Hydroxylapatite-Coated Acetabular Shells with Arc Deposited Titanium Surface Roughening and Dual Radius Design

William L. Jaffe, M.D., Hugh B. Morris, M.D., Joseph P. Nessler, M.D., Marybeth Naughton, B.S., and Jianhua Shen, M.S.

Abstract
A retrospective review of two multicenter prospective studies was performed of a dual radius design acetabular shell, one with a titanium arc deposited surface roughening and hydroxylapatite coating (AD HA) designed to optimize initial component stability and enhance biological fixation and the other grit-blasted and HA (GB HA) coated. The purpose of the study was to evaluate intermediate clinical and radiographic success of this device, as compared to a grit-blasted HA (GB HA) coated shell of the same design. Eighty-nine hips (83 patients) with a diagnosis of noninflammatory degenerative joint disease (NIDJD) were implanted with the AD HA shells (Group 1) by three surgeons at three sites. Patients were evaluated clinically and radiographically for 5 to 8 years postoperatively (mean, 5.5 years). Clinical and radiographic data for 179 cases with GB HA shells and a diagnosis of NIDJD (Group 2) were reviewed retrospectively at an equivalent time frame. Fifty-eight hips in each group with a minimum 5-year follow-up were identified through patient matching, based on age, gender, and preoperative body mass index, to provide the cohorts for this study. Radiographically, all patients in Group 1 were stable, and there were no cases of acetabular loosening or revision of the acetabular shell. Three patients in Group 2 had radiographic evidence of acetabular shell migration and eight shells (three dislocations, five acetabular loosenings) had been revised by 60 months postoperatively. Intermediate results with the AD HA shells are encouraging, as evidenced by clinical success, radiographic stability, and 100% survivorship at 5 to 8 years (mean, 66 months).

The success of total hip replacement surgery to treat degenerative joint disease is well established. The use of hydroxylapatite (HA) on femoral stem components has demonstrated excellent long-term fixation, with a mechanical failure rate of 0.5% at 10 to 13 years follow-up. Results for HA coated acetabular shells have been mixed. Previous studies suggest that poor initial mechanical stability and inadequate surface designs are responsible for the limited success with earlier HA coated shells. Revision rates due to aseptic loosening of 11.9% were reported for HA-coated cups at 8-year follow-up. Acetabular shells with a roughened surface treatment before application of the HA coating have demonstrated clinical improvement over earlier designs. Previous results of a comparison study at 4 years between AD HA and grit-blasted HA (GB HA) coated cups have been published.

The purpose of this investigation was to corroborate early studies and confirm through a multicenter study that the addition of an AD HA coating to an acetabular shell resolved the problem of early acetabular loosening. The rougher surface of the arc deposited (AD) coating, as hypothesized, provided better initial stability, leading to excellent intermediate results and the potential for long-term biologic fixation.

Materials and Methods
A prospective, multicenter study was conducted between August 1995 and October 1998 in which 89 hips (83 patients) were implanted with a dual radius external shell design with...
a commercially pure (CP) titanium AD surface roughening and hydroxylapatite (HA) coating. The shells consisted of a CP titanium substrate, with a titanium bond coat of arc deposited (AD) titanium beneath a plasma sprayed coating of manufactured HA. The amount of interference provided at the rim is enhanced by the roughened surface provided by the titanium bond coat of the AD HA coating. Three surgeons at three different institutions performed the procedures. Each surgeon implanted similar numbers of devices.

Fifty-eight hips in 55 patients with a minimum of 5-year follow-up (Group 1) were matched by age, gender, and body mass index (BMI) to 58 hips (56 patients) with minimum 5-year follow-up (Group 2) from an earlier prospective multicenter study of an HA-coated acetabular shell of similar design but without AD surface roughening. Although the patients in the previous study are now out to 15 years postoperative, only the data from a maximum of 8.2 years, analogous to the longest follow-up in Group 1, was included to allow for direct time-to-time radiographic and clinical comparison. All acetabular components in both groups were implanted without the use of bone cement, as were the HA-coated femoral stems.

Patients in both studies were evaluated preoperatively and postoperatively at 6 weeks, 6 months, 12 months, and yearly thereafter to a minimum of 5 years. Specific parameters collected at each interval included level of pain, range of motion, deformity, gait, mobility range, use of support, and activities of daily living. Harris Hip scores were calculated at each interval.

Anteroposterior (AP) and lateral radiographs were obtained at the same intervals as the clinical evaluations. Preoperatively, bone quality was assessed based on the Dorr classification. Criteria for postoperative measurements were those recommended by the Hip Society. At postoperative intervals, the acetabular radiographs were evaluated for radiolucency, component migration, osteolysis, and stability. Analysis employed the three equal zones established by DeLee and Charnley. Radiolucency was defined as a lucent area encompassing 50% of the zone length and at least 1 mm or greater in width.

Survival rates, defined as the absence of acetabular component revision or removal, were determined and graphed using the Kaplan-Meier method. Log-rank and the Wilcoxon test were used to compare statistically significant differences of survival distribution between Group 1 and Group 2. Harris Hip score data were summarized and analyzed by the repeated measure ANOVA to characterize the Harris Hip profile over time (Fig. 1).

The model incorporated the repeated measures taken over the evaluation times, the groups (Group 1 vs. Group 2), and the interaction of evaluation time and groups. All other differences between the groups of categorical data were determined using Fisher’s exact test; continuous data were determined using the Student’s t-test. A p value of ≤ .05 was considered statistically significant. All statistical analysis utilized SAS® software (Cary, North Carolina), version 8.2.

Demographics of the two study groups are noted in Table 1. This study represents a retrospective ongoing analysis of the previously published prospective multicenter studies described above.

Results

In Group 1, the mean Harris Hip score, preoperatively, was 45.6 (range, 27 to 65; SD, 10.4). At a minimum of 5 years, the mean score improved to 96.3 (range, 76 to 100; SD, 6.9). A total of 90% of the patients (52 procedures) reported no pain or slight pain at latest follow-up. Only one patient (1.7%) reported moderate pain. Similar results were reported for Group 2. Preoperatively, the mean score was 49.5 (range, 21 to 77; SD, 12.8), with a minimum 5-year mean score of 94.9 (range, 62 to 100; SD, 9.7). Forty-six hips (92%) had no pain or slight pain at a minimum of 5 years. While there was no difference in scores 5 years postoperatively (p = 0.4860), the cumulative scores over time were better for patients in Group 1 (p < 0.01) (Table 1).

There were no revisions of acetabular shells in Group 1. One patient, who complained of discomfort and a clicking noise, underwent liner exchange at approximately 3.5 years after the index procedure. At the time of the surgery, it was noted that the polyethylene liner had become disengaged from the shell; however, the shell was well fixed and removal...
was not necessary. The femoral stem and head were also left in place. This patient is included in the present study and continues to have excellent clinical results, with Harris Hip scores of 100 both before and after liner and head exchange. No patients in Group 1 required revision of any of the components for loosening, mechanical failure, or osteolysis.

By 60 months postoperatively a total of eight acetabular shells (13.8%) in Group 2 had been revised. Three patients had the acetabular shell and insert revised due to recurrent dislocations at 1.7, 2.2, and 2.5 years postoperatively, respectively. The five patients with acetabular loosening were revised at 3.8, 4.0, 4.3, 4.4, and 4.6 years after the index procedure. There were no revisions of the femoral component in Group 1 or Group 2 (Fig. 2). The mean follow-up in Group 1 was 5.5 years (range, 5 to 8 years). The follow-up in Group 2 was limited to a minimum follow-up of a 5-year mean of 6.9 years (range, 5 to 8 years).

Radiographic Results

Standard AP and lateral radiographs were evaluated at each visit interval. The films were reviewed by an independent reviewer preoperatively, for bone type, and postoperatively, for acetabular radiolucency, cortical erosion, component migration, and head penetration.

Group 1
The majority of patients in Group 1 had Dorr B bone type (58%). Thirty-three percent of the patients had bone type A, and 10% of the patients had bone type C. Postoperatively, no acetabular erosion or shell migration was observed. There were no patients with radiolucencies in all three DeLee and Charnley zones, nor were there any radiolucent lines greater than 2 mm wide in any zone.

Group 2
The distribution of patients by preoperative bone type was similar to Group 1. The majority of patients had Dorr B bone type (57%). Thirty-eight percent of the patients had bone type A, and 5% of the patients had bone type C. Postoperatively, there was no acetabular erosion at 5 years; however, shell migration was observed in three patients by 60 months postoperatively prior to revision for acetabular loosening.

Table 1 Demographics and Clinical Data

<table>
<thead>
<tr>
<th></th>
<th>AD HA (Group 1)</th>
<th>GB HA (Group 2)</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of hips</td>
<td>58</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Number of patients</td>
<td>55</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Gender, Male/Female</td>
<td>33/25</td>
<td>33/25</td>
<td></td>
</tr>
<tr>
<td>Mean Age</td>
<td>54.2</td>
<td>53.8</td>
<td>0.8489</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>29.1</td>
<td>28.8</td>
<td>0.7300</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>75% OA, 24% AVN</td>
<td>79% OA, 4% RA, 1% Other</td>
<td>0.4050</td>
</tr>
<tr>
<td>Follow-up</td>
<td>5 to 8 years</td>
<td>5 to 8 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Mean, 66 mos)</td>
<td>(Mean, 83 mos)</td>
<td></td>
</tr>
<tr>
<td>Mean HHS Preop</td>
<td>45.6</td>
<td>49.5</td>
<td>0.1147</td>
</tr>
<tr>
<td>Mean HHS 5 years</td>
<td>96.3</td>
<td>94.9</td>
<td>0.4860</td>
</tr>
</tbody>
</table>

OA, osteoarthritis; RA, rheumatoid arthritis; AVN, avascular necrosis.
Among the nonrevised shells, there were no patients with radiolucencies in all three DeLee and Charnley zones, nor were there any radiolucent lines greater than 2 mm wide in any zone at 5 years postoperatively (Table 2).

Head penetration was measured by the Martell method in approximately 50% of the patients in each group, based on adequate serial radiographs to perform the measurements. There was no difference in head penetration (Group 1 mean, 0.155 mm/year; Group 2 mean, 0.150 mm/year).

**Discussion**

The success of total hip arthroplasty (THA) depends on the design, fixation method, and materials of the acetabular shell, bearings, and femoral stem. One key to the potential success of any THA is the achievement of early stability of the implants. Roentgen stereophotogrammetric analysis (RSA), a means of assessing movement of the implants relative to the bone, has confirmed that early implant movement is a predictor of late failure of a device. Cementless hydroxyapatite-coated femoral stems have demonstrated excellent long-term fixation, with a mechanical failure rate of 0.5% at 10 to 13 years follow-up. Results for HA-coated acetabular shells have been mixed, and, in general, cementless acetabular fixation has not demonstrated the consistently excellent results of their well-designed femoral counterparts.

Achievement of a tight initial fit between implant and bone at the time of surgery is considered essential to long-term success. Good initial fit provides optimal conditions for the attainment and maintenance of the interlocking between implant and bone necessary for the stable fixation of an acetabular component over time. First-generation cementless HA acetabular designs have not met expectations due to initial inadequate fixation to bone.

Results of the present study demonstrate that 5 years after surgery with AD HA acetabular shells patients exhibited excellent clinical results, including an absence of revisions and high overall clinical success. These results are consistent with previous reports for devices with the same design and surface coatings. Jazrawi and associates reported encouraging early results for the same AD HA coating versus the earlier GB HA-coated cups. When radiographs for two groups of patients from a single surgeon’s practice, who were similar in age, sex, and preoperative diagnosis, were compared, it was found that four years after surgery, the use of AD HA acetabular components were associated with the presence of fewer radiolucent lines in all Charnley zones, particularly Charnley zone 3, when compared to smooth GB HA-coated acetabular components of the same geometric design.

Siverhus and Bryant reported on 93 hips implanted with AD HA-coated shells that did not require any shell revisions over a 4-year period. Capello and coworkers demonstrated excellent results and radiographic stability for the same external design AD HA shell when used with alumina-on-alumina bearings at a mean of 5.7 years (range, 4 to 7 years).

In the present study, the patients in Group 1 (AD HA) and Group 2 (GB HA) were matched by age, gender, and BMI to reduce variability based on patient characteristics. The shell geometry, bearing materials (metal and polyethylene), and associated femoral component (cementless HA-coated) were identical to allow for a direct comparison based on a single variable surface treatment of the shell before application of the HA coating. There were no revisions for aseptic loosening or evidence of radiographic instability in AD HA Group 1 at a minimum of 5 years (mean, 5.5 years), while there were five revisions for aseptic loosening (three with acetabular migration) at 5 years in Group 2 (p < 0.01). This trend continued with the patients in Group 2, as an additional nine patients had the acetabular shell revised (four for wear and five for acetabular loosening) between 5 and 8 years postoperatively.

Group 1 utilized acetabular dome bone screws in 48% (28) of the surgeries, compared to 17% (10 surgeries) in Group 2. There were no revisions or unstable components among the 30 surgeries performed without bone screws in Group 1. While the GB HA group utilized adjunctive bone screws in fewer patients and had a higher failure rate, the
presence or absence of bone screws in the AD HA group had no apparent effect on the stability of the device. This suggests the need for additional fixation in the GB HA group, and although screws may have helped in the short-term, the results were still not comparable to AD HA without screws.

Udomkiat and colleagues previously reported several criteria that are predictive of loosening for a cementless acetabular device. These parameters include occurrence or progression of radiolucent lines after two years, radiolucent lines in all three zones, radiolucent lines greater than 2 mm wide in any zone, and cup migration. More recently, Rohrl and associates reported the 5-year postoperative results of a prospective, randomized RSA study of 87 hips that compared porous press-fit, porous press-fit with screws or pegs, and porous press-fit and HA shell designs. The results demonstrated that the porous surface and HA displayed the best interface and fewest radiolucent lines. Stepwise linear regression revealed that low proximal migration was significantly associated with HA coating and few radiolucenties.

In our study, radiographic examination of the AD HA acetabular shell provided intermediate data to support the stability of the devices based on these criteria. There were no complete radiolucencies around the acetabular shell after 2 years, no radiolucencies greater than 2 mm in any individual zone, no radiolucencies at all in DeLee Charnley zone 3, and no evidence of acetabular migration at a minimum of 5 years postoperatively. Finite element studies have demonstrated that bone ingrowth may be more difficult to achieve at the inferior portion of the cup, where repetitive distraction of the component-bone interface can occur. Initiation of this failure mode could be manifested clinically as a radiolucent line in the DeLee-Charnley zone 3. The absence of a radiolucent line in zone 3 further supports stable fixation of the shell. In Group 2, three of the five components revised for acetabular loosening had evidence of component migration in a radiographic examination prior to revision. An additional patient had evidence of acetabular migration just prior to being revised at 6 years postoperatively.

Conclusion
This patient-matched study supports the hypothesis that the AD surface roughening and HA coating optimizes initial component stability and enhances bone-prosthesis contact as intended. The absence of radiolucent lines and component migration may be predictive of a long-term low revision rate due to aseptic loosening. Radiographic signs of shell migration and clinical loosening of the acetabular components, seen in the first-generation design are absent at an identical time frame in a similarly designed multicenter study with other parameters being on par.

Disclosure Statement
William L. Jaffe, M.D., Hugh B. Morris M.D., and Joseph P. Nessler, M.D., received funding for this study from Stryker Orthopaedics, Mahwah, New Jersey.

References


