10-year results of the uncemented Allofit press-fit cup in young patients

121 hips followed for 10–12 years

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Background and purpose — Uncemented acetabular components in primary total hip arthroplasty (THA) are commonly used today, but few studies have evaluated their survival into the second decade in young and active patients. We report on a minimum 10-year follow-up of an uncemented press-fit acetabular component that is still in clinical use.

Methods — We examined the clinical and radiographic results of our first 121 consecutive cementless THAs using a cementless, grit-blasted, non-porous, titanium alloy press-fit cup (Allofit; Zimmer Inc., Warsaw, IN) without additional screw fixation in 116 patients. Mean age at surgery was 51 (21–60) years. Mean time of follow-up evaluation was 11 (10–12) years.

Results — At final follow-up, 8 patients had died (8 hips), and 1 patient (1 hip) was lost to follow-up. 3 hips in 3 patients had undergone acetabular revision, 2 for deep infection and 1 for aseptic acetabular loosening. There were no impending revisions at the most recent follow-up. We did not detect periacetabular osteolysis or loosening on plain radiographs in those hips that were evaluated radiographically (n = 90; 83% of the hips available at a minimum of 10 years). Kaplan-Meier survival analysis using revision of the acetabular component for any reason (including isolated inlay revisions) as endpoint estimated the 11-year survival rate at 98% (95% CI: 92–99).

Interpretation — Uncemented acetabular fixation using the Allofit press-fit cup without additional screws was excellent into early in the second decade in this young and active patient cohort. The rate of complications related to the liner and to osteolysis was low.

Uncemented acetabular components are widely used all over the world. A variety of these components have been associated with excellent short- to medium-term clinical and radiographic outcomes (Hallan et al. 2010, Howard et al. 2011). During the second decade of use, a number of cementless cup designs have shown durable fixation, but problems related to wear and osteolysis often compromise the results, and the surgeon can face serious problems in revision surgery because of extensive bone loss. This is a particular problem with young and active patients (Kim et al. 2012). Currently, there are few reports on the survival of contemporary uncemented cups that are still in clinical use in young patient cohorts with a minimum of 10 years of follow-up (Akbar et al. 2009, Kim et al. 2012), despite being used frequently in this group of patients.

We evaluated the ten- or more-year results of an independent series of the non-porous, uncemented, press-fit Allofit cup in young patients (≤ 60 years old) implanted without any additional fixation (screws) and compared the results with those reported in the literature.

Patients and methods

We examined the clinical and radiographic results of the first 121 consecutive cementless THAs, using a cementless, grit-blasted, non-porous, titanium alloy press-fit cup (Allofit acetabular cup; Zimmer Inc., Warsaw, IN) (Figure 1) in 116 patients aged 60 years or younger at the time of surgery. The mean age at surgery was 51 (21–60) years (Table 1). Data on all patients were collected prospectively using our institutional

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Figure 1. The uncemented Allofit acetabular component with macrotextured surface, hemispherical periphery, and a flattened polar region.

Table 1. Demographics and distribution of hips

Demographics	Male	Female	Total
Mean age (SD)	50 (8.7)	51 (6.3)	51 (7.8)
No. of hips (%)	74 (61%)	47 (39%)	121 (100%)
Mean BMI (SD)	28 (4.4)	26 (4.6)	27 (4.5)
Right:left	40:34	22:25	62:59

joint replacement registry. The procedures were performed in a multi-surgeon series (17 surgeons) at our institution between January 1999 and June 2001. Osteoarthritis was the commonest diagnosis (Table 2). Informed consent was obtained from all patients. The institutional review board of the University of Heidelberg approved all procedures (S-496/2011) and the study was conducted in accordance with the Declaration of Helsinki, 1975, as revised in 2008.

The Allofit acetabular component design is modular and biradial with a hemispherical periphery and a flattened polar region. The metal backing is made of pure titanium (Protasul-Ti) and has a thickness of 2.9 mm irrespective of the shell size. The surface is prepared with a macrostructure of grooves and ridges that create "teeth" with a dimension of 400 µm to 600 µm. The entire external surface is grit-blasted with corundum. For optimal press-fitting, the cavity was under-reamed by 2 mm in relation to the peripheral dimension of the device. The implant is available with screw holes for additional fixation, or with a solid continuous outer surface without holes (Zenz et al. 2009). We used the solid device without additional screw fixation in all patients.

The bearing surfaces used were either a 28-mm Metasul (Zimmer, Winterthur, Switzerland), forged, high-carbide (0.2%–0.25%) CoCr alloy sandwich metal-on-metal articulation (86 hips) or a 28-mm Al_2O_3 ceramic head (Biolox forte; CeramTec, Plochingen, Germany) articulating with conventional (moderately crosslinked) calcium stearate-free UHMW polyethylene liner (Sulene; Zimmer, Winterthur, Switzerland) (34 hips). The Sulene liner is made of compression-molded, calcium stearate-free GUR 1020 resin and is sterilized by gamma irradiation at a dose of 25–40 kGy in a nitrogen environment. In one hip, a 28-mm Cerasul (Zimmer, Winterthur,

Table 2. Details of the diagnosis for the 121 hips

Diagnosis	No. of hips (%)
Osteoarthrosis	77 (64)
CDH	21 (17)
Avascular necrosis	13 (11)
Posttraumatic OA	3 (2)
Rheumatoid arthritis	2 (2)
Other	5 (4)
Giant-cell tumor	1 (1)
Osteochondrosarcoma	1 (1)
SCFE	1 (1)
Perthes'	1 (1)
Coxitis	1 (1)

CDH: congenital dysplasia of the hip;
OA: osteoarthrosis;
SCFE: slipped capital femoral epiphysis.

Switzerland) sandwich ceramic-on-ceramic articulation was used.

For femoral reconstruction, a cementless tapered titanium stem was used in 118 hips: 69 hips received a CLS Spotorno stem (Zimmer, Winterthur, Switzerland) and 49 hips received a G2 stem (Depuy Orthopaedics, Warsaw, IN). A cementless Vision2000 stem (Depuy Orthopaedics) was used in 2 hips, and a MUTARS proximal femoral replacement (implantcast GmbH, Buxtehude, Germany) was implanted in 1 hip.

Either a modified Watson-Jones approach (12 hips) or a transgluteal Bauer approach (109 hips) was used with the patient in the supine position. Postoperatively, partial weight bearing was recommended for 6 weeks. Routine prophylaxis for the prevention of heterotopic ossification was diclofenac, 75 mg twice a day for 2 weeks. Intravenous third-generation cephalosporin (1.5 g cefuroxime) was administered perioperatively. Anticoagulation therapy consisted of low-molecular-weight heparin (enoxaparin or nadroparin) administered subcutaneously on the day before surgery and continued for 6 weeks postoperatively.

Regular clinical and radiographic follow-up for hip arthroplasty patients at our institution is routinely recommended at 1 year postoperatively, at 3 years, at 5 years, and every 5 years thereafter. Data were prospectively collected preoperatively and at all follow-up visits using our institutional joint replacement registry. For this study, we invited all the remaining patients who had not had a 10- or more-year follow-up visit at our institution with complete clinical and radiographic data. The Harris hip score (HHS) (Harris 1969) was recorded preoperatively and at the follow-up visits. Patient activity levels were determined retrospectively using the UCLA score (Zahiri et al. 1998).

For radiographic evaluation, standard anterioposterior (AP) pelvic radiographs and lateral radiographs of the hip were taken. Acetabular inclination was measured using the transischial line as reference. The prevalence, location, and extent of radiolucent gaps or osteolysis at the acetabular bone-prosthesis interface were recorded at the last follow-up using the 3 zones described by DeLee and Charnley (1976). Osteolysis was defined as a lucent zone devoid of trabecular bone and usually with a sclerotic border not visible on the immediate postoperative radiograph (Zenz et al. 2009, Kim et al. 2012). The acetabular component was considered to be loose if there was migration of > 3 mm horizontally or vertically over time or a circumferential radiolucent line. Heterotopic ossification was graded according to Brooker et al. (1973).

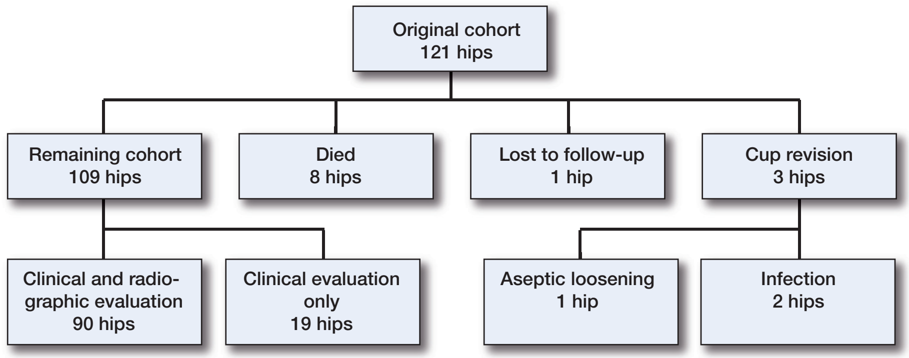

Figure 2. Distribution of hips at final follow-up.

Statistics

We used Kaplan-Meier survivorship analysis to determine survival rates for different endpoints. Differences in survival rates between groups of patients were tested for statistical significance using the two-sided log-rank (Mantel-Cox) test. Hazard ratios for the risk of revision with 95% confidence intervals (CIs) were calculated using the Mantel-Haenszel method. The assumption of proportional hazards was investigated by calculating the estimated hazard rate over time using a Epanechnikov kernel-smoothed hazard function. The plots were inspected visually and we found that the rates were almost equally distributed over time in both groups. Adjustment for bilaterality was not performed, as we did not find any differences in the survivorship analysis including either the first implantation or both, which is consistent with previous studies (Robertsson and Ranstam 2003, Lie et al. 2004, Hailer et al. 2010). A Kolmogorov-Smirnov test was performed after exploratory data analysis, testing the variables for normal distribution. As not all variables met the criteria for a normal distribution, non-parametric tests were used for comparisons. Paired data with continuous variables were analyzed with the Wilcoxon matched-pairs signed rank test. We considered p-values of < 0.05 to be statistically significant. IBM SPSS software version 20 and Graphpad Prism version 6.01 were used to record and analyze the data.

Results

Cohort

At a minimum of 10 years postoperatively, 8 patients had died (8 hips) during the study period from causes unrelated to their hip surgery, and 1 patient (1 hip) was lost to follow-up. In the patients who died, the acetabular component was in situ at the time of death (Figure 2). 3 hips (2%) underwent acetabular revision and the remaining 109 hips were available for review at a mean follow-up time of 11 (10–12) years. 19 (17%) of the 109 hips available had no radiographic follow-up at 10 years or more, as they had either had a radiograph taken less than 5 years previously or they had refused to come to our institution and no radiographs were available from any local physician.

Revisions

Of the 3 hips requiring acetabular revision, 2 were revised for deep infection (2-stage revision with cup and stem revision at 4 and 6 years postoperatively) and 1 was revised for aseptic acetabular loosening (isolated revision of the acetabular component and the modular femoral head at 3 years postoperatively). There were no isolated femoral component or inlay revisions up to the most recent follow-up. There were no impending revisions at the most recent follow-up.

Complications and reoperations

Intraoperative complications occurred in 8 hips (7%); of those, 7 were related to a proximal femur fissure and 1 was related to a fracture of the greater trochanter during insertion of the femoral component. These cases were managed with an additional cable wire/tension band/screw osteosynthesis. 2 of these patients with intraoperative complications had a reoperation for removal of internal fixation devices and they were later revised (1 for aseptic cup loosening and 1 for deep infection; see "Revisions"). No other reoperations on the hip were performed in any of the patients. There were 2 postoperative dislocations; both were successfully managed non-operatively by closed reduction. 1 patient received a primary THA for high-grade chondrosarcoma of the proximal femur (Allofit cup and MUTARS proximal femoral replacement) and underwent external hemipelvectomy for a local tumor recurrence 2 years postoperatively. All implants were well fixed at the time of hemipelvectomy. This patient was censored at the time of hemipelvectomy but was not considered to be revised.

Survival

The Kaplan-Meier survival analysis, using revision of the acetabular component for any reason (including isolated inlay revisions) as endpoint, estimated the 11-year survival rate at

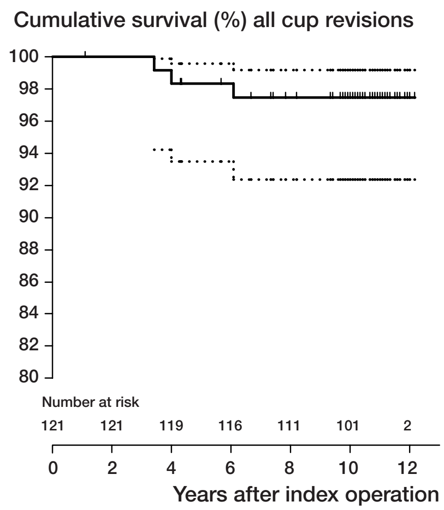

Figure 3. Kaplan-Meier survivorship curve and 95% CI with acetabular revision for any reason as endpoint. Eleven-year survival was estimated at 97.5% (95% CI: 92.4–99.2; 32 hips at risk).

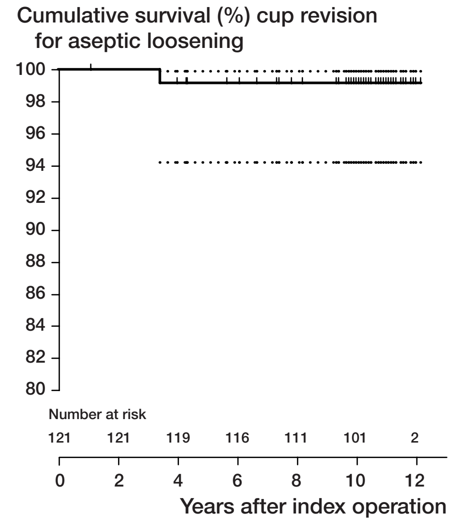

Figure 4. Kaplan-Meier survivorship curve and 95% CI with acetabular revision for aseptic loosening as endpoint. Eleven-year survival was estimated at 99.2% (95% CI: 94.2–99.9; 32 hips at risk).

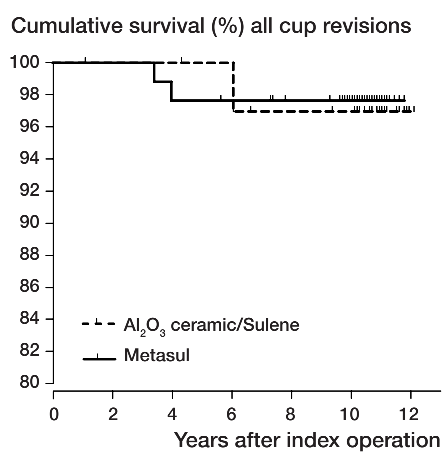

Figure 5. Comparison of Kaplan-Meier survivorship curves with acetabular revision for any reason as endpoint for hips with 28-mm Metasul articulation (n = 86) vs. ceramic-on-polyethylene articulation (n = 34) (log-rank test, p = 0.86)

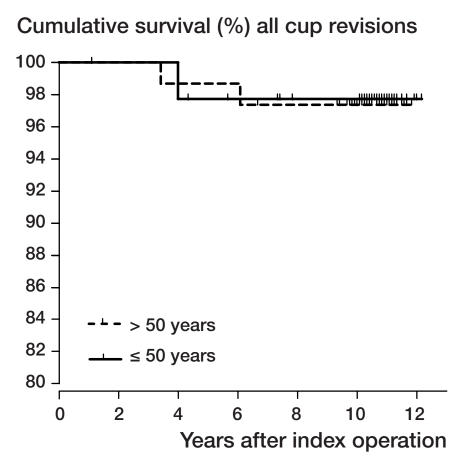

Figure 6. Comparison of Kaplan-Meier survivorship curves with acetabular revision for any reason as endpoint for patients aged ≤ 50 at the time of surgery (n = 45) vs. patients aged > 50 (n = 76) (log-rank test, p = 0.91).

97.5% (CI: 92.4–99.2; 32 hips at risk) (Figure 3). The survival rate after 11 years with acetabular revision for aseptic loosening as endpoint was estimated at 99.2% (CI: 94.2–99.9; 32 hips at risk) (Figure 4). The survival rate with femoral revision for any reason as endpoint was 98.3% (CI: 93.4–99.6); survival with femoral revision for aseptic loosening was 100% at 11 years. The survival rate (with revision for any reason as endpoint) was similar between hips with 28-mm Metasul (n = 86) and ceramic-on-polyethylene (n = 34) articulation (log-rank test, p = 0.9) (Figure 5). Patients aged 50 years or younger at the time of surgery (n = 45) did not have a higher revision risk at 11 years than patients aged between 51 and 60 years (n = 76) (hazard ratio = 0.88, CI: 0.08–9.24; p = 0.9) (Figure 6).

Radiographic evaluation

At the 10- or more-year follow-up, there was no radiographic evidence of loosening of the acetabular components in those hips that were evaluated radiographically (n = 90; 83% of the hips available at minimum 10 years) (Figure 7). We did not find periacetabular osteolytic lesions. In 2 hips, radiolucent lines around the acetabular component were found (DeeLee-Charnley zone I in 1 hip and zone III in 1 hip). The mean inclination angle was 42° (24–63). An inclination angle > 45° was observed in 25 hips. 4 of 34 hips with ceramic-on-polyethylene articulation showed signs of wear (slight decentration of the femoral head on the AP pelvic radiograph); these 4 hips had a cup inclination angle of > 50°. Revision surgery was not recommended for any of these patients. Heterotopic ossifica-

Figure 7. Anteroposterior radiograph of the left hip in a 44-year-old woman with CDH at 12 years after THA.

tion was found in 33 of 90 hips (37%): Brooker grade I (24 hips), grade II (8 hips), and grade III (1 hip), but no grade IV.

Clinical evaluation

The mean total HHS increased from 44 (14–89) points preoperatively to 92 (54–100) points at the 10- or more-year follow-up ($p < 0.001$). 99% of the patients were satisfied with the outcome. The mean patient activity level according to the UCLA score was 3.7 (1–9) preoperatively and 6.2 (3–10) at final follow-up ($p < 0.001$).

Discussion

Despite the frequent use of the Allofit acetabular component in primary THA, there have only been a few reports on outcome (Zenz et al. 2009, Schroeder et al. 2010). To our knowledge, there have been no independent reports with more than 10 years of follow-up and no reports on young patient cohorts. However, the demand for primary THA in patients younger than 65 has been projected to exceed 50% of THA patients of all ages in the near future (Kurtz et al. 2009). Here we report the results of this device in a group of patients with a mean age of 51 years, as there has been comparatively little information on the outcome of cementless acetabular reconstruction with contemporary implant designs in young patients in the second decade of use (Table 3).

It has been shown that cementless fixation of the metal shell can be maintained successfully at medium- to long-term follow-up (Della Valle et al. 2009, McLaughlin and Lee 2010, Kim et al. 2012), but problems related to polyethylene wear and osteolysis often compromise the long-term survival. This is a particular problem in young patients (Kim et al. 2012). Published reports on cohorts of young patients using a conventional (not highly crosslinked) polyethylene liner with more than 10 years of follow-up have consistently shown a marked decline in survivorship after 10 years (Duffy et al. 2004, Eskelinen et al. 2006, Utting et al. 2008, Akbar et al. 2009, Della Valle et al. 2009, Hallan et al. 2010, Kim et al. 2012).

The low rate of aseptic loosening that we found shows that cementless acetabular fixation using the Allofit cup was durable in this young and active patient cohort with a mean UCLA score of 6.2 at follow-up after 10 years or more. Our finding is consistent with a previous report from the developers

Table 3. Results of uncemented acetabular components with 10- or more-year follow-up in young patients. The inclusion criteria were (1) patients who were 60 years of age or younger at the time of surgery, and (2) patients with a minimum duration of follow-up of 10 years

A	B	C	D	E	F	G	H	I	J
Duffy et al.	2004	Harris-Galante I [a]	metal-poly	84	10	38	84.5 at 10 y	98.7 at 10 y	10
Utting et al.	2008	Harris-Galante I [a]	metal-poly	70	14	40	84 at 14 y	–	19
Akbar et al.	2009	DSP-CUP	ceramic-poly	72	14	35	86 at 14 y	–	–
Migaud et al.	2011	Armor [a]	28-mm Metasul	39	13	40	100 at 12 y	100 at 12 y	3
Hwang et al.	2011	Wagner [a]	28-mm Metasul	78	12	40	98.7 at 12 y	–	2
Kim et al.	2012	Duraloc	metal-poly	532	15	39.3	82 at 15 y	100 at 15 y	20
Current study	2014	Allofit	28-mm Metasul	86	11	50	97.6 at 11 y	98.8 at 11 y	0
			ceramic-poly	34	11	54	97.0 at 11 y	100 at 11 y	0

[a] No longer available for clinical use.
A Study
B Year
C Cup
D Articulation
E No. of hips
F Mean follow-up (years)
G Mean age at surgery (years)
H Survivorship, all cup revisions (incl. liner revision, %)
I Survivorship, aseptic cup loosening (%)
J Periacetabular osteolysis (%)

(Zenz et al. 2009). In a comparison of those patients aged 50 or younger at the time of surgery and those aged between 51 and 60, there was no difference in survival rates at 10 years or more.

Most published reports on cementless acetabular components in young patients have used porous-coated implants, which allow secondary stabilization by osseous ingrowth (Duffy et al. 2004, Utting et al. 2008, Migaud et al. 2011, Kim et al. 2012). Our results show that a non-porous device can provide excellent fixation in young patients into early in the second decade and the rate of aseptic loosening in this patient cohort compares well with that for porous-coated devices.

In previous reports on patients who were 60 years of age or younger at the time of surgery and who had a minimum duration of follow-up of 10 years (Table 2), supplemental initial fixation of the acetabular component with screws was used consistently (Duffy et al. 2004, Utting et al. 2008, Akbar et al. 2009, Hwang et al. 2011, Migaud et al. 2011, Kim et al. 2012). The low rate of aseptic loosening in our cohort shows that primary stability solely achieved by the press-fit effect without supplemental screw fixation can also give excellent results in young patients. We conclude that supplemental initial screw fixation is not required with this cup when a sufficient press-fit effect is achievable intraoperatively (Udomkiat et al. 2002, Roth et al. 2006).

We believe that there are several reasons for the encouraging results seen in our series. The Allofit cup has a high primary stability due to its grit-blasted macrostructure of grooves and ridges that create teeth, and the press-fit achieved by under-reaming of the cavity by 2 mm in relation to the peripheral dimension of the device. The grit-blasted surface allows secondary stabilization by osseous ongrowth onto the grit-blasted titanium surface of the cup. The flattened polar region optimizes press-fit and load transfer in the periphery of the cup (Morscher et al. 1997), which might enhance osseointegration and sealing of the periphery of the acetabular component and limit access of wear particles to the retroacetabular bone. The metal backing is relatively thin (2.9 mm) compared to other types of hemispheric cups. A comparatively low relative rigidity might enhance stress transfer to cancellous periacetabular bone and therefore reduce stress shielding (Kress et al. 2011).

Radiographic follow-up showed no periacetabular osteolytic lesions and small osteolytic lesions (< 0.5 cm^2) at the proximal femur in 30% of the hips evaluated radiographically at 10 or more years of follow-up. Wear debris is generally accepted to be the most important factor in the development of periprosthetic osteolytic lesions (Ollivere et al. 2012). Metal-on-metal articulations have been developed to reduce generation of wear debris. A major consideration in the past years has been the question of safety of these articulations, and adverse tissue reactions associated with them. The second-generation 28-mm sandwich type metal-on-metal Metasul articulation has shown encouraging results in young patients with low rates of periacetabular osteolysis (Delaunay et al. 2008, Hwang et al. 2011, Migaud et al. 2011). Our results are consistent with these reports. Problems of liner disassociation (Malik et al. 2009), metal hypersensitivity/ALVAL (Willert et al. 2005), and osteolysis with loss of femoral fixation (Zenz et al. 2009) have been reported, whereas metallosis and pseudotumors do not appear to be an issue with this smaller-head, metal-on-metal bearing. However, we have made a change in our clinical practice away from metal-on-metal articulations, as the long-term local and systemic effects of metal-on-metal THA are still not fully understood.

We recently reported a wear rate of 0.13 mm/year using a 28-mm alumina ceramic head on Sulene PE in young patients (Streit et al. 2012). One reason for the relatively low wear rate of this articulation compared to other series (Kim et al. 2012) might be the use of ceramic heads instead of metal heads (Jung and Kim 2010, Dahl et al. 2013). In addition, Sulene PE is mildly crosslinked because of its sterilization by gamma irradiation at a dose of 25–40 kGy in a nitrogen environment and it is made of compression-molded, calcium stearate-free GUR 1020 resin. In our series, there were no complications related to the bearings and no impending revisions, but we found visible migration of the femoral head in 12% of the hips with a Sulene polyethylene liner. These patients are prone to developing osteolytic lesions and might need revision surgery in the future, as more particulate wear can be expected during the second decade after surgery. However, the absence of periacetabular osteolysis at 10 years or more with both articulations used is encouraging, and the bearing type did not have an influence on survival at 10 years or more.

There were several limitations to our study design. The use of 2 types of bearings made the group heterogeneous and the evaluation of osteolysis using radiographs, as the incidence of osteolysis might be underestimated on radiographs compared to evaluation by computed tomography or magnetic resonance imaging (Walde et al. 2005). There was possibly bias in the radiographic results, as 17% of the hips available had no radiographic follow-up. We also recognize that a 10-year follow-up might not be long enough to draw definitive conclusions. Finally, the sample size may have been inadequate for detection of a real difference between the sample groups, so the study may have been underpowered to show a difference in survival rates between articulation groups or age groups. The strength of the study was that < 1% of hips were lost to follow-up (Britton et al. 1995, Murray et al. 1997).

MRS, SW, FA, TB, and CM: data analysis and interpretation, and drafting and writing of the manuscript. MRS, SW, CM, FA, JPK, and VE: study design, acquisition of data, and critical revision of the manuscript. TW: radiographic measurements and drafting of the manuscript.

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No competing interests declared.

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