

Excellent results from proximally HA-coated femoral stems with a minimum of 6 years follow-up

A prospective evaluation of 100 patients

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Background There have been few reports on the mid- and long-term follow-up results of the proximally HA-coated femoral stem. We evaluated this type of stem prospectively, with 6–12 years of follow-up.

Methods The survival rate, Harris hip score and radiographic features of 106 hips in 100 consecutive patients were evaluated. The mean age at operation was 51 years (SD 8.2).

Results The mean Harris hip score at the time of the latest follow-up was 95 points. Spot welds occurred in 95% of the patients and were first observed at a mean follow-up of 1.4 years in one or more of the Gruen regions, corresponding to the coated part of the femoral stem. A higher grade of stress shielding correlated with a less favorable Harris hip score and pain subscore. According to the criteria of Engh, all stems were graded as stable and durable bone-ingrown. No femoral component was revised.

Interpretation At an average follow-up of 8 years, this proximally HA-coated femoral component showed favorable clinical and radiological outcome and excellent survivorship.

To our knowledge, there have been relatively few reports on the HA-coated, uncemented femoral stem with a follow-up of 5 years or more (Capello 1994, D'Antonio 1996, Capello et al. 1997, Araujo et al. 1998, Rokkum et al. 1999, McNally et al. 2000, Tonino et al. 2000, D'Antonio et al. 2001, Capello et al. 2002, 2003, Geesink 2002, Hernandez Cortes et al. 2002, Reikerås and Gunderson

2003, Skinner et al. 2003, Theis and Ball 2003, Oosterbos et al. 2004). In 7 of these studies, proximally HA-coated stems were used.

Our prospective single-center study concerns the 6–12 year follow-up results of an uncemented titanium-alloy femoral component. We hypothesized that there would be a clinical and radiographic advantage of using the proximally HA-coated femoral stem relative to the recently published results of its porous-coated variant (Meding et al. 2004).

Patients and methods

118 primary cementless total hip arthroplasties were implanted in 112 patients between 1992 and 1998. 6 patients were operated bilaterally. During the follow-up period, 7 patients died. None of these deaths were related to the index operation. 5 patients moved and were unable to return for follow-up. Thus, 106 hips in 100 patients underwent clinical and radiographic examination (Table 1). The mean follow-up time was 8.3 (6–12) years.

From 1992 until the time of writing, we have used the Bi-Metric stem (Biomet, Warsaw, IN) as primary uncemented total hip arthroplasty at our hospital. This stem has a 3° tapered stem design, 0° anteversion, a CCD-angle of 135° and is available in 11 sizes. The diameter of the reamers used at insertion corresponds to the stem diameter. The proximal one-third of the stem is plasma-sprayed with an HA-coating of approximately 50 µm thickness. This coating has a crystallinity of 50–70%

Table 1. Patient characteristics

No. of hips	106
No. of patients	100
Gender ^a	
Male	43 (43%)
Female	57 (57%)
Height (m)	1.73 (1.53–1.92)
Weight (kg)	80 (55–120)
Body Mass Index	27 (19–39)
Age at operation (years)	51 (22–63)
Diagnosis ^b	
Osteoarthritis	81 (76%)
Osteonecrosis	17 (16%)
Rheumatoid arthritis	3 (3%)
Developmental dysplasia	3 (3%)
Post-trauma	2 (2%)
Side ^b	
Right	55 (52%)
Left	51 (48%)
Approach ^b	
Posterior	97 (92%)
Lateral	9 (8%)
Follow-up	
Average (years)	8.3 (SD 1.7)

^a number of patients (percentage)
^b number of hips (percentage)

and a minimal phase purity of 95%. The distal non-coated part is grit-blasted with a roughness of approximately 5.7 µm.

A Ringloc (Biomet) acetabular component—the multi-holed variant until 1994 and the solid variant thereafter—was used. Systemic prophylactic antibiotics (cefazoline 2 g intravenously) and pharmacological thromboprophylaxis (initially nandroparin 7500 IU subcutaneously the first days and followed by and acenocoumarol—target INR 2–3—until 3 months postoperatively) were used.

Patients with a minimum follow-up of 6 years were included in the study. They were evaluated preoperatively and postoperatively at 6 weeks, 3 months and 6 months, 1 year, and annually thereafter. We monitored the Harris (1969) hip score. Pelvic anteroposterior and lateral hip radiographs were taken postoperatively, after one year, and annually thereafter. Spot welding, a sign of endosteal condensation and osseointegration, the presence of radiodense or radiolucent lines in each Gruen et al. (1979) region and the time when these changes appeared for the first time was recorded. Pedestal formation (endosteal reactive radiodensity, distally from the tip of the stem), grading of heterotopic bone formation (Brooker et al. 1973),

osteolysis, grading of stress-shielding (Engh et al. 1987) and cortical hypertrophy were noted. We measured the radiographic difference in leg length (Woolson et al. 1999) and varus/valgus shifting of 5o or more of the stem (Khalily and Lester 2002). Directly after the operation and at the final follow-up, subsidence was recorded if 2 mm or more was observed between the superior tip of the greater trochanter and a standard point at the prosthesis (Engh et al. 1990). With these parameters, the state of bone-ingrowth was evaluated according to the criteria of Engh et al. (1990).

Kaplan-Meier analysis of the survival of the femoral component was performed for all hips from the original cohort. The best-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result throughout the study period), the standard-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result at the time of the last follow-up) and the worst-case scenario (in which all hips with less-than-complete follow-up were considered to have failed) were determined.

Statistics

Statistical analysis was performed using SPSS software (SPSS 11.0, Chicago, IL). Student's t test and linear regression were used, and significance was assumed if $p < 0.05$.

Results

Clinical

We recorded a median preoperative Harris hip score of 56 (12–79) and a subscore of 20 (10–30) points for pain. This score improved to a median of 95 (36–100) and 40 (10–44), respectively, at the final follow-up. The improvement was mainly observed in the first year after surgery (Table 2). 6 patients complained of moderate, activity-related thigh pain, with an average Harris hip score and pain subscore of 92 and 37 at final follow-up.

Radiographic findings

Spot weld formation was observed in 95 of the cases in one or more of the Gruen regions 1, 7, 8 and 14 (mostly at the medial or lateral junction of

Table 2. Average Harris hip score and pain subscore during follow-up

Postoperative time	Average Harris hip score (SD)	Average pain subscore (SD)
Preoperative	56 (11)	15 (6)
6 weeks	78 (13)	40 (6)
3 months	88 (11)	42 (6)
6 months	93 (12)	41 (6)
1 year	96 (11)	42 (6)
5 years	95 (10)	42 (5)
10 years	96 (6)	43 (3)

the coated to uncoated part), corresponding to the HA-coated proximal one-third of the stem (Table 3). All spot welds occurred within the first five years postoperatively, but predominantly (70–80%) during the first postoperative year.

All hips showed grade 1 stress shielding (rounding of the calcar) at 1 year. Grade 2 stress shielding (loss of medial cortical density in zone 1) occurred predominantly 2 or 3 years postoperatively. Grades 3 (loss of medial cortical density in zone 2) or 4 (loss of medial cortical density distal from zone 2) were rarely seen (Table 4). Linear regression showed that a higher grade of stress shielding was significantly correlated with a less favorable Harris hip score and pain subscore (Table 5). Typical signs of stress transfer, such as distal cortical hypertrophy and pedestal formation, were frequently observed.

Table 3. Prevalence of spot weld formation per Gruen zone (%)^a

Zone	Year					Cumulative percentage at 5 years of follow-up
	1	2	3	4	5	
1	67	20	5	1	2	95
2	33	7	1			41
3	17	5	1			23
4	7	1	1	1		10
5	16	5	2			23
6	20	3	2			25
7	62	6	6	1	1	76
8	64	9	4	1	1	79
9	14	2	1			17
10	7	2	1			10
11	3	1	1			5
12	6	2	2			10
13	9	1	1			11
14	66	8	3	1	2	80

^a Zones representing the HA-coated part of the femoral stem are shown in bold.

Reactive lines or adverse clinical features were not observed in any of the hips showing a pedestal. 7 hips showed radio-dense lines which were located in the Gruen regions corresponding to the HA-coated part of the stem. In the uncoated, distal part, all but one of the other lines were located round the tip of the stem and continued to a pedestal (13 hips).

Table 4. Prevalence of the radiological parameters according to Engh (1987, 1990) (%)

Parameter	Year						Cumulative percentage at 6 years of follow-up
	1	2	3	4	5	6	
Spot welds	67	20	5	1	2		95
Radio-dense lines (HA)	4	1	1				6
Radio-dense lines (Non-HA)	10	1	1	1			13
Stress shielding							
Grade 1	100						100
Grade 2	9	46	16	1	4		76
Grade 3	1	5	2	2	0	6	16
Grade 4	1	2	1	1	1		6
Cortical hypertrophy	24	31	13	6	4		78
Pedestal	12	26	21	6	2		66
Intramedullary osteolysis	0	0	0	1			1
Subsidence	33						33

Table 5. Relationship between the mean Harris hip score, pain subscore and grade of stress shielding

	Grades of stress shielding				Adj. R ²	P-value ^a
	1 (n 36)	2 (n 55)	3 (n 8)	4 (n 7)		
Average Harris hip score (SD)	98 (4)	96 (9)	87 (13)	85 (24)	0.11	0.002
Average Pain score (SD)	44 (1)	43 (4)	42 (5)	36 (14)	0.11	0.002

^a Linear regression.

Distal intramedullary osteolysis was identified in 1 hip in Gruen regions 1 and 7 at 6 months, and disappeared after 4 years; spot welds occurred at 5 years postoperatively in these regions. According to the limits described by Engh et al. (1990), 35 stems subsided, of which 7 stems subsided by 5 mm or more. All cases of subsidence were observed in the first postoperative year.

Preoperatively, an average difference in leg length of 2 mm (operated side shorter) was measured. In the 7 patients with a subsidence of 5 mm or more, a decreased leg length of 6 mm was observed, while the average leg length in all hips was 0.5 mm (operated side longer) at final follow-up ($p = 0.05$, Student t-test).

According to the criteria of Engh et al. (1990), all stems showed bone ingrowth and stability 1 year after the operation and thereafter. All but 2 stems were placed within 5° of alignment. 1 stem was placed in 6° valgus and one in 8° varus; both stems stayed in their position during follow-up. Heterotopic bone formation was observed in 28 hips, of which 24 had a posterior approach and 4 a lateral approach. According to Brooker, 25 hips showed grade 1, 1 hip showed grade 2 and 2 hips showed grade 3 heterotopic bone formation, all at the first year follow-up, without progression later. 4 hips, all of which had been operated with a posterior approach, dislocated during follow-up. 3 hips dislocated once: 2 in the first year and one 8 years postoperatively. 1 hip underwent revision of the acetabular component after 3 episodes of dislocation, with a successful result. This revision was the only one in the study, thus none of the femoral stems were revised. Survival of the femoral component of the original cohort at final follow-up was 100% (95% CI: 99–100) in a best-case scenario, 100% (95% CI: 99–100) in a standard-case sce-

nario and 90% (95% CI: 89–91) in a worst-case scenario.

Discussion

HA coating

Hydroxyapatite is the crystalline portion of natural bone mineral. Synthetic HA is biocompatible and osteoconductive, and when in contact with bone it often develops a mechanically tight bond (Geesink et al. 1988) which is probably of a chemical nature (van Blitterswijk et al. 1985). Human retrieval studies have shown that the formation of newly woven bone adjacent to the HA layer does not pass through an intermediate stage of fibrous tissue, and therefore secondary fixation is enhanced in this prosthesis (Bauer et al. 1991).

Porous versus HA-coated implants

Coathup et al. (2001) investigated human retrievals on the implant-bone interface around the proximally HA-coated and porous-coated Bi-Metric femoral stem and observed significantly more ingrowth and attachment of bone to the HA-coated surface. Studies evaluating (both clinically and radiographically) proximally HA-coated stems and also a porous-coated version of the stem as used in the present study, all with a follow-up of 5 years or more, are listed in Table 6. As various reports were essentially based on the same cohort, we selected studies most suitable in our opinion (D'Antonio et al. 2001, Oosterbos et al. 2004). Compared with a porous-coated variant with identical geometry, matched pair or bilateral studies established a clinical and radiographic (Soballe et al. 1993, Donnelly et al. 1997) or only radiographic (McPherson et al. 1995, Scott and Jaffe 1996) advantage of the HA-

Table 6. Summary of results of minimum 5-year follow-up with proximally HA-coated stems* and a proximally porous-coated Bi-Metric stems

	Carcia Araujo (1998)	Theis (2003)	Oosterbos (2004)	D'Antonio (2001)	Geesink (2002)	Hernandez (2002)	Skinner (2003)	Current study	Meding (2004)
Type of stem	ABG (HA)	ABG (HA)	ABG (HA)	Omnifit (HA)	Omnifit (HA)	Ti fit (HA)	Freeman (HA)	Bi-metric (HA)	Bi-Metric (PC)
Patients (hips) in follow-up	32 (33)	69 (82)	62 (68)	314 (274)	118 (99)	52 (52)	100 (100)	106 (100)	105 (95)
Years of follow-up (range)	5 (NR)	7.3 (5–10)	10	11.1 (10–13)	12 (11–13)	11 (NR)	10	8.3 (6–12)	10.4 (10–12)
Age (range)	51.4 (25–78)	57.4 (31–74)	72 (55–84)	51 (18–81)	53 (21–73)	65 (45–67)	56.8 (NR)	51 (22–63)	56 (27–78)
Clinical results ^a	G/ E ^b	G/E ^b	G/E ^b	E ^c	E ^c	G/E ^b	NR	E ^c	E ^c
Spot welds (%) (location; or/ if Gruen-zones)	52	54	77, 80	89	NR	NR	83	95, 76	62
Radioactive lines (%)	2, 6	M&LJ	M&LJ	MJ	NR	NR	M&LJ	M&LJ	NR
(% HA-coated; % non-coated)	30	75	43	55	NR	31	50	19	10
Cortical hypertrophy (%)	0	0	0	2.5		NR	11	6	NR
Pedestal (%)	30	75	43	52		NR	39	13	NR
Subsidence (% P) (mm)	NR	NR	29	62	NR	42	NR	78	83
Distal intramed. osteolysis (%)	NR	NR	NR	NR	NR	4	NR	66	47
% Heterotopic bone formation (grade and %)	6	1	1	1.3	NR	0	100	7.5	1
Dislocation (%)	2–5	NR	> 5	> 3			< 7.6	> 5	> 5
Stems revised (%)	NR	NR	2	0	0	1.9	1	1	1
Cups revised (%)	48	41	46	26	NR	23	NR	26	NR
Grades of stress shielding (%) (Gruen zones if grade is NR)	1: 33	1–2: 40	1–2: 45	1–3: 24		1–2: 20		1–2: 24	
Stable fixation (%) ^d	0	6	3–4: 1	3: 1	4: 2	0	NR	3: 3	3: 2
	0	1	NR	NR	3.3	7.6	0	NR	3.8
	0	1	4	3	7.6	0	0	0	0
	0	3.6	3	12.1	4.2	9.6	3	1	9
	70	11	1: 51	NR	NR	NR	NR	1: 100	1: 100
	30	zone 6, 7	2: 73					2: 76	2: 100
	zone 1, 2							3: 15	3: 53
	NR	NR	100	100	100	88	NR	4: 6	4: 17
								100	100

^a E Excellent, G Good
^b Harris hip score.
^c Merle d'Aubigne score.
^d According to Engh et al. 1990
NR = Not recorded.

coating, while others could not demonstrate a difference (Rothman et al. 1996, Dorr et al. 1998, Yee et al. 1999, Sharp et al. 2000, Kim et al. 2003).

Soballe et al. (1993) used X-ray stereophotogrammetric analysis to detect differences in migration in identical HA-coated and porous-coated Bi-Metric stems. HA-coated stems stop migrating at three months postoperatively, whereas porous-coated stems continued to migrate for at least

1 year. Significantly higher Harris hip and pain scores were found in the HA-coated group. The latter report and those of others (Table 6) were not in accordance with the results of our study, where vertical migration of the stem was evident in two-thirds of the hips, which is rather high. According to Engh et al. (1990), the limits of error, measuring subsidence, are 2 mm or more. Meding et al. (2004) used a limit of 5 mm (Loudon 1986) and had only

one case above that limit. In our study there were 7 cases which showed subsidence of more than 5 mm. There was no adverse relationship between subsidence of 2 mm or more and clinical or radiographical results, apart from the subsequent leg-length difference in patients with a subsidence of 5 mm or more at final follow-up.

An average increase in bone mineral density value of 48% was observed around HA-coated implants, when compared with bilaterally-placed porous-coated implants of the same geometry (Scott et al. 1996). In comparison with their porous-coated variant (Meding et al. 2004), our stems showed more spot welds—which also developed earlier. In conclusion, radiographically, an earlier and more stable state of bone ingrowth (according to Engh) was observed in the HA-coated stem than in the porous-coated variant.

Stress shielding

Morscher and Dick (1983) concluded that the stress concentrations will increase with increasing rigidity of the implant. Engh et al. (1987), however, found that stress-related bone loss does not influence the clinical results adversely. In our study, a less favorable Harris hip score and pain subscore were correlated with higher grades of stress shielding. Compared to the HA-coated stem in this study, its porous-coated variant showed a higher incidence of stress-shielding for all grades, but relation to clinical findings was not recorded (Meding et al. 2004). It can be hypothesized that there is more and earlier cancellous bone formation at the HA-coated part and therefore less distal stress concentration and bone remodeling. Although studies with fully HA-coated stems show favorable results (Rokkum et al. 1999, McNally et al. 2000, Reikerås et al. 2003), proximally ingrown uncemented implants can be expected to result in a more uniform stress transfer over the full length of the stem, and should therefore show less stress shielding than fully ingrown press-fit stems (Huiskes 1990).

Cortical hypertrophy

Distal cortical hypertrophy can serve as a secondary stabilizer of the stem (D'Antonio et al. 2001). Adolphson (1997) evaluated distal cortical hypertrophy in the same HA-coated stem as used in the current study. In contrast to cemented

hip arthroplasties, they observed an increase in the outer diameter of the distal femur and no widening of the distal medullary canal in cases of cortical hypertrophy, as in the present study. It was concluded that the uncemented HA-coated device causes a different stress transfer to the cortical femoral bone, compared with the cemented device.

Compared to other studies listed in Table 6, the incidence of cortical hypertrophy was rather high in our study. The incidence in our material is rather close to that of the porous-coated variant of the same implant (Meding et al. 2004), which suggests that the anatomical design of the stem is the main reason. Hernandez Cortes et al. (2002) suggested a relationship between cortical hypertrophy, endosteal irritation and thigh pain, a theory not supported by our findings.

Osteolysis

Similar to the stem materials presented in Table 6, which are all representative designs with circumferential, proximal coating, our study also shows a very low incidence of distal intramedullary osteolysis. Non-circumferential coating has been associated with a higher prevalence of osteolysis (Clohisy and Harris 1999). Thus, the circumferential bone ingrowth possibly has a relative sealing influence and may impede polyethylene from migrating distally into the femoral canal.

To conclude: the survival rate of the evaluated proximally HA-coated femoral component is excellent. This stem showed no obvious advantage over the porous-coated variation of this design (historical control).

No competing interests declared.

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