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ORIGINAL PAPER

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Favourable mid-term results of the VerSys CT polished cemented femoral stem for total hip arthroplasty

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Abstract We evaluated the mid-term clinical and radiographical performance of a cohort of patients who underwent primary total hip replacement with a modern, forged cobalt–chrome, polished cemented femoral stem with proximal and distal centralisation. Sixty-seven patients with 73 hybrid total hip replacements were followed up clinically and radiographically for an average of 6.1 years (4–8.5). No patient was lost. No hips required revision, and all stems are radiographically well-fixed. Four hips developed localised osteolysis: one at the site of a proximal periprosthetic fracture, another at the level of a lateral femoral window of a previous core decompression, the third at the mid third of the femoral component, and the fourth on the greater trochanter, associated with accelerated polyethylene wear. This modern polished stem yielded excellent, predictable clinical and radiographic results at an intermediate follow-up.

Résumé Nous évaluons à moyen terme un groupe de patients après arthroplastie totale primaire de la hanche avec une tige cimentée, en chrome cobalt poli, a centralisation proximale et distale. Soixante sept patients avec 73 prothèses hybrides étaient suivis cliniquement et radiologiquement pendant une durée moyenne de 6,1 ans (4–8,5), sans perdu de vue. Aucune hanche n'avait eu de révision chirurgicale, et toutes les tiges étaient radiologiquement bien fixées. Quatre hanches avaient, une ostéolyse localisée : au niveau d'une fracture péri-prothétique proximale, au niveau de la fenêtre corticale d'un précédent forage, à hauteur du tiers moyen de la tige et au niveau du grand trochanter associé à une usure précoce du PE. Cette tige fémorale donne un excellent résultat à moyen terme.

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Introduction

Two of the first successful cemented femoral components were highly polished stems: the flatblack Charnley [9], and the double-tapered Exeter [3, 7, 8, 14, 26, 38]. The survivorship, free of revision for aseptic loosening, for the Charnley stem ranged from 90 to 98%, after a follow-up of 20 to 30 years [3, 7, 8, 38]. The long-term results of the original Exeter stem, demonstrated femoral aseptic loosening in seven of 374 patients (1.8%) after a follow-up of 11 to 16 years [14].

Poor metallurgy led to plastic deformation [24] and stem fracture [10], which was reported in 0.23% [10] to 11% [27] of the first-generation stainless steel, or cast cobalt–chrome cemented stems. In addition, inconsistent stem centralisation and finger-packing of the cement led to areas of incomplete cement mantle, which were considered detrimental to the long-term survivorship of the arthroplasty [1, 21, 23].

The senior author (EAS) has implanted a modern, forged cobalt-chromium, polished, tapered cemented femoral stem, with proximal and distal centralisation (VerSys CT, Zimmer, Warsaw, IN) since December 1996 (Fig. 1). The aim of study is to analyse the midterm clinical and radiographic performance of a cohort of patients who underwent primary total hip replacement with this femoral stem.

Fig. 1 Anteroposterior view of the polished VerSys CT stem utilized in the present study

Materials and methods

Between December 1996 and February 1998, 67 patients underwent 73 primary hybrid total hip replacements (six of them one-stage bilateral) by the senior author (EAS) utilizing a polished cemented femoral stem (VerSys CT, Zimmer, Warsaw, IN). The main features of the stem included an anatomic design, tapered in the frontal plane, with rounded corners, a micro-collar and highly polished surface finish (radius, 0.5 μm). It was made of forged cobalt–chromium in six standard sizes (12 to 17), and with a high offset for the sizes 13 to 16. It had a 12/14 Morse taper and rectangular neck geometry, minimised in the anteroposterior dimension to maximise range of motion. The head sizes were provided in 22, 26, 28 and 32 mm, and the lengths in −3.5 mm, 0, +3.5, +7, and +10.5 (the latter two with a skirt). It was cemented in place with proximal and distal polymethylmethacrylate centralisers.

The operation was performed through a posterolateral approach under hypotensive epidural anaesthesia [33]. All stems were implanted utilizing modern cementing technique which included a cement restrictor (Kinamed, Amarillo, CA, USA) and vacuum-mixed Simplex P bone cement, which was injected in a retrograde fashion with a cement gun. Prior to cementation, the femoral canal was irrigated copiously and aspirated until it was dry. During cement injection and after the proximal femur had been filled, the surgeon occluded the proximal femoral opening and continued to inject cement under pressure. During insertion of the stem, the assistant's thumb was placed in the medial aspect of the proximal femoral opening to prevent cement extrusion. The femoral component and the polymer were heated to 40°C to decrease polymerisation time and interface porosity [4, 12, 20, 29]. A cobalt–chromium modular head was used in all patients, with a 28 mm diameter in 64 hips (87.67%), 22 mm diameter in seven hips (9,59%), and 32 mm and 26 mm diameter in one hip each (1,37%). The 22 mm heads were implanted in young patients with a small acetabular diameter to maximise polyethylene thickness. A Trilogy (Zimmer, Warsaw, IN, USA) cementless acetabular cup was implanted in all patients, and the mid-term follow-up study of the acetabular component has been recently published [16].

None of the patients was lost to follow-up. Of the original group of 67 patients (73 hips), three patients (three hips) died of causes unrelated to surgery three, four and five years after surgery with an intact total hip arthroplasty. Thus, the study group consisted of 64 patients (44 women, 20 men) with 70 hips (27 right hips, 31 left hips and 6 bilateral). The mean age of the patients at the time of surgery was 69 years (range 40–86, SD 10.3). The average height was 1.63 meters (range 1.44–1.85, SD 9.8) and the average weight was 69 kilograms (range 44–115, SD 12.3). Preoperative diagnosis was osteoarthritis in 61 hips, osteonecrosis in five, post-traumatic arthritis in two and dysplasia and rheumatoid arthritis in one hip each. Nine patients (nine hips, 12%) could not return for the last follow-up, and were evaluated by telephone with a detailed questionnaire. No recent radiographs of these patients were available, and they were excluded from the radiographic analysis, leaving

Table 1 Average, minimum, maximum, and standard deviation values for HSS Hip Scoring system preoperatively and postoperatively

Preoperative					Postoperative				
Pain	Gait	ROM	Function	Total	Pain	Gait	ROM	Function	Total
4.1	3.9	4	4	16.7	9.9	9.6	8.9	9.4	37.8
3	3	3	3	12	8	4	4	6	28
8	8	8	8	56	10	10	10	10	40
1	1	1	1	6.2	0.5	1.1	1.5	1.2	2.9

All differences are significant (P<0.0001)

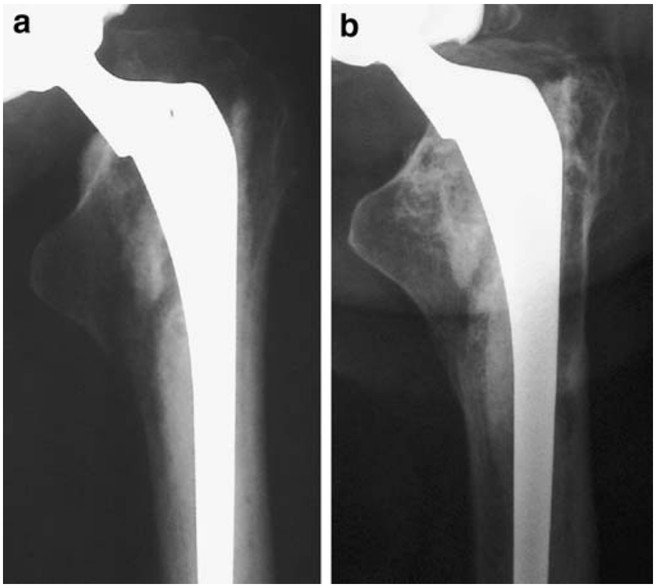

Fig. 2 **a** Non-displaced periprosthetic fracture. There is a fracture of the cement mantle at the level of the lesser trochanter. The stem remains well fixed. **b** Five years latter, osteolysis developed in the lateral cortex of the femur at the site of the cement fracture

55 patients (61 hips) with a minimum 4-year radiographic follow-up (mean 6.2 years, range 4.2–8.5).

Patients were scored according to the Hospital for Special Surgery (HSS) hip scoring system [30], which was calculated at the last follow-up by two of the authors (AGDV, AZ). The score rates pain, walking ability, motion, and function from 0–10 for a maximum of 40 points. Scores greater than 31 were considered excellent, 31–22 good, 21–16 fair, and 15 or less poor. The differences in the four categories of the HSS hip score before and after surgery were compared using the paired *t*-test.

On the 6-week postoperative radiographs we measured the alignment of the stem in the frontal plane in degrees [positive (+) for varus alignment and negative (−) for valgus alignment]. The cement mantle was classified according to Barrack et al. [2] On the radiographs obtained at the last follow-up, we determined the radiographic fixation of the femoral stem according to Harris and McGann [19]. The presence, extent, and location of progressive radiolucent lines measuring more than 1 mm, and the areas of femoral osteolysis were evaluated according to the zones defined by Gruen et al. [18]. Radiographic osteolysis was defined as punched-out areas devoid of trabecular bone, usually with a sclerotic border. All radiographs were evaluated and measured by a single observer (AGDV) who was not involved in the surgery, to avoid inter-observer variation and outcome bias.

Results

Clinical results

None of the patients developed aseptic loosening of the femoral component or required revision for any reason. The HSS hip score improved from an average of 16.7 points (range 12–32) preoperatively to 37.8 points (range 28–40) postoperatively at an average follow-up of 6.13 years (range 4–8.5) ($P<0.0001$) (Table 1). The clinical results at the last follow-up in the 64 living patients was excellent in 61 patients, and good in three. Two patients (2.8%) had a dislocation of the prosthesis at four and seven years after primary surgery. They both had 28-millimeter heads. They were treated with closed reduction and instructed to follow dislocation precautions, without recurrence.

Radiographic results

The average alignment of the stem was 0.04° (range: −3 to +2). The cement mantle was classified as type A in 12 hips, B in 40, C1 in 16, and C2 and D in one hip each. At an average follow-up of 6.2 years (range 4.2–8.5), all 55 femoral components were radiographically well fixed. There were no progressive radiolucent lines.

Four hips (7.2%) demonstrated osteolytic lesions. The first patient was a 61-year-old female who sustained a periprosthetic fracture in a skiing accident 26 months after surgery. The fracture occurred in the proximal femur, at the level of the lesser trochanter (Type B1 of the Vancouver Classification [5]); it was minimally displaced, but the fracture extended through the proximal cement mantle (Fig. 2a). The mid and distal stem remained well-fixed. The patient was treated conservatively, with an uneventful healing of the fracture. Five years after the fracture, she developed an osteolytic lesion in Gruen zone 2, where the cement fracture had occurred (Fig. 2b). The second patient was a 40-year-old female who underwent total hip replacement after a failed core decompression for osteo-

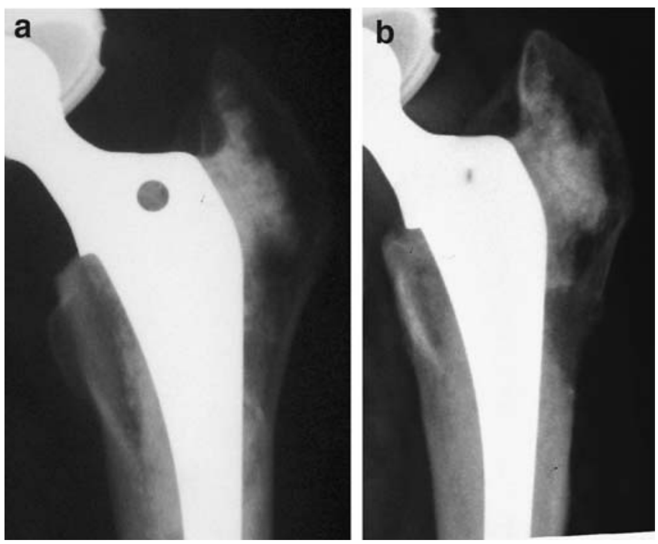

Fig. 3 **a** Postoperative radiograph of a total hip arthroplasty with the VerSys CT stem after a failed core decompression for osteonecrosis of the femoral head. **b** Eight years later, osteolysis developed at the site of the lateral femoral opening. The stem remains well fixed

Table 2 Mid-term results of other polished stems

Author	Year of publication	Femoral stem	Number of hips	Mean age at surgery (years old)	Revisions for femoral aseptic loosening	Radiolucent lines/ osteolysis (%)	Follow-up (years)
Wroblewski et al. [39]	2001	C-Stem	500	53.7	0%	NA (*)	3.5
Williams et al. [37]	2002	Exeter Universal	325	67.5	0%	8.9	10 to 12
Yates et al. [40]	2002	CPT	76	65	0%	7.9	5
Present study	–	VerSys CT	70	69	0%	7.2	6.1

(*) NA: not available. No stem was considered to be at risk of loosening

necrosis (Fig. 3a). Eight years after THA, she presented with an osteolytic lesion at the level of the femoral window in the lateral femoral cortex (Fig. 3b). The third patient was a 66-year-old male who developed a 10×5 mm osteolytic lesion in Gruen zone 6, five and a half years after surgery. The fourth patient was a 74-year-old male with osteolysis in the greater trochanter, in association with accelerated polyethylene wear (0.26 mm/year). These four patients have well-fixed stems, are asymptomatic, and the osteolytic areas are under observation with radiographic follow-up every 6 months. They are treated with calcium, vitamin D and diphosphonates and have been advised to avoid strenuous activities.

Discussion

In this study, we report the mid-term clinical and radiographical results of a cemented polished tapered stem for total hip arthroplasty. The design of the stem is inspired by the original Charnley stem, with the addition of proximal and distal centralisation to achieve a homogeneous, circumferential cement mantle. The stems were implanted with modern cementing technique [26].

At 4.2 to 8.5 years of follow-up, the results have been excellent, with no mechanical failures. Low rates of aseptic loosening and osteolysis have been also reported for other modern, polished tapered stems at intermediate follow-up (Table 2). These findings contrast with the high rates of revision for aseptic loosening observed by us [15], and reported by several surgeons, with rough or precoated stems at similar follow-up (Table 3).

During the first three months of this study, the senior author implanted two other versions of the cemented VerSys femoral stem : one was collared, proximally textured, with a rough surface finish (Ra 1.4–2 μm), and the other was identical but with a satin finish (Ra 0.4–0.5 μm). They were implanted according to availability, with identical cementing techniques and with the same acetabular component (Trilogy). All patients have been followed up for a minimum of four years (range: 4 to 6.8), or until death or failure. The clinical results have been recently reported [15] and serve as a historical control. Among 64 rough VerSys stems, eight (12.5%) developed aseptic loosening to date. Among 138 satin VerSys stems, none developed aseptic loosening. The femoral bone cement interface revealed progressive radiolucent lines or osteolysis in ten of 64 rough stems (15.6%) and in three of 138 satin stems (2.2%).

In the current study, osteolysis occurred in four patients (7.2%) with well-fixed cemented femoral stems. In three of these patients, osteolysis could be related to the following factors: a proximal periprosthetic fracture compromising the cement integrity in one (Fig. 2a), the site of a previous

Table 3 Series reporting failures with different roughened or precoated stems

Author	Year	Femoral stem	# of hips	Mean age at surgery (years old)	Revisions for femoral aseptic loosening	Follow-up (years)
Callaghan et al. [7]	1996	Iowa Precoat	131	68	6.1%	8 to 9
Sporer et al. [34]	1998	Iowa Precoat	45	<50	18%	5 to 10
Dowd et al. [13]	1998	Harris Precoat	154	70	13.6%	6.3
Kawate et al. [25]	1999	Harris Precoat	55	67	5.5%	8
Sylvain et al. [35]	2001	Centralign Precoat	84	61.4	11%	2.9
Ong et al. [28]	2002	Harris Design-2	192	59	4.16%	13.5
Ong et al. [28]	2002	Harris Precoat	429	55	10%	8.4
Sanchez-Sotelo et al. [31]	2002	Harris Design-2	249	66	7%	10 to 20
Grose et al. [17]	In press	Spectron EF	20	62	25%	5.2
Datir et al. [41]	2005	Harvard	51	66	16%	10

Table 4 Comparative analysis between the present study and our historic control groups

	Stem design	Ra (μm)	Number of hips	Average followup (years)	Osteolysis/radiolucent lines (number of cases and %)	Revisions for aseptic loosening (number of cases and %)
Present study	VerSys CT	0.05	54	6.1	4 (7.2%)	0 (0%)
Historic control groups	VerSys Satin (25)	0.4–0.5	138	5.2	3 (2.2%)	0 (0%)
	VerSys Rough (25)	1.4–2	64	5.7	10 (15.6%)	8 (12.5%)

core decompression in another (Fig. 3a), and accelerated polyethylene wear in the third. No clear explanation for the small osteolytic lesion in the fourth patient could be established.

Several authors have observed a communication of the stem–cement interface with the bone–cement interface in well-functioning and failed total hip replacements [22, 32]. Such communication can be present from the time of implantation, if the cement mantle is not circumferential and homogenous; or if there are cement voids [22], or cracks occuring before or after stem loosening [22, 36]. When such communication exists, osteolysis may develop [1, 23, 32]. Anthony et al. [1] described the flow of particle-loaded fluid at the stem–cement interface as a possible cause of femoral osteolysis in Exeter cemented femoral stems. He postulated that polyethylene loaded synovial fluid can flow at the stem–cement interface when there is no bond between the metal and the cement. In addition, in areas of incomplete cement mantle or at the site of cement cracks, the synovial fluid is forced by the cyclical local loads into the biological interface, generating osteolysis.

In conclusion, there were no mechanical failures in this series and in the satin historical controls. Despite the relatively small series presented in this study, these favourable results are significantly better than our experience with the rough VerSys stem, in which there were eight (12.5%) mechanical failures, requiring revision (p=0.03) (Table 4). We continue to follow up our patients prospectively to determine if the favourable mid-term results persist over time. Based on our experience [11, 15] and that of others (Tables 2 and 3), we believe that the surface finish of cemented femoral stems should be satin or polished.

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