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Uncemented acetabular components with polyethylene or alumina liners

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Abstract Sixty consecutive patients (60 hips) were allocated in two matched-pair groups. Patients were matched for age, gender, body mass index, level of activity, and bone stock. Both groups received an uncemented total hip arthroplasty with a modular press-fit cup and an alumina femoral head. In the first group, an acetabular liner made of polyethylene was used; in the second group, an alumina liner. Both groups were followed for a minimum of 5 years. No hip required revision, and there was no radiographic evidence of aseptic loosening in either group. Mean Harris hip score was 94.7 (87.1–99) points in the polyethylene group and 93 (88.5–100) points in the alumina group.

Résumé Soixante malades consécutifs (60 hanches) ont été répartis dans deux groupes appairés pour l'âge, le genre, l'index de masse corporelle, le niveau d'activité, et le stock osseux. Les deux groupes ont reçu une arthroplastie totale de la hanche non-cimentée avec une cupule acétabulaire modulaire et une tête fémorale en alumine. Dans le premier groupe un insert acétabulaire en polyéthylène a été utilisé, dans le deuxième groupe un insert d'alumine. Les deux groupes ont été suivis avec un

minimum de 5 années. Aucune hanche n'a nécessité de révision, et il n'y avait aucun signe radiographique de descellement aseptique dans l'un ou l'autre groupe. Le score moyen de Harris était 94.7 (87.1–99) points dans le groupe polyéthylène, et 93 (88.5–100) points dans le groupe alumine.

Introduction

Previous studies showed a substantial reduction of wear debris using alumina-on-alumina pairing in total hip arthroplasty [1, 19]. These alumina-on-alumina pairings require the use of modular acetabular components inserted without cement [21]. Cemented alumina components have shown a high rate of aseptic loosening, mainly caused by fracture of the cement mantle [10, 17].

Recently, concerns have emerged regarding the high stiffness of such implants, which could cause impairment of fixation and early loosening. Boehler et al [2] reported a high revision rate of uncemented acetabular components using an alumina liner at a minimum 4-year follow-up. The revision rate of the same prosthesis inserted with a polyethylene liner was markedly lower. We have compared clinical and radiological outcomes, as well as survivorship associated in a matched-pair series of modular press-fit cups with similar geometry and surface finish using either an alumina or a polyethylene liner.

Material and methods

Seventy-three consecutive patients (73 hips) who received a total hip arthroplasty between March 1995 and June 1996 using acetabular liners made of polyethylene (43 hips) or alumina (30 hips) were considered potential candidates for inclusion in the study. The protocol for human subjects was approved according to the relevant laws and regulations. All patients signed an informed consent. The main criteria for inclusion were primary and secondary osteoarthritis, quality of the bone adequate for uncemented fixation, and age younger than 70 years at index operation.

A matched-pair study design was used to achieve two homogeneous groups of patients. Matching criteria were age, gender, body

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Table 1 Patient data

Parameter	Group 1 (polyethylene) 30 patients (30 hips)	Group 2 (alumina) 30 patients (30 hips)
Gender (male/female)	M=2; F=18	M=11; F=19
Age (years)	60±3.1	58.8± 3.3
Body mass index (kg/m ²)	25.1±2.0	24.7±2.3
Activity level		
Sedentary	None	None
Semi-sedentary	1	1
Light labour	19	17
Moderate manual labour	8	10
Heavy manual labour	2	2
Functional status (Charnley rating) [4]		
A (unilateral) [5]	25 hips	23 hips
B (bilateral)	5 hips	7 hips
Previous operations	3 hips	2 hips
Bone stock (Singh rating) [21]		
5 (Ward area is empty)	2 hips	3 hips
6 (inferior ward area well defined)	23 hips	21 hips
7 (normal)	5 hips	6 hips

mass index, level of activity, and bone stock. After matching, 30 pairs of hips (polyethylene group, 30 hips; alumina group, 30 hips) (Table 1) were selected for comparative analysis. Matching patient data were obtained using commercially available computer software (SAS Institute, Cary, NC, USA).

Total hip arthroplasty was performed with the patient supine under general anaesthesia, and a direct lateral approach was used. All operations were done by two experienced surgeons. All hips received an uncemented femoral component with tapered design (Cementless-Stem, Brehm, Weisendorf, Germany) and an alumina femoral head with a diameter of 28 mm (BioloX Forte). The modular acetabular component (cup) was made of Ti6-Al-V4 with a pure Ti powder coating (TiRC) (Phönix, Brehm, Weisendorf, Germany). The thickness of the coating ranged between 200 and 300 µm, and porosity between 100 and 120 µm.

In the polyethylene group, an ultra-high-molecular-weight polyethylene liner (Chirulen 1020, ISO 5834 Typ 1, Poly Hi Solidur, Vreden, Germany) was used. In the alumina group, an alumina liner (BioloX Forte, CeramTec, Plochingen, Germany) was used (Fig. 1). Post-operatively, partial weightbearing up to 20 kg was allowed during the first 6 weeks. Patients were assessed clinically using the Harris hip score [11].

Radiographic evaluation of the acetabular and femoral components was done by an experienced independent observer using published criteria [13] and a digitising tablet (UMAX Mirage II, Hsinchu, Taiwan). Any change in inclination or migration was noted. Radiolucent lines were assessed according to the recommendations of Freeman [7]. The location of radiolucent lines, osteolysis, and cortical hypertrophy was defined according to the criteria of DeLee and Charnley [6] and Gruen et al. [9]. Blinded interpretation was not possible, because modular cups with ceramic and polyethylene liner can be easily distinguished radiographically. Wear of the 60 modular components of the main study was measured using the method of Charnley and Halley [5], as modified by Livermore et al. [14]. The classification of Brooker et al. [3] was used for evaluation of heterotopic ossification. Intra-observer variability in interpretations was not ascertained. Precision of the digital measurement technique was evaluated by double examination in a separate study. Precision of the measurement system was rated ±0.5 mm of proximal migration and ±0.5 mm of medial migration, and 1.5° tilting.

Demographic and radiological data were analysed with a two-tailed, unpaired *t*-test. A repeated measures analysis of variance and a Newman-Keuls test for inter-group comparisons were done for all radiological determinations. Multivariate analysis was done

Fig. 1 The alumina liner (left), the ultra-high-molecular-weight polyethylene liner (right), and the 28-mm alumina femoral head are shown. Fixation of the liners is obtained with a morse-taper design of the acetabular component (CeraLock)

to identify the particular combinations of clinical and radiological findings. Differences were considered statistically significant at $P < 0.05$.

Results

Complete clinical and radiological follow-up (mean 5.6, range 5–7 years) was available for all hips. Mean pre-operative Harris hip score of patients who received polyethylene liners was 54 (47–70) points and improved to 95 (87–99) points at the latest follow-up. Mean pre-operative Harris hip score of the patients who received alumina liners was 50 (45–66) points and improved to 93

Fig. 2A–C **A** Post-operative antero-posterior radiograph showing an alumina-on-alumina pairing; **B** antero-posterior, and **C** lateral radiographs at 5-year follow-up. There are no signs of migration or loosening

Table 2 Radiological findings

Parameter	Group 1 (polyethylene) 30 patients (30 hips)	Group 2 (alumina) 30 patients (30 hips)
Acetabular angle (degrees)	39 (± 3.5)	35.5 (± 4.2)
Bony ingrowth of cup	30 hips	30 hips
Cranial migration of cup (millimetres)		
0–0.5	9 hips	8 hips
>0.5, <1	3 hips	2 hips
>1, <2	None	None
Central migration of cup (millimetres)		
0–0.5	5 hips	7 hips
>0.5, <1	2 hips	3 hips
>1, <2	None	None
Tilting of cup (degrees)		
<3	2 hips	1 hip
>3	None	None
Radiolucent lines without progression (cup) [6]		
DeLee and Charnley zone 1	3 hips	1 hip
DeLee and Charnley zone 2	none	none
DeLee and Charnley zone 3	3 hips	2 hips
Migration of stem (millimetres)		
0–0.5	3 hips	5 hips
>0.5, <1	1 hip	1 hip
Radiolucent lines without progression (stem)		
Gruen zone 1	3 hips	2 hips
Gruen zone 7	3 hips	3 hips
Heterotopic ossifications (Brooker) [3]		
Grade 1	4 hips	3 hips
Grade 2	1 hip	2 hips

(88–100) points. Occasional thigh pain was present in three patients in the polyethylene group and in one patient in the alumina group. Range of hip motion was less than 110° in two patients in the polyethylene group and in one patient in the alumina group. One patient in the

alumina group was unable to walk long distances without a cane. The clinical outcome was assessed by an independent observer. In the polyethylene group it was considered satisfactory (less than 90 points) in five hips, good in 15, and excellent in ten. In the alumina group,

the clinical outcome was satisfactory in three hips, good in 20, and excellent in seven.

There was no aseptic loosening of the acetabular component at a minimum follow-up of 5 years (Fig. 2). All acetabular components were considered radiologically stable with bony ingrowth. One year post-operatively, a limited cranial migration (<1 mm) was found in 12 hips in the polyethylene group and in ten in the alumina group. No progression of migration was found at the 5-year follow-up (Table 2). Radiolucencies with periprosthetic sclerosis without signs of progression were found in zone 1 in three hips and zone 3 in three hips in the polyethylene group and, respectively, in one hip and two hips in the alumina group. A mean polyethylene wear of 1.3 (0.8–2.3) mm was measured in six hips. There was no measurable wear in the alumina group.

There was no migration or aseptic loosening of the femoral components in either group. Radiolucencies with a sclerotic reaction at the bone-implant interface without progression were found in zone 1 in two hips in the polyethylene group and in three hips in the alumina group. A slight cortical hypertrophy was seen in one hip in the alumina group.

Discussion

Pairing of acetabular polyethylene liners and femoral alumina heads is common in total hip arthroplasty [22] and has good tribologic properties. An even better tribologic combination is alumina liner and alumina femoral head [21]. Alumina-on-alumina bearings will markedly reduce the volume of wear debris and thereby reduce loosening due to osteolysis [19].

Unfortunately, cemented acetabular components made of alumina have high loosening rates. Riska [17] reported a revision rate of cemented alumina cups of 9.1% (13 of 143 hips) at a mean followup of 6.7 (1–12) years. In 12 hips, the revision was caused by fracture of the cement mantle. On the other hand, the revision rate of uncemented alumina cups at a mean follow-up of 3.6 (1–7) years was only 1.8% (2 of 112 hips). Also, Hamadouche et al. [10] observed a high failure rate of cemented alumina cups, reporting a survival rate at 20 years of 61.2%, with revision for any reason as end point. In contrast, the 20-year survival rate of uncemented alumina cups was 85.6%.

Results of uncemented acetabular components with alumina liners are also controversial. Boehler et al. [2] reported four revisions of 23 acetabular components with alumina liner at a minimum 4-year follow-up. Revision rate for the same cup using a polyethylene liner was only one in 50. Migration analysis using Ein Bild Röntgen Analyse (EBRA) showed a marked and progressive vertical displacement of the acetabular components inserted with alumina liner. The reason for this high failure rate is uncertain. However, the pre-operative demographic and clinical conditions of the patients operated on using alumina liners were not comparable to those operated on us-

ing polyethylene liners. A large number of patients operated on using alumina liner had marked osteoporosis.

Acetabular components designed for insertion with alumina liners need a solid metallic shell to avoid micromotion at the taper junction and thus prevent the risk of fracture. Alumina has a high modulus of elasticity, and therefore the construct shows a high structural stiffness. An in vitro analysis showed a 50-times higher stiffness of modular cups with alumina liners compared to identical cups with polyethylene liners [2]. This stiffness could cause unfavourable contact stresses around the periacetabular bone, leading to stress-shielding phenomena, bone resorption, and loosening. Biomechanical studies showed no correlation between stiffness of modular acetabular components and initial stability pattern [15, 18]. A previous in vitro study performed to compare fixation quality of the same press-fit cup as used in the current study with either polyethylene or alumina liners showed stable conditions in both groups [16]. The mean micromotion at the level of the os ilium, pubis, and ischium did not exceed 120 μ m during the maximal cyclic load of 2.39 kN both with polyethylene and alumina liner. A recent finite-element analysis showed a distribution of bone load in the periphery of the acetabulum with cups using alumina liners [12]. This is a condition approaching the physiological loading behaviours. However, finite-element analysis showed that the load was located in the acetabular floor when the same cups were inserted using polyethylene liners.

The aim of the current investigation was to compare the clinical and radiological results of patients with acetabular alumina liners to patients with polyethylene liners. There was no marked difference of outcome in the two study groups. No acetabular component required revision, and all implants were radiologically stable, with an average Harris hip score of 93 points at a mean 5-year follow-up. Pain requiring pharmacological or physical treatment was not observed in any of the 60 patients. Occasional thigh pain was present in three patients in the polyethylene group and in one patient in the alumina group. Groin pain was not observed. These findings do not contrast with data reported by other authors who investigated the clinical and radiological outcomes of modular acetabular components. [1, 8, 19].

The profile of the cup used in the current study is hemispherical, and the solid wall is designed to sustain the ceramic liner. Owing to these design features, the cup appears relatively bulky. This construct was the first one, which was released for clinical use in Europe with the innovative BioloX-Forte alumina-alumina ceramic pairing.

The most important limitation of the current study was that patients were not randomised. All patients were operated on by two experienced surgeons. One surgeon used exclusively cups with polyethylene liners; the other used only alumina liners. However, the matched-pair design of the clinical investigation provided a comparison between two homogeneous groups of patients.

Another limitation of the study was the single observer. One observer can produce more consistent findings

but can also introduce systemic bias. Blinded observer rating was not possible, as modular cups with ceramic and polyethylene liners can be easily distinguished in radiographs.

Strengths of the current study are represented by the homogeneity of the groups, the use of the same acetabular cup in all hips, and the use of a digitising tablet for radiographic assessment. A digitising tablet is more precise than conventional manual technique. To the authors' knowledge, this study has the longest follow-up of modular acetabular components inserted using a modern alumina-alumina ceramic pairing. Sedel reported very satisfactory middle- and long-term results using a similar construct, but no comparative data of cups with polyethylene liners are available [19].

In the present study, the clinical and radiological outcome of a hemispherical press-fit cup with a Ti powder coating inserted with an alumina liner at a minimum 5-year follow-up was satisfactory, with no need for revision and no signs of aseptic loosening. Clinical and radiological results do not contrast with those achieved using the same implant inserted with a polyethylene liner. With a longer follow-up, a higher rate of wear can be expected in the group with polyethylene liners, as well as bone resorption and a higher extension of radiolucent lines.

References

1. Bizot P, Larrouy M, Witvoet J, Sedel L, Nizard R (2000) Press-fit metal-backed alumina sockets. A minimum 5-year follow-up study. *Clin Orthop* 379:134–142
2. Boehler M, Krismer M, Mayr G, Muehlbauer M, Salzer M (1998) Migration measurement of cementless acetabular components: Value of clinical and radiographic data. *Orthopedics* 21:897–900
3. Brooker AF, Bowerman JW, Robinson RA, Riley LH Jr (1973) Ectopic ossification following total hip replacement. Incidence and a method of classification. *J Bone Joint Surg [Am]* 55:1629–1632
4. Charnley J (1979) Numerical grading of clinical results. In: Charnley J (ed) *Low friction arthroplasty of the hip*. Springer, Berlin Heidelberg New York, pp 20–24
5. Charnley J, Halley DK (1975) Rate of wear in total hip arthroplasty. *Clin Orthop* 112:170–179
6. DeLee JG, Charnley J (1976) Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop* 121:20–32
7. Freeman MAR (1999) Radiolucent lines: A question of nomenclature. *J Arthroplasty* 14:1–2
8. Garino JP (2000) Modern ceramic-on-ceramic total hip systems in the United States. *Clin Orthop* 379:41–47
9. Gruen TA, McNeice GM, Amstutz HC (1979) Modes of failure of cemented stem-type femoral components: A radiographic analysis of loosening. *Clin Orthop* 141:17–27
10. Hamadouche M, Boutin P, Daussange J, Bolander ME, Sedel L (2000) Alumina-on-alumina total hip arthroplasty. A minimum 18.5-year follow-up study. *J Bone J Surg [Am]* 84:69–77
11. Harris WH (1969) Traumatic osteoarthritis of the hip after dislocation and acetabular fractures: Treatment by mould arthroplasty: An end-result study using a new method of result evaluation. *J Bone Joint Surg [Am]* 51:737–755
12. Hendrich C, Kaddick C, Willmann G (1999) Krafteinleitung in das knöcherne Becken bei keramischen Pfanneneinsätzen: Eine Finite-Elemente-Analyse. *Z Orthop* 137 (Suppl):31
13. Hendrich C, Kaddick C, Willmann G (2000) Klinische Erfahrungen und Migrationsanalyse. *Plasmacup*. In: Willmann G, Zweymüller K (eds) *Bioceramics in hip joint replacement*. Thieme, Stuttgart, pp 26–34
14. Livermore J, Ilstrup D, Morrey B (1990) Effect of femoral head size on wear of the polyethylene acetabular component. *J Bone Joint Surg [Am]* 72:518–528
15. Pitto RP, Sterzl M, Hohmann D (1996) Observations on the initial stability of acetabular components in total hip arthroplasty. *Chir Organi Mov* 81:107–118
16. Pitto RP, Willmann G, Schramm M (2001) Initial stability of modular acetabular components: Comparative in-vitro study with polyethylene and ceramic liners. *Biomed Tech (Berl)* 46:109–112
17. Riska EB (1993) Ceramic endoprosthesis in total hip arthroplasty. *Clin Orthop* 297:87–94
18. Schneider E, Schönenberger U, Giraud P, Bürgi M (1992) Primärstabilität und Beckendeformation bei zementierten und nichtzementierten Hüftpfannen. *Orthopäde* 21:57–62
19. Sedel L (1999) Evolution of alumina-alumina implants. In: Sedel L, Willmann G (eds) *Reliability and long-term results of ceramics in orthopaedics*. Thieme, Stuttgart, pp 2–6
20. Singh M, Nagrath AR, Maini PS (1970) Changes in trabecular pattern of the upper end of the femur as an index of osteoporosis. *J Bone Joint Surg [Am]* 52:456–467
21. Willmann G (2000) The evolution of ceramics in total hip arthroplasty. *Hip Int* 10:193–203
22. Willmann G (2000) Ceramic femoral head retrieval data. *Clin Orthop* 379:22–28