Original Article

Mid term results of total hip arthroplasty using polyethylene-ceramic composite (Sandwich) liner

Tao Wang, Jun-Ying Sun, Guo-Chun Zha, Sheng-Jie Dong, Xi-Jiang Zhao**

Abstract

Background: Ceramic-on-ceramic (COC) couplings are an attractive alternative bearing surfaces that have been reported to eliminate or reduce problems related to polyethylene wear debris. However, the material in total hip arthroplasty (THA) remains one of the major concern regarding the risk of fracture. The present study aims at reporting the fracture rate of bearings in a series of COC THAs with the use of a sandwich liner and attempt to detect the relative risk factors, the possible cause and assess the clinical results.

Materials and Methods: We retrospectively evaluated 153 patients (163 hips) using the sandwich liner COC THA between 2001 and 2009. Patient assessment was based on demographic factors, including age, weight, gender and body-mass index (BMI). All patients were evaluated clinically and radiographically or using computed tomography viz-a-viz dislocation, osteolysis, periprosthetic fracture, infection, loosening and implant fracture.

Results: Three ceramic sandwich liners fracture (1.84%) were observed at an average of 7.3 years' followup. The factors which were found to be non-significant to the ceramic liner fracture, included age ($P = 0.205$), weight ($P = 0.241$), gender ($P = 0.553$), BMI ($P = 0.736$), inclination ($P = 0.199$) and anteversion ($P = 0.223$). The overall survival was 91.4% at 12-year with revision as the endpoint. Other complications included osteolysis in 4 (2.45%), dislocation in one and periprosthetic fracture in one. In no hip aseptic loosening of the implants was seen.

Conclusions: Our experience with the ceramic-polyethylene sandwich liner acetabular component has been disappointing because of the high rate of fracture and osteolyis. We have discontinued the use of this device and recommend the same.

Key words: Fracture, osteolysis, sandwich liner, total hip arthroplasty

MeSH terms: Arthroplasty, replacement, hip, hip prosthesis

Introduction

Compared with traditional metal-on-polyethylene bearing surfaces, alumina ceramic-on-ceramic (COC) total hip arthroplasty (THA) has reduced polyethylene debris-associated complications, so it has been widely used during the last three decades, especially in young and active patients.[1] Nevertheless, this material in THA persists to be a cause of concern viz-a-viz the risk of fracture. In the early period, some authors believed that the fractures were the result of the modulus mismatch of the implant and the bone.[2] To reduce the modulus mismatch, those authors designed liner consisting of a layer of polyethylene between the metallic cup and a layer of alumina, which was also called the sandwich liner. This sandwich insertion, which perhaps increases the longevity of the artificial joint, could reduce the rigidity of the COC coupling.[3-5] Ravasi and Sansone[4] reported the 5 years followup for 53 patients, with positive and encouraging results. But, some authors also reported sporadic cases of fracture of the femoral head and the ceramic liner.[6,7] Accordingly, the present retrospective study aims to (1) evaluate the clinical results of a consecutive series of COC bearing THAs with the sandwich liner; (2) determine the incidence of the sandwich liners fractures and osteolysis and (3) analyze the possible reason for the sandwich fracture and osteolysis.

Materials and Methods

From March 2001 to July 2009, 168 primary total hip arthroplasties (THAs) without cement were performed in 158 patients with the sandwich liner insertion consisting of a polyethylene-ceramic composite liner within a metal acetabular shell. Of these, two patients (two hips) were lost

Department of Orthopaedics, The First Affiliated Hospital of Soochow University, 188 Shizi Street, Suzhou, Jiangsu 215006, P. R. China
*Tao Wang and Xi-Jiang Zhao contributed equally and therefore share first authorship

Address for correspondence: Dr. Jun-Ying Sun,
Department of Orthopaedics, The First Affiliated Hospital of Soochow University, 188 Shizi Street, Suzhou, Jiangsu 215006, P. R. China.
E-mail: wtfamily@163.com

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to followup and three patients (three hips) died for reasons unrelated to surgery and the rest 153 patients (163 hips) were available for a complete analysis. The demographic features of the patients are presented in Table 1, including age, gender, weight, body-mass index (BMI) and primary diagnosis. This study was approved by the Ethics Committee of The First Affiliated Hospital of Soochow University.

All surgical procedures were performed through a modified Hardinge approach for the primary THA. All patients had undergone THAs with a COC bearing with the SPH Contact acetabular component [Lima-Lto, Udine, Italy, Figure 1a and b]. This uncemented acetabular component consists of a preassembled, polyethylene-alumina composite liner that is held in a metal backed cup which 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, Udine, Italy,] which included C2 stem [Figure 1c], F2L [Figure 1d] stem and a self-locking stem [Figure 1e]. These femoral stems were fixed without cement and 28 mm alumina head (Biolox Forte, Ceramtec, Germany) was used in all cases. The C2 stem was implanted in 61 hips (37.42%), the F2L stem was implanted in 99 hips (60.74%) and the self-locking stem in 3 hips (1.84%). All patients received intravenous antibiotic prophylaxis perioperatively and were given a low-molecular-weight heparin for prophylaxis against thromboembolism. All patients underwent isometric exercises on the 1st postoperative day. Patients were allowed to stand or walk with partial weight-bearing on the 7th postoperative day. Full weight-bearing was allowed after 6–8 weeks.

Clinical and radiographic evaluations were performed at 6 weeks, 3 and 6 months, and 1-year after surgery and annually thereafter. Patients were clinically evaluated for pain, walking and range of motion using the Harris Hip Scores (HHSs) system.[8] HHS was assessed preoperatively and at the last followup examination in all cases. Postoperatively complications including aseptic loosening, osteolysis, infection, periprosthetic fracture, dislocation and implant fracture were recorded. We evaluated the anteroposterior pelvic and lateral hip radiographs routinely or computed tomography (when required), for signs of osteolysis, loosening and to see the component placement. Cup position was assessed according to the acetabular abduction angle and the anteversion angle on the Picture Archiving and Communications System digital X-ray system with use of the method of

Table 1: Demographic data

Variable	Number (%)
Number of patients	153
Number of hips	163
Duration of followup (year)	7.3 (range 4-12)
Age at time of index arthroplasty (number of patients)	
<50 years	65 (42.5)
50-65 years	75 (49)
>65 years	13 (8.5)
Age (years)	51.9 (range 17-84)
Gender	
Male	78 (51)
Female	75 (49)
Weight (kg)	64.1 (range 43.5-100)
Average BMI (kg/m^2)	21.33 (range 17.31-30.42)
Preoperative diagnosis (number of hips)	
Femoral head necrosis	41
Ankylosing spondylitis	12
Osteoarthritis	22
Posttraumatic arthritis	10
DDH	30
FNF	34
Rheumatoid arthritis	7
Others	7

BMI=Body mass index, FNF=Femoral neck fracture, DDH=Developmental dysplasia of the hip

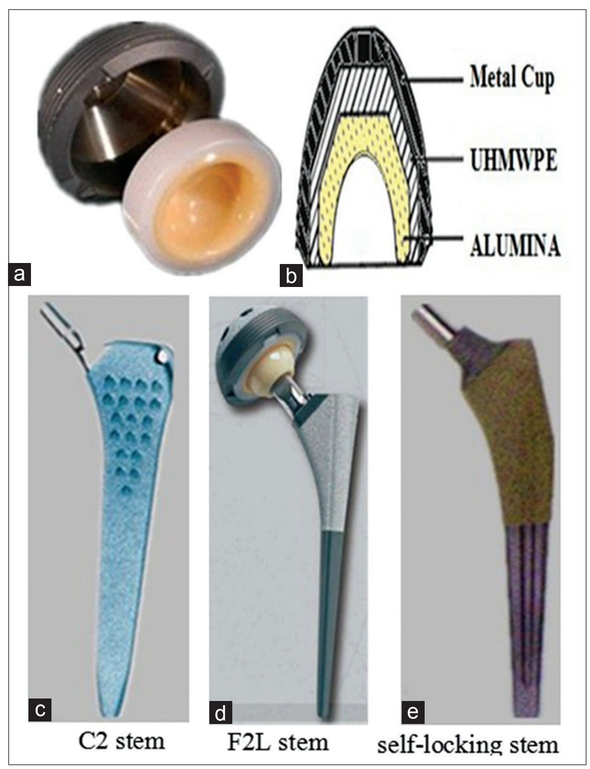

Figure 1: Photographs showing (a) Acetabular component with three different layers: The outer metal shell, polyethylene liner and inner alumina ceramic liner (b) The contact acetabular component section with three different layers. Femoral component (Lima-Lto) including: (c) C2 stem (d) F2L stem (e) Self-locking stem

Murray[9] and Lewinnek *et al.*[10] Osteolysis was recorded at the acetabulum according to the zone described by DeLee and Charnley[11] and at the femoral component as described by Gruen *et al.*[12] 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.[13,14] Loosening of acetabular components 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.*[14] Heterotopic ossification was classified according to the system of Brooker *et al.*[15]

The statistical analysis was performed using the SPSS19.0 (SPSS Inc, IBM, Chicago, USA) 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 nonfracture and the fracture group to evaluate the risk factors associated with the ceramic liner fracture. Survivorship analysis was performed using the Kaplan–Meier method, with fracture or revision for any reason as an endpoint. The level of significance was set at $P < 0.05$.

Results

153 patients (163 hips) were available for followup at a mean 7.3 years (range 4-12 years). Among these 153 patients, there were 75 females and 78 males with a mean age at the time of the index arthroplasty of 51.9 years (range 17-84 years). The right hip was operated on 70 (45.8%) patients and the left hip on 73 (44.8%) patients. A bilateral replacement was performed in 10 (9.4%) patient. At the last followup, fracture of the alumina liner occurred in three hips (three patients) and these were revised at 4, 7 and 11 years after the index operation, respectively [Figure 2]. Three ceramic liner fractures occurred during normal activity of daily living and were not related to unusual traumatic events [Table 2]. Among those with liner fracture, there were two men and one woman with an average age of 44 years (range 37–52 years) and a mean BMI of 23.79 kg/m^2 (range 21.45–25.71 kg/m^2) at the time of THA. The mean abduction angle and anteversion of the acetabular component were 43.3° (range 42°-48°) and 13.6° (range 8°-18°) respectively, in the ceramic fracture group and 44.0° (range 30°-53°) and 15.2° (range 0°-26°) respectively, in the nonfracture group. There was no significant difference between the ceramic fracture group and the nonfracture group viz-a-viz age ($P = 0.205$), weight ($P = 0.241$), gender ($P = 0.553$), BMI ($P = 0.736$), inclination ($P = 0.199$) and anteversion ($P = 0.223$) of the acetabular component.

Of the remaining hips, four cases (four hips) presented with local areas of osteolysis around the acetabular component [Figure 3]. Two hips developed radiolucency in zone 1 and others in zone 2 adjacent to the acetabular

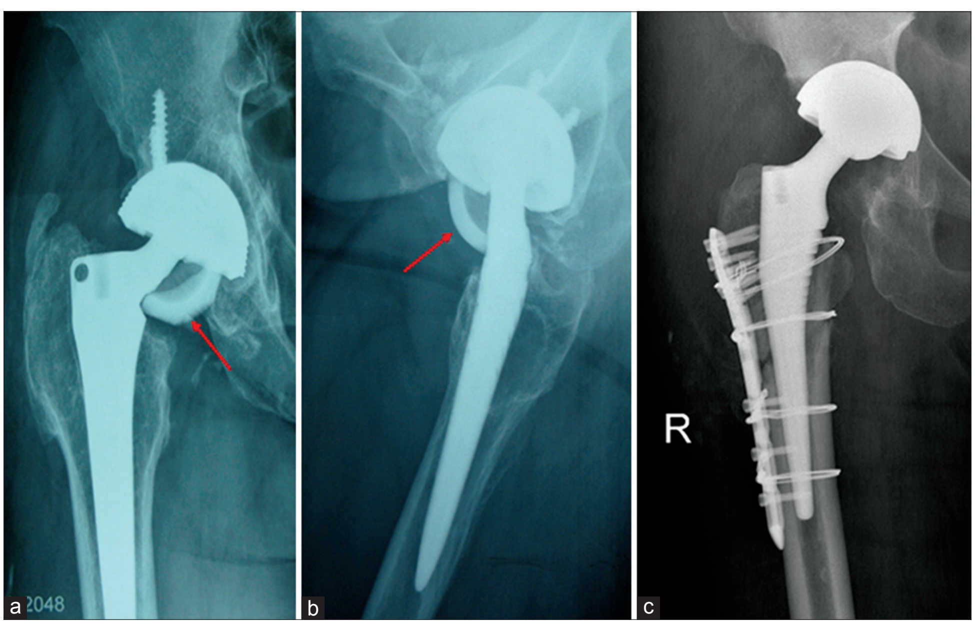

Figure 2: (a) Anteroposterior view. (b) Lateral view radiographs of (Rt) hip joint showing fracture of the right ceramic sandwich liner (red arrow). (c) Radiograph of same hip after revision of a ceramic sandwich fracture and a fourth generation alumina ceramic bearing was implanted

Table 2: Data on patients with ceramic failures

Case	Gender	Age (year)	Weight (kg)	BMI (kg/m²)	Primary diagnosis	Internal time for revision	Mode of ceramic failure	Type of femoral stem	Acetabular cup			Cause of failure
									Size (mm)	Abduction (in degree)	Anteversion (in degree)	
1	Male	37	70	25.71	FNF	7	Liner fracture	F2L	54	40	18	Squatting
2	Male	43	75	24.21	FHN	4	Liner fracture	C2	52	42	15	Waking
3	Female	52	62	21.45	DDH	11	Liner fracture	F2L	46	48	8	Waking

BMI=Body mass index, DDH=Developmental dysplasia of the hip, FNF=Femoral neck fracture, FHN=Femoral head necrosis

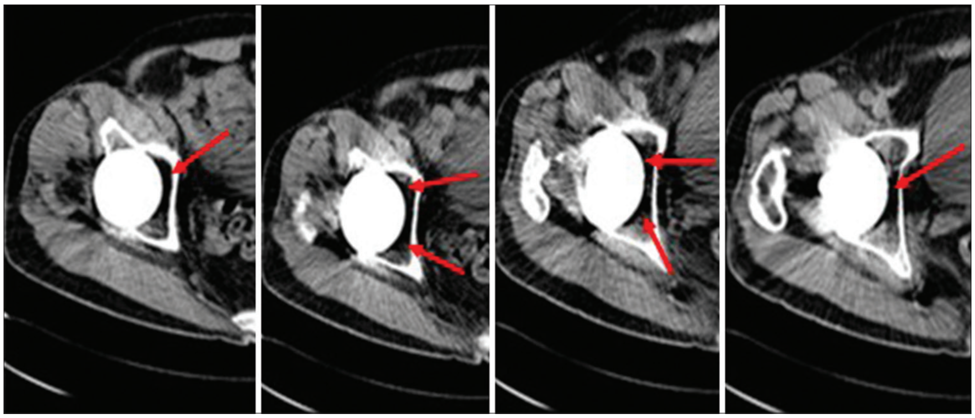

Figure 3: Computed tomographic scan of the right hip 12-year after surgery, revealing local osteolysis around the acetabular component

component. On the femoral side, no radio-graphically detectable osteolysis was observed in any hip. It didn't affect the stability of the acetabular component and were not revised. One patient (one hip) had a peri-prosthetic fracture; one had a dislocation and heterotopic ossification was seen in fourteen cases (Brooker I in 12 hips and Brooker II in 2 hips). There were no infections and two patients had a deep venous thrombosis. None of the hip had aseptic loosening of either the acetabular or the 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 HHS had improved markedly from 47 points (22–56 points) preoperatively to 96 points (87–100 points) at the last followup 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 4].

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 retrieved alumina inserts showed 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 5a]. 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 5b].

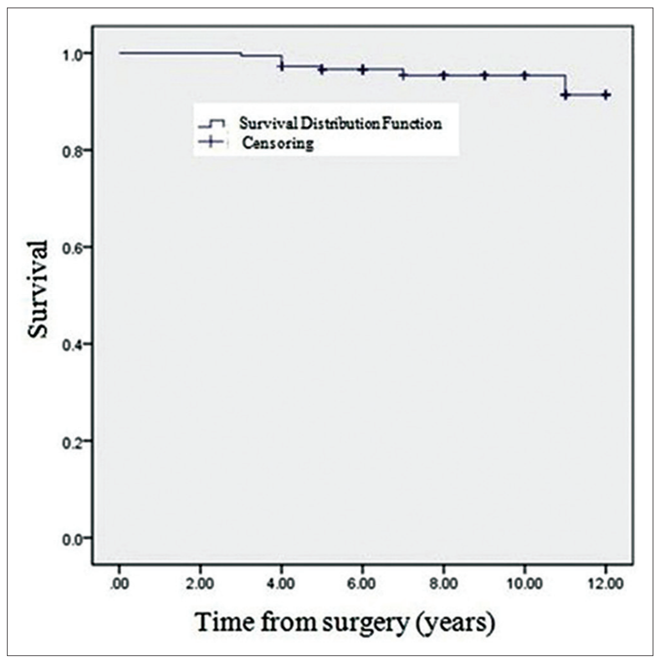

Figure 4: Survival curves with revision due to ceramic liner fracture as endpoint

Discussion

The COC bearing in THA was developed in the early 1970 by Pierre Boutin in France.[16] In the past three decades, the mechanical properties of ceramic material have been improved by hot isocratic pressing, laser marking, and nondestructive proof-testing. Authors of more recent studies using the current generation of alumina-on-alumina bearings reported lower

Figure 5: (a) 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. (b) 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

occurrence of osteolysis and loosening, when compared with the metal-on-polyethylene bearings.[17,18] However, there is a concern regarding the risk of fracture because of the rigidity of alumina ceramic. 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%, [5,7] while the contemporary ceramics-on-ceramic bearings have been associated with a fracture of <0.004%. In this study, we assessed the clinical results of these "sandwich" liners in our patients. The results showed a relatively high rate of layered liner fracture (1.84%, three of 163 hips) at an average of 7.3 years followup.

As to the above fact that there exists high fracture incidence for the sandwich liner, we ascribed it to its design defects. First, Alumina ceramic is inherently brittle because of excellent compression strength; bending strength is limited. Hence, it has no way to deform without breakage. Second, the wettability of the polyethylene and ceramic were different. Polyethylene of the sandwich-type liner is hydrophobic, whereas the other (ceramic) is highly hydrophilic.[19] 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 situations. Third, 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.[5,20]

Multiple scratches were observed on the taper of the 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 5b]. So we believe that the neck-liner impingement is an important cause of ceramic liner fracture.[5,6] Cup mal-position and a wrong posture may increase the possibility of impingement in COC THA. Barrack *et al*. showed that optimal component positioning is crucial with COC component.[21] 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 the area of the femoral head and acetabular component.[6,22] Some authors also reported that excessive inclination is a significant risk of ceramic liner fracture.[7] 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 mal-position was a possible cause of the ceramic fracture. Recently, some authors reported that repeated sitting in a 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 and liner fracture.[5,6] This might cause edge loading and/or stress concentration in the peripheral portion of the liner resulting from hyperflexion and wide abduction. This was evident in the first case. So, wrong posture may predispose to a liner fracture.

Like previous studies,[23,24] stripe wear existed in the sandwich liner COC THA in our study [Figure 5a]. Besides the manufacturer-special factors, stripe wear, which is a narrow edge of the damage seen on the femoral head from a COC hip bearing couple, may be another cause for ceramic liner fracture.[25] Stripe wear is caused most likely by component mal-position 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 while squatting.[24] 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.[24] Furthermore, impingement has been suggested as a mechanism for stripe wear generation.[21] Repetitive impingement between the metal neck and a metal acetabular cup rim produces significant quantities of metallic particles. Microscopic metal debris could produce third-body wear in the COC bearing and accelerate the femoral head damage, leading to stripe wear.

In addition, we found that the incidence of osteolysis was 2.45% (4/163 hips) for the "sandwich" liner THA in the present study, which was higher than between 0% and 1.4% in the alumina COC THA. The possible reason was the unreasonable design of the polyethylene liner. Wear debris is generated in the metal backed-cup and polyethylene insert interface and the screws head against the backside of the polyethylene liner. The metal backing-insert interface and the rim of the liner may become a source of polyethylene debris contributing to acetabular osteolysis, particularly when locking mechanism failure occurs resulting in gross micromotion and accelerated wear debris generation.

The limitations of our study are: First, it is a retrospective study and the inherent nature of a retrospective review has well-known limitation and biases. Second, it is a single center study. Although such a study eliminates potentially confounding variables such as surgeon experience and patients selection, it might make the outcomes less generalizable. Third, because of the small number of liner fracture, the calculated statistical power was not sufficient to differentiate the two groups and we were unable to explore factors relating to the fractures.

Conclusion

With 91.4% 12-year survivorship from all cases, the present results were moderately satisfactory, but with a 1.84% and 2.45% incidence of ceramic liner fracture and osteolysis.

References

1. Kress AM, Schmidt R, Holzwarth U, Forst R, Mueller LA. Excellent results with cementless total hip arthroplasty and alumina-on-alumina pairing: Minimum ten-year followup. Int Orthop 2011;35:195-200.
2. Hamadouche M, Boutin P, Daussange J, Bolander ME, Sedel L. Alumina-on-alumina total hip arthroplasty: A minimum 18.5-year followup study. J Bone Joint Surg Am 2002;84-A: 69-77.
3. Hasegawa M, Sudo A, Uchida A. Alumina ceramic-on-ceramic total hip replacement with a layered acetabular component. J Bone Joint Surg Br 2006;88:877-82.
4. Ravasi F, Sansone V. Five-year followup with a ceramic sandwich cup in total hip replacement. Arch Orthop Trauma Surg 2002;122:350-3.
5. Park YS, Hwang SK, Choy WS, Kim YS, Moon YW, Lim SJ. Ceramic failure after total hip arthroplasty with an alumina-on-alumina bearing. J Bone Joint Surg Am 2006;88:780-7.
6. Popescu D, Gallart X, Garcia S, Bori G, Tomas X, Riba J. Fracture of a ceramic liner in a total hip arthroplasty with a sandwich cup. Arch Orthop Trauma Surg 2008;128:783-5.
7. Hasegawa M, Sudo A, Hirata H, Uchida A. Ceramic acetabular liner fracture in total hip arthroplasty with a ceramic sandwich cup. J Arthroplasty 2003;18:658-61.
8. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am 1969;51:737-55.
9. Murray DW. The definition and measurement of acetabular orientation. J Bone Joint Surg Br 1993;75:228-32.
10. Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg Am 1978;60:217-20.
11. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res 1976:20-32.
12. Gruen TA, McNeice GM, Amstutz HC. Modes of failure of cemented stem-type femoral components: A radiographic analysis of loosening. Clin Orthop Relat Res 1979:17-27.
13. Sugano N, Takao M, Sakai T, Nishii T, Miki H, Ohzono K. Eleven- to 14-year followup results of cementless total hip arthroplasty using a third-generation alumina ceramic-on-ceramic bearing. J Arthroplasty 2012;27:736-41.
14. Engh CA, Massin P, Suthers KE. Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. Clin Orthop Relat Res 1990:107-28.
15. Brooker AF, Bowerman JW, Robinson RA, Riley LH Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg Am 1973;55:1629-32.
16. Boutin P. Total arthroplasty of the hip by fritted aluminum prosthesis. Experimental study and 1st clinical applications. Rev Chir Orthop Reparatrice Appar Mot 1972;58:229-46.
17. Böhler M, Mochida Y, Bauer TW, Plenk H Jr, Salzer M. Wear debris from two different alumina-on-alumina total hip arthroplasties. J Bone Joint Surg Br 2000;82:901-9.
18. Clarke IC, Good V, Williams P, Schroeder D, Anissian L, Stark A, *et al.* Ultra-low wear rates for rigid-on-rigid bearings in total hip replacements. Proc Inst Mech Eng H 2000;214:331-47.
19. Ha YC, Kim SY, Kim HJ, Yoo JJ, Koo KH. Ceramic liner fracture after cementless alumina-on-alumina total hip arthroplasty. Clin Orthop Relat Res 2007;458:106-10.
20. Kircher J, Bader R, Schroeder B, Mittelmeier W. Extremely high fracture rate of a modular acetabular component with a sandwich polyethylene ceramic insertion for THA: A preliminary report. Arch Orthop Trauma Surg 2009;129:1145-50.
21. Barrack RL, Burak C, Skinner HB. Concerns about ceramics in THA. Clin Orthop Relat Res 2004:73-9.
22. Park MS, Yoon SJ, Yoo MJ. Repeated ceramic head fracture after ceramic-on-ceramic total hip arthroplasty. J Korean Hip Soc 2012;24:59-64.
23. Poggie RA, Turgeon TR, Coutts RD. Failure analysis of a ceramic bearing acetabular component. J Bone Joint Surg Am 2007;89:367-75.
24. Walter WL, Insley GM, Walter WK, Tuke MA. Edge loading in third generation alumina ceramic-on-ceramic bearings: Stripe wear. J Arthroplasty 2004;19:402-13.
25. Elkins JM, Pedersen DR, Callaghan JJ, Brown TD. Do obesity and/or stripe wear increase ceramic liner fracture risk? An XFEM analysis. Clin Orthop Relat Res 2013;471:527-36.

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