Incidence of Ceramic Liner Malseating in Trident[®] Acetabular Shell

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Abstract The low wear rates associated with ceramic hip articulations have made them a popular bearing for younger patients. Although few complications have been observed, one report revealed several instances of incomplete seating of the ceramic liner in the metallic shell. We performed a cohort study of consecutive THAs using a ceramic-ceramic bearing. Radiographic analysis showed 50 (7.2%) of the group of 694 hips had evidence of incomplete seating of the liner in the metallic shell. Although we observed no adverse effects at 6 to 12 weeks, we encourage surgeons to carefully assess liner placement in the metal shell at the time of surgery to avoid this unintended consequence and to assess placement at the time of followup so patients can be properly followed when incomplete seating is identified.

Level of Evidence: Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Component wear and osteolysis have been the major long-term concerns in THA, especially in younger individuals. Ceramic bearing surfaces for arthroplasty have been in use since 1970 [2]. Zirconium oxide and aluminum oxide ceramics have increased wettability and decreased coefficients of friction on polyethylene and ceramic [3, 12]. One concern with ceramic bearings is that they are very brittle and catastrophic failure of head and acetabular components has been reported [1, 5, 6, 8, 10]. With recent technologic developments, including decreased grain size and fewer inclusions, the risk of fracture reportedly is reduced and their use is increasing [2].

One commonly used ceramic implant is the Trident[®] system (Stryker Orthopaedics, Mahwah, NJ), which has a titanium-backed ceramic press-fit liner in a hydroxyapatite-coated, titanium alloy acetabular shell. There are two types of shells: hemispherically or equatorially expanded (peripheral self-locking). The FDA approved this product in 2003. The ceramic is recessed in a titanium backing sleeve to prevent impingement of the femoral neck on the ceramic liner rim, potentially causing ceramic chipping, a problem previously described with ceramic components [4, 5]. This metal-backed ceramic liner is impacted in the shell using antirotation tabs on the shell to ensure correct seating. The liner is designed to engage in the shell as an angular taper. When the liner is malseated, the edge is visible, separate from the edge of the shell (Fig. 1).

Acetabular liners in older systems placed in a canted, nonseated position have been described [6], and in several cases these implants fractured in a very short time; however, one report noted a single liner that was chipped on the periphery and left in place with no clinical consequence during the followup time [5]. In a recent article about the

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that a waiver of informed consent for participation in the study was granted.

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Fig. 1 A photograph shows an example of a malseated liner placed in a Sawbones[®] pelvis. The arrow indicates the gap where the liner is not completely seated.

Trident[®] liner, Langdown et al. found an incidence of malseating of approximately 16.4% in their patient cohort [7]. We also observed incompletely seated liners on followup radiographs of some patients.

Our goal therefore was to determine the incidence of malseating of Trident[®] acetabular liners in a consecutive series of ceramic-on-ceramic THAs. In addition, we determined whether the incidence of malseating was a factor influenced by volume of surgical cases using this device.

Materials and Methods

We reviewed prospectively collected data for all 674 patients (764 hips) who had THA with the cementless titanium alloy Trident[®] PSL and hemispheric acetabular shells and the Secur-Fit[®] stem with alumina-alumina bearings (Stryker) from May 2003 to January 2006. Ninety were implanted bilaterally. Of the 674 patients, 61 either were lost to followup or had incomplete radiographic studies; in no instance did we rely on the postoperative recovery room radiographs to identify malseating. This left a cohort of 694 hips (613 patients, 81 of whom had bilateral THAs) for analysis. There were 316 women and 378 men in this cohort, with an average age of 58.6 years. The average age was 62.0 years for women and 55.8 years for men. The minimum followup was 6 weeks, with liner malseating observed on the 3-month radiographs of five patients. Institutional Review Board approval for this study was obtained.

All surgical procedures were performed through the posterior approach to the hip. These procedures were performed by 20 surgeons, all trained in hip arthroplasty.

Fig. 2 A radiograph shows an incorrectly seated liner with a visible gap. The lower arrow indicates the gap evident on the radiograph when the liner is malseated. The upper arrowhead shows an apparently well-seated liner.

All available radiographs for the 694 hips were examined by one reviewer (ANM) who was not involved in the surgery. The anteroposterior (AP) and lateral hip films were reviewed from the time of surgery to the most recent followup to identify any instances of shell liner divergence indicative of incomplete seating or malseating of the insert. A liner was considered malseated if divergence was seen on any film at any time. Any films deemed either possibly or definitely unseated were reviewed independently by all four senior authors (DEP, ES, MPGB, BJN) to reach a consensus on the position of the liner. Each of the senior authors made an independent opinion regarding whether there was liner divergence or proper seating.

The liners that were unseated had a distinct gap visible on radiographs between the metal sleeve of the liner and the acetabular shell (Fig. 2). The quality of some films was not sufficient to specifically outline this gap, but the angle of the planes of the acetabular shell opening and the liner opening were used to determine the seating. If there was no visible gap or divergent angulation between the liner and shell, we presumed the liner was correctly seated (Fig. 3).

The percentage of liner malseating for the entire cohort and the number and incidence for each of the 20 individual surgeons were determined. A Pearson correlation was performed to determine any relationship between number of hips implanted and incidence of liner malseating.

Results

Of the 694 hips, 50 (7.2%) had evidence of component malseating detected on either the AP or lateral radiograph. Thirty-two of the 378 hips (8.5%) in male patients and 18 of the 316 hips (5.7%) in female patients were malseated. All of the radiographs showing a malseated liner had the

Fig. 3A–B Radiographs show examples of (A) well-seated and (B) malseated acetabular liners. The arrow indicates the gap where the liner is not completely seated.

gap in the anteroinferior quadrant, usually at the level of the teardrop (Fig. 2).

Of the 81 patients with bilateral THAs (162 hips), 11 had malseating on one side only (11 hips) and two had bilateral malseating (four hips), for an incidence of 9.3%. Twenty-nine of these patients (58 hips) had their procedures performed on different days, with six total malseated liners (including one bilateral), for an incidence of 10.3% compared with an incidence of 9.0% for patients who had their procedures performed on the same day (100 hips with nine unseated).

The incidence of malseating by surgeon varied from 0% to 100% (Table 1). However, owing to ranges in numbers of procedures performed, we observed no correlation ($r = -0.05$; $p = 0.82$) between the surgical volume and incidence of component malseating.

During the followup of 6 to 12 weeks we observed no ceramic fractures, late liner dissociations, or component revisions related to liner malseating.

Discussion

The low wear rates associated with ceramic hip articulations have made them a popular bearing for younger patients. Although few complications have been observed, a recent report [7] revealed several instances of incomplete seating of the ceramic liner in the metallic shell. The

purpose of our study was to examine the incidence of liner malseating in a consecutive series of patients undergoing ceramic-on-ceramic THA.

We note several limitations of this study. We had a large group of patients ($n = 70$) for whom we could not verify component placement. Also, it is possible some malseated components were missed on our radiographic examinations owing to poor quality or poorly executed radiographs. We tried to eliminate any bias by declaring any hip lacking clearly visible cup and liner edges on the radiographs as being incomplete. With this in mind, we cannot say the exact incidence of malseating, and it could be much higher than the 7.2% recorded here. If all 70 of the missing radiographs had malseated liners, the incidence would increase to 17%. Although there have been no revisions related to liner malseating in this group to date, there is limited followup.

Our finding of a 7.2% incidence of this phenomenon, although less than that reported by Langdown et al. [7], confirms the phenomenon is real and raises several issues. Failure to completely engage a modular taper is a concern. Incomplete seating of the ceramic liner in the socket theoretically could lead to liner dissociation from the shell, and metal fretting attributable to motion between the interfaces. Both of these problems have led to reports of catastrophic failure [5, 6, 8–10, 13]. Although we observed an incidence of 7.2% in this large cohort, fortunately there have been no adverse consequences to date.

Table 1. Incidence of malseating categorized by surgeon

Surgeon	Total number of hips	Total number of malseated hips	Number of bilateral malseated hips/total number of bilateral hips
1	1	0 (0%)	0/0 (0%)
2	143	7 (4.9%)	0/22 (0%)
3	95	6 (6.3%)	2/25 (8%)
4	1	0 (0%)	0/0 (0%)
5	36	2 (5.6%)	1/12 (8.3%)
6	1	0 (0%)	0/0 (0%)
7	2	0 (0%)	0/0 (0%)
8	3	0 (0%)	0/2 (0%)
9	9	1 (11.1%)	0/2 (0%)
10	108	4 (3.7%)	1/33 (3.0%)
11	5	0 (0%)	0/0 (0%)
12	6	1 (16.7%)	0/0 (0%)
13	21	1 (4.8%)	0/0 (0%)
14	2	0 (0%)	0/0 (0%)
15	17	0 (0%)	0/6 (0%)
16	6	0 (0%)	0/1 (0%)
17	82	12 (14.6%)	3/20 (15%)
18	150	14 (9.3%)	8/35 (22.9%)
19	4	0 (0%)	0/0 (0%)
20	2	2 (100%)	0/0 (0%)

There are several theories regarding how malseating occurs. One theory is that there may be soft tissue interposition that could contribute to the problem. As it is a widely recognized practice to ensure the acetabular shell and liner are clear before seating components or relocating the hip, we believe this is a minor contributor, if at all. Others have suggested permanent shell deformation during impaction of the cup, which could change the tolerances between shell and insert and ultimately lead to malseating. This has been reported with the DePuy Pinnacle™ acetabular cup (DePuy Orthopaedics, Inc, Warsaw, IN) (although not used with ceramic liners) [7, 11]. This deformation could occur especially in cases of dense, sclerotic bone. With deformation, the angular taper geometry of the shell would be altered slightly and this then would prevent full insertion of the liner. As the ceramic components often are used in younger patients with dense bone, the likelihood of shell deformation may be increased. The fact that we saw a higher incidence in men (8.5% as compared with 5.7% in women) with dense, sclerotic, bone might be consistent with this explanation. Unlike Langdown et al. [7], we did not see any patients with resolution of the malseating with time, although we have limited followup for this cohort.

Another possible cause of malseating is placement of the ceramic liner in a canted position before impaction. With

the Trident® liner's elevated titanium sleeve, observation of the cup and seating could be impaired (Fig. 1). This is consistent with the observation that all of the malseated components in this study were gapped in the inferior portion of the liner, which is often the hardest quadrant to see. As all of these procedures were performed from a posterior approach, it also makes sense that the gaps would be in the more anterior portion of the liner, which was observed on our radiographs and those of another study [8]. The implication is that surgical exposure may play a role. Factors such as body mass index and incision length, which certainly can affect exposure, may influence the incidence of this occurrence and will be evaluated as we continue to follow this cohort of patients.

There was a wide variability among surgeons in the rates of malseating. However, the incidence of malseating was not related to the number of ceramic cases the surgeons performed, so perhaps it is an inherent problem in either the particular surgeon's technique or that surgeon's patient population.

Although the long-term consequences of liner malseating are unknown, we will continue to follow these patients. Only with longer followup will we be able to determine the effects of liner malseating on implant performance. With the high incidence of malseating we observed, it is important for surgeons to be aware of this problem and make a thorough check at the time of surgery to ensure the liner is seated. We recommend all surgeons using this implant complete a check of each quadrant of the shell liner to ensure proper seating of the ceramic bearing.

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