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Midterm Survivorship of a Press-Fit, Plasma-Sprayed, Tri-Spike Acetabular Component

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Abstract: Press-fit acetabular cups without screw holes can limit migration of particulate wear debris and reduce risk of acetabular osteolysis and device loosening. The Tri-Spike cup (Biomet, Inc, Warsaw, Ind) includes a titanium alloy plasma spray porous surface and does not require screw fixation. We retrospectively examined the incidence of cup loosening and acetabular osteolysis after implantation of 45 cups (44 patients) with mean follow-up of 7.3 years (range, 4-9 years). Only one patient (one cup) had evidence of less than 1 mm of retroacetabular radiolucency at 3 years (nonprogressive), which was found to remain firmly fixed during revision of the aseptically loosened femoral component. No cups were removed or revised at latest follow-up. Projected Kaplan-Meier survivorship at 9 years was 100% for cup loosening/revision and 97.8% for radiolucency. **Key words:** total hip arthroplasty, aseptic loosening, osteolysis, acetabular, cup, press-fit.
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Currently, cementless porous-coated acetabular cups are commonly used in acetabular reconstructions with the goal of increased longevity [1-8]. Hemispherical porous-coated cups have displayed low complication rates for up to 10 years [4,5,9,10]. Initial fixation is required, however, so that successful bone ingrowth can occur over time [1,7,8,11]. Several investigators have introduced the concept of press-fit fixation of cementless cups, which leads to a uniform transfer of load to the acetabulum [7,8,12,13]. Initial stability can be augmented by screws, spikes, pegs, or fins [10,11,14-22]. Screws, however, have been linked to fretting wear, corrosion between the screws and the shell, impingement on the polyethylene insert, polyethylene debris, screw fracture, screw migration, as well as vascular and nerve injury [8,11,17,18,23]. Spiked cups have also been used for many years [10,16]. Widmer et al [13] described the long-term survivorship of porous-coated cups using spikes, screws, or the press-fit technique for initial fixation. Using revision for aseptic cup loosening as an end point, 15-year survivorship was greater than 90% for all fixation methods. The incidence of aseptic loosening was slightly higher among spiked cups (4%, 11/255); however, the tri-spike cups were implanted without the press-fit technique, and the authors thought that the nonmodular design made it difficult to determine whether the component was fully seated during implantation.

Because of the many variables associated with cup/bearing design, it is difficult to extrapolate the results of survivorship studies from one implant to another. Thus, the propensity for aseptic loosening can only be adequately understood by clinical evaluation of the specific implant design. Little survivorship data exist regarding press-fit tri-spike

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Fig. 1. Tri-spike acetabular component. Left: Cup showing spikes, apical hole, and porous plasma spray coating. Right: Cup with polyethylene liner.

cups and none regarding a press-fit, porous plasma-sprayed, tri-spike acetabular component (Tri-Spike acetabular cup, Biomet, Inc, Warsaw, Ind). Consequently, we retrospectively examined the clinical results obtained from 45 implanted, press-fit, cementless Tri-Spike cups (44 patients), with an average of 7.3-year follow-up (range, 4-9 years), to ascertain the rate of osteolysis, cup loosening, and revision. Our hypothesis was that, over this midterm interval, the specific design features of this cup would result in high survivorship in terms of lack of revision and the absence of osteolysis.

Materials and Methods

Cup and Liner Description

The Tri-Spike Ti6Al4V acetabular component is hemispheric to provide uniform transfer of force throughout the acetabular vault, with diameters ranging from 46 to 70 mm in 2-mm increments (Fig. 1). The outer shell is coated with titanium alloy (Ti6Al4V) porous plasma spray (noninterconnected pore structure; mean pore size, approximately 250 μm) to provide opportunity for bone ingrowth and permanent fixation [24-28]. Three dome spikes, spaced 120° apart, provide initial stability and are uncoated so as to not induce stress shielding and allow proper seating. The spikes project 1.3 mm beyond the apex of the cup and range in length from 9 mm for the smallest cup (46-mm-diameter) to 18 mm for the largest cup in the series (70-mm-diameter). There is one threaded apical dome hole with which to engage the insertion instrument. The hole also provides a means to visualize apposition to the acetabular floor to ensure proper seating. After placement, the apical hole is sealed with a threaded plug containing a positive stop. The rim of the shell contains 6 to 8 antirotation tabs to minimize micromotion at the shell/liner interface (RingLoc, Biomet Inc) [28,29]. The liner, a hemispheric design, is machined from isostatically molded ArCom (Biomet Inc) ultrahigh molecular weight polyethylene (UHMWPE) [29]. The machined cup is then sterilized by γ irradiation in an inert argon atmosphere to permit cross-linking although avoiding oxidation, enhancing wear resistance [29,30]. Five polyethylene liner options exist: standard, Hi-Wall, 10°, 10° Hi-Wall, and +5 mm. The high wall refers to a rim that is elevated approximately 3 mm over a 150° arc. There can be impingement in the area of the high wall, but its use is a clinical decision based on the position of the cup and the stem. The 10° and the +5-mm liners are lateralized.

Study Population and Design

From March 1997 through August 1998, 95 consecutive primary hip arthroplasties were performed by 5 surgeons in 99 patients using the tri-spike acetabular component and RingLoc liner. After obtaining institutional review board approval, we retrospectively examined these patients, with focus on the status of the cup and the retroacetabular bone. The inclusion criteria were patients who had received the implant for primary hip arthroplasty regardless of diagnosis, with longer than 4 years of follow-up. Patients whose status after hip hemiarthroplasty was converted into total hip arthroplasty because of femoral component failure and those without evidence of acetabular bone erosion were included. Patients who did not have complete preoperative and operative records (15), had died for reasons unrelated to the implant or its surgery (10), who were lost to follow-up (17), or who

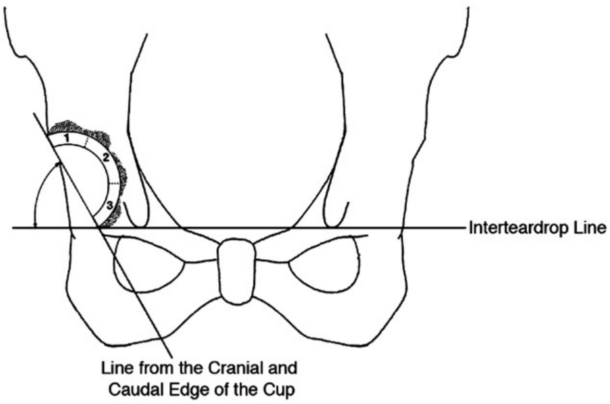

Fig. 2. Radiographic evaluation: cup inclination and zones of DeLee and Charnley.

refused to come in for follow-up radiographs (8) were excluded. This left a total of 45 hips in 44 patients for analysis.

Study patients included 17 men and 27 women. The mean age at the time of surgery was 67 years (range, 34-88 years). The mean of the body mass index at the time of surgery was 29.1 kg/m^2 (range, 20.6-42.5 kg/m^2). The primary diagnosis was osteoarthritis in 40 hips, posttraumatic arthritis in 2 hips, avascular necrosis in 1 hip, rheumatoid arthritis in 1 hip, and osteoarthritis secondary to developmental dysplasia of the hip in 1 case. Comorbidities were categorized as cardiovascular disorders (hypertension, coronary artery disease) in 13 patients, metabolic disorders (diabetes, thyroid disease, parathyroid disease) in 7 patients, and neoplastic disorders (colon or breast cancer) in 2 patients. Four hips had previous operations, that is, 3 had undergone hemiarthroplasty and 1 had open reduction and internal fixation of an acetabular fracture. The acetabular fracture had healed and was deemed to be equivalent to a primary hip.

Retrospective chart review was performed to gather preoperative data (date of birth, age at surgery, sex, height, weight, primary diagnosis, concomitant diseases, and history of previous hip surgery—see above) and radiographic evaluation (cup inclination angle and the location and size of any retroacetabular radiolucent lines as per DeLee and Charnley [31]—see below) at the following postoperative intervals: 2 weeks (physical examination only), 2 months, 1 year, 4 years, and 7 years. To the extent possible, patients were brought into the clinic to supplement the chart review with a latest follow-up radiographic examination. If patients could not be contacted or refused to report for examination, their latest follow-up radiographs obtained from the chart review were used.

Surgical Technique

The posterior surgical approach was used in all cases. The acetabulum was carefully exposed and then reamed with progressive hemispheric reamers until there was optimal circumferential fit between the rim of the reamer and of the bone, with bleeding walls present. Cysts and bone irregularities were curetted and filled with cancellous morcellated graft obtained from the femoral heads. A finishing reamer (DePuy Inc, Warsaw, Ind), 1 mm smaller than the last reamer, was used to impact the bone graft into the cysts. A Tri-Spike cup 2 mm larger than the finishing reamer was press fit into the prepared acetabulum, being careful to avoid the insertion of spikes into thin walls of the acetabulum. After full impaction, seating was checked through the apical hole that was then sealed with the threaded plug.

The size of the acetabular components ranged from 46 to 58 mm. The liner component was 28 mm Hi-Wall in 43 hips and 28 mm 10° Hi-Wall in 2 hips. The femoral component was Mallory-Head (Biomet Inc) cemented in 22 hips, Integral 180 primary/revision (Biomet Inc) in 20 hips, Mallory-Head Modular Calcar (Biomet Inc) cemented in 2 hips, and Mallory-Head press fit (Biomet Inc) in 1 hip. Neck angles were 135° to 140°. All the hips used a 28-mm modular head. The length of the neck was standard in 13 hips, +3 mm in 18 hips, +6 mm in 8 hips, +9 mm in 1 hip, −3 mm in 4 hips, and −6 mm in 1 hip.

Radiographic Evaluation

The radiographic evaluation included an anteroposterior and a lateral view of the hip. Radiolucent lines in the 2-month postoperative radiograph and in the most recent follow-up radiograph were identified. The location of radiolucent lines was recorded in the 3 zones described by DeLee and Charnley [31]. The sizes of the radiolucent lines were categorized as follows: no radiolucency, less than 1 mm, 1 to 2 mm, and greater than 2 mm. Inclination of the cup was measured as the angle between the interteardrop line and a line drawn from the cranial and caudal edge of the cup (Fig. 2) [32].

Statistical Evaluation

For each patient, the cup inclination angle obtained from the 2-month postoperative radiograph was compared with that obtained at final follow-up using a 2-tailed paired *t* test. The difference between the population means was considered to be significant for $P < .05$.

Table 1. Summary of Radiographic Results and Complications

	Last F/U		Cup Inclination		Radiolucency		
Hip	Age (y)	(y)	2 mo	Last	2 mo	Last	Complications
1	63	6.6	65	65	No	No	No
2	61	7.0	50	50	No	No	No
3	46	7.0	48	48	No	No	No
4	34	7.7	51	53	No	No	No
5	70	6.9	42	42	No	No	No
6	73	7.4	40	40	No	No	No
7	71	7.5	47	47	No	No	No
8	71	6.5	48	48	No	No	No
9	72	6.9	45	45	No	No	No
10	58	7.0	48	48	No	No	No
11	67	7.7	40	42	No	No	No
12	74	7.4	50	54	No	No	No
13	82	8.0	36	37	No	No	No
14	61	7.3	45	46	No	No	No
15	77	7.1	65	66	No	No	No
16	62	8.4	46	50	No	No	No
17	77	8.1	42	41	No	No	No
18	64	7.2	30	30	No	No	No
19	67	8.0	60	60	No	No	No
20	86	7.6	72	73	No	No	No
21	80	7.9	44	42	No	No	No
22	39	7.5	63	65	No	No	No
23	88	7.5	38	39	No	No	No
24	55	4.2	51	48	No	No	No
25	69	4.7	48	49	No	No	No
26	71	4.0	48	48	No	<1 mm zones I and II	Revise Femoral
27	76	7.3	N/A	45	No	No	No
28	66	7.2	N/A	42	No	No	No
29	66	7.7	N/A	55	No	No	No
30	74	7.0	N/A	32	No	No	No
31	60	6.9	N/A	36	No	No	No
32	72	7.0	N/A	70	No	No	No
33	54	7.3	N/A	32	No	No	No
34	74	9.0	N/A	45	No	No	No
35	67	7.5	N/A	50	No	No	No
36	70	7.5	N/A	43	No	No	No
37	79	7.6	N/A	45	No	No	No
38	74	7.5	N/A	46	No	No	No
39	71	7.6	N/A	38	No	No	No
40	80	8.2	N/A	60	No	No	No
41	72	7.5	N/A	50	No	No	No
42	64	8.0	N/A	51	No	No	No
43	63	7.9	N/A	55	No	No	No
44	57	8.0	N/A	45	No	No	No
45	68	7.8	N/A	44	No	No	No

N/A indicates not available.

Kaplan-Meier survivorship analysis was performed for the Tri-Spike acetabular cup using 2 sets of end points: (1) identification of radiolucent lines indicative of osteolysis and (2) revision of the cup. Ninety-five percent confidence limits for the estimated survivorship function were computed.

Results

All patients at clinical follow-up had a radiograph. There were no surgical complications. The mean last follow-up for all 45 hips was 7.3 years (range, 4.0-9.0 years). All patients had a postoperative radiograph. In 19 patients, the postoperative films were unavailable for review; however, these patients had a complete postoperative radiologic report, and this report was considered for the postoperative evaluation. Those 19 charts, however, did not include cup inclination angle (Table 1).

Cup inclination angle was 48.5°±9.7° for the 26 patients for which this measurement was available at 2-month follow-up. The corresponding value for the latest interval (mean, 7.0 years; range, 4.0-8.4 years) for these same 26 patients was 49.1°±9.9°. The means of the paired differences

Fig. 3. Radiolucent line in the zones 1 and 2 of DeLee and Charnley in hip 26. Femoral component was Mallory-Head cemented.

Fig. 4. Mallory-Head cemented femoral component loosening at 3 years of follow-up in hip 26. Arrow shows regions of femoral radiolucency and osteolysis.

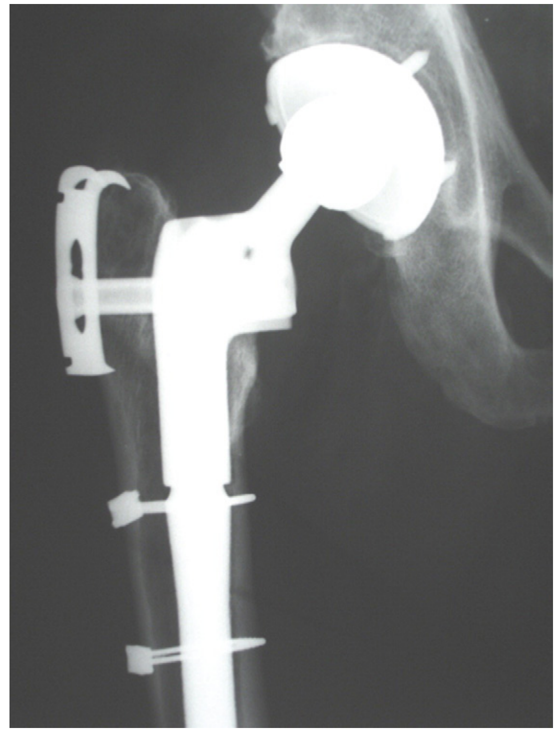

Fig. 5. Femoral component revision in hip 26.

were not significantly different (P = 0.080). Although 19 patients did not have a postoperative radiograph for comparison with the most recent radiograph, the implants were stable, and it was felt

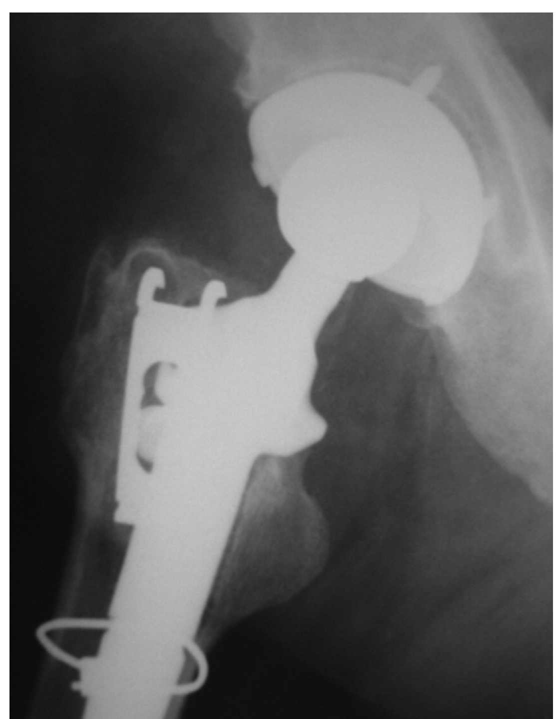

Fig. 6. No progression of radiolucent line at 4 years of follow-up in hip 26.

Table 2. Kaplan-Meier Survivorship Analysis for Tri-Spike Cup Revision

Interval (y)	No. of at risk at start of interval	No. of censored during interval	No. of at risk at end of interval	No. of failures at end of interval	Proportion surviving interval	Cumulative survival at end of interval
4	45	0	45	0	45/45 = 1.00	1.00
6	45	3	42	0	42/42 = 1.00	1.00
7	42	5	37	0	37/37 = 1.00	1.00
8	37	29	8	0	8/8 = 1.00	1.00
9	8	7	1	0	1/1 = 1.00	1.00

by the authors that no positional changes occurred. At the latest interval (mean, 7.6 years; range, 6.9-9.0 years), the cup inclination angle for these 19 patients was 46.5° ± 9.4°, which was not significantly different than that at the latest interval for the other 26 patients for whom a postoperative measurement was available (2-tailed t test, $P = 0.39$). Despite some cups being abducted greater than 45°, there were no obvious signs of accelerated polyethylene wear.

No Tri-Spike cups were removed or revised among the 45 hips that comprised the study population, as well as among the 8 patients who refused follow-up radiographs and, to the best of the authors' knowledge, among the 17 patients who were lost to follow-up, the 15 patients with incomplete records, and the 10 patients who died for reasons unrelated to their implant or surgery. Only one hip had evidence of a radiolucent line less than 1 mm in the zones 1 and 2 of DeLee and Charnley [31] as determined during an unscheduled 3-year follow-up (Fig. 3). This patient presented with clinical symptoms and radiologic signs of aseptic loosening of the Mallory-Head cemented femoral component (Fig. 4), which was revised at this time. During revision surgery, the femoral component was replaced, but the acetabular component was left in place because it was well fixed into the acetabulum (Fig. 5). The cup liner was also revised. A follow-up radiograph was taken 1 year after the revision (year 4)—there was no sign of progression of the radiolucencies around the cup (Fig. 6). This patient recently died from an unknown cause.

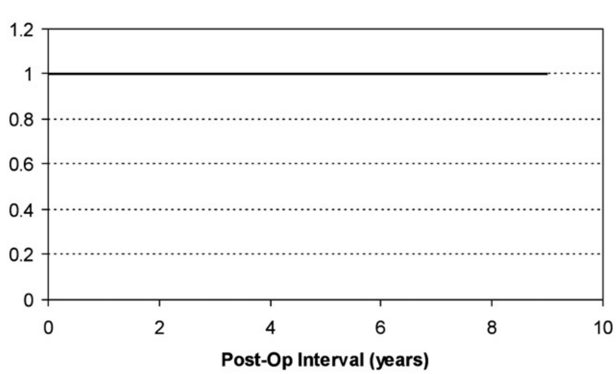

Fig. 7. Kaplan-Meier survivorship plot for Tri-Spike acetabular component using implant revision as end point.

Table 2 shows the results of the Kaplan-Meier survivorship analysis using revision of the Tri-Spike cup as an end point. Because no hips underwent cup revision or removal, the analysis shows a projected survivorship of 100% at 9 years. The plot of estimated survivorship is shown in Fig. 7. Because there were no failures as defined here, a confidence interval could not be computed. Alternatively, we can state that there was 100% survivorship of the cup at a mean follow-up of 7.3 years.

Table 3 summarizes the Kaplan-Meier survivorship analysis using the first appearance of retro-acetabular radiolucency as an end point, with a single such occurrence at 3 years. The survivorship was thus 97.8% at 9 years (Fig. 8). The 95% confidence interval of the estimated survivorship over this period, for the end point as defined, was 93.5% to 100%.

Discussion

Our study demonstrated excellent Kaplan-Meier survivorship of a hemispheric, plasma-sprayed, porous-coated, Tri-Spike acetabular cup, with a projected value of 100% at 9 years using device revision as an end point. With the less stringent end point of the appearance of radiolucent lines in the acetabulum behind the cup, the Kaplan-Meier survivorship was 97.8% (44/45) at 9 years (95% confidence interval, 93.5%-100%). In addition, based on the cup inclination angle data, the positioning of the cups over the course of the study appeared to be stable. These results compare favorably with those of prior studies using porous-coated cups [10,23,33,34]. For instance, a retrospective study performed by Engh et al [10] of 4289 total hip arthroplasties performed with 6 types of hemispheric porous-coated cups showed a general

Table 3. Kaplan-Meier Survivorship Analysis for Retroacetabular Radiolucency

Interval (y)	No. of at risk at start of interval	No. of censored during interval	No. of at risk at end of interval	No. of failures at end of interval	Proportion surviving interval	Cumulative survival at end of interval
3	45	0	45	1	44/45 = 0.978	0.978
6	44	2	42	0	42/42 = 1.00	0.978
7	42	5	37	0	37/37 = 1.0	0.978
8	37	29	8	0	8/8 = 1.00	0.978
9	8	7	1	0	1/1 = 1.00	0.978

pattern of survivorship declining at a rate of about 0.5% per year during the first 7 years, then increasing to about 2% per year between years 7 and 15. The 15-year survivorship for a hemispherical, porous-coated, tri-spike cup was 82.9%. Clohisy and Harris [34] found 96% survivorship at an average of 10-year follow-up of the Harris-Galante porous-coated, hemispherical, acetabular component where failure was defined as cup revision. Grobler et al [33] found for the Duraloc 300 (DePuy), a tri-spike, porous-coated, less than hemispherical design, that 10-year survivorship for cup loosening was 100% and for revision of the liner was 95.4%. Our survivorship results compare favorably with these.

There are pros and cons to the use of spikes for initial cup fixation. Benefits of 3 spikes include immediate fixation and rotational stability. However, once seated, adjustment is difficult. Although, theoretically, the spikes may engage differently based on the degree of bony sclerosis, as long as the driver is properly engaged with the cup, rigid control of the seating of the cup can compensate for sclerotic areas of the bone.

Many factors can influence the survivorship of an acetabular component, including its ability to achieve short- and long-term fixation, the degree to which wear particles are generated, and their ability to migrate to the periprosthetic bone. Although it is difficult to attribute clinical outcomes to specific implant design aspects, either individually or collectively, it is instructive to examine the device features to gain insight into their possible effect on performance.

Both the rough porous surface of the cup and the presence of the 3 spikes help provide initial fixation. Markel et al [25] performed a biomechanical study and concluded that the aggressiveness of the plasma-sprayed coating could enable the under-reamed pelvis to "grab" the cup.

Ultimately, long-term fixation is provided by bone ingrowth into the porous coating. The Integral hip stem is circumferentially coated with the same coating used on the Tri-Spike cup. Mauerhan et al [27] performed a 5- to 8-year follow-up study on 139 hips receiving this stem. In this series, there was radiographic evidence of endosteal bone apposition and osseointegration.

The propensity of the UHMWPE liner to generate wear particles is a function of the liner material and how it is processed, as well as its design. The ArCom UHMWPE used was γ irradiated (2.5-4.0 Mrad) in an inert argon atmosphere to prevent oxidation from occurring and enable cross-links to form in the polymer to enhance wear resistance [35-37]. The enhanced wear resistance of ArCom UHMWPE was demonstrated in a clinical study by Head et al [29] in which there was a 40% reduction in wear compared with liners derived from ram-extruded or sheet-molded bar stock.

Backside wear can occur in modular acetabular components that can lead to wear particle generation [23]. The magnitude of this may be associated with the liner/cup locking mechanism, the amount of micromotion, and the surface finish of the metal [23]. The RingLoc mechanism uses 6 to 8 antirotation tabs on the shell to minimize micromotion at the shell/liner interface. Yamamoto et al [28] demonstrated the superiority of the RingLoc mechanism compared with an alternative, the Hexloc (Biomet Inc). Push-out and lever-out test

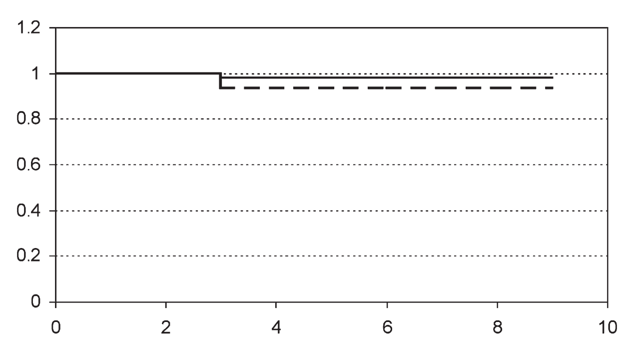

Fig. 8. Kaplan-Meier survivorship plot for Tri-Spike acetabular component using retroacetabular radiolucency as end point. Dashed line represents the 95% lower confidence interval.

values for the RingLoc compared with the Hexloc were 10-fold and 5-fold greater, respectively.

There are 2 potential means by which the pathway for migration of wear particles to the retroacetabular bone was limited. First, as shown by Emerson et al [24], this plasma-sprayed porous coating, applied circumferentially to hip stems, significantly reduced osteolysis at approximately 8 years compared with stems that were only partially coated. This was consistent with the ability of the porous coating to prevent or minimize wear debris migration when the bone/coating interface is complete. Second, screw holes in the acetabular cup are an obvious pathway for wear particle debris to migrate to the retroacetabular bone [38]. There were no screw holes in the Tri-Spike cup, only the apical dome hole that was sealed with a threaded plug. As such, there was theoretically no direct pathway through the cup for wear particles to travel to the retroacetabular bone.

There were several limitations to our study. First, only 45 hips (44 patients) were followed. Although this number is not large, it was felt to be sufficient to be able to reasonably characterize the osteolytic propensity and loosening rate for the Tri-Spike cup. Second, we did not attempt to quantify polyethylene wear during the 4- to 9-year follow-up period. Although several radiographic methods exist to measure polyethylene wear, they have limitations that, to date, have prevented their widespread use [39]. Consequently, we were unable to correlate the survivorship of the device with an estimated polyethylene wear rate. Third, only midterm follow-up was available. Because cup survivorship may decrease substantially after 7 years [10], it would be prudent to follow patients for a longer interval, perhaps 15 years.

In summary, the press-fit, plasma-sprayed, porous-coated, Tri-Spike acetabular cup exhibited excellent midterm survivorship, with no revisions for up to 9 years and a radiolucency in only one at 3 years, which was nonprogressive. It is possible that the wear-resistant polyethylene and the liner/cup locking mechanism minimized wear particle generation, and the noninterconnected pore characteristic of the coating plus the absence of screw holes limited the ability of any particles that were generated to reach the acetabulum. Finally, the presence of the 3 spikes provided initial fixation until bone was able to grow into the porous coating. These results contribute in a small way to the cumulative body of literature that attests to the overall success of total hip arthroplasty and can be used to provide information to help develop future, even more successful, designs.

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