Fixation and metal release from the Tifit femoral stem prosthesis

5-year follow-up of 64 cases

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We stratified the fixation of the femoral component in 64 hips with degenerative joint disease into 3 groups, cemented (C), proximal hydroxyapatite coating (HA) or proximal porous coating (P). All implants had the same basic design and were made of TiAlV alloy. The migration of the implants was assessed by radiostereometry. After 5 years, the mean subsidences in the cemented and porous-coated groups were 0.16 and 0.31 mm, whereas the HA-coated implants displayed a mean proximal migration of 0.1 mm. 7 stems (2 C, 1 HA, 4 P) showed a continuous subsidence (> 0.25 mm) between the 2- and 5-year follow-up. 1 porous-coated stem was revised after the 2-year follow-up, because of pain and implant failure (previously reported) and 1 cemented stem was revised after 5 years because of pain and osteolysis.

In a subset of patients, all with a femoral head made of aluminum oxide, the levels of metal were determined using atomic adsorption spectrometry. Subsidence of the stem between the 2- and 5-year follow-up was associated with increased levels of aluminum in the blood at 2 years. Generation of metallic particles from abrasive wear of the stem followed by third body abrasion of the ceramic femoral head could be one explanation of this finding.

5 hips which had shown high levels of titanium and aluminum in joint fluid at the 2-year follow-up displayed increased subsidence and developed proximal radiolucencies or osteolysis at the 5-year follow up. One of these was the cemented hip which was subsequently revised.

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Submitted 97-05-04. Accepted 98-01-05

In animal models, coating of non-porous metallic implant with hydroxyapatite (HA) may result in a stronger interface; HA-coating may stimulate bony fixation (Søballe 1993). Retrieval studies have suggested that these observations have relevance also as regards porous-coated implants in patients (Bloebaum et al. 1993). Radiostereometric studies up to 2 years after implantation have revealed that coating with hydroxyapatite (Søballe et al. 1993, Önsten et al. 1996a) or a mixture of HA and tricalciumphosphate (Kärrholm et al. 1996) will result in small early micromotions suggesting long-term survival. Adverse reactions to particulate HA, resorption of the coating or wear have been proposed as possible causes of failure with these implants, but so far this has not been reported to be common (Geesink and Hoefnagels 1995, D'Antonio et al. 1996, Vedantam and Ruddlesdin 1996).

In 1989, we initiated a radiostereometric study of femoral stems made of Ti-6Al-4V alloy (Tifit, Smith and Nephew, Memphis, Tennesse, USA), where the fixation was randomized to cementing, HA or porous coating. In a subset of these patients, samples of blood, urine and joint fluid were analyzed with respect to the contents of titanium, aluminum and vanadium (Kärrholm et al. 1994b). The results up to 2 years after implantation have been reported (Kärrholm et al. 1994c). We now present the 5-year follow-up data.

Patients and methods

64 hips (60 patients) with primary or secondary arthrosis of the hip were studied. There were 28 men and 32 women with a median age of 55 (38–66) years. The fixation of the femoral stem was stratified into cemented fixation (C, n 20), proximal HA coating (HA, n 23) or proximal porous coating (P, n 21) of the stem, based on age, gender, weight, radiographic

Table 1. Number of hips evaluated at the radiostereometric examinations

Months after operation	Evaluation of translations/rotations		
	Cemented	HA-coated [a]	Porous-coated [a]
2	19/17	18/11	19/17
6	20/18	20/9	19/16
12	20/17	18/12	19/15
24	20/16	21/12	19/14
60	19/17 [b]	21/17	18/16 [c]

[a] 2 cases primarily excluded, due to poor quality of postoperative radiographs
[b] 1 patient died
[c] 1 patient revised because of loosening

bone quality and type of arthrosis. All stems were of the same basic design. The stems used for cemented fixation had a grit-blasted surface. The HA coating was placed on the proximal third of the prosthesis, the distal third was grit-blasted. A non-circumferential porous coating was placed on the proximal third of the implant in the third group. The remaining part of the surface was polished. Details of these surface treatments have been described in a previous report (Kärrholm et al. 1994c). All patients received a hemispherical and porous-coated press-fit cup with additional screw fixation (Harris-Galante I or II, Zimmer, Warshaw, USA). A modular 32 mm femoral head made of aluminum oxide (n 60) or cobalt-chromium (n 4) was used.

Tantalum markers were inserted into the proximal femur and into the femoral stem after predrilling. 2 markers were inserted into the prosthetic shoulder, 3 were inserted along the medial side of the stem and 1 at the tip. In cases where the edge of the femoral head could be accurately visualized, we also computed the position of the femoral head center. In 12 cases this point was included in the femoral segment.

Radiostereometric examinations were done postoperatively (7–10 days), after 2 and 6 months, 1, 2 and 5 years (Table 1). At the last follow-up, 6 patients were not evaluated with radiostereometry. 1 patient had died after the 2-year follow-up due to heart disease (C), 1 had been revised 2 years and 2 months after the index operation, because of stem loosening and fracture of the prosthetic collar (P), and in 4 cases the quality of the postoperative stereoradiographs did not allow a proper evaluation.

Vertical migration, subsidence (–) or proximal migration (+) were represented by translations of the center of gravity of the implant markers. Rotations are also accounted for. During the follow-up of these patients, three different radiostereometric set-ups were used. The one with the most inferior precision was employed (Kärrholm et al. 1994c).

Conventional radiographic examinations were done postoperatively, after 2 and 5 years. The radiographic evaluation was done according to Kärrholm and Snorrason (1993) and Kärrholm et al. (1994c). Measurements on conventional radiographs were done on a digitizing table (Ortho-Graphics Inc., Salt Lake City, UT, USA) connected to a computer. Because lateral radiographs of sufficient quality were available in only half of the cases, the analysis of radiolucent lines on these radiographs is not presented.

Measurements of bone mineral density were done at the 5-year follow-up in 25 cases with uncemented prostheses (13 HA, 12 HA), using a Lunar DPX-L. The selection of these patients was primarily based on the willingness of the patient to undergo this type of examination. Because no postoperative examination was available, we calculated only the relative distribution of bone mineral in terms of quotients between the distal and the proximal regions of the femur on the medial (Gruen regions 5/7) and the lateral (regions 3/1) sides of the stem.

At 2 years, samples of joint fluid were obtained from 19 of the 36 hips operated on in Umeå (Kärrholm et al. 1994b). All these 36 hips had femoral heads made of aluminum ceramic. No samples of joint fluid were collected at the 5-year follow-up. Samples of blood and urine were taken from 28/22 and 22/18 patients at the 2/5-year follow-ups, respectively. In this presentation, mainly paired observations corresponding to successful analyses at both the 2- and 5-year follow-ups were evaluated. Sampling and storage were done using selected materials to avoid contamination. Atomic absorption spectrometry (Perkin-Elmer Model 4100 ZL) was used to determine the levels of titanium, aluminum and vanadium. At the first evaluation the instrumental detection limits (3 SD) for blank solutions were 1.3, 0.8 and 0.4 ng/g for these 3 metals, respectively. The detection limits, including the entire process, were found to be twice as high at the time of the 2-year follow-up. Improvements in the technique at the 5-year follow-up, resulted in better accuracy for titanium and aluminum (< 2 and < 1 ng/g, respectively).

The clinical follow-up (Harris hip score) after 5 years and the change of scores in relation to the preoperative evaluation are presented.

Statistics

All evaluations were done using SPSS for Windows (7.5.1, SPSS Inc. Chicago, IL, USA). In a previous study (Kärrholm et al. 1994a), we noted that recordings of the direction of the migration of the stem have clinical relevance. The statistical analysis was there-

Table 2. Distal (-) / proximal (+) migration of stem center in mm. See Table 1 for number of hips at each follow-up occasion. Median (1), range (2) and 95% confidence limits (3)

	Cemented			Hydroxyapatite-coated			Porous-coated		
	1	2	3	1	2	3	1	2	3
2 months	0.01	-0.27–0.21	-0.23–0.23	0.03	-0.6–0.23	-0.46–0.43	-0.07	-0.36–0.30	-0.39–0.26
6 months	-0.01	-0.28–0.37	-0.30–0.28	0.04	-0.9–0.22	-0.70–0.64	-0.10	-0.70–0.20	-0.57–0.36
1 year	0.00	-0.56–0.25	-0.38–0.30	0.07	-1.20–0.80	-0.81–0.81	-0.09	-0.70–0.40	-0.65–0.40
2 years	-0.13	-0.78–0.28	-0.66–0.34	0.05	-1.20–0.82	-0.59–0.70	-0.10	-2.73–0.30	-1.78–1.15
5 years	-0.16	-1.61–0.22	-1.05–0.65	0.07	-1.26–0.86	-0.74–0.85	0.00 [a]	-3.18–0.32	-1.45–0.32

[a] 1 stem revised after the 2-year follow-up

fore based on signed values. Non-parametric tests were used, because most of the parameters analyzed were not normally distributed. Comparisons between the 3 modes of fixation were mainly based on Kruskal-Wallis tests to reduce the number of computations. If a difference was regarded as established ($p < 0.05$), further analysis using the Mann-Whitney U-test was done. When the sample sizes were small, SPSS Exact tests™ were used to obtain the exact probability of a certain outcome.

Results

Radiostereometry—proximal (+)/distal (–) migration of stem center

At the 5-year follow-up, the median migration in the 3 groups (C, HA, P) were –0.16, 0.07 and 0.00, respectively ($p = 0.02$, Kruskal-Wallis test; Table 2; Figure 1). The HA-coated stems displayed less subsidence than the cemented ones ($p = 0.006$, Mann-Whitney U-test), but not significantly less than the porous stems ($p = 0.06$). The amount of subsidence at 2 years correlated to the values recorded at the next follow-up occasion (Spearman's rho = 0.67, $p < 0.0005$).

At the 2-year follow-up, 14 stems (5 C, 2 HA, 7 P) had subsided 0.25 mm or more (99% significance limit). In 3, all with porous coating, the distal migration was 1 mm or more (1.0–2.7 mm). 1 of these was revised after the 2-year follow-up. 1 HA-coated and 2 porous-coated stems continued to subside (> 0.25 mm) between 2 and 5 years. 4 more stems (2 C, 2 P) with a subsidence smaller than 0.25 mm up to 2 years, migrated (> 0.25 mm) distally during this period. In 2 cases (1 C, 1 P) there was a substantial increase between the 2- and 5-year follow-up (1.4 and 3.1 mm).

Radiostereometry—rotations

The median rotations of the stem up to 5 years were less than 0.5 degrees in all groups (Table 3). The widest scatter was noted, when rotations around the longitudinal axes were analyzed (retro- or anteversion). Maximum rotation into retroversion of 9–10 degrees was recorded in one cemented and one porous-coated stem. The 2 uncemented designs displayed increased valgus rotation of the stem (C vs. HA: $p = 0.01$; C vs. P: $p = 0.005$, Mann-Whitney U-test).

Conventional radiography

The relative length of the radiolucent lines increased between the 2- and 5-year follow-up in the cemented ($p = 0.02$, Wilcoxon signed ranks test), but not in the cementless groups (HA: $p = 0.07$, $P = 0.5$; Table 4). The increase in the cemented group was small and the distribution between the different modes of fixation

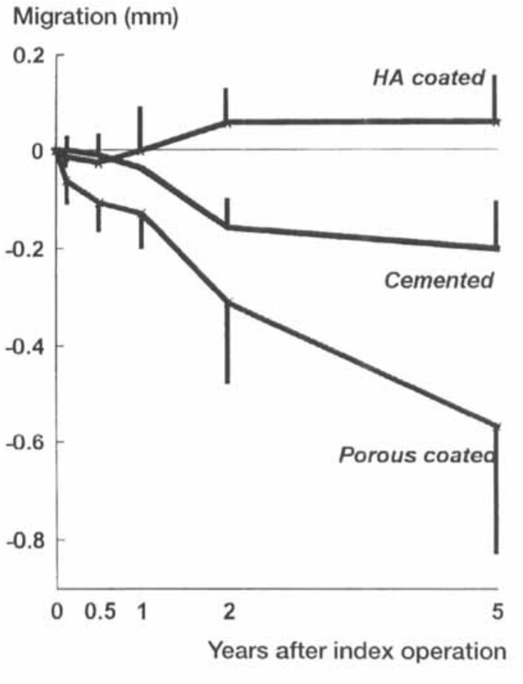

Figure 1. Proximal (+) / distal (–) migration of stem center. Mean and SEM.

Table 3. Rotations of the stems 0–5 years in degrees. Median (1), range (2), number of implants showing migration above the 99% significance limit of the RSA method (3) and 95% confidence limits of the recorded values (4)

	Cemented, n 17				Hydroxyapatite-coated, n 17				Porous-coated, n 16				
Rotations, degrees	1	2	3	4	1	2	3	4	1	2	3	4	p-value [a]
Anterior tilt [b]	0.4	-1.0–0.9	7	-1.3–1.3	-0.2	-1.4–0.6	5	-2.9–2.3	-0.2	-1.6–0.9	4	-1.5–1.0	0.3
Retroversion [b]	0.3	-2.0–9.8	2	-4.7–6.3	-0.3	-3.2–2.5	3	-3.0–2.7	0.1	-5.0–9.5	5	-6.2–7.5	0.5
Valgus tilt [b]	0.1	-0.6–0.3	1	-0.5–0.4	0.2	-0.3–1.0	4	-0.5–1.1	0.4	-0.5–1.9	8	-0.8–1.6	0.007

[a] Kruskal-Wallis test
[b] Negative values denote posterior tilt, anteversion and varus tilt, respectively.

Table 4. Radiographic results

	Cemented	HA-coated	Porous-coated	p–value [a]
Radiolucent lines, total [b, c]				
2 years, AP (%)	5 (0–30) 0–25 [d]	9 (0–29) 0–30	31 (10–70) 0–78	<0.0005
5 years, AP (%)	9 (0–60) 0–59	7 (0–31) 0–24	38 (9–72) 2–73	<0.0005
Radiolucent lines, Gruen [e] (0, ≤50, 50–99, 100%)				
1. Proximal, lateral	5, 7, 1, 6	19, 3, 1, 0	4, 7, 3, 6	<0.0005
2. Middle, lateral	14, 2, 2, 1	19, 4, 0, 0	2, 4, 1, 3	<0.0005
3. Distal, lateral	16, 2, 0, 1	22, 0, 1, 0	11, 5, 2, 2	0.005
4. Tip	18, 0, 1, 0	9, 3, 5, 6	1, 1, 1, 17	<0.0005
5. Distal, medial	16, 2, 1, 0	20, 2, 1, 0	13, 4, 3, 0	0.2
6. Middle, medial	14, 2, 3, 0	16, 7, 0, 0	6, 7, 5, 2	0.003
7. Proximal, medial	8, 4, 4, 3	20, 2, 1, 0	9, 6, 1, 4	0.004
Hypertrophy of distal cortex (none, slight, obvious)	13, 5, 1	4, 7, 12	10, 8, 2	<0.0005
Sclerosis–tip of stem (cm^2) [b]	not measured	0.3 (0.0–1.5) 0–1.3	0.5 (0.0–0.9) 0.1–1.0	0.2 [f]
Localized resorption of bone [g] (none, CG, GT, CB)	11, 5, 0, 3	17, 3, 1, 1	17, 0, 3, 0	0.1

[a] Kruskal-Wallis test.
[b] Median, (range), 95% confidence limits.
[c] Includes only patients followed for 5 years.
[d] 1 value incorrectly read in a previous publication (Kärrholm et al. 1994c).
[e] Gruen et al. 1979.
[f] Mann-Whitney test.
[g] CG calcar granuloma, GT localized resorption of trabecular bone in greater trochanter, CB localized erosion of endosteal cortical bone.

remained approximately the same (Table 4). There was a tendency to increased extension of the radiolucent lines with increasing subsidence (Spearman's rho = –0.37, p = 0.004).

The cemented implants had mainly radiolucent lines proximally (Gruen regions 1 and 7). In 3 cases, these lines occupied 100% of the interface both medially and laterally. In the HA-coated stems, short radiolucent lines were occasionally found immediately distal to the end of the coating (regions 2 and 6), proximally at the collar and the shoulder and at the tip. The porous-coated implants had the most extensive lines. In 11 of these 20 stems, these lines occurred in region 7, corresponding to the location of the porous coating. Almost all had a lucent line at the tip of the implant. 2 cases had complete radiolucencies (100%) in both regions 1 and 7.

Between 2 and 5 years, cortical hypertrophy increased in the HA-coated stems (p = 0.04, Wilcoxon signed ranks test–Exact significance), but not in the other 2 modes of fixation (C: p =0.4, P: p=0.09). Accordingly, this phenomenon was commoner in the former group also at the 5-year follow-up (Figure 2). None of the hips with an obvious hypertrophy showed significant subsidence (> 0.25 mm).

The area of the intramedullary sclerosis at the prosthetic tip seemed to remain stationary between the 2 follow-up occasions (HA: p = 0.6, P: p = 0.1).

3 cemented stems had developed endosteal resorption of cortical bone. In 2 cases the osteolytic lesions occupied areas of 4.8 and 7.1 cm^2 and were localized at the midstem regions (2 and 6) or more distally (3–5). The third case had a radiolucency, which surrounded 60% of the stem surface. There was a cortical erosion laterally (region 2) and the lucent line became wider in regions 1 and 7.

Figure 2. Postoperative (A) and follow-up AP radiograph at 5 years (B) of a Tifit stem with proximal HA coating. Thinning and resorption of the proximal cortical bone medially and distal hypertrophy, especially medially. Probably there has also been a resorption of the trabecular bone in the greater trochanter. The stem subsidence was 0.08 mm at the 5-year follow-up.

In 1 patient with a HA-coated stem, there was a minimal cortical erosion at the tip of the stem. In another one, a small localized radiolucent area (< 1 cm^2) was noted in region 2. In 4, pronounced resorption of the trabecular bone in the greater trochanter was noted, which was judged to be caused by stress-shielding.

Three cases with porous-coated implants displayed lytic areas between 0.8 and 1.7 cm^2, in all cases mainly with involvement only of the trabecular bone in the greater trochanter.

Bone mineral density

Both designs of uncemented stems had an uneven distribution of bone mineral between the proximal and distal parts of the femoral bone, both medially and laterally. In the HA-coated group, the medial and lateral quotients (regions 5/7 and 3/1) were 2.78 (CI 1.60–3.98) and 2.40 (CI 2.16–3.66), indicating increased density distally and/or decreased density proximally. The corresponding quotients in the group with porous coating were smaller—i.e., 1.99 (CI 0.75–3.39) and 2.15 (CI 1.23–2.83), p = 0.03 and 0.02, Mann-Whitney U-test).

Metal levels in blood and urine

At 2 years, titanium was not detected in any of the cases. At 5 years, values above the detection limit were found in 4 of 17 cases (3 C, 1 P). Whether this was an increase or not could not be evaluated, because the values recorded (2.1–2.8 ng/g) did not exceed the detection limit of titanium, which was found in the evaluation at 2 years. No titanium was detected in the urine in any of the cases (Table 5).

No vanadium was detected in blood at 2 years. At 5 years, 7 of 17 cases (all cemented) had values between 1.2 and 1.7 ng/g (cemented vs. cementless femoral component: p = 0.06, all 22 available observations at 5 years: p = 0.01, Mann Whitney U-test–Exact significance; 2 vs. 5 years: p = 0.02, Wilcoxon signed-ranks test–Exact significance). Vanadium was not detected in urine at 2 years. At the 5-year follow-up, 1 (C) of 11 patients had a vanadium level of 17 ng/g.

The blood levels of aluminum increased by 2 ng/g or more in 9 cases (6 C, 2 HA, 1 P) and decreased with 5.3 ng/g in 1 case (HA) (all cases: 2 vs. 5 years: p = 0.04, Wilcoxon signed-ranks test–Exact significance). A corresponding increase in aluminum in urine was found in 8 cases (8 C) and a decrease of 2.3 ng/g in 1 (HA). The levels increased more in patients who had a cemented femoral component than in those with a cementless one (p = 0.02 , Wilcoxon signed-ranks test–Exact significance). Further, an increase in subsidence between the 2- and 5-year follow-up was associated with an increase in the blood levels of alu-

Table 5. Metal levels (nanogram/gram) in blood and urine at 2 and 5 years in patients where paired observations were available. Median, (range) and 95% confidence limits in groups with more than 3 observations and at least one value above the detection limit

		n	2 years			5 years		
Titanium								
C	Blood	12	<2.6 [a]			0.0	(0–2.8)	2.1–3.4
	Urine	11	<2.6 [a]			<2 [a]		
HA	Blood	2	<2.6 [a]			<2 [a]		
	Urine	1	<2.6 [a]			<2 [a]		
P	Blood	3	<2.6 [a]			0.0	(0–2.1)	–
	Urine	0						
All	Blood	17	<2.6 [a]			0.0	(0–2.8)	0–3.0
	Urine	11	<2.6 [a]			<2 [a]		
Vanadium								
C	Blood	12	<0.8 [a]			1.3	(0–1.7)	0–2.6
	Urine	11	<0.8 [a]			0.0	(0–17)	0–13
HA	Blood	2	<0.8 [a]			<0.8 [a]		
	Urine	1	<0.8 [a]			<0.8 [a]		
P	Blood	3	<0.8 [a]			<0.8 [a]		
	Urine	2	<0.8 [a]			<0.8 [a]		
All	Blood	17	<0.8 [a]			0.0	(0–1.7)	0–2.2
	Urine	13	<0.8 [a]			0.0	(0–17)	0–12
Aluminum								
C	Blood	11	2.1	(0–3.9)	0.7–4.9	4.3	(0–35)	0–32
	Urine	10	4.1	(1.3–14)	0–13	10.3	(3.1–179)	0–153
HA	Blood	3	1.6	(0–7.7)	–	2.4	(2.4–4.1)	–
	Urine	2	–	(1.7–2.3)	–	–	(0–2.3)	–
P	Blood	2	–	(2.1–4.7)	–	–	(3.3–7.7)	–
	Urine	1	3.7	–	–	2.4	–	–
All	Blood	16	2.1	(0–7.7)	0–6.6	4.2	(0–35)	0–26
	Urine	13	3.7	(1.3–14)	0–12	4.2	(0–179)	0–130

[a] not detected in any of the samples

minum (Spearman's rho = 0.61, p = 0.01).

As previously reported (Kärrholm et al. 1994b), high levels of titanium and aluminum were found in the joint fluid of cases with cemented Tifit stems at the 2-year follow-up. The radiographic parameter at the 5-year follow-up that best seemed to mirror a high level of titanium, and to some extent that of aluminum in the joint fluid 3 years earlier, was the development of a proximal radiolucency (titanium: adjusted $r^2 = 0.5$, $p = 0.001$, aluminum: adjusted $r^2 = 0.2$, $p = 0.05$, stepwise linear regression). 5 cases with titanium levels above 20 ng/g had either a 100% (n 2) or a 50–99% lucency proximally (regions 1 and 7), whereas none of the other 12 cases with joint levels below 20 ng/g had a lucency that occupied > 50% of the interface. These 5 cemented hips with levels above 20 ng/g had migrated distally 0.16–1.6 mm after 5 years, whereas 3 more cemented stems with lower levels had a vertical migration between 0.05 mm distally and 0.21 mm proximally (p = 0.04, Mann-Whitney U-test–Exact significance). The 3 cemented cases with cortical osteolysis had had titanium levels of 6, 32 and 64 ng/g in the synovial fluid 3 years earlier.

There was no correlation between the concentration of metal in joint fluid at 2 years and the concentrations in blood and urine at 5 years (Spearman rank correlations).

In the total material, the presence of a bilateral prosthesis (n 8, all with contralateral stems made of cobalt-chromium alloy) or bilateral femoral heads of aluminum (n 5) 5 years after the index operation was found to have no influence on the levels of metal. Nor did the these factors influence the change in the concentration in blood or urine between the 2 follow-up occasions.

Clinical results

The total hip score, pain score or the differences between the preoperative and 5-year follow-up evaluation was approximately the same in the 3 groups of fixation (Table 6).

Table 6. Harris hip score. Median range

	Cemented		HA-coated		Porous-coated	
5 years						
Pain score	42	20–44	42	30–44	44	30–44
Total hip score	96	69–100	95	73–100	96	78–100
Change (preop. → 5 years)						
Pain score	30	10–44	32	10–44	34	10–44
Total hip score	47	13–77	45	29–78	52	20–77

Figure 3. Lateral view of the cemented stem that was revised after the 5-year follow-up. On the postoperative lateral view (A), there is no or a very thin cement mantle at the tip of the stem and anteriorly due to forward tilting. The stem had a slight valgus (1°, median cemented group = 0.2° varus) position on the AP view (not illustrated). At the 5-year follow-up (B), there is a localized resorption of bone around the hip, a proximal and anterior lucency between the cement and bone and a lucency between the stem and the cement (arrow heads), indicating debonding at this interface.

Revision after 5 years

1 cemented stem was revised after the 5-year follow-up (5 years 8 months), due to pain in the thigh and osteolysis (Figure 3). At the 2- and 5-year follow-up, stem subsidence of 0.17 and 1.6 mm was recorded. The stem had also rotated 0.7° anteriorly, 9.8° into retroversion and 0.6° into varus.

At 2 years, the levels of titanium were 0, 0, 56 ng/g in blood, urine and joint fluid, respectively. Vanadium was not detected in either of the samples. The corresponding levels of aluminum were 1.6, 8.3 and 12.3 ng/g. At the 5-year follow-up, titanium was not detected in blood or urine. The blood levels of vanadium and aluminum had increased to 1.7 and 35 ng/g. Vanadium in urine was still < 1 ng/g , whereas aluminum had increased to 179 ng/g.

During surgery, the stem was found to have loosened from the cement mantle, which was partially fixed to the bone and difficult to remove. There was a cement fracture close to the tip of the stem. A synovial specimen taken close to the cup during the revision had a titanium concentration of 11.7×10^3 ng/g. The other 2 elements were not analyzed.

Discussion

Hydroxyapatite has osteoconductive properties, accelerates ingrowth into porous coatings (Hofmann et al. 1993, Tisdel et al. 1994) and biologic fixation by bidirectional bone growth (Bloebaum et al. 1991, Hardy et al. 1991, Hofmann et al. 1993). This theoretical advantage of HA coating has not so far influenced the clinical outcome in comparative studies. In a randomized study, Cicotti et al. (1994) noted less pain at 12 weeks and 3 months, but no difference at longer follow-up, when HA had been applied to a proximally porous-coated Taperloc stem (Biomet, Warshaw, IN, USA). In a matched-pair study, Rothman et al. (1996) used the same implant and noted the same clinical and radiographic outcomes, whether HA coating had been added or not. Studies primarily based on measurements of migration of cementless implants have, however, indicated improved fixation (Kroon and Freeman 1992, Søballe et al. 1993). In our study, the HA-coated implants displayed the smallest subsidence, which had clinical relevance. The 2 revisions in the porous and cemented groups were both preceded by inferior fixation.

Different qualities and thickness of the HA coating have been used. Several implants with a clinical documentation (Geesink and Hoefnagels 1995, Tonino et al. 1995, D'Antonio et al. 1996) between 2 and 5 years have utilized coatings with a thickness of about 50 microns. The Tifit stem had a thicker coating (200±50 microns) with a comparatively low shear strength (17 Mpa), which could be more susceptible to fracture and delamination. So far, we have not noted any clinical complications that could be related to such an event. We have, however, used the Tifit stem in 1 revision case, where the stem loosened early. During the second revision, delamination of the coating was noted, indicating that this could become a problem also in our series of primary cases. In retrievals, remodeling and resorption of the coating have been observed (Bauer et al. 1991, Collier at al. 1993). Despite a continuous resorption of the HA, it seems probable that the fixation can be maintained by the development of a direct contact between the metal and bone (Collier et al. 1993, Buma and Gardeniers 1995), which would imply that loosening due to delamination should occur comparatively early and before the area of bone metal contact has become sufficiently extensive.

Early subsidence of femoral stems has turned out to be a predictor of later revision due to clinical loosening (Kärrholm et al. 1994a). This was partly confirmed in the present study. In 2 cases, however, a pronounced increase in the subsidence was noted after the 2-year follow-up. In the cemented case, fracture of the cement mantle seems to be the most probable reason. In the case with a porous coating, fatigue fracture of a partially ingrown porous surface or disruption of a fibrous fixation might have been the etiology (Taylor and Tanner 1997). The clinical relevance of increased valgus tilting in the cementless groups is not quite clear. In cases followed with RSA clinical loosening has been preceded by a more or less pronounced tilting into varus, suggesting that the risk of clinical loosening is low in most of our remaining cases operated on with an uncemented implant.

Adaptive remodeling of the bone occurs as a result of changed loading pattern of the femur after a THR. In a retrieval study, Maloney et al. (1996) recorded maximum bone loss of the proximal and medial cortices in both cemented and cementless stems, mainly with an extensive porous coating. A marked individual variability was noted in both groups. We detected significant differences between the 2 cementless groups, probably an effect of different fixation and load transfer. The incomplete coating and tendency to increased subsidence in the porous-coated group might have been of importance (Huiskes 1990). D'Antonio et al. (1996) found cortical hypertrophy in almost half of their cases of Omnifit stems (Osteonics, Allendale, NJ, USA), whereas Tonino et al. (1995) noted the same phenomenon in only about 5% of their cases. They used the ABG stem (Howmedica, Europe, Staines, England), which has a proximal HA coating and a narrow distal part, intended not to contact the inner cortex. Geesink and Hoefnagels (1995) also noted increased periosteal bone formation in cases with a very tight fit of the tip in the femoral canal. These different reactions of the cortical bone to various designs could indicate that the ABG stem more commonly has a fibrous fixation in its more narrow distal part. The fact that distal hypertrophy varies, depending on design, and also occurs in hips with cemented or porous-coated stems indicates that this phenomenon reflects a specific type of fixation and load transfer and that it is not induced by the very presence of HA.

Willert et al. (1996) reported on 28 failed Müller prostheses made of titanium alloy. Numerous particles identified as titanium alloy, corrosion products, bone cement, contrast medium and polyethylene were identified. The proximal part of the stem was mainly subjected to abrasion, whereas in the distal part corrosion dominated. The authors believed that crevice corrosion was the dominating problem and concluded that titanium alloys could no longer be recommended for cementation. Stereoradiographic studies (Thanner et al. 1995, Nivbrant and Kärrholm 1997) have indicated that debonding commonly occurs, also when grit-blasted stems made of cobalt-chromium alloy are used. If this surface treatment is used on a comparatively soft metal, an increased amount of particle production can be expected. On the other hand, smooth and polished stems, which may easily debond from the mantle, will produce less wear. Low revision rates of such stems have been reported, even if they were made of titanium alloy (Espehaug et al. 1995).

When our study was initiated, the ambition was to make the implant as equal as possible. A design of the Tifit stem, originally meant for uncemented press-fit fixation was chosen to represent the cemented group. In a previous article (Kärrholm et al. 1994b), we reported high concentrations of titanium and aluminum in the joint fluid in these implants and were concerned about this finding. The proximal radiolucencies and osteolyses in cases with high levels of titanium point toward a casual relationship. In these cases, the stem has probably debonded from the cement mantle, as noted in the revised case. Because the titanium alloy has an easily abradable oxide layer, more metal particles can gain access to the joint, where they may cause further damage by increasing the wear of the joint surfaces. It is tempting to speculate that the increasing levels of aluminum in the blood and its association to increased subsidence of the stem mirror a part of the loosening process. Aluminum is released from the femoral head and the stem to the surrounding tissues and is transported away with the blood. 7 patients with cemented hips had measurable levels of vanadium at the 5-year follow-up (> 0.8 ng/g), which is higher than expected (Apostoli et al. 1984, Fleisher et al. 1991) and supports this theory. Absence of a corresponding increase in titanium might be related to a different clearance or compartmental distribution between the tissues.

Önsten et al. (1996a) compared the fixation of HA-coated Omnifit with Charnley stems and found no difference. In another study they compared cemented with HA-coated Omnifit stems in 21 patients operated bilaterally. They noted that the subsidence increased more on the cemented side (Önsten et al. 1996b). In 1 patient, the cemented stem was revised because of loosening. This study and ours cannot be interpreted in such a way that cemented fixation in general is inferior to cementless fixation using HA-coating. This is only true as regards the designs studied. In both instances stems with no documentation were used as cemented control, which, at least in our study, resulted in unexpected complications. Since changes in the design can cause complications that are difficult or impossible to predict, we strongly recommend that the control group in randomized trials of new prosthetic designs or fixation concepts should be a well-documented implant.

The coating of the porous implants was not circumferential, which is another cause of concern in view of today's standard. Compared with the Harris-Galante type I stem (de Nies and Fidler 1996), the frequency of osteolysis seemed to be less. We believe that the use of a polished surface on the non-coated part of the implant is the main reason.

In summary, both the cemented and HA-coated Tifit stem displayed small micromotions up to 5 years. However, the cemented stems seemed to have less tolerance to these micromotions, as reflected by increased release of metal and the appearance of proximal radiolucencies and cortical erosions in some cases. The micromotions in the HA-coated group were of about the same magnitude as reported concerning other designs of stems with similar coatings after 2 years (Thanner et al. 1996, Önsten et al. 1996a). These findings and other clinical reports (Geesink and Hoefnagels 1995, Havelin et al. 1995, D'Antonio et al. 1996) suggest that HA coating may become a viable alternative to long-term fixation of a femoral stem. The true incidence of possible negative effects in the long run must be evaluated and compared with the best-documented cemented stems, until the efficacy of HA-coated stems can be definitely established.

This study was financially supported by the Swedish Medical Research Council (MFR B96-17x-07941-10A, MFR B96-17x-10856-03A), Ingabritt and Arne Lundbergs Research Foundation.

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