III. ACETABULAR FIXATION IN PRIMARY TOTAL HIP ARTHROPLASTY

Fixation, Polyethylene Wear, and Pelvic Osteolysis in Primary Total Hip Replacement

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A multicenter retrospective review was performed analyzing 1081 primary total hip replacements in 944 patients using the Harris Galante-I cementless acetabular component with screw fixation. All patients were followed up for a minimum of 5 years with a mean followup of 81 months. Linear polyethylene wear averaged 0.11 mm/year (range, 0–0.86 mm/year). Pelvic osteolysis was seen in 25 patients (2.3%). Migration of the acetabular component was seen in four hips. A subgroup of patients was reanalyzed at a minimum followup of 10 years. The mean linear polyethylene wear rate remained 0.11 mm/year. In this group, only one socket had migrated. There was an association between wear rate and age. On average, younger patients had higher wear rates. The risk for having pelvic osteolysis develop and the need for revision surgery also was age-related. Twenty-two percent of hip replacements (15 hips) in patients younger than 50 years of age at the time of their index operation had pelvic osteolysis develop. In contrast, for patients older than 50 years of age at the time of surgery only 7.8% (eight hips) had osteolysis of the pelvis de-
velop. For patients older than 70 years of age at the time of primary total hip replacement, none had pelvic osteolysis develop.

To improve the results of cemented total hip replacement in the 1970s modifications in cement technique were made. These modifications included plugging the femoral canal, pulsatile lavage of the prepared bone surface, and pressurization of cement in the bone. As a result of the change in cementing techniques, improved survivorship of cemented femoral components was reported in several studies.\textsuperscript{14-18} However, technique changes have not been shown to have a significant effect on the survival of cemented sockets. For example, in a 15-year followup study of patients with cemented total hip replacements using second generation techniques, Mulroy et al\textsuperscript{16} reported a 7\% mechanical failure rate on the femoral side. In contrast, in the same report the mechanical failure rate on the acetabular side had increased from 42\% at 11 years to 56\% at 15 years. Similarly, the socket revision rate increased from 2\% at 11 years to 16\% at 15 years.

Cementless technology was introduced as another strategy to improve the results of cemented hip replacement in the 1970s. Autopsy studies showed that excellent bone ingrowth can be obtained in hemispherical porous-coated implants inserted without cement.\textsuperscript{4,8} It has been shown that once short-term fixation has been established, polyethylene wear, periprosthetic osteolysis, and late aseptic failure become problems with time.\textsuperscript{3} The purpose of the current study is to report on the intermediate- to long-term results with respect to poly-

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Fig 1A–B. (A) Anteroposterior radiograph obtained 6 weeks after primary total hip arthroplasty. No evidence of pelvic lysis can be seen. (B) Anteroposterior radiograph obtained 123 months after the index procedure. The osteolytic lesion in the supraacetabular lesion can be seen. The socket remains radiographically stable.
ethylene wear, pelvic osteolysis, and aseptic loosening in association with the Harris-Galante porous-coated acetabular component in primary total hip replacement.

MATERIALS AND METHODS

Two distinct patient populations were reviewed. An initial multicenter review consisted of 941 patients who had undergone 1081 primary total hip replacements using a porous-coated acetabular component inserted without cement. At each institution, the Harris-Galante I socket (Zimmer, Warsaw, IN) was used for primary hip replacements. In this initial review, the followup rate was 84%. These patients were reviewed at a minimum of 5 years after surgery. The mean followup was 81 months and maximum followup was 129 months. There were 511 females and 430 males. The patients ranged in age from 16 years to 87 years at the time of surgery (mean, 56 years). Patient weight averaged 165 lb (range, 83–282 lb). In each case, the patient underwent a primary total hip replacement using a Harris-Galante I acetabular component. The Harris-Galante socket is a hemispherical socket made of commercially pure Ti. It has a Ti fibermesh porous coating with multiple screw holes. The technique used for implantation included reaming the socket line to line. For example, if a 50-mm socket was to be implanted, a 50-mm reamer was used to prepare the acetabulum. Primary fixation was obtained using screws. A minimum of two and a maximum of six screws were used. Twenty-eight millimeter heads were used in the majority of patients (854 hips). The remaining patients had 22-mm heads (46 hips), 26-mm heads (133 hips), and 32-mm heads (48 hips).

Subsequently, the patients from one institution (Rush-Presbyterian) with minimum 10-year fol-
lowup data were reanalyzed. In this group there were 184 patients who underwent 204 primary total hip arthroplasties using the Harris Galante-I socket. Eight-two (45%) of the patients were male and 102 were female (55%). Twenty-two patients with 26 hips died before the 10-year followup evaluation. At the time of the patients’ deaths, the sockets were radiographically stable. An additional four patients (four hips) were lost to followup in this group. The remaining 174 hips were included in this second review. Radiographs were analyzed in an identical fashion as described above.

Initial postoperative radiographs were compared with final followup radiographs. At each institution, one reviewer reviewed the radiographs. Acetabular stability was evaluated using established criteria. Briefly, cup migration was assessed by referencing the center of the femoral head to the interteardrop line. Vertical migration was measured along a perpendicular line from the hip center to the interteardrop line. Horizontal migration was assessed by measuring the distance from the teardrop to the intersection of the perpendicular line from the hip center and the interteardrop line.

Radiolucenties were defined as gaps present between the implant and bone not present on the initial postoperative radiograph. The inclination or abduction of the acetabular component was measured on the anteroposterior (AP) radiograph of the pelvis. Sockets showing a change of position, migration of more than 4 mm, or a complete radiolucency between implant and bone were considered loose.

The presence and location of pelvic osteolysis was noted. Demarcated lytic lesions that were not linear and were more than 3 mm in diameter were considered osteolytic lesions.

Liner polyethylene wear was measured using the technique previously described by Griffith et al and Livermore et al. The center of the femoral head was determined by using a series of concentric rings. The distance from the hip center to the edge of the acetabular component was measured on the initial postoperative radiograph. A similar measurement was made on the final followup radiograph recording the shortest distance (maximum wear) from the hip center to the edge of the hemispherical socket. The measurement was corrected for magnification by using the known diameter of the femoral head and the measured diameter of the femoral head. Linear wear per year then was calculated by dividing the total wear by the number of years after surgery.

Statistical analysis was done using analysis of variance (ANOVA). Statistical significance was set at p < 0.05.

RESULTS

Initial Review: 5- to 10-Year Followup

Migration of the acetabular component was seen in four of 1081 hips. One of these four patients had radiation necrosis of the pelvis. This patient underwent revision surgery to a cemented reconstruction. In a second patient, the primary reconstruction was performed using a bulk graft. The socket migrated 2 mm and then stabilized. The third patient had a pelvic fracture secondary to a motor vehicle accident. The final patient with a radiographically unstable socket had chronic sepsis. As a result the socket failed and the patient required a resection arthroplasty. Four additional sockets were considered loose based on complete implant-bone radiolucency. The loosening rate (excluding sepsis) was 0.006% (seven of 1081).

Linear polyethylene wear ranged from 0 to 8.5 mm. The polyethylene wear rate ranged from 0 to 0.86 mm/year with a mean of 0.11 mm/year. All but 55 hips had measurable wear rates of less than 0.3 mm/year. Of the 56 hips with wear rates greater than 0.3 mm/year, 45 had wear rates between 0.3 and 0.4 mm/year, eight had wear rates between 0.4 and 0.5 mm/year, and two had wear rates greater than 0.8 mm/year (0.81 and 0.86 mm/year).

Pelvic osteolysis was identified in 25 hips (2.3%). The majority of cases were peripheral (20 of 25 hips). In the remaining five hips with pelvic osteolysis, the lesions were retroacetabular. Revision surgery was performed in 18 patients for polyethylene wear and pelvic osteolysis. In 16 of the 18 revision surgeries, a polyethylene liner exchange was performed. In the remaining two patients, an acetabular revision was performed. Both sockets were bone ingrown. An additional revision was performed in a patient with broken tines and a liner dissociation. In this case, the socket also was bone ingrown. The mechanical failure rate including the socket revisions, liner ex-
changes and radiographically loose sockets was 2.4%.

Subsequent Review: Minimum 10-Year Followup

Fixation at 10 years remained excellent. There was no deterioration of fixation with time. Of the 168 hips with 10 year radiographs, 167 were radiographically stable. One patient noted above had a socket reconstruction with a bulk graft. The socket migrated early, but stabilized at 24 months and remained stable at 10 years.

The wear rate remained constant at 0.11 mm/year for the 10-year group. There was a statistically significant relationship between wear rate and age. On average, the older a patient was at the time of their index operation, the lower the wear rate. The mean wear rate for patients in their third decade of life was 0.22 mm/year. The mean wear rate for patients in their fifth decade of life was 0.12 mm/year, and for patients in their seventh decade of life the mean wear rate was 0.08 mm/year.

Using the criteria described above, osteolysis of the pelvis was identified in 23 hips (12.2%) (Figs 1, 2). The mean time to the diagnosis of pelvic osteolysis was 104 months (range, 44–143 months). In 20 of the 23 cases of osteolysis of the pelvis, the lesions were peripheral. The remaining three cases of pelvic osteolysis were retroacetabular.

In the patients in the minimum 10-year followup group, nine patients underwent revision surgery on the socket that was related to polyethylene wear and/or osteolysis. Two sockets were revised for lysis. Both were bone ingrown. Today these would have been grafted and the liners exchanged. A third patient had a retroacetabular osteolytic lesion debrided and grafted and the liner was exchanged. Six additional patients underwent liner exchange for polyethylene wear. Two additional patients underwent socket revision for reasons other than loosening, wear, or lysis. One patient had recurrent hip dislocations and required socket revision. The socket was bone ingrown at the time of the revision. A second patient had the socket revised at another institution at the time of a femoral revision. That socket also was stable. There were no socket revisions for aseptic loosening.

The risk for having pelvic osteolysis develop and the need for revision surgery also was age-related. Twenty-two percent of hip replacements (15 hips) in patients less than 50 years of age at the time of their index operation had pelvic osteolysis develop. In contrast for patients older than 50 years at the time of surgery only 7.8% (eight hips) had osteolysis of the pelvis develop. For patients older than age 70 at the time of their primary total hip replacement, none had pelvic osteolysis develop. Seven of the nine revision surgeries were in patients younger than 50 years of age. Two patients who were older than 50 years underwent revision surgery on the socket for wear and lysis. One was a revision for lysis and the other was a liner exchange. The revision for lysis was in a patient who was 51 years old at the time the initial hip replacement.

DISCUSSION

For an implant to be successful in the long-term, osseointegration must occur. Osseointegration is a term commonly used and was coined by Branemark. The term osseointegration implies that several criteria have been met. From the histologic standpoint, osseointegration means that the implant and bone are in close apposition with no intervening gaps or fibrous tissue. From the biomechanical standpoint, there must be a functional connection between implant and bone capable of transmitting physiologic loads. In addition, there must be no progressive motion between implant and bone during the lifetime of the patient. Finally, from the patient’s perspective, an osseointegrated implant provides functional support under physiologic loads without pain or loosening.

For an implant to become osseointegrated, several criteria must be met. These include a fixation surface on the implant capable of becoming osseointegrated, contact of implant with viable host bone, and a surgical technique that provides satisfactory initial implant sta-
bility to bone and not fibrous tissue to form at the implant-bone interface. It is clear from the review of the data presented in the current study that a hemispherical socket with a Ti fibermesh fixation surface inserted with line to line reaming technique and screws to provide initial implant stability met these criteria.

Sufficient time has passed to allow comparisons to be made between cemented sockets and the data presented in this study. In a study by Sutherland et al.\textsuperscript{22} of 100 consecutive cemented total hip replacements followed up a minimum of 10 years, 12\% of the cemented sockets required revision and an addition 17\% were radiographically loose giving a mechanical failure rate for aseptic loosening of 29\% at 10 years. In a more recent study by Mulroy and Harris\textsuperscript{15} reporting on 93 patients with 10- to 12.7-year followup evaluation, 39.8\% (39 hips) of the cemented sockets were radiographically loose and an additional four sockets had been revised for symptomatic aseptic loosening.

These reports show that long-term osseointegration with cemented sockets is problematic. Polyethylene wear has been correlated with failure of cemented sockets in multiple studies.\textsuperscript{7,9,10,21} Sochart and Porter\textsuperscript{21} reported that an increased annual wear rate was found to be significantly associated with migration of cemented sockets and revision surgery in young patients with a primary diagnosis of developmental dysplasia of the hip, osteoarthritis, and rheumatoid arthritis. Joshi et al\textsuperscript{9} reported that a high wear rate, component loosening, and osteolysis also were associated with migration of cemented sockets. Kobayashi et al\textsuperscript{10} used multivariate survival analysis with a Cox proportional hazards survival model to identify risk factors for aseptic failure. There was a direct correlation between polyethylene wear and aseptic loosening. In a retrieval study Jasty et al\textsuperscript{7} also reported that polyethylene failure correlated with socket loosening.

The mechanism by which polyethylene wear leads aseptic loosening has been delineated by Schmalzried et al.\textsuperscript{19} Polyethylene wear debris results in an inflammatory reaction that erodes the interface between cement and bone in a cemented cup. This process begins circumferentially at the intraacetabular margin and progresses in a three-dimensional fashion toward the dome of the socket. The stability of the socket correlates with the three-dimensional extent of the membrane that develops at the cement-bone interface. Although the average linear wear rate reported here (0.11 mm/year) is similar to what has been reported with cemented sockets, a similar mechanism has not been seen radiographically or at autopsy in patients with the Harris-Galante I socket. Aseptic loosening of the Harris-Galante I socket at 10 years is not an issue.

There are those who would argue that although the mechanical failure rate with cemented sockets is higher at 10 years many of the patients with loose cemented sockets are asymptomatic. The authors’ response to that argument is that a loose cemented socket is not osseointegrated and results in progressive bone loss. This is not a desired outcome and with time the revision rate continues to increase. In addition, revision of a loose cemented socket is a major procedure that is more technically demanding than a liner exchange and bone grafting. Liner exchange and bone grafting of lytic lesions in the pelvis in the presence of a well-fixed porous cup has been shown to be a relatively straightforward procedure with reliable results.\textsuperscript{13}

These results will not apply to all hemispherical noncemented sockets. Each individual fixation surface must be evaluated individually. Engh et al\textsuperscript{3} reported on the AML (DePuy, Warsaw, IN) socket at a minimum 10-year followup. The AML socket was made of CoCr and had a beaded fixation surface. Each cup had three spikes for additional fixation. The survivorship for the cup at 10 years was 92\%. Seven acetabular cups (of 174) were loose and four of these were revised. An additional 10 patients required revision surgery on the socket for excessive polyethylene wear. In eight of 10 patients, the acetabular liner was exchanged. In the remaining two patients, the socket was revised because it was too small to accommodate a new polyethylene
liner of adequate thickness. The authors' point out that 3/4 of the sockets had polyethylene that was less than 6 mm thick. Astion et al reported on the original PCA socket (Howmedica, Rutherford, NJ). The PCA socket was a one-piece CoCr socket with a beaded fixation surface and two pegs to enhance initial stability. In their series, 12% (23 hips) of the acetabular components failed because of severe osteolysis, loosening or both. Thirteen hips were revised an average of 69.5 months after the primary total hip replacement. There was increased risk of osteolysis developing in cups with an outer diameter of 55 mm or less. This corresponded to a polyethylene thickness of 8.5 mm or less. Thirty-two millimeter femoral heads also were used in this series.

In addition, variations in implantation technique also must be evaluated individually. There has been a recent trend toward the insertion of porous-coated sockets with a solid (no screw holes) shell using a press-fit technique. The rationale for this technique is to enable the surgeon to eliminate the screw holes that may act as an access channel for wear debris. With this technique, the initial stability of the socket is dependent on the interference fit between implant and bone. It is difficult to quantify fit and stability in vitro and failure to provide satisfactory initial stability may result in a fibrous tissue formation at implant-bone interface, which in turn may predispose to late loosening especially in the face of significant polyethylene wear.

Despite that the fact that the Harris-Galante I porous-coated socket is radiographically stable with a high likelihood of being osseointegrated during the first decade, polyethylene wear remains a problem. The cause for revision surgery in patients in the current series is polyethylene wear and the biologic consequences of wear, osteolysis. The pattern of particle induced bone resorption with ingrown porous coated sockets is different compared with what commonly is seen around cemented sockets. Typically a linear pattern of osteolysis develops around a cemented socket. This process disrupts the mechanical stability of the implant and results in loosening. In contrast, the pattern of osteolysis around an ingrown porous-coated socket usually is expansive ballooning lesion that may originate at the implant-bone interface but which tends to extend into the pelvis. These lesions usually are asymptomatic and can lead to severe bone destruction without loosening. For this reason, it remains important to periodically followup patients with total hip replacements with radiographs.

During the first decade of use, the problem of wear with the Harris-Galante I socket seems to be a problem associated with patients of a relatively young age. Almost all of the patients with wear-related complications requiring revision surgery were younger than 50 years of age at the time of their index operation. None of the patients older than 70 years of age at the time index procedure required revision surgery in the first 10 years after their operation. Although not addressed in the current study, the most likely cause for the association between age and wear is activity level. A study by Schmalzried et al has quantified activity and has shown that there is a tremendous variation in activity in the population of patients who had total hip replacement. However, they also showed that activity level is age-related. With increased number of gait cycles, more wear can be expected. Future efforts to decrease wear and limit access of debris to periprosthetic bone should additionally improve these results.

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References


