary embolus (0.6%), fracture (0.6%), and ossification (0.6%). Loosening was evident in 32% of the cases. Analyses showed no significant difference in the outcomes of either implant.

A comparison was performed by Jacobsson et al²⁴ on a series of McKee-Farrar metal-on-metal patients and a series of Charnley metal-on-polyethylene patients. No major differences were observed between the two groups with regard to radiographs, Harris Hip Scores or walking ability. At 12 years, average Harris hip scores for the McKee-Farrar and Charnley were 82 and 83, respectively. At 20 years, average Harris hip scores were 75 and 77. Sixteen McKee-Farrar and eight Charnley devices were removed. No debris was noted in the McKee-Farrar retrievals. The infection rate is 2.8% for McKee-Farrar and 4.3% for the Charnley. The dislocation rate is 2.8% for the McKee-Farrar and 1.4% for the Charnley. Loosening of the McKee-Farrar was noted in 5 cups and 6 stems; 4 cups and 4 stems were loose in patients receiving the Charnley device. Extensive scalloping was observed in 5/11 Charnley devices. Nerve damage (1.9%) and femoral fracture (0.9%) were also reported with the McKee-Farrar device. Trochanteric pain (7.1%), deep venous thrombosis (4.3%), nerve damage (1.5%), pulmonary embolus (1.4%) and ectopic bone (1.4%) were experienced in the Charnley patients. This study determined that there was no statistically significant difference in survivorship at more than 11 years: 82% for the McKee-Farrar patients compared to 89% for the Charnley patients.

Jantsch²⁵ analyzed followup at 14 years in a series of 248 patients with 330 McKee-Farrar devices. Only 56% of the patients were followed clinically to this period (24% died, 17% untraceable, 3% refused participation). Using the Mayo rating system, 48% of the patients were found to have excellent/good ratings (62% if revisions are excluded). Based on radiographs available, 34% of the cups and 26% of the stems were unstable. There were 36 retrievals (22 cup and stem, 7 cup, 7 stem).

McKee³⁵ reports on four series of patients treated with the various iterations of the McKee-Farrar device from 1956-1971. As shown in the attached tables, postoperative outcome improved through each design iteration, with approximately 89% achieving excellent or good outcomes in the 1965-69 series (4-7 year followup) and 97% achieving excellent or good outcomes in the 1971 series (2 year or less followup). Retrievals have occurred in 4% of the 1965-69 series and 0% of the 1971 series. Fifteen (15) deaths were reported in the 1965-69 series; two were reported in the 1971 series. The reported rate of infection was 4% in the 1965 series and 0% in the 1971 series. Two dislocations (2%) were also reported in each of these series. Other complications include pulmonary embolus, deep venous thrombosis, shaft perforation, hematoma and heterotopic ossification.

Ring⁵² presents results on 106 metal-metal Ring prostheses with 7-17 years followup. Postoperatively, 83% were assessed as excellent/good clinically. Outcomes of the various design iterations is again presented in this article. Thirteen retrievals have occurred (7 femoral failures, 2 pelvic failures, 3 combination failures, 1 ankylosis). Survivorship of

patients implanted from 1968-73 was 81% at 18 years; survivorship was 95% at 16 years for those implanted from 1972-79.

Thirteen McKee-Farrar patients (15 devices) with an average follow-up of 23.7 years are presented by Schmalzried⁵⁸. The average Harris hip score of these patients was 86 with 11 patients having an excellent/good rating. These patients outscored a matched metal-on-poly control population on the SF36 Health Status questionnaire. Activity levels were also reported to exceed the averages for this age population. The only complication reported is that of lysis in three femurs and one acetabulum.

Zaoussis⁷⁹ presents results on 38 McKee Farrar patients followed for 12-20 years, with 26 having greater than 15 years followup. At the time of this evaluation, 45% were found to have very good outcomes. Fifty-three percent (53%) of the patients were pain free and 79% had 60-90° range of motion. Three infected components and four loose components were retrieved. There have been five dislocations (all in one patient). Nine components show looseness. Other complications include five peroneal nerve palsies, one cortical perforation and one ossification.

The review of the published literature suggests that good long term results comparable to current metal-on-polyethylene prostheses can be achieved with well designed metal-on-metal devices. As outlined, the complications encountered with metal-on-metal devices are common to current total hip arthroplasty. This review further highlights the importance of preventive therapies and proper surgical technique in good clinical outcomes.

Published reports by Dorr, et al. (1996), (2000), Hilton, et al. (1996), Wagner and Wagner (1996) and Weber (1996) of the clinical experience with the Metasul® (Sulzer Orthopedics, Austin, TX) metal/metal semi-constrained hip designs lend further support to the conclusions drawn from the results reported here. Copies of these reference articles are provided in Appendix 3.

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|--------------------------|--------|---|---|--|---|--|---|---|---|
| Albrecht- Olsen, 1 | Ring | 238 dev. (only 127 followed to 9 yrs) | 67 (20-82) (for all 238 hips) | 205-Prim. OA 33-Sec. OA or post trauma OA | 9 yrs. (6-17) (for 127 hips followed) | Charnley: Pain: 98% with ≤ 3/6 Motion: 83% with ≤ 3/6 Walking: 69% with ≤ 3/6 | Charnley: Pain: 87% with ≥ 4/6 Motion: 76% with ≥ 4/6 Walking: 57% with ≥ 4/6 | Charnley rating postop: 38% exc/good 62% fair/poor | Pt. assessment postop: 90% exc/good 10% fair/poor Of original 238 hips, 17 pts. were unwilling to participate, 51 pts. died (nondevice), and 23 were revised (131 devices). |
| Almby, 2 | Muller | 93 pts./ 106 dev. (only 63 pts. followed) | 64 (36-83) | 68%-OA 12%-RA 17%- Post. Trauma 3%-CDH | 57% with ≥ 10 yrs. | | Charnley rating (for 38 pts): Pain > 90% with ≥ 4/6 > 90% with ≥ 100 deg ROM | | Of original 93 pts., 30 died over 10 years (80% of these survived 5 years). 38/63 pts. retained device @ 16 yrs. Survivorship: ~80% @ 5 years ~57% @ 10 years |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|-----------------|--|-----------------|--|---------------------|--|--|---|--|
| Andrew, 3 | Ring | 179 pts. (only 116 pts/154 hips were followed long term) | 63 (21-83) | 138-OA 6-RA 6-Pagets 2-CDH 1-Ankyl.Spond. 1-Avasc. Nec. | 8 yrs. (5-12) | | Harris: 33% w/ 80 points or greater 13% w/70-80 points | Ring rating: 75(49%)- exc/good 67(44%)- fair/poor 12(7%)- no class | Postop Charnley range of movement for most hips was 101-160 degrees Of original 179, 55 died (nondevice related). Of remaining 124, only 116 were able to be followed clinically. |
| August, 4 | McKee Farrar | 175 pts./ 230 dev. | 60.3 (24-78) | 87.5%-OA 6.5%-RA 2.0%-CDH 2.0%-Post Trauma 2.0%-Other | 13.9 yrs (10-22) | | 76.4 (Harris) | 48.9%-exc/good 78%-Occ. Pain or no pain 90%-Pts. satisfied per self assessment | Survival: 84.3% at 14 years 27.5% at 20 years |
| Baldursson, 5 | McKee Farrar | 78 pts./ 105 dev. | 56 (20-75) | RA | 47 mos. (9-85) | d'Aub.: Pain- 1.8/6 Walking: 1.7/6 Mobility: 3.2/6 | d'Aub.: Pain- 5.5/6 Walking: 2.4/6 Mobility: 4.6/6 | | 14 pts. considered failures |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|--|--|-------------------------------------|--|-----------------------|---|---|---------------------------|-------------------|
| Bentley, 6 | McKee Farrar (M/F) Charnley (Ch) | 85 pts./ 101 dev. (M/F) 112 pts./ 128 dev. (Ch) | 51-80 (M/F) 38-84 (Ch) | 155-OA 32-RA | 1-4 yrs. | Charnley: Pain ≤ 3/6: 95%-M/F 92%-Ch Disability ≤ 3/6: 94%-M/F 89%-Ch ROM ≤ 100: 82%-M/F 88%-Ch | Charnley: No Pain: 83%-M/F 96%-Ch Disability ≥ 4/6: 85%-M/F 97%-Ch ROM ≥ 100: 88%-M/F 88%-Ch | | |
| Breck, 9 | Urist | 46 pts./ 47 dev. | 59.4 (23-84) | 17-unknown 6-RA 6-Injury w/o fracture 5-Fracture 3-Primary 2-Protrusio 2-Congenital 1-Dysplasia 1-Brain tumor 1-Cereb.Palsy 1-Asept. Necr. 1-Prior failure 1-Fract. Disloc. | 2.1 yrs. (6m-4yrs) | | 21- excellent 18- good | | |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|--|--------------------------------------|------------------|-----------------------------------|------------------------|----------------|-----------------|--|---|
| Bryant, 10 | Ring | 214 pts./ 253 dev. | | 96%-OA | | | | | Survival: 70.6% at 10 years 60.4% at 20 years |
| Debeyre, 13 | Urist | 54 pts./ 63 dev. | majority > 60 | "crippling coxarthrosis" | 33 > 2 yr 17 > 3 yr | | | d'Aub.: Pain: 74% w/ ≥ 5/6 Mobility: 65% w/ ≥ 5/6 | |
| Djerf, 14 | McKee Farrar (MF), Charnley (Ch) | 177 dev. 107 MF, 70 Ch. | 66.9 | 80%-OA 11%-Neck Fract 9%-RA | 5 yrs. | | | 94% with no pain 78% with improved flexion | Analysis of results showed no significant difference in McKee Farrar and Charnley implants |
| Dorr, 15 | Weber Metasul Cup/ APR Stem | 70 pts. (only 54 followed) | | | 2.7 yrs. (2y-4y) | 49 (Harris) | 93 (Harris) | 98% rated good or excellent 94% pts. had good or excellent self-assessment | Hip aspirates taken on metal/metal group and a metal/poly control group: <u>Metal/Metal</u> 10/22 w/metal particulate 6/22 w/poly particulate <u>Metal/Poly</u> 7/14 w/metal particulate 11/14 w/poly particulate |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|---|-------------------------|---|---|---|--|---|--|---|
| Evarts, 18 | Ring | 32 pts./ 34 dev. | 67 (43-83) | 16-Deg. Arthr. 5-RA 4-Avasc. Necr. 2-CDH 1-SCFE 1-Protrusio 1-Paget 1-Ank. Spond. 1-Cup | 2.5-3 yrs. | Iowa score: 33.5/100 Avg. ROM: 90 | Iowa score: 64.9/100 Avg. ROM: 150 | 36% had exc/good outcome at 3 yrs. compared to 72% at 1 yr. | Major loss of rating at 3 yrs. was due to pain and function category. Deep persistent groin pain was a common complaint. |
| Freeman, 20 | Howse McKee Farrar | 297 pts./ 360 dev. | OA pts: 65.7 (14-85) Polyarth Pts: 56.6 (24-80) | 191-OA 106-Polyarthr. | OA pts: 20.9 mos (6-72) Polyarth. Pts.: 28.8 mos (6-72) | | d'Aub.: 86% v.good/ good | OA pts: 91% V.good/good Polyarthr. Pts.: 77% V.good/good | Author cites difficulty in assessing polyarthritis pts. due to overall condition and involvement of disease. |
| Hilton, 23 | Weber Metasul- Cup/APR Stem | 74 pts. | | | 2.2 yrs. (6m-4y) | 48 (Harris) | 91 (Harris) | 99% rated good or excellent 95% pts. had good or excellent self-assessment | |
| Jacobson, 24 | McKee- Farrar (MF); Charnley (Ch) | 107 (MF) 70 (Ch) | 66 (MF) 68(Ch) | Osteoarthritis 76% - MF 85% - Ch. Rheumatoid 11% - MF 6% - Ch. | 29 MF @ 20 yrs. 11 Ch. @ 20 yrs. | | Harris score @ 12 years 82 - MF 83 - Ch 20 years 75 - MF 77 - Ch | | Survivorship Analysis: @ 12 years 82% - MF 89% - Ch. @ 20 years 77% - MF 73% - Ch No Statistically Significant Difference |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Oher Clinical Outcome | Other Comments |
|----------------------------|-----------------|--|-----------------|---|----------------------|----------------|---|--------------------------|---|
| Jantsch, 25 | McKee Farrar | 248 pts./ 330 dev. (Only 56% able to be followed long term) | 70 | 56%-Idio.Coxa. 31%-Dysplasia 5.2%-RA 3.9%-Post Trauma | 14 yrs. | | Mayo rating: Revisions excluded: 62% with exc/good Revisions included: 48% with exc/good | | Of original population: 24% died over long term 17% were untraceable 3% refused to participate (leaving 56% able to be followed) |
| Kreusch- Brinker, 28 | McKee Farrar | 531 pts/ 617 dev. | 61.8 (28-80) | Coxarthrosis 66% Post-trauma 16.5% Nutritional disorders and inflammatory processes 16.5% | 13.2 yrs. (11-18) | | | | Of original 531 pts., there were 153 deaths and 81 pts. lost to followup leaving 297 pts./335 dev. available. |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|---|---|----------------|---|---|----------------|--|---------------------------|-------------------|
| Langenskiold, 30 | McKee Farrar | 116 dev. | 63 (41-82) | | | | Charnley rating: Pain- 99% with ≥5/6 Walking: 97% with ≥4/6 ROM: 99% with >3/6 | | |
| Leinbach, 31 | Muller (Mull.), McKee Farrar (M/F), Ring (R), Charnley (Ch), Huggler (H) | 612 pts./ 700 dev. 427 Mull, 120 M/F, 40 R, 30 Ch, 16 H | 72 (22-89) | 58%-Deg. Arth. 7.5%-RA 12%-Revision 12%-Nonunion of femoral neck 4.5%-Idiop. Aseptic Necr. 3.5%-Sec. Arth. 2.5%-Other | 126@4yr 194@3yr 186@2yr 107@1yr 87@6 mo | | d'Aub. Rating: 46% excell., 45% good | | |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|---|---|----------------|--|--|---|--|--|---|
| Lindholm, 32 | Ring | 37 pts./ 40 dev. | 61 (44-74) | 36-OA 1-RA | 3 yrs. (1-6) | d'Aub.: Pain: 39/40 @ <u><2/6</u> Mobility: 33/40 @ <u><2/6</u> Gait: 40/40 @ <u><3/6</u> | d'Aub.: Pain: 27/40 @ <u>>4/6</u> Mobility: 29/40 @ <u>>4/6</u> Gait: 22/40 @ <u>>4/6</u> | Overall rating: 17.5% - Excellent 35% - Good | |
| McKee, 35 | McKee Farrar, multiple designs (`56-`60, `61-`64, `65-`69, `71-) | 526 dev. `56-`60- 26 dev. `61-`64- 100 dev. `65-`69- 300 dev. `71- 100 dev. | | 73%-OA 12%-Salvage 8%-RA For `65-`69 series only | 4-7 yrs. (for `65-`69 series only) <u>< 2 yrs</u> (for `71 series only) | | 57.6% fair/good /excellent (`56-`60 series) 80% exc/good (`61-`64) 89% exc/good (`65-`69) 97% exc/good (`71-) | | Article cites development of method/device over time. Improvements included technic, fixation of components to bone, design, and material. |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|--|--|----------------|---|---|---|--|--|--|
| McKee, 36, 37 | McKee Farrar | 50 dev. | | Chronic arthritis | | | 94% (47 pts.) had exc/good result | | |
| McMinn, 41 | McMinn | 235 devices (70 press fit, 6 HA, 43 cement, 109 hybrid) | 48.7 | Osteoarthritis 73.6% Inflammatory 8.5% Sec. Arthritis 10.6% Avasc. Necrosis 7.2% | Pressfit 50.2 mos; HA 40.2 mos; Cement 33.2 mos; Hybrid 8.3 mos. | Charnley score: Pressfit ~ 9/18 HA ~9/18 Cement ~9.5/18 Hybrid ~9.5/18 | Charnley score: Pressfit ~16.5/18 HA ~17.3/18 Cement ~16.5/18 Hybrid ~16.5/18 | | Hybrids (current practice) consist of HA coated M/M acetabular component with cemented femoral component |
| Morris, 42 | McKee Farrar (MF), Charnley (Ch) | 313 pts./ 399 dev (97 MF, 302 Ch) | | | | 89% w/ disabling pain 98% w/ restricted function 72% w/ movemt. Markedly reduced | Slight or no Pain: 86% MF 92% Ch Function of $\geq 5/6$: 59% MF 56% Ch Movemt. of $\geq 5/6$: 66% MF 83% Ch | Postop results represent 180 devices/131 pts. followed (125 Ch, 55 MF) | |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|--|-----------------------------------|------------------------|--|---|--|---|--|---|
| Nicholson, 43 | McKee Farrar (MF), Charnley (Ch) | 86 M/F, 939 Ch. | 73.4% ≥61 | 63%-OA 10%-RA 27%-Failures, misc. diagnoses | to ~6 yrs. | Charnley score: Pain: 2.79/6 Walking: 2.41/6 Movemt: 3.10/6 | | | Loosening of M/F led to preference for and long term followup of Charnley. |
| Patterson, 44 | McKee Farrar | 403 dev. (368 followed) | 70% were >60 yrs | 241-Idio.OA 42-Post.Traum. 39-RA 16-Dysplasia 7-Ank.Spond. 23-Other | 1.4 yrs. (3m-4y) 87 > 2 yrs | | | Charnley rating: 85% - pain improvement 76% - ROM improvement 69% - ability to walk improved | 20.1% of population had a previous operation of hip |
| Postel, 45 | Low Friction Band | 100 dev. | 67 | "variety of indications but in the usual proportions" | 6 yrs. | | | | |
| Postel, 46 | McKee Farrar | 113 dev. | 64 | 53%-Prim. OA 26%-Sec. OA | 9 yrs. (33% with 15 years) | | Rating: 56% V. Good/ Good 44% Poor/ V. Poor | For 91 nonrevised hips with 9 yrs followup, average pain/motion/ stability score is 14.8/18. | |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|---|--|--|---|--|---|---|---|--|
| Ring, 52 | Ring (Metal on Metal= M/M, Metal on Poly= M/P) | 172 dev. (106 M/M, 66 M/P) | 13 < 30 29 @ 31-40 130 @ 41-50 | "Young hips with primary or secondary degenerative changes" | 7-17 yrs (M/M) 1-7 yrs (M/P) | | Rating: 83% exc/good (M/M) 95.5% exc/good (M/P) | | Survivorship: Patients implanted 1968- 73 is 81% @ 18 yrs. Patients implanted 1972- 79 is 95% @ 16 yrs. |
| Ring, 50 | Ring | 128 pts./ 158 dev. | 69 (40-79) | 114 - Deg.Arth. 3 - Cup arthro. 2 - Judet revis. 3 - Osteotomy 5 - RA 1 - Ank.Spond. | Up to 4 yrs. | | Rating: 53.5%- excellent 42.5%- good | 82% no pain, 18% min. weight bearing pain 86 - >90 ROM 51 - 60-90 ROM | |
| Ring, 51 | Ring, 3 types (Metal- Metal, Poly Head, Metal- Poly) | 1598 pts./ 1808 dev. M/M-649 devices, Poly Head- 1159 devices | | | 5-14 yrs. | M/M only: 75%- Excellent 18%- Good | | | Metal/Metal results comparable to Metal/Poly results: 78%-Excellent 18%-Good |
| Ring, 53 | Ring | 1000 dev. 3 design modif. 193-Early 569-Mid 238-Curr | majority @ > 60 | 890-OA 62-Misc. 37-RA 7-CDH 4-Ank.Spond. | Early: 5-8 yrs. Mid.: 1-5 yrs. Current: < 1 yr. | | Early: 74%- exc/good Mid/ Current: 90% exc/good | | |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|---|--|-----------------------------|---|--|-------------------------|--|---|--|
| Ruszkowski, 54 | Ring | 59 pts./ 63 dev. | majority 60-70 | 69.8%-OA 11.2%-CDH 6.4%-RA 6.4%-Ank.Spo. 4.7%-Necrosis 1.5%-Injury | 36.8%- 4-5 yrs. 9.5%- 3-4 yrs. 31.8%- 2-3 yrs. 26.9%- <2 yrs. | | 33.3%- excellent 50.8%- good | | |
| Salenius, 55 | McKee Farrar | 126 pts./ 143 dev. | 20-76 (110 @ <50) | OA, RA | | | d'Aub rating: 78%- exc/good 9% - fair | Postoperatively, 103/139 reached ROM of 60-100 degrees | |
| Schmalzried, 56 | McMinn (MM); Wagner (W) | 19 pts./ 21 dev. (17 MM, 4 W) | 42 (22-64) | 7 - OA 3 - Dysplasia 2 - PTA 2 - Juv. Rheum. 2 - SCFE 5 - Other | 16 mos. (10-25) | UCLA score: 20/40 | UCLA score: 34/40 | Range of motion/function increased to better than that of a standard THR | All patients underwent trochanteric osteotomy |
| Schmalzried, 57 | McKee- Farrar (MF); Sivash (S) | 6 dev. (5 MF, 1 S) | 40.8 (21-57) | 2 - Legg Perthes 2 - OA 1 - Tuberculosis 1 - Avasc. Nec. | 21.3 yrs. (19-24.5) | | | | All were removals. Estimated wear was 4.2 µm/yr. |

Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|--|-----------------------|-----------------------------|--|---|-----------------------------------|-----------------------------------|---|---|
| Schmalzried, 58 | McKee Farrar (MF) | 13 pts./ 15 dev. | 58.3 (41-67) | 11-OA 2 - Juv. Rheum. 2 - Dysplasia | 23.7 yrs. (21-26) | | Harris score: 86 (71-95) | 11/13 pts. had excellent/good rating | Patient outscored matched control pop. on SF36. The average activity levels also exceeded the average for this age. |
| Shorbe, 63 | McBride | 92 pts/ 103 dev. | 83 pts. ≥ 50 | 52-Coxarthr. 17-Avasc. Nocr. 13-RA | | | 58-Good 22-Fair 6-Poor | | Of original 92, 3 were lost, 2 died, and 1 was revised. |
| Sivash, 66 | Sivash | 164 pts./ 200 dev. | | 107-Ank.Spond. 56-Tuber. Cox. 24-Bilat.Arth. 10-Pseudarthr. 3-Injury | 1-9 yrs. | | | 105/107 Ankylosing Spondylitis pts. had "excellent" results | |
| Smith, 67 | Gaenslin cup with Austin Moore or Leinbach stem | 36 pts./ 40 hips | 40-87 (20 > 60 years) | 19-Degen.Arth. 7-Prior surgery 4-RA 3-CDH | to 8 yrs. | | 75%-exc 12.5%- v. good | | |
| Smith, 68 | Gaenslin cup with Austin Moore stem | 92 pts./ 112 dev. | 33-87 | 71-Degen.Arth. 15-RA 13-Painful cup/stem | 56 @ 2-5 years 26 @ 5+ years 30 @ <2 years | d'Aub.: 106 dev. ≤ 7/18 | d'Aub.: 95 dev. ≥ 14/18 | | |

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Table 8 - Clinical Outcomes

| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|--|---|--|---|--|--|---|---|--|
| Wagner, 73 | Metasul | 105 dev. (70 thr, 35 resurf) | 49.5 (thr); 36.2 (resurf) | 47-Dysplasia 25-OA | 34.3 mos. (thr) 20 mos. (resurf) | Harris: 36 (thr) 32 (res.) d'Aub.: 9.3 (thr) 8.3 (res.) | Harris: 96(thr) 94 (res.) d'Aub.: 17.6 (thr) 17 (res.) | No thigh pain reported. | |
| Weber, 75 | Weber Metasul | 110 dev. (100 followed) | 59 (22-78) | 48 - OA 23 - Dysplasia 18 - Slip. Epip. 7 - RA 4 - Idio. Necr. | 3.5 yrs. (2-7) | Harris: 98%- fair/poor (70 points or less) | Harris: 98%- good/exc. (80 points or more) | | Retrievals @ 4,5,6 years showed signs of wear of 4.7, 4.5, 5.9 μ m |
| Wilson, 76 | Stanmore 3 groups based on design modif. | 101 pts./ 108 dev. Gr I: 14 dev. Gr II: 36 dev. Gr. III: 43 dev. | 21-81 | 55-Prim. OA 21-Failures 9-Tumor 6-RA 5-Other Arth. 4-Post Trauma 1-Ankyl.Spond. | 1.5-9 yrs. Gr I: 6-9 yrs. Gr II: 5-6 yrs. Gr III: 1.5-4 yrs. | | d'Aub: Pain free: Gr I: 57% Gr II: 72% Gr III: 93% ROM >60: Gr I: 86% Gr II: 83% Gr III: 95% | d'Aub. function, hips with minor to no restriction: 64% - Gr I 61% - Gr II 100% - Gr III | Clinical evaluations exclude tumor patients |

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| Author/ Ref. No. | Device | Patients/ Devices | Age (Range) | Diagnoses | Follow- up | Preop Score | Postop Score | Other Clinical Outcome | Other Comments |
|---------------------|-----------------|----------------------|---------------------|--|---|--|--|--|---|
| Wilson, 77 | McKee Farrar | 86 pts/ 100 dev. | 61 pts. > 60 yrs | 38-Bilateral Degen. Disease, 15-Unilateral Degen. Disease, 16-Failed Dev., 12-RA, 2-Ank. Spondy., 3-Post-Trauma | 2 years on all pts. (16@3yr) | Harris, Pain: 79 < 4/10 Walking: 65 < 4/10 Motion: 64 < 4/10 Function: 67 < 4/10 | Harris, Pain: 75 > 6/10 Walking: 63 > 6/10 Motion: 66 > 6/10 Function: 52 > 6/10 | | 21 failures not included in clinical evaluations |
| Zaoussis, 79 | McKee Farrar | 38 pts/ 43 dev. | | 25-OA 7-RA 5-Ank. Spond. 6-CDH | 12-20 yrs (26 pts w/ > 15 yrs) | | Rating: 45%-very good 36%-fair | 23(53%)- pain free 34(79%)-ROM of 60-90 | |

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Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|--------------------------|--------|--|---|--|---|---------------------------------|---------|---|-------|--|
| Albrecht- Olsen, 1 | Ring | 238 dev. (only 127 followed to 9 yrs) | 9 yrs. (6-17) (for 127 hips followed) | 40 (17%) Most for Pain 2 infect. 1 fracture | 51 (Add'1 20 lost to followup) | 16 super. 6 deep 2.5% | 4 | | | |
| Almby, 2 | Muller | 93 pts./ 106 dev. (only 63 pts. followed) | 57% with ≥ 10 yrs. | 29 pts/ 32 dev. 19 Asept. Loose. 7 Sept. loose 4 Stem Fx 1 Fx | 30 pts/ 31 dev. 26 nonrel. 1 PE 1 Ileus 1 renal 1 Sepsis | 9 deep | | 39 with signs of loosening (23-acet., 16 femoral secondary to cement settling + calcar resorp.) | | |
| Andrew, 3 | Ring | 179 pts. (only 116 pts/154 hips were followed long term) | 8 yrs. (5-12) | 15 7 femur 2 acetab. 6 both | | 2 | 4 | | | 5-Gr. IV ossification 4-Fracture 4-Emb. Attack 3-Pulm. Embolus 1-Sciatic palsy |

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| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|-----------------|-----------------------|---------------------|---|-------|-------------------|---------|--|-------|---|
| August, 4 | McKee Farrar | 175 pts./ 230 dev. | 13.9 yrs (10-22) | 64 loosening , stem fx., bone fx. | | | | 51.1%- cup 50.0%- stem 62.5% of RA protruded | | 2.7%- Gr. IV ossification |
| Baldursson, 5 | McKee Farrar | 78 pts./ 105 dev. | 47 mos. (9-85) | 5 1 disloc. 2 loose due to perforat'n 2 severe pain (14 are consid. "failures" due to loosening , sev. Pain, infection) | 1 | 9 super 2 deep | 1 | 9- cup migr, 11- fem.stem, 3- stem + cup | | 10-femoral perforation 6-Sign. Ossification 4-acetabular fracture 1-cerebral hemor. 1-hemiparesis 1-fracture |

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| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|--|--|-----------------------|---|---|---|---------------|--|-------|---|
| Bentley, 6 | McKee Farrar (M/F) Charnley (Ch) | 85 pts./ 101 dev. (M/F) 112 pts./ 128 dev. (Ch) | 1-4 yrs. | | 3 1 MF: cardiac arrest sec. to MI, 2 Ch: cardio- resp. fail. | Super: 4 MF 3 Ch Deep: 3 MF 0 Ch | 1 MF 2 Ch | 3 MF 0 Ch | | Small hematoma (5 MF, 12 Ch), Large hematoma (4 MF, 3 Ch), Urinary complication (6% overall) Embolism (2% overall) |
| Breck, 9 | Urist | 46 pts./ 47 dev. | 2.1 yrs. (6m-4yrs) | 3 2 disloc. 1 rheum. Arthritis | | | 5 | | | 6-Sciatic Palsy 3-Embolus |
| Bryant, 10 | Ring | 214 pts./ 253 dev. | | 67 (26.5%) 54-loose 2-sepsis 2-stem fx 2-disloc. 6-pain 1-ankyl. | 111 (43.9%) | | | | | |
| Dandy, 12 | McKee Farrar | 1042 dev. | | 27 (11-cup, 10-stem, 6-both) | | 2.3% (25 required reop) | 19 (1.86%) | 83 (44-cup, 25-stem, 14-both) | | 11-acet. Wall fracture 5-component fracture 3-sciatic palsy 2-femoral palsy |

Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|--|--------------------------------------|------------------------|--|-------|-----------|----------|--|-------|---|
| Debeyre, 13 | Urist | 54 pts./ 63 dev. | 33 > 2 yr 17 > 3 yr | | | | 1 cup | 49%- cup change 34%- stem settled | | |
| Djerf, 14 | McKee Farrar (MF), Charnley (Ch) | 177 dev. 107 MF, 70 Ch. | 5 yrs. | | 12% | 6 (3.4%) | 4 (2.3%) | 32% | | |
| Dorr, 15 | Weber Metasul Cup/ APR Stem | 70 pts. (only 54 followed) | 2.7 yrs. (2y-4y) | 2 (1 for recurrent disloc.) | 0 | 2% | 4% | 0 | 0 | 2% Peroneal Palsy |
| Evarts, 18 | Ring | 32 pts./ 34 dev. | 2.5-3 yrs. | 3 | 0 | 1 | 1 | Yes, mainly for decreased ROM and increased pain | | -Deep persistent thigh pain -Decreased ROM -Increased pain -DVT |

Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|---|-------------------------|---|---|------------------|---|----------------------------|---|-------|--|
| Freeman, 20 | Howse McKee Farrar | 297 pts./ 360 dev. | OA pts: 20.9 mos (6-72) Polyarth. Pts.: 28.8 mos (6-72) | | 16 all MI | OA: 3(1.4%) Polyarth: 10(7.4%) | OA-9 Polyarth- 5 | OA-4 Polyarth- 3 | | 8-DVT (7 OA, 1 PA) 3-PE (1 OA, 2 PA) 5-Acet.Fx (2 OA, 3 PA) 5-Fem. Fx (3 OA, 2 PA) 2-Ectopic bone (1 OA, 1 PA) |
| Hilton, 23 | Weber Metasul Cup/APR Stem | 74 pts. | 2.2 yrs. (6m-4y) | 1 (recurrent disloc.) | 0 | 1% | 4% | 0 | 0 | 1% Peroneal palsy 1% Femoral Fracture |
| Jacobbson, 24 | McKee- Farrar (MF); Charnley (Ch) | 107 (MF) 70 (Ch) | 29 MF @ 20 yrs. 11 Ch. @ 20 yrs. | 16 MF (no debris noted) 8 Ch | 0 | 2.8% MF 4.3% Ch | 2.8% MF 1.4% Ch | MF - 5 cup 6 stem Ch- 4 cup 4 stem | | McKee Farrar- 1.9% Nerve Damage 0.9%-Fem.Fracture Charnley 7.1%-Troch. Pain 4.3% DVT 1.5% Nerve Dmg-Ch 1.4%-Pulm. Embolus 1.4%-Ectopic bone Extensive scalloping in 5/11 Charnleys |

Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|----------------------------|-----------------|--|----------------------|---|--|---------------------------------------|---------|---|-------|--|
| Jantsch, 25 | McKee Farrar | 248 pts./ 330 dev. (Only 56% able to be followed long term) | 14 yrs. | 36 (22 cup/stem, 7 cup, 7 stem) Only 1 metal staining noted | | | | 34%-cup not stable 26%-stem not stable | | 24% pts - died without undergoing any reoperation 25%-Lost for followup |
| Kreusch- Brinker, 28 | McKee Farrar | 531 pts/ 617 dev. | 13.2 yrs. (11-18) | 101 84- aseptic loosening 17- inflam. loosening | 153 pts/ 183 dev. | 2.8% (17 inflam. Loose.) | | 84 aseptic loosening | | 22 cases of grade III ossification noted in 196 pts who still had prosthesis at avg. 14.8 yrs. |
| Langenskiold, 30 | McKee Farrar | 116 dev. | | | 3 2 uremia/ ileus 1 eucopenia | 3 | | 1 cup | | 8-hematomas 2-troch. Fracture 2-severe ossification 1-sciatic irritation 1-sciatic palsy 1-DVT 1-Super. Thromboph. 1-Cortex penetration |

Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|---|---|--|---|--|---|--|--|-------|--|
| Leinbach, 31 | Muller (Mull.), McKee Farrar (M/F), Ring (R), Charnley (Ch), Huggler (H) | 612 pts./ 700 dev. 427 Mull, 120 M/F, 40 R, 30 Ch, 16 H | 126@4yr 194@3yr 186@2yr 107@1yr 87@6 mo | 8 M/F (4 from femoral necrosis) | 12 | 7 (only 1 M/F) | 4 All M/F | 8 M/F (8 cups, 1 stem) 4 Ring | | 8-DVT (5M/F, 3R) 4-PE (3 M/F, 1 R) |
| Lindholm, 32 | Ring | 37 pts./ 40 dev. | 3 yrs. (1-6) | 12.5% | 0 | 5% deep | 0 | 40% | | 5%-Peroneal palsy 5%-DVT 2.5%-Rim fracture |
| McKee, 35 | McKee Farrar, multiple designs (`56-`60, `61-`64, `65-`69, `71-) | 526 dev. `56-`60- 26 dev. `61-`64- 100 dev. `65-`69- 300 dev. `71- 100 dev. | 4-7 yrs. (for `65-`69 series only) ≤ 2 yrs (for `71 series only) | `56-`60- 38% `61-`64- 30 revisions `65-`69- 4% `71- 0 | `56-`60- unknown `61-`64- unknown `65-`69- 15 (2 early, 13 late) `71- 2 (0 early, 2 late) | `56-`60 unknown `61-`64- 2% `65-`69- 4% `71- 0 | `56-`60- unknown `61-`64- 1% `65-`69- 2% `71- 2 disloc. | | | `65-`69- 3%-PE 1.3%-DVT 1%-Shaft perforation 0.3%-Hematoma `71- 2%-PE 3%-DVT 1 ossification 2 hematomas |

Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|--|--|---|---|---------------------------------|--------------------|---------------------------------------|---|-------|----------------|
| McKee, 36, 37 | McKee Farrar | 50 dev. | | 9 due to loosening , pts. fell, technique | 1 unrelated to device | 2 (superf.) | | | | |
| McMinn, 41 | McMinn | 235 devices (70 press fit, 6 HA, 43 cement, 109 hybrid) | Pressfit 50.2 mos; HA 40.2 mos; Cement 33.2 mos; Hybrid 8.3 mos. | Press fit- 6 HA- 0 Cement- Unknown Hybrid- 0 | None noted | Press fit- 2 | 0 (in all groups) | | | |
| Morris, 42 | McKee Farrar (MF), Charnley (Ch) | 313 pts./ 399 dev (97 MF, 302 Ch) | | | | | 0.25%- deep 2.5%- super. | 3.5%-Ch 0%-M/F Sublux. 3.2%-Ch 0%-M/F | | 13.2%-PE |

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|---------------------|--|-----------------------------------|---|---|---|--|---------------|---|-------|--|
| Nicholson, 43 | McKee Farrar (MF), Charnley (Ch) | 86 M/F, 939 Ch. | to ~6 yrs. | | 12 | 20 (11- in hospital 9- @1~2 yr) | 0 M/F 1 Ch | 16.3% - M/F | | 57-neck resorption 6-coronary disease 4-PE 1-Fat embolism 1-pneumonia 1-renal failure 1-M/F stem fracture |
| Patterson, 44 | McKee Farrar | 403 dev. (368 followed) | 1.4 yrs. (3m-4y) 87 > 2 yrs | 63 (15.5%) 36 mech. 17 biol. 10 tech. | 5 (1.36%) 2 serum hepatitis 1 myocar. Infarction 1 CVA 1 septic. | 30 (8.2%) | 8 (2.1%) | 27 (7.33%) 9 Aseptic 18 Septic | | 13(3.5%)- Nerve lesion 32(8.7%) - Periartic. Ossification 22(5.98%)- Thrombophlebitis 10(2.71%)- Gr. Troch. Nonunion 5(1.36%) - Pulm. Embolus |
| Postel, 45 | Low Friction Band | 100 dev. | 6 yrs. | 26 | | | | Yes, mostly in ischial region | | |
| Postel, 46 | McKee Farrar | 113 dev. | 9 yrs. (33% with 15 years) | 22 18 aseptic 4 septic | | | | 35 (31%) cup loose 5 stem loose | | |

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| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|---|--|---|--|--|------------------------|---------|--------------------|-------|----------------------------|
| Ring, 52 | Ring (Metal on Metal= M/M, Metal on Poly= M/P) | 172 dev. (106 M/M, 66 M/P) | 7-17 yrs (M/M) 1-7 yrs (M/P) | 13 M/M 7- fem. fail. 2- pelv. fail. 3- fem&pelv fail. 1-Ankyl. | | | | | | |
| Ring, 50 | Ring | 128 pts./ 158 dev. | Up to 4 yrs. | | 2 (pneum., Pulm. Embolus) | 1 | 0 | 0 | | 3-DVT 1-Cerebrovascular |
| Ring, 51 | Ring, 3 types (Metal- Metal, Poly Head, Metal- Poly) | 1598 pts./ 1808 dev. M/M-649 devices, Poly Head- 1159 devices | 5-14 yrs. | 101 (5.5%) mainly for pain | 21 (1.3%) (11/21 for PE) | 9 (0.5%)- deep inf. | 4 | 37% had changes | | 1-sciatic palsy |

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|---------------------|-----------------|---|--|--|--|-----------|---------|---|-------|---|
| Ring, 53 | Ring | 1000 dev. 3 design modif. 193-Early 569-Mid 238-Curr | Early: 5-8 yrs. Mid.: 1-5 yrs. Current: <1 yr. | 35 (3.7%) (14/16 loose in early group) | 11 (1.1%) (2 coron., 1 GI hemorr., 1 stroke, 7 PE) LOST: 58 | 0.7% | 0.3% | | | 7%-DVT 1.5%-PE 6-ossification 5-acet. thread fracture (in Gr I) |
| Ruszkowski, 54 | Ring | 59 pts./ 63 dev. | 36.8%- 4-5 yrs. 9.5%- 3-4 yrs. 31.8%- 2-3 yrs. 26.9%- <2 yrs. | 3 infection | | 3 | 0 | 5 (3 infection 2 unknown) | | 0 fractures 0 sciatic palsy |
| Salenius, 55 | McKee Farrar | 126 pts./ 143 dev. | | | 2 | 7(4.9%) | 4 | 18 (11.9%) (10-cup, 6-stem, 2-both) | | 4-Ossification 3-Cardiac infarct 2-PE 1-peroneal palsy |

Table 9 - Adverse Events/Complications

| Author/ Ref. No. | Device | Patients/ Devices | Follow- up | Retrieval | Death | Infection | Disloc. | Loose. | Lysis | Other Comp. |
|---------------------|--|--|------------------------|--|--|--------------------|---------|--------------------------------|----------------------|---|
| Schmalzried, 56 | McMinn (MM); Wagner (W) | 19 pts./ 21 dev. (17 MM, 4 W) | 16 mos. (10-25) | 1 for acet. Migration | | 0 | | | | 1-Femoral palsy 1-hematoma |
| Schmalzried, 57 | McKee- Farrar (MF); Sivash (S) | 6 dev. (5 MF, 1 S) | 21.3 yrs. (19-24.5) | 6 all for femoral loosening | | | | | 3 | 2-impingement 2-burnishing Smaller volumes of metal particles/foreign body reaction in MF retrievals |
| Schmalzried, 58 | McKee Farrar (MF) | 13 pts./ 15 dev. | 23.7 yrs. (21-26) | | | | | 0 | 3 femurs, 1 acet. | |
| Shorbe, 63 | McBride | 92 pts/ 103 dev. | | 1 for deep infection | 2 serum hepatitis, pneum. | 3 super. 2 deep | 4 | 1 stem, 1 cup - migrated | | Quadriceps pain secondary to muscle tone loss |
| Sivash, 66 | Sivash | 164 pts./ 200 dev. | 1-9 yrs. | | | | | | | |
| Smith, 67 | Gaenslin cup with Austin Moore or Leinbach stem | 36 pts./ 40 hips | to 8 yrs. | 6 (2-broken screws, 2-loose cup, 2-poor cup position) | 0 | 1 | 0 | | | 1-Phlebitis |

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|---------------------|--|---|--|---|--|-------------------|---------|--|-------|---|
| Smith, 68 | Gaenslin cup with Austin Moore stem | 92 pts./ 112 dev. | 56 @ 2-5 years 26 @ 5+ years 30 @ <2 years | 19 (8 screws, 7 loose, 3 infect., 1 disloc.) | 1 myoc. Infarction | 2-super 4-deep | 3 | 7 femoral stem | | 19-broken screws 3-ossification 1-foot drop 1-pneumonia 1-erythema nodosum 1-thrombo. |
| Wagner, 73 | Metasul | 105 dev. (70 thr, 35 resurf) | 34.3 mos. (thr) 20 mos. (resurf) | 3 2-limiting ossificat. 1-infect. | | 0 | 1 | | 0 | 1-Peroneal palsy 1-Fracture No thigh pain or migration reported |
| Weber, 75 | Weber Metasul | 110 dev. (100 followed) | 3.5 yrs. (2-7) | 4-Heads 1-Cup | | | | | | 1-Troch. Bursitis 1-Painful ossification Only 1 metallosis reported due to 3 rd body cement wear |
| Wilson, 76 | Stanmore 3 groups based on design modif. | 101 pts./ 108 dev. Gr I: 14 dev. Gr II: 36 dev. Gr. III: 43 dev. | 1.5-9 yrs. Gr I: 6-9 yrs. Gr II: 5-6 yrs. Gr III: 1.5-4 yrs. | 19 "failures" (7 loose stems, 9 loose cups, 2 unknown 1 sepsis) | 7 (4 natural causes, 2 recur. Tumor, 1 coronary) | | 2 | 20, all in Gr I and Gr II (9-cups, 6-stems, 5-both) | | 15-Broken troch. Wire 8-DVT 7-Detached troch. 2-PE 2-Acetab. Fracture 2-Peroneal palsy 2-sciatic palsy 1-broken stem |

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|---------------------|-----------------|----------------------|---|---------------------------------------|-------|-----------|------------------|----------------------------------|-------|---|
| Wilson, 77 | McKee Farrar | 86 pts/ 100 dev. | 2 years on all pts. (16@3yr) | 21 (12 in first 40 hips) | | 12 | 0 | 20 11 septic 9 aseptic | | 14-UTI 7-Thrombophleb. 4-Hepatitis 3-Pulm. Atelect. 2-Pulm. Embolus |
| Zaoussis, 79 | McKee Farrar | 38 pts/ 43 dev. | 12-20 yrs (26 pts w/ > 15 yrs) | 7 3-infect. 4-loose | | 3 | 5 (1 patient) | 9 | | 5-Peroneal palsy 1-Cortex perforation 1-Ossification |