Ceramic Failure After Total Hip Arthroplasty with an Alumina-on-Alumina Bearing

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This information is current as of February 3, 2010

**Supplementary material**

Commentary and Perspective, data tables, additional images, video clips and/or translated abstracts are available for this article. This information can be accessed at [http://www.ejbjs.org/cgi/content/full/88/4/780/DC1](http://www.ejbjs.org/cgi/content/full/88/4/780/DC1)

Letters to The Editor are available at [http://www.ejbjs.org/cgi/content/full/88/4/780#responses](http://www.ejbjs.org/cgi/content/full/88/4/780#responses)

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**Publisher Information**

The Journal of Bone and Joint Surgery
20 Pickering Street, Needham, MA 02492-3157
[www.jbjs.org](http://www.jbjs.org)
Ceramic Failure After Total Hip Arthroplasty with an Alumina-on-Alumina Bearing

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Background: The mechanical properties of alumina ceramic, now in its third generation, have been markedly improved through the evolution of design features and manufacturing processes and the introduction of proof-testing. Nonetheless, because of the lack of ductility of alumina ceramic, there is concern regarding the risk of fracture during insertion or in vivo use. The purpose of the present study was to present a multicenter review of primary total hip arthroplasties performed with use of a polyethylene-ceramic composite liner combined with a ceramic femoral head, with particular attention to failure of the ceramic bearing.

Methods: We evaluated 357 primary total hip arthroplasties that had been performed in 319 patients with use of a contemporary alumina-on-alumina bearing design incorporating a polyethylene-ceramic composite liner within a titanium-alloy shell coupled with a 28-mm-diameter ceramic femoral head. The procedures were performed at four participating centers from 1998 to 2001. Ceramic failure without trauma occurred in six hips (1.7%). All of these hips were revised, and the retrieved alumina implants were examined by means of visual inspection and scanning electron microscopy equipped with energy-dispersive x-ray spectrometry.

Results: Two femoral heads fractured during the first postoperative year, and four alumina liners fractured after an average of 36.8 months in vivo. All four of the explanted alumina liners revealed evidence of rim contact with the metal neck of the femoral component. Composition analysis confirmed that surface-stain materials were titanium particles transferred from the femoral component.

Conclusions: Despite the theoretical improvement in the fracture toughness of a polyethylene-alumina composite liner, a relatively high rate of catastrophic ceramic bearing surface failure was still observed at the time of short-term follow-up. This finding prompted us to discontinue the use of this type of alumina bearing design.

Level of Evidence: Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.
ene-ceramic composite liner combined with a ceramic femoral head, with particular attention to failure of the ceramic bearing.

**Materials and Methods**

From November 1998 to December 2001, 329 patients (367 hips) who had undergone primary cementless total hip arthroplasty with an alumina-on-alumina bearing with use of the SPH Contact acetabular component (Lima-Lto, Udine, Italy) incorporating a polyethylene-ceramic composite liner within a titanium-alloy shell were identified at four participating academic institutions. Of these, eight patients (eight hips) had been lost to follow-up and two patients (two hips) had died for reasons unrelated to the arthroplasty, leaving 319 patients (357 hips) available for complete analysis. All ten hips that were dropped from the study had been performing well and had showed no evidence of prosthesis-related problems at the time of the last follow-up. The design and protocol of this multicenter retrospective study were approved by the institutional review board at each center, and all patients provided informed consent.

The indications for the use of this composite alumina liner coupled with an alumina femoral head varied among the centers. Two centers used this bearing for the majority of patients who had a primary total hip arthroplasty, whereas the other two centers reserved it for patients who were less than fifty years old and who were engaged in a high level of activity. The average age of the patients at the time of the index arthroplasty was 51.4 years (range, nineteen to seventy-four years), and 195 (61.1%) of the patients were less than fifty years old. The average duration of follow-up was 46.5 months (range, thirty-six to seventy-two months). The demographic features of the patients, including age, gender, weight, body-mass index, and primary diagnosis, are presented in Table I.

One surgeon at each center (Y.-S.P., S.-K.H., W.-S.C., and Y.-S.K.) performed all of the surgical procedures. The operative approach was anterolateral in 230 hips (64.4%) and posterolateral in 127 hips (35.6%). All patients received antibiotic prophylaxis perioperatively, and a standard protocol of low-dose warfarin for prophylaxis against thromboembolism was used selectively in high-risk patients. All patients were allowed partial weight-bearing on the second or third postoperative day and full weight-bearing after four to six weeks.

All patients who were enrolled in this series received the SPH Contact acetabular component. This modular component consists of a preassembled, polyethylene-alumina composite liner that is held in a titanium-alloy shell. The three components are assembled into each other reciprocally by means of a Morse taper system (Fig. 1). The titanium-alloy shell contains screw-holes, slanted circumferential grooves in the equatorial area, and a surface coating with plasma-sprayed pure titanium.

![Fig. 1](The SPH Contact acetabular component consists of a preassembled, polyethylene-alumina composite liner that is held in a titanium-alloy shell by means of a Morse taper system. The alumina insert has an identical internal dimension to fit the 28-mm modular alumina head.)

**Table I: Demographic Data**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>319</td>
</tr>
<tr>
<td>Number of hips</td>
<td>357</td>
</tr>
<tr>
<td>Duration of follow-up (mo)</td>
<td>46.5 (36-72)</td>
</tr>
<tr>
<td>Age at time of index arthroplasty (no. of patients)</td>
<td></td>
</tr>
<tr>
<td>&lt;50 years</td>
<td>195 (61.1%)</td>
</tr>
<tr>
<td>50-65 years</td>
<td>81 (25.4%)</td>
</tr>
<tr>
<td>&gt;65 years</td>
<td>43 (13.5%)</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>51.4 (19-74)</td>
</tr>
<tr>
<td>Gender (M/F) (% male)</td>
<td>204/115 (63.9%)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>61.4 (41.86)</td>
</tr>
<tr>
<td>Average body-mass index</td>
<td>24.2 ± 3.4</td>
</tr>
<tr>
<td>Number of patients with body-mass index of ≥30</td>
<td>9 (2.8%)</td>
</tr>
<tr>
<td>Diagnosis leading to arthroplasty (no. of hips)</td>
<td></td>
</tr>
<tr>
<td>Osteonecrosis of the femoral head</td>
<td>231 (64.7%)</td>
</tr>
<tr>
<td>Secondary osteoarthritis</td>
<td>72 (20.2%)</td>
</tr>
<tr>
<td>Inflammatory disease</td>
<td>24 (6.7%)</td>
</tr>
<tr>
<td>Primary osteoarthritis</td>
<td>17 (4.8%)</td>
</tr>
<tr>
<td>Miscellaneous conditions</td>
<td>13 (3.6%)</td>
</tr>
</tbody>
</table>

*The values are given as the average, with the range in parentheses. †The values are given as the number of male patients followed by the number of female patients, with the percentage of male patients in parentheses. ‡The values are given as the average and the standard deviation. Body-mass index = weight (in kilograms)/height (squared).
The socket has an outer diameter ranging from 46 to 62 mm, and in each case it was press-fit into a 2-mm under-reamed acetabulum. If the socket fixation was not rigid, one or more screws were inserted. All alumina inserts had identical internal dimensions and were of the same thickness (4.8 mm), whereas mating polyethylene shells varied in thickness to fit the titanium-alloy shell.

On the femoral side, all patients who were enrolled in this series received either a C2 stem (Lima-Lto) or an F2L stem (Lima-Lto); both were fixed without cement after broaching with a rasp, and a 28-mm alumina head was always used. The C2 stem is a straight, rectangular, tapered, titanium-alloy implant with a rough, sandblasted surface. The neck-shaft angle is 131°. The neck has a polished metal surface and a circular cross-sectional geometry. The diameter of the taper is 12/14. The F2L stem is a modular, multi-necked, tapered, titanium-alloy implant with a proximal hydroxyapatite coating. The neck-shaft angle can be changed from 125° to 135° with use of modular neck components, which are made in three types (straight, lateralized, and antverted) and two different lengths (short and long). The modular neck has a polished metal surface and a circular cross-sectional geometry. The diameter of the taper is 12/14. The C2 stem was implanted in 282 hips (79%), and the F2L stem was implanted in 75 hips (21%). All ceramic implants were hot isostatic pressed, laser-marked, and proof-tested third-generation BIOLOX forte alumina (CeramTec, Plochingen, Germany).

Clinical and radiographic evaluations were performed at six weeks, three and six months, and one year after surgery and then annually thereafter. Forms with items related to the demographic characteristics of the patients, the operative procedure, details regarding the implant, and intraoperative and postoperative complications were completed by the contributing surgeons at each center. Serial radiographs were examined by an independent observer who was not involved in the clinical care of the patients at each center; only one of these observers (S.-J.L.) was an author of the present study. Six-week anteroposterior, frog-leg lateral, and cross-table lateral radiographs were considered the baseline for all comparisons. The radiographs were made from a standard distance and with standard positioning of the patient. The position of the acetabular component was determined according to the method of Woo and Morrey. Anteversion was measured on the true lateral radiograph as the angle formed by a line drawn tangential to the face of the acetabular component and a line drawn perpendicular to the horizontal plane. Abduction was measured on the anteroposterior pelvic radiograph as the angle formed by lines drawn tangential to the acetabular component and tangential to the inferior margins of the ischial tuberosities.

During the study period, ceramic failure occurred in six (1.7%) of the 357 hips that were evaluated. All six of the patients underwent an urgent revision operation, and intraoperative findings were reported by each contributing surgeon. All of the explanted alumina implants were examined by means of visual inspection and with use of scanning electron microscopy equipped with energy-dispersive x-ray spectrometry (XL30 ESEM-FEG; Philips, Eindhoven, The Netherlands).

Statistical analysis was done with use of the SPSS statistical software system (version 11.5; SPSS, Chicago, Illinois). The demographic data for the overall group and the group with ceramic failure were compared with use of the Mann-Whitney U test for continuous variables and the chi-square test (or, when necessary, the Fisher exact test) for dichotomous values. The level of significance was set at p < 0.05.

### Results

Two femoral heads fractured postoperatively at seven and eight months, and four alumina liners fractured after an average of 36.8 months (range, sixteen to fifty-eight months) in vivo. No evidence of fracture of the ceramic components was seen at the time of the primary procedure as the alumina liner and head were scrutinized after impaction. All of these failures occurred during normal activities of daily living and were not related to unusual traumatic events. All six of the ceramic failures occurred in men, and the primary diagnosis leading to the hip arthroplasty was osteonecrosis in all six hips. The average age and weight of the patients at the time of the index arthroplasty was 51.4 years (range, nineteen to seventy-four years) and 61.4 kg (range, 41 to 86 kg), respectively, in the overall group and 50.0 years (range, twenty-nine to sixty-four years) and 66.7 kg (range, 54 to 86 kg), respectively, in the ceramic failure group. The average abduction angle and anteversion of the acetabular component were 44.6° (range, 27° to 58°) and 14.1° (range, 0° to 23°), respectively, in the overall group and 41.0° (range, 27° to 58°) and 14.1° (range, 0° to 23°), respectively, in the ceramic failure group.

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Age (yr)</th>
<th>Weight (kg)</th>
<th>Occupation</th>
<th>Primary Diagnosis</th>
<th>Service Time In Vivo (mo)</th>
<th>Activity at Time of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>57</td>
<td>72</td>
<td>Laborer</td>
<td>Osteonecrosis</td>
<td>7</td>
<td>Descending staircase</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>48</td>
<td>68</td>
<td>Desk worker</td>
<td>Osteonecrosis</td>
<td>8</td>
<td>Rising from chair</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>29</td>
<td>54</td>
<td>Laborer</td>
<td>Osteonecrosis</td>
<td>16</td>
<td>Jumping</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>64</td>
<td>80</td>
<td>Farmer</td>
<td>Osteonecrosis</td>
<td>29</td>
<td>Walking</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>47</td>
<td>65</td>
<td>Farmer</td>
<td>Osteonecrosis</td>
<td>44</td>
<td>Walking</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>55</td>
<td>61</td>
<td>Farmer</td>
<td>Osteonecrosis</td>
<td>58</td>
<td>Walking</td>
</tr>
</tbody>
</table>
(range, 30° to 49°) and 12.7° (range, 8° to 16°), respectively, in the ceramic failure group. With the numbers available, there was no significant difference between the overall group and the ceramic failure group with regard to the gender (p = 0.091), age (p = 0.433), or weight (p = 0.751) of the patients; the primary diagnosis (p = 0.141); or the abduction angle (p = 0.261) or anteversion (p = 0.270) of the acetabular component. Data characterizing the six alumina failures are summarized in Table II.

At the time of revision surgery, composite acetabular liners and modular femoral heads were removed and component fixation was assessed. All acetabular and femoral components were found to be well-fixed and therefore were left in place after an attempt at complete débridement and synovectomy to remove as much of the alumina debris as possible. In two hips, a cobalt-chromium head was inserted on the scratched Morse taper and a polyethylene liner was inserted to replace the damaged polyethylene-alumina composite liner. A new alumina-on-alumina bearing was implanted in the remaining four hips, which had no macroscopically apparent damage to the Morse taper. Of the six hips that were treated with modular exchange of the composite acetabular liner and femoral head, one underwent repeat revision of an unrevised acetabular cup because of recurrent dislocation after revision surgery with a new cobalt-chromium head and a polyethylene liner for the treatment of alumina head fracture. The remaining five hips did not require an additional reoperation, and the four revision alumina heads did not fracture during the remainder of the follow-up period (range, six to thirty-six months).

Intraoperative examination of the two hips with fracture of the ceramic femoral head (Cases 1 and 2) showed multiple alumina head fragments of varying sizes as well as a black stain and curvilinear crack on the articulating surface of the alumina insert (Fig. 2). The top surface of the Morse taper was scratched in both hips. These findings indicated that the alumina insert had been contacted by the metal taper following the fracture of the alumina head.

The four hips with fracture of the ceramic liner (Cases 3 through 6) had multiple small alumina liner fragments along with slight black staining of the surrounding tissues. The alumina inserts had dissociated from the polyethylene shells (Fig. 3-A), which remained well-seated within the metal cup. The superior portions of the polyethylene shells were grossly deformed. The retrieved alumina inserts showed extensive rim fractures in an arc of varying degrees and a conspicuous black stain on the surface of the unbroken rims (Fig. 3-B). Scanning electron microscopy revealed multiple pits on the inner edge of the unbroken rims (Fig. 3-C), and energy-dispersive x-ray spectrometry demonstrated that the surface-deposited materials on

![Fig. 2](image-url)

Case 1. Photograph showing the fractured alumina head fragments with many small chips and the retrieved polyethylene-alumina composite liner. Note the black stain (arrow) and the curvilinear crack (arrowheads) on the inner surface of the alumina insert, which occurred after the alumina head fracture.
the black-stained areas were titanium particles. The surfaces of the retrieved alumina heads showed some scratches and cracks on visual inspection and on scanning electron microscopy (see Appendix). A deep notch corresponding to impingement was identified on the neck of the femoral component in one case (see Appendix), but the top of the Morse taper was not damaged macroscopically in any case.

Discussion

Recent clinical studies on the current generation of alumina-on-alumina hip prostheses have shown mostly excellent results at intermediate-term follow-up\(^\text{10-14}\), and some manufacturers have emphasized that the risk of alumina chipping or fracture seems to be a negligible problem. Our results did not, however, support these observations because a relatively high rate of alumina bearing surface failure (1.7%, six of 357) was identified at short-term follow-up. Our findings were similar to those in sporadic cases in which alumina liner fracture has been reported without trauma after total hip arthroplasty with use of a polyethylene-alumina composite liner\(^\text{19,20}\). All four of the alumina liners that were retrieved in our series showed evidence of rim contact with the metal neck of the femoral component, as demonstrated by extensive rim fractures as well as multiple pits and the conspicuous black stain on the surface of the unbroken rim. Composition analysis of the black-stained areas with use of scanning electron microscopy with energy-dispersive spectroscopy confirmed that the surface-deposited materials were titanium particles that had been transferred from the femoral component.

We believe that impingement occurs in some hips, especially those in which the components are suboptimally positioned and those with a high range of motion. Furthermore, repetitive impingement can occur during normal activities of daily living, particularly in Asian patients, who frequently squat or sit in the cross-legged position. Evidence of femoral neck-to-acetabular rim contact has been recognized as a common occurrence following total hip replacement, with impingement being seen in 39% of 111 retrieved polyethylene acetabular liners in one report\(^\text{21}\). We believe that interposing a polyethylene layer between the alumina liner and the metal shell provides little benefit, except for a reduced risk of liner chipping during implantation. Unfortunately, we believe that this design modification results in a thinner alumina insert, which increases the likelihood of a peripheral chip fracture and subsequent crack propagation through the brittle alumina material under impingement conditions. In addition, the second modular interface may unnecessarily introduce the potential for dissociation between the alumina and the polyethylene (Fig. 4).

Recently, some manufacturers of ceramic-on-ceramic hip systems have changed the shape of the neck of the stem into a...
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Fig. 3-C
Scanning electron microscopic image of the surface of the unbroken rim of the alumina insert, showing gray-colored stains (arrows) and multiple pits of varying sizes (arrowheads).

Fig. 4
Illustrations depicting a possible mechanism of alumina liner fracture and dissociation. I: Impingement between the femoral neck and the alumina insert generates the contact forces. II: These contact forces initially produce peripheral chips of the alumina insert, and subsequent crack propagation through the insert results in extensive rim fractures. III: As a result of the extensive rim fractures of the alumina insert, the alumina head becomes eccentric, causing the stem neck to impinge readily against the opposite rim of the alumina insert. The stem neck may impinge against the opposite rim of the alumina insert even without eccentric location within the cup. IV: The contact forces generated by secondary impingement then propagate through the weak link between the broken alumina insert and polyethylene shell, leading to the dissociation of the broken alumina insert from its polyethylene shell.
trapezoidal cross-sectional geometry in an effort to minimize femoral neck impingement against either the ceramic insert or the outer cup itself. All of the patients in the present study had received a stem with a circular neck cross-section combined with a 28-mm-diameter femoral head, resulting in a relatively low head-to-neck ratio, which may have contributed to impingement of the stem neck with the alumina insert, as described by Barrack et al.\textsuperscript{22}.

It is also notable that two ceramic femoral heads fractured during the first postoperative year in the absence of any specific traumatic event, even though a proof-tested, third-generation alumina had been used. Recently reported data have indicated that the fracture rate for currently available alumina ball heads has been reduced to a level of one fracture per 10,000 implants\textsuperscript{4,5,23,24}. However, we believe that, despite this extremely low rate, it may not be possible to eliminate the actual risk of alumina head fracture, and therefore patients should be informed about the potential for this calamitous complication before receiving an alumina-on-alumina bearing.

At the time of revision surgery following a ceramic implant fracture, the use of a new ceramic head on a damaged Morse taper is not recommended because it creates an area of plant fracture, the use of a new ceramic head on a damaged femoral component in situ, after complete débridement and synovectomy in order to remove as many of the alumina particles as possible. In the four hips with fracture of the alumina liner and no macroscopic damage to the Morse taper, we performed a modular exchange with a new alumina-on-alumina bearing because we believed that the new ceramic head would be harder than a new cobalt-chromium head and therefore would be better able to resist the abrasive wear that can be caused by undetectable microscopic ceramic debris. There was no fracture or abnormal wear of the reimplanted femoral heads during our relatively short follow-up period.

The number of failed alumina implants was small, which precluded any statistical analysis of our results to determine the prognostic factors associated with the time to alumina implant failure. Another limitation of the present study was a lack of uniform indications for the use of this alumina ceramic bearing at the four participating centers.

This relatively high rate of catastrophic alumina bearing failure at short-term follow-up prompted us to discontinue the use of this type of alumina bearing design. If it is used, we recommend that every effort should be made to prevent impingement by meticulous component positioning and, whenever possible, the use of a larger femoral head combined with the optimal design of acetabular liner and femoral neck to realize the potential long-term durability of a total hip replacement with an alumina-on-alumina bearing.

**Appendix**

Images of additional hips are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on “Supplementary Material”) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).

**References**


