Similar effect of stem geometry on radiological changes with 2 types of cemented straight stem

The Müller stem and the Virtec stem compared in 711 hips

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Background and purpose — There are 2 basic principles in cemented stem fixation: shape-closed and force-closed. We investigated 2 shape-closed straight stems, the Müller (MSS) and the Virtec (VSS), which differ only in geometrical cross section, to determine whether the difference in stem shape would affect the radiological results or long-term survival.

Patients and methods — We included 711 hips (in 646 patients) that were operated on between July 1996 and July 2003. Patients randomly received either an MSS (n = 356) or a VSS (n = 355) and were followed prospectively. Radiographs taken at a follow-up of > 10 years were analyzed for osteolysis. Kaplan-Meier (KM) survival analysis was performed using various endpoints. We also performed Cox regression analysis to identify risk factors for aseptic loosening and osteolysis of the stem.

Results — After 10 years, KM survival with "revision of any component for any reason" was 92% (95% CI: 88–95) for the MSS and 95% (CI: 92–97) for the VSS (p = 0.1). With "revision for aseptic loosening of the stem" as the endpoint, KM survival was 96% (CI: 9–98) for the MSS and 98% (CI: 97–100) for the VSS (p = 0.2). Cox regression showed that none of the risk factors analyzed were independent regarding aseptic loosening of the stem or regarding osteolysis.

Interpretation — The MSS and the VSS showed excellent survival for aseptic loosening after 10 years. For the 2 different stem designs, we did not find any independent risk factors for aseptic loosening or development of osteolysis.

The optimal shape of the femoral component in cemented total hip replacement (THR) is still being debated (Hamadouche et al. 2008, Ellison 2012). There are 2 main basic theoretical principles in cemented stem fixation: shape-closed and force-closed (Scheerlinck and Casteleyn 2006) and the long-term success of both principles is well documented (Fowler et al. 1988, Howie et al. 1998, Kerboull et al. 2004, Morscher et al. 2005, Buckwalter et al. 2006, Hamadouche et al. 2008, Clauss et al. 2009, El Masri et al. 2010). In force-closed fixation (taper-slip), the stem is completely covered by a continuous cement mantle. Fixation is enhanced by the stem sinking within the cement mantle. In shape-closed fixation (composite-beam), the stem is partially surrounded by a thin or incomplete cement mantle, also known as the "French paradox" (Langlais et al. 2003). Fixation is enhanced by an additional press-fit fixation of the stem against the cortical bone (Kerboul 1987, Clauss et al. 2010).

The Müller straight stem (MSS) has a rectangular cross section; the femoral canal is filled in the anterior-posterior (ap) plane and has a small proximal collar. The Virtec straight stem (VSS) is similar to the MSS in the ap view, but the edges are rounder and the stem is wider in the sagittal plane (Figure 1). The proximal transection is oval and the geometry follows the philosophy of the Kerboul stem, in order to prevent stress risers in the cement mantle and consecutive tears in the cement (Kerboul 1987).

We have used the shape-closed MSS for more than 30 years at our hospital, and have reported good long-term results (Clauss et al. 2009). Later modifications of the material and surface of the MSS have shown inferior survival (Clauss et al. 2013). The VSS was introduced at our clinic in 1996 as a potential successor of the MSS, and was used in parallel with the established MSS. The only difference between the stems was the shape. There were no differences in material, surface, taper, cup, or operating technique.

The aim of this prospective registry-based study was to determine whether the difference in stem shape would affect the radiological results or survival in the long term.

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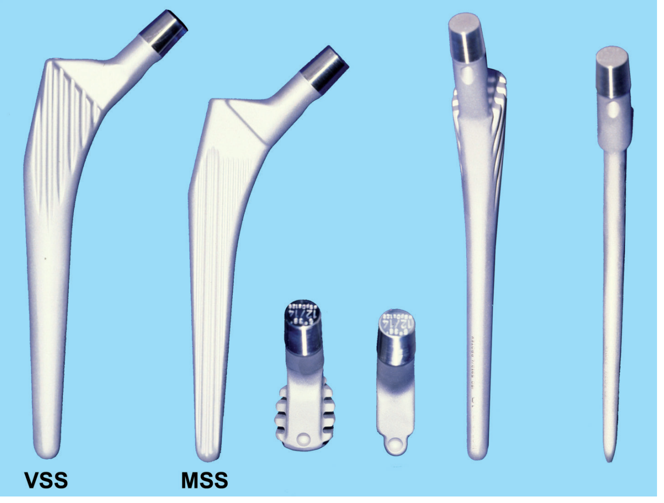

Figure 1. The Virtec (VSS) straight stem and the Müller (MSS) straight stem (lateral version).

Patients and methods

Stem design

The MSS and VSS have an identical geometry of the neck, with a CCD angle of 135°, and are available in standard and lateralized versions with a difference in offset of 6 mm. They are made from the same alloy (CoNiCrMo, ISO 5832-6, Protasul-10; Zimmer, Winterthur, Switzerland) and have the same homogeneous blasted surface finish (R_a: 0.5–1.5 µm). They differ in their geometrical cross section. The MSS has a double taper and a rectangular cross section, with longitudinal grooves running anteriorly and posteriorly and a small proximal collar. The VSS, which was developed from the MSS, is also double-tapered but has an oval cross section. Due to the reduced rotational stability, longitudinal fins running anteriorly and posteriorly were added. The VSS is therefore wider in the sagittal plane and fills a larger part of the femoral canal (Figure 1). Both stems are cemented line-to-line with the final broach (El Masri et al. 2010).

Between July 1996 and July 2003, all the patients who were planned for primary THR with a cemented straight stem at our hospital (713 patients, 764 hips) received either a cemented MSS or a cemented VSS (both Zimmer) according to a list that was randomly generated. All the patients gave their written informed consent to participate in the study. Preoperative planning was done for both stem types on the day before surgery. The stem to be used was announced just before surgery.

Demographics

Of the 764 primary THRs, 53 hips were excluded. In 37 of these hips, the femoral cavity was too narrow for the smallest MSS (size 5), and therefore—being available in size 4—a VSS had to be used. Furthermore,16 THRs were excluded because the patients declined participation in the study (n = 12) or were by mistake not randomized (n = 4). 711 hips (in 646 patients) remained. 356 hips received an MSS and 355 hips received a VSS. The groups were similar in age, sex (Table 1), diagnosis (Table 2), and cups used (Table 3). All femoral heads had a diameter of 28 mm. 85 metal heads (CoCr, Zimmer) and 626 ceramic heads (Sulox, Zimmer) were used. Head length was not documented in the register.

Table 1. Demographics

	Müller straight stem (MSS)	Virtec straight stem (VSS)
Number of hips	356	355
Sex (male / female)	202 / 154	217 / 138
Mean age at surgery (SD)	69 (10)	69 (11)

Table 2. Diagnosis at operation

	Müller straight stem (MSS) (n = 356 hips)	Virtec straight stem (VSS) (n = 355 hips)
Osteoarthritis	269	257
Rheumatoid arthritis	5	4
Femoral neck fracture	17	19
Dysplasia	44	49
Other	21	26

Table 3. Acetabular components

	Müller straight stem (MSS) (n = 356 hips)	Virtec straight stem (VSS) (n = 355 hips)
SL cup	271	272
SL cup with Metasul PE	26	33
ARR ring (Müller)	51	45
AP cage (Burch-Schneider)	2	1
Polyethylene cemented	6	4

Operative technique

All operations were standardized using a lateral transgluteal approach with the patient in supine position. All patients received a single shot of antibiotic as prophylaxis (cefuroxime, 1.5 g) 30–60 min before surgery. The largest implant that fitted in the medullary canal was implanted, aiming for a primary press-fit fixation in the AP plane according to the French paradox (Langlais et al. 2003, Clauss et al. 2010). Implants were cemented line-to-line with the final broach (El Masri et al. 2010), but in contrast to other canal-filling implants such as the Kerboul stem, the medullary canal was prepared with broaches that did not remove cancellous bone in the sagittal plane (Kerboul 1987, Clauss et al. 2010). A second-generation cementing technique was used (no vacuum mixing, plug, ret-

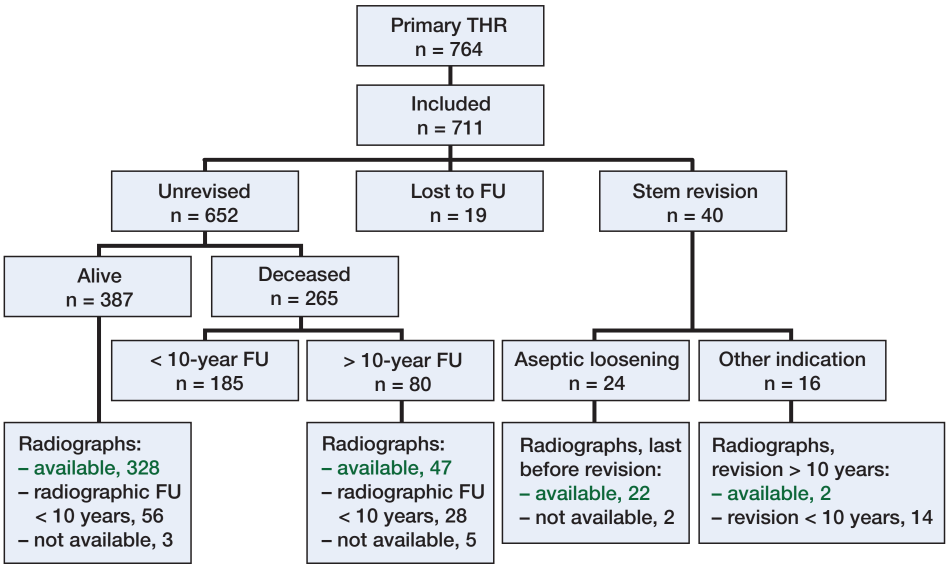

Figure 2. Survival status at latest follow-up with the 399 included radiographic examinations for osteolysis analysis and the excluded radiographic examinations due to missing data or follow-up time that was too short.

rograde filling, and no jet-lavage). Until December 1997, the cement used was low-viscosity Sulfix-60 (Zimmer) (147 hips); this was then followed by high-viscosity Palacos R (Hereaus, Dübendorf, Switzerland) (564 hips), both without antibiotics. Anticoagulation was done for 6 weeks postoperatively either with low-molecular-weight heparin or warfarin according to the co-morbidities of the patient. The postoperative rehabilitation was the same for all patients, with initial full weight bearing starting on the first postoperative day.

Follow-up and radiological analysis

Patients were followed at 4 months, 1 year, 2 years, and 5 years, and then every 5 years after surgery. Standardized AP views were taken, centered on the symphysis and showing the entire stem. For radiological analysis, the last radiograph of all unrevised patients with a minimum radiological follow-up of > 10 years or the last radiograph prior to revision was included (Figure 2). Films were rated according to Gruen. Osteolysis was defined as a progressive, newly developed endosteal bone loss with a diameter of greater than 3 mm with either a scalloping or a bead-shaped lucency at the cement-bone interface (Joshi et al. 1998, Clauss et al. 2009). Subsidence was assessed by measuring the vertical increase in any radiolucency created by distal migration of the shoulder of the prosthesis from any overlapping proximal cement in Gruen zone 1, and considered abnormal if it was > 2 mm (Clauss et al. 2009). Debonding was defined as a radiolucent line at the prosthesis-cement interface that was not visible on the first postoperative radiograph (Clauss et al. 2009). Stems were rated as being radiographically loose in cases of circumferential osteolysis/radiolucencies in all Gruen zones (Harris et al. 1982) and/or excessive subsidence (> 10 mm).

Statistics

We performed Kaplan-Meier (KM) survival analysis using various endpoints: (1) revision of the stem and/or cup (including exchange of the liner) for any reason, (2) aseptic loosening of the stem, (3) stem loosening for any reason, and (4) a worst-case scenario with all cases that were lost to follow-up being judged as aseptic loosening of the stem. Differences between survival rates after 10 years were compared by log-rank analysis.

We performed univariable Cox regression analyses to identify factors associated with an increased incidence of aseptic loosening and osteolysis of the stem. These included age (≤ 59, 60–69, 70–79, ≥ 80 years), sex, primary diagnosis (primary osteoarthritis, rheumatoid arthritis, fracture, dysplasia, other), type of implant (MSS, VSS), stem offset (standard or lateralized), stem size (7.5, 10, 12.5, ≥ 15), type of cup (cemented or cementless), and bone cement (Sulfix-60, Palacos R). We calculated the hazard ratios for revision for aseptic loosening (Table 6, see Supplementary data) and for osteolysis (Table 7, see Supplementary data), with 95% confidence intervals (CIs). Furthermore, hazard ratios were calculated to compare in detail the risk of revision and development of osteolysis between the 2 stems under investigation (Table 8). To investigate the assumption of proportionality, hazard function plots and log-minus-log plots of all covariates were inspected visually. For each of the analyses, there was no sign of insufficient proportionality, and log-minus-log plots ran parallel for all covariates. The hazard ratio was used as a measure of relative risk (RR) (Rud-Sorensen et al. 2010). Adjustment for bilaterality was not performed (Robertsson and Ranstam 2003), as we found no differences in the Cox regression when we included only the first implantation or both.

We used the SPSS statistical package version 21.

Results

19 hips (3%) were lost to follow-up after a mean of 3.7 (SD 2.8) years (9 MSS and 10 VSS). 165 patients (185 hips) had died before the 10-year follow-up, of causes unrelated to surgery (MSS: 97 hips; VSS: 88 hips) at a mean of 5.2 (SD 2.8) years after operation. 344 patients (387 hips) were alive and had not undergone stem revision (MSS: 188; VSS: 199) at mean of 13 (SD 1.9) (range: 10–17) years (Figure 2).

74 hips were revised during follow-up, 20 without exchange of any component (Table 4). 24 stems (3%) were revised for

Table 4. Revisions (74 hips)

Revised components	Müller straight stem (MSS) (n = 44 hips) n	%	Time to revision	Virtec straight stem (VSS) (n = 30 hips) n	%	Time to revision
Both components	13	3.7	4.4 (0.8–16.3)	9	2.5	4.2 (1.7–11.1)
Stem	11	3.1	7.1 (1.9–14.2)	7	2.0	6.0 (1.0–12.0)
Cup	7	2.0	3.5 (1.5–7.8)	3	0.8	8.0 (3.7–10.6)
Only inlay	1	0.3	3.3	3	0.8	0.5 (0.3–0.7)
Reoperation [a]	12	3.4	3.2 (0.3–11.4)	8	2.3	4.6 (0.1–13.3)

[a] without component exchange

Table 5. Stem revisions for different reasons (40 hips)

Revised components	Müller straight stem (MSS) (n = 24 hips) n	%	Time to revision	Virtec straight stem (VSS) (n = 16 hips) n	%	Time to revision
Aseptic loosening	15	4.1	7.2 (1.3–16.3)	9	2.5	6.3 (1.0–12.0)
stem	11	2.2	6.8 (4.2–12.1)	6	1.4	6.5 (3.8–12.0)
both components	4	0.6	2.6 (1.3–4.0)	3	0.6	2.9 (2.8–3.0)
Infection	8	2.2	3.7 (0.8–9.9)	5	1.4	3.7 (1.7–9.4)
Periprosthetic fracture	1	0.3	2.4	1	0.3	8.1
Malposition	0	–	–	1	0.3	2.5

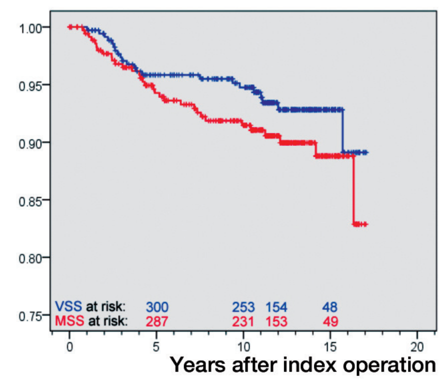

Figure 3. Kaplan-Meier survival curve with component revision for any reason as endpoint.

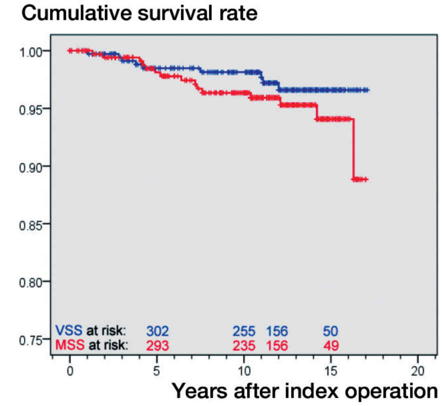

Figure 4. Kaplan-Meier survival curve with revision for aseptic loosening of the stem as endpoint.

aseptic loosening with similar distribution between the groups (Table 5). 13 hips (2%) were revised due to infection after a mean of 3.4 (SD 3.0, range 0.8 to 9.9) years with similar distribution between the groups. 1 stem was changed due to malposition and 2 were changed due to periprosthetic femoral fracture.

Survival

After 10 years, KM survival with (1) "revision of any component for any reason (stem and/or cup (including exchange of the liner))" as endpoint was 92% (95% CI: 88–95) for the MSS group and 95% (CI: 92–97) for the VSS group (p = 0.1, log-rank test) (Figure 3).With (2) "revision for aseptic loosening of the stem" as the endpoint, KM survival at 10 years was 96% (CI: 94–99) for MSS group and 98% (CI: 97–100) for the VSS group (p = 0.2, log-rank test) (Figure 4). Survival rates with (3) "stem revision for any reason" as the endpoint were 94% (CI: 91–96) for MSS and 96% (CI: 94–98) for VSS (p = 0.2, log-rank test). Counting all 19 stems that were lost to follow-up and 1 stem being radiologically loose but not revised as (4) "revised for aseptic loosening (worst-case scenario)", survival was 91% (CI: 87–94) for MSS and 93% (CI: 90–96) for VSS at 10 years (p = 0.2, log-rank test).

Radiological results

For 92 hips, only a clinical follow-up was available (the patients were too sick to come), leaving 399 hips (196 MSS and 203 VSS) for radiological assessment. The average radiological follow-up was 11 (10–16) years for the unrevised hips included and 6.8 (1–16) years for the revised hips included. 17 of 22 stems that were revised for aseptic loosening showed progressive osteolysis on the final radiograph before revision. Osteolysis was more frequent for the MSS in Gruen zones 2 (p = 0.06), 6 (p = 0.07), and 7 (p = 0.04) (Table 8). Subsidence was detected in 9 stems (5 MSS and 4 VSS) (2%). Debonding in the cement-prosthesis interface was rare (6 MSS and 4 VSS) and always occurred in Gruen zone 1. From all unrevised stems, 2 additional MSS stems were rated as being radiographically loose at final follow-up (10 and 11 years after surgery).

Cox regression showed that none of the risk factors analyzed was independent regarding aseptic loosening of the stem or regarding osteolysis (Tables 6 and 7, see Supplementary data).

Discussion

Regardless of the fixation philosophy, modifications in stem design may have a great influence on survival (Howie et al. 1998, Langlais et al. 2003, El Masri et al. 2010, Clauss et al.

Table 8. Risk of revision and osteolysis in THA patients with the Virtec straight stem (VSS) or the Müller straight stem (MSS)

Risk analysis	MSS events	%	VSS events	%	HR (95% CI)	p-value
Any revision	(n = 356)		(n = 355)			
any exchange	32	9.0	22	6.2	0.7 (0.4–1.2)	0.2
Stem revision						
aseptic	15	4.2	9	2.5	0.6 (0.3–1.3)	0.2
any cause	24	6.7	16	4.5	0.7 (0.3–1.2)	0.2
worst case	33	9.3	26	7.3	0.8 (0.5–1.3)	0.3
Osteolysis	(n = 196)		(n = 203)			
any	40	20	28	14	0.7 (0.4–1.1)	0.1
G1	10	5	4	2	0.4 (0.1–1.3)	0.1
G2	23	12	12	6	0.5 (0.3–1.0)	0.06
G3	15	8	7	3	0.5 (0.2–1.1)	0.09
G4	7	4	4	2	0.6 (0.2–2.0)	0.4
G5	18	9	10	5	0.5 (0.3–1.2)	0.1
G6	26	13	15	7	0.6 (0.3–1.1)	0.07
G7	23	12	11	5	0.5 (0.2–1.0)	0.04

2013). The Charnley-Kerboul and the MSS are the 2 major representatives of stems fixed according to the shape-closed fixation concept. The Charnley-Kerboul stem was developed from the original Charnley design but with a more bulky proximal shape to prevent stress risers in the cement mantle with consecutive tears in the cement, and to transfer load directly to the bone (Kerboul 1987). In contrast to the Charnley-Kerboul, the MSS is more sword-shaped, leaving a thick cement mantle anteriorly and posteriorly (Clauss et al. 2010). For both designs, the surface finish of the stem has been shown to be a major risk factor for aseptic loosening (Hamadouche et al. 2008, Clauss et al. 2013). But there is only limited information on how stem shape influences survival. The aim of our study was to analyze the effect of stem shape on the long-term survival of 2 shape-closed cemented straight-stem systems.

The survival rates of 96% for the MSS and 98% for the VSS after 10 years are comparable to data already presented for the MSS (Clauss et al. 2009, 2013) and the Charnley-Kerboul stem (Langlais et al. 2003, Hamadouche et al. 2008) with comparable surface roughness to that of other successful cemented designs such as the Exeter (Herberts et al. 2004, Young et al. 2009) and the Lubinus SP II (Herberts et al. 2004, Prins et al. 2014). Small design variables for the femoral stem have been shown to have a major influence on the outcome after THR (Thien and Karrholm 2010, Hallan et al. 2012, Clauss et al. 2013).

As the failure rate in our series was low, in the univariable analysis we did not find any independent risk factors for aseptic loosening of the stems or development of osteolysis. Also, an exploratory multivariable analysis did not show any significant findings (results not presented). Despite the positive outcome from a clinical viewpoint, the low event rate impairs the statistical precision to rule out any of the variables studied as an independent risk factor for aseptic loosening of the stems or the development of osteolysis. This should be considered to be a limitation of the present study.

4 out of 5 stems revised for aseptic loosening showed progressive osteolysis prior to revision, and osteolysis was more common with the MSS. The presence of an intra-articular pump has been proposed as a central mechanism in the process of osteolysis and aseptic loosening in hip arthroplasty (Anthony et al. 1990). The fluid pressure created at the cement-stem interface is higher for rough stems than for polished stems (Bartlett et al. 2009). Surface roughness of the stem has been shown to be a risk factor for aseptic loosening, with excessive failure rates for stems with an enhanced roughness proximally (Langlais et al. 2003, Clauss et al. 2013). In our series, surface roughness was the same, so differences in the development of osteolysis could not be attributed to the surface roughness. All other implant-related factors such as offset, bearing surface, and fixation of the cup were perfectly matched in the 2 groups, leaving only the different stem geometry as a possible explanation for the differences in development of osteolysis. The 2 major differences between the 2 stems are that the VSS is thicker in the sagittal plane, filling a larger part of the femoral canal, and has a more oval shape than the rectangular MSS. A postmortem analysis of the MSS has shown complete cement filling of the medullary canal below the minor trochanter (Gruen zones 2, 3, 5, and 6) but bony contact at the corners of the stem, creating a thin or incomplete cement mantle (Clauss et al. 2010).

In a cadaver study, Scott et al. (2005) showed that the Freeman stem cemented line-to-line with the final broach as the MSS and the VSS create a higher cement pressurization in the distal parts of the stem (Gruen zones 2, 3, 5, and 6) with less radiolucent lines. Both stems in our series were cemented line-to-line, but given the larger diameter of the VSS as compared the MSS, cement pressurization must have been higher for the VSS. This should be even more meaningful, as none of the stems was cemented using jet-lavage or a proximal seal to create enhanced cement penetration (Breusch 2005). Rotational stability of the Freeman stem (Scott et al. 2005) and the VSS is only created in the proximal part of the stem (Gruen zones 1 and 7), where the cement mantle is thick and complete, but protects the cement mantle distally. The MSS creates rotational stability along the whole length of the sword-like implant (Clauss et al. 2010). Combining these findings with RSA data showing that the surface of all stems "debonds" from the cement, creating an entrance plane for wear particles (Karrholm et al. 1994), one must expect superior survival and reduced development of osteolysis in the VSS compared to the MSS—as can be seen from our data.

Our results appear to question the clinical relevance of a dogmatic characterization of femoral stems into shape-closed and force-closed. The mode of fixation, and also failure, appears to be more complex. Irrespective of the design philosophy, it should be re-emphasized that an incomplete and therefore deficient cement mantle would not necessarily jeopardize mechanical fixation, but might allow access of wear particles to the bone-cement interface, which might be the precursor of particle-induced osteolysis and failure.

Supplementary data

Tables 6 and 7 are available on the Acta Orthopaedica website, www.actaorthop.org, identification number 8472

MC analyzed the data and radiographs and wrote the manuscript, LB performed the statistical analyses, DB analyzed the data, PEO initiated the study and wrote the manuscript, and TI wrote the manuscript.

No conflict of interest declared.

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