Fractures of a sandwich ceramic liner at ten year follow-up

Anthony Viste · Julien Chouteau ·
Romain Desmarchelier · Michel-Henri Fessy

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Abstract

Purpose The aim of this study was to understand the causes of sandwich liner fractures implanted at our institution by evaluating the long-term results of this device.

Methods We retrospectively assessed 143 patients (151 hips) consecutively operated upon in our department by the same senior surgeon between 1999 and 2001 and with a mean follow-up period of 9.9 years (range 8.5–11.5). The components used were Cerasul® sandwich ceramic liners within a cementless cup. Patient assessment was based on demographic factors (age, gender, body mass index), the clinical scores according to Devane (activity), the potential complications and a radiographic analysis from an anteroposterior pelvic radiograph (cup inclination). Revision cases and their cause were classified (implant fracture, loosening, dislocation, periprosthetic fracture).

Results Five cases of liner fracture (3.7%) were observed at a mean seven year (4.5–8.5) follow-up. The risk factor for implant failure was found to be patient activity: the mean preoperative Devane score was 3.5 in the fracture group vs 2.6 in the control group ($p=0.008$). Mean cup inclination was 52°. The survivorship analysis at ten years was 85% with revision as the endpoint. Prosthetic complications accounted for

8.6% of all 151 hips (fractures included): one case of aseptic loosening (0.7%), two cases of sepsis (1.4%), four cases of isolated dislocation (2.8%) and one case of recurrent dislocation (0.7%).

Conclusions Alumina sandwich liners remain a subject of concern since the increasing clinical follow-up period may predispose them to fatigue failure. This system has been abandoned in our department since 2005.

Introduction

The ceramic-on-ceramic bearing was introduced in 1970 by Pierre Boutin in France [4]. The advantage of this hard-on-hard bearing couple, when compared with polyethylene (PE), was the reduced wear rate [21, 26] associated with the absence of osteolysis or loosening events [13, 20, 22, 24]. The main complication of alumina-on-alumina bearing couples remains the risk of fracture [8, 9, 11, 15]. The incidence of ceramic fractures has greatly diminished since the development of a fourth generation alumina ceramic (grain microstructure, hot isostatic pressing, proof testing) in 1997 [3, 23, 25].

In 1993, the Lima Society based in Italy was the first to commercialise sandwich ceramic liners, that is a ceramic liner set with PE. The aim of that system was to reduce the fracture rate by decreasing the stress applied to the ceramic component, the stiffness of the bearing couple and the impingement occurring between the femoral neck and the edge of the ceramic liner [11, 19]. This system demonstrated real benefits such as an easily machinable PE, facilitated insertion and removal of the metal back and compatibility with already available cups for a metal-PE bearing couple. This could provide, at a reduced manufacturing cost, an easy transition from a hard-on-soft bearing couple to a hard-on-hard bearing couple, thus avoiding PE wear-related complications.

A. Viste (✉) · J. Chouteau · R. Desmarchelier · M.-H. Fessy
Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, Chirurgie
Orthopédique, Traumatologique et Médecine du Sport,
Lyon, France
e-mail: anthony.viste@chu-lyon.fr

A. Viste · J. Chouteau · M.-H. Fessy
Université de Lyon,
F-69000, Lyon, France

A. Viste · J. Chouteau · M.-H. Fessy
IFSTTAR, UMR_T9406, LBMC, Bron,
Université Lyon1,
Villeurbanne, France

Unfortunately, the concept demonstrated a significantly high rate of ceramic liner fractures [11, 15]. The *in vivo* fracture rate observed with Biolox forte® ceramic liners was about 0.021% per year. A fracture rate 50–300 times higher than usually observed was reported for these liners.

We were interested to understand the reasons for sandwich liner failures from our institution. We therefore decided to evaluate the long-term results of a consecutive series of patients treated by the same senior surgeon between 1999 and 2001 to discover the causes of fractures.

Materials and methods

Patients and procedures

This study was approved by our Institutional Review Board.

Between early 1999 and late 2001, 151 sandwich ceramic liners (83 left hips, 55% and 68 right hips, 45%) were consecutively implanted in 143 patients in our department by the same senior surgeon. The mean age at surgery was 61.2 years (15.9–82.5) in 80 men and 63 women with a mean body mass index (BMI) of 26 kg/m² (range 18–35). In 90% of the cases, liners (*n*=136) were implanted in primary surgery and in 10% (*n*=15) revision surgery. The aetiologies for primary surgery were primary osteoarthritis of the hip (*n*=96, 64%), aseptic osteonecrosis (*n*=6, 4%), dysplasia (*n*=16, 10.6%), post-traumatic osteoarthritis of the hip (*n*=5, 3.3%), coxalgia (*n*=4, 2.6%), rapidly destructive osteoarthritis of the hip (*n*=5, 3.3%) and sequelae of epiphysiolysis or Legg-Calvé-Perthes disease (*n*=4, 2.6%). The mean Devane score was 2.6 (range 1–5).

The patient was placed in the lateral position. A Moore posterolateral surgical approach was performed in all cases. The cementless cup implanted was in all cases a titanium alloy metal shell, Allofit® (Zimmer, Winterthur, Switzerland). A Cerasul alpha neutral® liner (Zimmer, Winterthur, Switzerland) was used in all cases. The pelvitrochanteric muscles and posterior capsule were reattached at the end of surgery. Full weight-bearing was allowed the day after surgery. The femoral stems were Alloclassic® (Zimmer, Winterthur, Switzerland) (*n*=126, 83.4%), Corail® (DePuy, J&J, Warsaw, IN, USA) (*n*=21, 13.9%), Morphometric® (*n*=2, 1.3%) and Conus® (*n*=2, 1.3%). The mean size of the acetabular cup was 54 (52–64).

The Cerasul alpha® (Fig. 1) was a sandwich ceramic liner featuring a third generation Biolox® forte alumina (CeramTec, Plochingen, Germany) set in a standard ultrahigh molecular weight PE shell, launched in 1998 by the Sulzer Society (Zimmer, Winterthur, Switzerland). The PE/ceramic assembly was performed through thermocompression of PE

Fig. 1 Cerasul® sandwich-type liner

powder around a ceramic shell. Snap-fit PE fixation within the capsule was able to provide a thicker PE component than morse taper fixation. The thickness of the ceramic component was 4 mm. The liner was only available from size 52 to maintain a satisfactory PE thickness. The inner diameter of the implant was 28 mm.

Methods

We retrospectively assessed all patient records with Cerasul® liner implanted between 1 January 1999 and 31 December 2001. Patient assessment was based on demographic factors (age, gender, BMI), the clinical scores according to Devane (activity), the potential complications and a radiographic analysis from an anteroposterior pelvic radiograph (cup inclination). Revision cases and their cause were classified (implant fracture, loosening, dislocation, periprosthetic fracture).

A statistical analysis was performed using the R 2.12.0 software. Demographic data were compared using the Mann-Whitney test for continuous variables and Fisher's exact test for ordinal variables. The level of significance was set at *p*<0.05. Therefore we could compare the data between the control group and the "liner fracture" group to detect the risk factors associated with implant fracture. Kaplan-Meier survivorship analysis was performed using revision for any reason or fracture as the endpoint.

Results

Among the 143 patients, 11 died (8.4%) after a mean follow-up of 61.4 months (5.9–102.7) but their status regarding the operated hip was known. Eleven subjects (7.7%) were lost to follow-up. A total of 121 patients (84%), that is 124 hips, were reviewed at last follow-up.

Fig. 2 Survivorship analysis with sandwich liner removal for any cause as endpoint

Five cases of liner fracture were observed (3.7%). The mean follow-up period in the group of uncomplicated patients was 9.9 years (8.5–11.5).

The mean Devane activity score at last follow-up was 3.8. All acetabular cup and femoral stems were radiographically stable at the last follow-up. The mean radiographic cup inclination was 52° (38–66). Prosthetic complications accounted for 8.6% ($n=12$) of all 151 hips ($n=8$ revisions, 5.2%): five cases of ceramic liner fractures (3.3%), one case of aseptic loosening at 9.6 years after surgery (0.7%), two cases of sepsis at ten and 2.9 years (1.4%) and four cases of dislocation (2.8%), one case of recurrent dislocation having required revision surgery at three years. The survivorship analysis at ten years after surgery was 85% with revision as the endpoint (Fig. 2).

Liner fracture study group

Among the five patients (five hips), there were four men and one woman with a mean age of 52.5 years

Fig. 3 Survivorship analysis with revision due to liner fracture as endpoint

Fig. 4 Radiograph of a ceramic sandwich fracture

(15.9–70.7) at surgery and a mean BMI of 26 (22.9–30.9). All of these failures occurred during normal activities of daily living and were not related to unusual traumatic events. Among these cases, one was asymptomatic and the others complained of hip pain and cracking noises for several months.

The mean implant survival rate was seven years (4.5–8.5 years). The Kaplan-Meier survivorship analysis was calculated for liner fracture events (Fig. 3).

The mean preoperative Devane score was 3.5 (range 2–5) and 4.3 (range 3–5) in the postoperative period. The mean cup inclination was 52° and the mean cup size was 53.3. The femoral stem was a Corail® stem in three cases, an Alloclassic® stem in two cases and a Morphometric® stem in one case.

All cases were rapidly revised: all cups and femoral heads were removed and new ceramic-on-ceramic bearings were implanted (Figs. 4 and 5). All femoral components were found to be well fixed and therefore were left in place. A complete debridement and synovectomy was performed to remove as much of the alumina debris and metallosis as possible. In one case, the femoral stem was revised because of femoral neck damage. At latest follow-up, no complication was reported.

Fig. 5 Radiograph after revision of a ceramic sandwich fracture

Table 1 Comparison between fracture and control group

	Liner fracture group	Control group	<i>p</i>
Age	52.5	60.6	0.4 ^a
BMI	26	26	0.9 ^a
Gender			
Male	4	66	0.4 ^b
Female	1	50	
Cup size	53.3	54.3	0.4 ^b
Cup inclination	52	52	0.8 ^a
Activity (Devane)			
Preoperative	3.5	2.6	0.008 ^b
Postoperative	4.3	3.8	0.2 ^b

^a Mann-Whitney test^b Fisher's exact test

Comparison between the control group and the liner fracture study group

The only risk factor found to be statistically significant (Table 1) was the patient's activity ($p=0.008$).

Discussion

This is one of the first studies conducted on sandwich acetabular cups having such long-term results. The main risk of ceramic-on-ceramic bearing couples remains fracture of the femoral head or acetabular liner with a rate of 0.004% and 0.21%, respectively, each year according to CeramTec™. Impingement of the femoral neck on the rim of the ceramic liner is one mechanism of ceramic fracture in sandwich cups [12, 18]. We analysed the long-term results of these alumina liners in our department. The results reported in our series were associated with a 3.7% fracture rate at a mean seven year follow-up period. This rate is comparable with other studies on this issue (Table 2).

Preoperative activity was found to be the only contributing factor associated with an increased fracture rate. This was

demonstrated by the small discriminant aspect of the postoperative Devane score: when all patients return to a higher level of activity, it is difficult to find any statistical difference due to the small number of fractures and despite the fact that these cases were more athletic (cycling, soccer, golf ...). In fact, pre- or postoperative activity was globally more important in the cases, but only the preoperative difference was found to be statistically significant.

The number of patients reviewed in a single centre and the ten year follow-up period represent the strengths of our study. The limitations of the work are inherent to the implant fractures: small absolute number of cases making it difficult to find any contributing factor.

One case of complete liner dissociation with no associated fracture of the ceramic component has been described [1]. Ha et al. [7] reviewed 122 patients with a mean four year follow-up period. Five patients (3.5%) reported an acetabular liner fracture at a mean follow-up of three years. Cup anteversion was found to be the contributing factor in the fracture group when compared with the control group. For these Korean patients used to squatting, impingement appeared to be the cause of fracture. Hasegawa et al. [11] reviewed 35 consecutive hips with a layered component at six years and reported two liner fractures (5.7%). Iwakiri et al. [27] reported a fracture rate of 5.6% (4/82) at eight years associated with periacetabular radiolucent lines (cemented cup) and could determine three causes: small ceramic thickness (four mm), small alumina clearance (five to 35 μ m) and small oscillation angle ($<120^\circ$). Park et al. [15] reported a 1.1% (4/357) fracture rate of the sandwich liner at three year follow-up in a multicentre study. A microscopic analysis of the explants was performed and traces of contact between the neck and the edge of the liner could be observed. So they stated that impingement between neck and rim of the liner caused rim fractures directly, not because of a subluxation of the head on the opposite side [2]. Poggie et al. [17] described a study conducted by the US Food and Drug Administration (FDA) with a fracture rate of 4.4% (14/315). A finite element analysis was performed, and no fracture of the alumina

Table 2 Review of the literature

Authors	Period	Country	Implantations, <i>n</i>	Fractures, <i>n</i> (%)	Manufacturer	Delay (years)	Causes
Ha et al. [7]	1999–2001	Korea	157	5 (3.5)	Lima	3	Excessive anteversion
Hasegawa et al. [11]	1999–2000	Japan	35	2 (5.7)	Kyocera	2	Too inclined
Park et al. [15]	1998–2001	Korea	357	4 (1.1)	Lima	3	Impingement
Poggie et al. [17]	1999–2003	USA	315	12 (3.8)	Implex	2	Weight >91 kg, dissociation
Iwakiri et al. [27]	1998–2000	Japan	82	4 (5.6)	Kyocera	5.6	Clearance, oscillation angle $<120^\circ$
Kircher et al. [28]	1999–2001	Germany	50	9 (18)	Keramed	2.5	Design features
Our study (2011)	1999–2001	France	153	5 (3.7)	Zimmer	7	Activity + inclination

component even under extreme weight-bearing conditions was reported. Biomechanical in vitro testing could not reproduce the mechanism of ceramic component dissociation. That test demonstrated that weight was likely to increase the amount of stress applied to the ceramic component.

The main reason for failure of this device seemed to be the ceramic component thickness (four mm) [15]. In our study, fracture of the liner component seemed to be induced by a fatigue failure as suggested by the time to fracture unlike the other studies. An excessively inclined cup, the high level activity of the patient and the thin liner were associated factors that we observed. An acetabular cup inclined greater than 45° may induce stress distribution on a small contact area located between the head and the ceramic liner [6, 10]. This higher contact pressure that is generated between the head and the rim of the liner caused some ceramic grains to break off. The head then wedged between the fractured rim and the PE shell, which led to an eccentric motion until the liner came out [2]. Moreover, microseparation during the swing phase of walking and relocation on heel-strike between the head and cup could create high stresses on ceramic [14]. Water interposition between PE, hydrophobic, and ceramic, highly hydrophilic, could be an additional factor which could separate the two parts of the liner in an aqueous environment [7].

The stress concentration at the rim of the liner can be reduced by placing the cup more horizontally <45° [10]. For revision hip replacement after ceramic fracture, we recommend use of a new ceramic-on-ceramic bearing to avoid third-body wear [9]. The femoral stem must be removed if macroscopic damage of the neck is found; removal of a well-fixed femoral component should be avoided because of its complexity, increase in blood loss, operative time and depletion of bone stock. Minimally symptomatic or asymptomatic liner fractures are not rare. This is why it is essential to monitor patients with ceramic-on-ceramic bearing couples and especially sandwich acetabular cups.

Conclusion

As in most countries, this system has been abandoned in our department since 2005. We chose to use fourth generation ceramic bearings using larger head diameters [5]. Unlike Park et al. [16], we believe that the reported fracture rate is bound to increase over time.

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