A multi-center retrospective comparative study of third generation Ceramic-on-Ceramic total hip arthroplasty in patients younger than 45 years with or without the sandwich liner: A ten-year minimum

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Abstract

Background: Ceramic-on-ceramic couplings are attractive alternative bearing surfaces that have been reported to eliminate or reduce problems related to polyethylene wear debris. However, the material in THA still remains one of the major concerns about the risk of fracture, due to its brittleness.

Objective: The present study aims at reporting the fracture rate of a series of ceramic-on-ceramic THAs with use of the sandwich liner combined with a ceramic femoral head, and attempt to detect the relative risk factors, possible cause and assess the medium-term clinical results.

Methods: We retrospectively evaluated 282 patients (300 hips) with use of the sandwich liner ceramic-on-ceramic THA between 2001 and 2009 at three-centers. Patient assessment was based on demographic factors, including age, weight, gender and body-mass index. All patients were evaluated clinically and radio-graphically or computed tomography in consideration of dislocation, osteolysis, periprosthetic fracture, infection, loosening and implant fracture.

Results: Five ceramic sandwich liners fracture (1.7%) were observed at an average of 7.3 years follow-up. These factors were irrelevant to the ceramic liner fracture, including age (p = 0.205), weight (p = 0.241), gender (p = 0.553), body-mass index (p = 0.736), inclination (p = 0.727), and anteversion (p = 0.606). The overall survival was 91.4% at 12 years with revision as the endpoint. Other complications included dislocation in two, perprosthetic fracture in two and osteolysis in eight hips. No hip had aseptic loosening of the implants was seen.

Conclusions: We found that the sandwich liner may be lead to a high rate of alumina fracture and osteolysis. We have discontinued the use of sandwich liner with THA since 2009.

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Ceramic-on-ceramic articulations have been in use in total hip arthroplasty since the 1970s, but early implants had a high failure rate. More recently developed third-generation alumina ceramic bearings have improved fixation methods as well as a metal-backed acetabular component and improved material properties to resist wear and fracture. Compared with traditional metal-on-polyethylene bearing surfaces, alumina ceramic-on-ceramic total hip arthroplasty (THA) has reduced polyethylene debris-associated complication, so it has been widely used during the last three decades, especially in young active patients. In the early period, however, some authors believed that this hard-on-hard bearing couple has a high stiffness and there is a mismatch in elasticity between bone and alumina ceramic, which can result in failures. To explore this issue, a design scheme of adding a layer of polyethylene liner between metal cup and alumina layer was proposed by those authors, which also was called the sandwich liner. This sandwich insertion, which perhaps increases the longevity of the artificial joint, could reduce the rigidity of the ceramic-on-ceramic coupling and also prevent an impingement between the rim of the ceramic liner and the metal femoral neck. Meanwhile, some authors also reported sporadic cases of the fracture of the femoral head and ceramic liner. Accordingly, the present retrospective study aims to (1) evaluate the medium-term clinical results of a consecutive series of ceramic-on-ceramic bearing THAs with the sandwich liner; (2) determined the incidence of the sandwich liners fractures and osteolysis, and (3) were interested to understand the reason for the sandwich liner fracture.

**Patients and methods**

From March 2001 to July 2009, 300 total hip arthroplasties (THAs) without cement were performed in 282 patients with the sandwich insertion which was a polyethylene-alumina composite liner within a metal acetabular shell, in the Orthopedic Department at three-centers. In 93.3% of the cases, liners (n = 280) were implanted in primary surgery and in 6.7% (n = 20) revision surgery. Of these, three patients (three hips) had been lost to follow-up and four patients (four hips) had been dead for reasons irrelevant to the total hip arthroplasty, and the rest 275 patients (293 hips) available for complete analysis. There were 155 females and 120 males. The right hip was operated on 123 (44.7%) patients and the left hip on 134 (48.7%) patients. A bilateral replacement was performed in 18 (6.6%) patients. The mean follow-up time of the remaining 275 patients (293 hips) was 7.3 years (range, 4–12 years). And the average age of patients at the time of the index arthroplasty was 52.6 years (range, 17–84 years). The demographic features of the patients are presented in Table 1, including age, gender, weight, body mass index and primary diagnosis.

All surgical procedures were performed by senior surgeon through a modified Hardinge or posterior approach for the primary THA and a posterior or original approach for the revision THA. All patients had undergone THAs with a ceramic-on-ceramic bearing with use of the SPH Contact acetabular component (Lima-LTO s.p.a, Italy, Figure 1). This uncemented acetabular component consists of a pre-assembled, polyethylene-alumina composite liner that is held in a metal backed cup. The cup contains screw-holes. If the cup fixation was not rigid, one or more screws were inserted. The stock has an outer diameter ranging from 46 to 62 mm. On the femoral side, all of patients who were enrolled in the study received the femoral component (Lima-LTO, Italy, Figure 2) including C2 stem, F2L stem, self-locking stem and revision stem. These femoral stems were fixed without cement and a 28-mm alumina head (BIOLOX-forte, Ceram-Tec, Germany) was always used. The C2 stem was implant in 106 hips (36.03%), and the F2L stem was implanted in 167 hips (57.19%), the revision stem for 15 hips (5.08%) and the self-locking stem for 5 hips (1.7%). All patients received intravenous antibiotic prophylaxis perioperatively and were given a low-molecular-weight heparin for prophylaxis against thromboembolism. Patients were mobilized on the first postoperative day and were allowed to stand on or walk with partial weight-bearing after seven postoperatively day, and full weight-bearing was allowed after six to 8 weeks.

Clinical and radiographic evaluations were performed at 6 weeks, 3 and 6 months, and 1 year after surgery, and then annually thereafter. If patients hadn’t returned regularly, we contact the patient by phone. We clinically evaluated patients for pain, walking, and range of motion using the Harris Hip Scores system. All patients’ Harris Hip Scores (HHS) was assessed preoperatively and at the last followed-up examination. We recorded postoperatively complication including aseptic loosening, osteolysis, infection,
periprosthetic fracture, dislocation and implant fracture. We evaluated the AP pelvic and lateral hip radiographs routinely or CT, when necessary, for sings of component position, osteolysis, and loosening. Cup position was assessed according to the acetabular abduction angle and anteversion angle on the PACS digital x-ray system with use of the method of Murray and Lewinnek. Osteolysis was recorded at the acetabulum according to the zone which described by DeLee and Charnley and at the femoral component as described by Gruen et al. Osteolysis was defined as a sharply demarcated lucent area adjacent to the acetabular or femoral component that was not evident on the immediate postoperative radiographs. Loosening of the acetabular and femoral components was categorized according to previously accepted criteria. Loosening of an acetabular component was defined as a migration of ≥2 mm in all three acetabular zones described by DeLee and Charnley or a change in the abduction angle of that component of ≥5°. Femoral component was considered to be unstable when there was progressive subsidence exceeding 3 mm, any change in position and a continuous radiolucent line wider than 2 mm. Bony ingrowth was described according to criteria of Engh et al. Heterotopic ossification was classified according to the system of Brooker et al.

A statistical analysis was performed using the SPSS 19.0 statistical software system. Demographic data were compared using the Mann-Whitney test for continuous variables and the chi-square test (or when necessary, the Fisher’s exact test) for ordinal variables. Therefore, we could compare the data between the overall group and the liner fracture group to find the risk factors associated with the ceramic liner fracture. Survivorship analysis was performed with the Kaplan-Meier method, with fracture or revision for any reason as the endpoint. The level of significance was set at \( p < 0.05 \).

### Results

At the last follow-up, alumina liner fractures occurred in five hips (five patients) and these were revised at 4, 6, 7, 10 and 11 years after the initial operation, respectively (Figure 3). Of the remaining hips, eight ases (eight hips) had presented location of areas of osteolysis around the acetabular component (Figure 4). Two hips had developed radioluency in zone 1 and others in zone 2 adjacent to the acetabular component. On the femoral side, no radiographically detectable osteoysis was observed in any hip. It didn’t affect the stability of the acetabular component and were not revised. Two patient (two hips) occurred periprosthetic fracture; and two cases of dislocation and heterotopic ossification in fourteen (Brooker I in 12 hips, and Brooker II in 2 hips). There were no infections and two patients had a deep venous thrombosis. No hip had aseptic loosening of any acetabular or femoral component. All surviving implants had radiographic evidence of stable bony ingrowth. The clinical results of the remaining patients who did not undergo revision revealed the mean Harris Hip Score had improved markedly from 47 points (22–56 points) pre-operatively to 96 points (87–100 points) at the last follow-up examination. The Kaplan-Meier survivorship analysis revealed a 12 year survival rate of 91.4% (95% confidence interval, 82.97%–99.83%) with revision for any cause as the end-point (Figure 5).

Five ceramic liner fractures of those THAs occurred during normal activity of daily living and were not related to unusual traumatic events (Table 2). Among the five patients (five hips), there were three men and two woman with an
average age of 46 years (range, 37–55 years) and a mean BMI of 23.78 kg/m² (range, 21.6–25.7 kg/m²) at the time of THA. The mean abduction angle and anteversion of the acetabular component were 43° (range, 40°–48°) and 13.2° (range, 8°–18°), respectively, in the ceramic fracture group and 44.0° (range, 30°–53°) and 15.2° (range, 0°–26°), respectively, in the overall group. With the data available, there was no significant difference between the ceramic fracture group and the overall group with regard to the age ($p = 0.205$), weight ($p = 0.241$), gender ($p = 0.553$), body-mass index ($p = 0.736$), the abduction angle ($p = 0.727$) and the anteversion ($p = 0.606$) of the acetabular component.

All cases of the ceramic liner fractures were rapidly revised. A complete debridement and synovectomy was performed to remove as much of the alumina debris and metallosis as possible and a fourth generation alumina ceramic bearing was implanted. The inferior portions of the polyethylene shells were greatly deformed indentations.

Figure 2. Femoral component (Lima-Lto) including (a) C2 stem, (b) F2L stem, (c) Revision stem and (d) Self-locking stem.

Figure 3. (a) AP and (b) lateral view radiographs show the prosthesis with fracture of the right ceramic sandwich liner (red arrow). (c) Radiograph after revision of a ceramic sandwich fracture and a fourth generation alumina ceramic bearing was implanted.
The retrieved alumina inserts showed extensive rim fracture and a significant black stain on the surface of the unbroken rims. For the femoral head, we saw a narrow edge of damage (Figure 6). Note the notching of the femoral stem (red arrow) and the ceramic liner rim (red arrow) indicating sites of impingement between the femoral stem neck and the ceramic liner rim (Figure 7).

**Discussion**

The ceramic-on-ceramic bearing (COC) in total hip arthroplasty was developed in the early 1970 by Pierre Boutin in France. In the past three decades, the mechanical properties of ceramic material have been improved by hot isocromatic pressing, laser marking, and nondestructive proof-testing. Authors of more recent studies using the current generation of alumina-on-alumina bearings reported lower occurrence of osteolysis and loosening, when compared with the metal-on-polyethylene bearings. Nonetheless, as result of the rigidity of alumina ceramic, there is a concern regarding the risk of fracture. The polyethylene-alumina composite liner was designed to address this problem. Theoretically, the polyethylene backing improves the toughness of the alumina ceramic bearings and thus reduces the risk of chipping or fracture of the alumina liner. Previous studies reported that the fracture rate of the “sandwich” liner ranges from 1.1% to 5.7%, while the third generation of ceramics-on-ceramic bearings have been associated with a fracture of less than 0.004%. In this study, we assessed the medium-term results of these “sandwich” liners in our department. The result reported was a relatively high rate of layered liner fracture (1.7%, five of 293 hips) at an average 7.3 years follow up period.

We believe the high fracture rate of sandwich ceramics was related to the design defects of the prosthesis. For this “sandwich” liner, there are some deficiencies in manufacturer-special factors such as the quality and the design of the ceramic insert. Firstly, Alumina ceramic are inherent brittle because of excellent compression strength; bending strength is limited. So it has no way to deform without breakage. Secondly, the wettability of the polyethylene and ceramic were difference. Polyethylene of the sandwich-type liner is hydrophobic, whereas the other (ceramic) is highly hydrophilic. The link between polyethylene and ceramic in an aqueous environment might be subjected to water interposition, which could separate these two parts of the liner and cause edge loading in certain

![Figure 4](image_url). Computed tomographic scan of the right hip 12 years after surgery, revealing local osteolysis around the acetabular component.

![Figure 5](image_url). Survival curves with revision due to ceramic liner fracture as endpoint.
situations. Thirdly, the reduced thickness of the ceramic used in the polyethylene-ceramic insert may increase the likelihood of a peripheral chip fracture and subsequent crack propagation through the brittle alumina material under impingement condition. In addition, the incidence of osteolysis was 2.73% (8/293 hips) in the present study, which was higher than between 0% and 1.4% in the alumina ceramic-on-ceramic THA.

Table 2. Data on patients with ceramic failures.

| Case | Gender | Age (y) | Weight (kg) | BMI (kg/m²) | Internal time for revision | Mode of ceramic failure | Type of femoral stem | Acetabular cup | Cause of failure |
|------|--------|---------|-------------|------------|---------------------------|------------------------|---------------------|----------------|-----------------|
| 1    | M      | 37      | 70          | 22.9       | 7                         | Liner fracture         | F2L                 | 54             | 40              | 18              | Squatting       |
| 2    | M      | 43      | 75          | 24.5       | 4                         | Liner fracture         | C2                  | 52             | 42              | 15              | Waking          |
| 3    | F      | 52      | 62          | 24.2       | 11                        | Liner fracture         | F2L                 | 46             | 48              | 8               | Waking          |
| 4    | F      | 43      | 58          | 21.6       | 6                         | Liner fracture         | C2                  | 48             | 45              | 10              | Squatting       |
| 5    | M      | 55      | 72          | 25.7       | 10                        | Liner fracture         | C2                  | 52             | 40              | 15              | Waking          |

Figure 6. Photograph of the retrieved alumina insert, polyethylene shell, and alumina head. The polyethylene show deformed indentations and scrape, and the alumina insert shows extensive rim fracture and a black stain on the surface of the unbroken rim. A narrow edge of damage, called stripe wear, on the surface of the femoral head.

Figure 7. Note the notching of the femoral stem (red arrow) and the ceramic liner rim (red arrow) indicating sites of impingement between the femoral stem neck and the ceramic liner rim.
The possible reason was the unreasonable design of the polyethylene liner. Wear debris is generated in the metal back-esh and polyethylene insert interface and the screws head against the backside of the polyethylene liner. If the locking mechanism fails, the convex liner surface and the rim of the liner may become a source of polyethylene debris contributing to osteolysis.

Multiple scratches were observed on the taper of neck of the femoral stem and the rim of the sandwich liner, and a deep groove was found on the postero-superior aspect of the neck in our study (Figure 7). So we believe that neck-liner impingement is an important cause of the ceramic liner fracture. A wrong posture and cup mal-position increase the possibility of impingement in ceramic-on-ceramic THA. Some authors reported that repeated sitting in cross-legged position, squatting, and kneeling, which are more common in Asian populations than in the Western population, were probably responsible for the increasing impingement between the rim of ceramic liner and the stem neck. Barrack et al. showed that optimal component positioning is crucial with ceramic-on-ceramic component. The acetabular component should be placed at an optimum zone within less than 45°abduction and 10°–15° anteversion to optimize the distribution of forces over area of the femoral head and acetabular component. Some authors reported that excessive inclination has a great risk of the ceramic liner fracture. They considered that excessive inclination could increase the risk of impingement between the rim of the liner and the stem neck and generated uncontrolled stress concentrations to the ceramic liner. Therefore, correct orientation of the acetabular cup would reduce the risk for impingement, and cup malposition was a possible cause of the ceramic fracture.

Like the previous investigates, stripe wear existed in the sandwich liner ceramic-on-ceramic THA (Figure 6). Besides the manufacturer-special factors, stripe wear, which is a narrow edge of damage seen on the femoral head from a ceramic-on-ceramic hip bearing couple, may be another cause for ceramic liner fracture. Stripe wear were caused most likely by component malposition in which high contact stress were seen between the femoral head and the edge of the liner and edge loading when the hip is flexed, such as squatting. On the other hand, micro-separation of the bearing centers occurs during the swing phase of normal walking and that subsequent edge loading with heel strike leading to stripe wear. Furthermore, impingement has been suggested as a mechanism for stripe wear generation. Repetitive impingement between the metal neck and the metal acetabular cup rim produced a lot of metallic particles. Microscopic metal debris could produce third-body wear in the ceramic-on-ceramic bearing and accelerate the femoral head damage, leading to stripe wear.

There are limitations to our study. First, it is a retrospective study and the inherent nature of a retrospective review has well-known limitation and biases. Second, Although it was a multicenter study, there may be involved potentially confounding variables such as surgeon experience and patients selection, which might make the outcomes less generalizable. Third, the average follow-up is not long enough. The rate of alumina liner fracture and osteolysis may increase with the time. Fourth, because of the small number of liner fracture, the calculated statistical power was not sufficient to differentiate the two group.

In conclusion, with 91.4% 12-year survivorship from all cases, the present results were moderately satisfactory, but with a 1.7% incidence of ceramic liner fracture. As in most countries, the polyethylene-alumina composite liner system has been abandoned in our department since 2009 because of the high rate of fracture (1.7%), which are unacceptable, especially in a young and active population. At present, we choose to use the fourth generation ceramic bearings which is much more toughness and strength than the third generation, and we believe that the reported fracture rate is bound to increase with time.

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