Femoral remodeling after arthroplasty of the hip

Prospective randomized 5-year comparison of 120 cemented/uncemented cases of arthrosis

Astor Reigstad, Magne Røkkum, Kjell Bye and Merete Brandt

We compared radiographically the femurs for 5 years after cemented (Landos Titane) and uncemented (Zweymüller/Endler) hip arthroplasty (THA) for coxarthrosis in 120 patients. The bone changes followed a characteristic time-course with rapid initial remodeling and almost no further changes after 3–4 years. No association between bone changes and clinical results was found. The groups did not differ in bone atrophy and ectopic bone formation, whereas the incidence of distal cortical hypertrophy and proximal radio-opaque double line was higher around uncemented stems. The age and body weight of the patients and the stem size did not affect the bone changes, but women with uncemented stems developed more bone atrophy than did men.

National Orthopedic Center, Dept. Kronprinsesse Märthas Institutt, Jörgen Lövlandsgate 2, N-0570 Oslo, Norway.
Tel +47-22 954300. Fax -22 954523
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In a well-bonded cemented THA, resorption of the calcar and proximal medial cortex was described as atrophy due to stress shielding by Charnley and Cupic already in 1973. The results of finite element analysis (Lewis et al. 1984, Huiskes et al. 1989) and in vitro measurements (Oh and Harris 1978), have indicated amounts and localization of bone resorption and hypertrophy that correspond to the radiographic findings in some long-term studies of cemented THA (Thomas et al. 1986, Ritter and Fechtman 1988). It is widely held that the remodeling changes seen around uncemented femoral stems appear in a shorter period of time and tend to be more severe than those observed around cemented stems (Brown and Ring 1985, Galante et al. 1991). We have compared the radiographic femoral changes in a prospective series of randomized cemented and uncemented THA.

Patients and methods

In the period January 1985–April 1986 a prospective randomized study of the cemented Landos Titane and the uncemented Zweymüller/Endler polyethylene THA was undertaken on patients with coxarthrosis in the age group 56–72 years. Women/men ratio, age and body weight of the patients, right/left ratio, and clinical and radiographic assessments of the arthrosis were similar in the 2 groups (Table 1). The Hardinge (1982) incision was used. The same surgical team performed both types of prostheses. The cemented and uncemented femoral prostheses were available in 8 and 12 sizes, respectively. A reamer for each size allowed press-fit fixation for the uncemented prostheses and application of a limited amount of cement for the cemented prostheses. The cementing technique included a polyethylene plug distally in the femoral canal and pressurizing the cement. Both groups had the same postoperative training program, which included a partial weightbearing-period of 4 months.

1 cemented stem was inserted in the varus position. The remaining stems had a neutral or slight valgus position. No serious operative or postoperative complications occurred. 9 patients died during the follow-up period of causes unrelated to surgery. 2 loose uncemented Endler acetabular prostheses have been revised because of mechanical loosening about 4 years after insertion. 1 additional Endler cup in a pain-free patient was radiographically loose at the 5-year follow-up. No femoral prosthesis in either group and no cemented cup were considered loose. No femoral prosthesis in either group has subsided or shifted into the varus position during the follow-up period.

The stem-to-bone diameter ratio, which was assessed at a level 4 cm above the distal end of the prosthesis, was the same in the cemented and uncemented groups (*P* 0.086).

The clinical results were graded according to Merle d'Aubigné and Postel (1954) and they will be reported entirely in a separate study. The pain score was not associated with any of the bone changes in the 2

Table 1. Preoperative patient data

	Cemented n 60	Uncemented n 60
Mean age	65 (56–72)	64 (56–72)
Men	15	17
Women	45	43
Mean body weight (kg)	71 (50–105)	69 (48–103)
Right	37	40
Left	23	20
Dysplasia	9	7
Acetabular protrusion	2	1
Earlier femoral neck fracture	5	2
Pain score (mean)	2.1	2.0
Walking ability score (mean)	2.2	2.2
Total hip mobility score (mean)	3.4	3.3

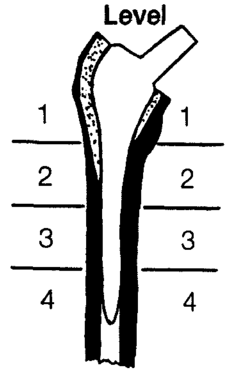

Figure 1. 4 levels for studying bone remodeling (Engh et al. 1987).

implant groups.

The postoperative anteroposterior and lateral radiographs of each femur were standardized by using the same film quality, developing process, exposure, target distance, magnification, field, and keeping the leg in the same position. The standard serial radiographs which provide good information on bone remodeling (Engh et al. 1990) were examined for subsidence, radio-opaque parallel line formation, bone atrophy, bone hypertrophy and ectopic bone formation 4 months and 12 months postoperatively and at subsequent annual visits using the 3-week radiograph as reference. Femoral bone atrophy was assessed according to Engh et al. (1987) at 4 levels(Figure 1).

Cortical hypertrophy was defined as a fusiform enlargement of the cortical bone (Ritter and Fechtman 1988); it appeared first distally, and we graded it according to the level in which it appeared.

The radio-opaque double line was defined as radiolucencies with parallel surrounding sclerosis (Amstutz et al. 1989). It was seen first proximally, and it was also graded according to the level in which it appeared. The ectopic bone formation was graded according to Brooker et al. (1973).

The statistical evaluations were carried out with the Mann-Whitney test.

Results

Bone atrophy

Bone atrophy was seen already at the 4-month follow-up in both implant groups, but in the majority of cases the atrophy was only of Grade 1. From 4 months to 1 year a rapid progression of bone loss occurred (Table 2, Figure 2). By 1 year more than one fourth of femora in both groups had developed atrophy of Grade 2 or more (Figure 3). The bone loss around both types of stems stabilized by 3–4 years. Only 7 patients with cemented stems and 5 patients with uncemented stems had progression of the bone atrophy beyond 3 years; beyond 4 years no progression was seen around any uncemented stem, whereas 3 cemented stems progressed from Grade 2 to 3. Localized endosteal erosion (Maloney et al. 1990) was not seen in any case.

Cortical hypertrophy

Distal cortical hypertrophy around cemented stems occurred in only 1 case by 1 year and in 2 by 5 years (Figure 2). Cortical hypertrophy was observed around one third of the uncemented stems after 1 year and in half after 2 years (Figure 3). From 3 to 5 years only 3 hips developed more cortical hypertrophy.

Radio-opaque double line

A double line between the cement and bone was rare, and did not occur before 4 years (Figure 2). Around uncemented stems the double line was apparent in one third already by 1 year and progressed to about two thirds (Figure 3). Between 3 and 5 years only 2 hips developed a double line, and by 5 years the double line was found distal to level 1 in only 3 hips. In none of the hips was the line visible around the entire stem, and no distal pedestal formation (Engh et al. 1990) was seen.

Ectopic bone formation

The frequency of ectopic bone formation around the 2 types of prostheses varied insignificantly after 5 years (Table 2). The ectopic bone formation did not progress much after 1 year. In 2 uncemented hips ectopic bone was removed due to reduced mobility.

Table 2. Radiographic observations 4 months–5 years after hip arthroplasty for arthrosis

Follow-up	4 months			1 year			2 years			3 years			4 years			5 years		
Implant type	C		U	C		U	C		U	C		U	C		U	C		U
Deaths	1		0	1		0	2		0	3		0	4		2	6		3
No. of hips evaluated	59		60	59		60	58		60	57		60	56		58	54		57
Bone atrophy																		
None	29		40	19		25	16		22	14		21	13		19	12		18
Grade 1	25		16	24		19	18		19	10		18	9		15	9		15
2	5	ns	4	14	ns	14	19	ns	15	25	ns	14	25	ns	15	21	ns	15
3	1		0	2		2	4		4	7		7	7		7	10		7
4	0		0	0		0	1		0	1		0	2		2	2		2
Cortical hypertrophy																		
None	59		60	58		37	57		26	56		25	54		24	52		22
Level 4	0		0	0		7	0		7	0		6	1		6	1		7
3	0	ns	0	0	***	12	0	***	17	0	***	15	0	***	14	0	***	13
2	0		0	1		3	1		9	1		13	1		13	1		14
1	0		0	0		1	0		1	0		1	0		1	0		1
Radio-opaque double line																		
None	59		58	59		37	58		33	57		30	55		28	52		26
Level 1	0		2	0		22	0		24	0		26	1		26	1		27
2	0	ns	0	0	***	1	0	***	3	0	***	3	0	***	3	1	***	3
3	0		0	0		0	0		0	0		1	0		1	0		1
4	0		0	0		0	0		0	0		0	0		0	0		0
Ectopic bone formation																		
None	51		49	48		43	45		43	42		43	41		43	40		41
Brooker 1–2	7	ns	10	9	ns	14	11	ns	11	13	ns	12	13	ns	11	12	ns	12
3–4	1		1	2		3	2		6	2		5	2		4	2		4

C cemented, U uncemented, *** $P < 0.001$.

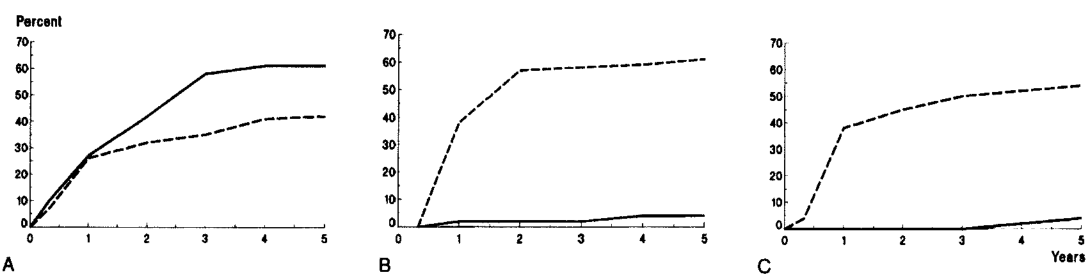

Figure 2.
A. Frequency of femoral bone atrophy Grade 2 or worse,
B. Cortical femoral hypertrophy, and
C. Radio-opaque double line formation.
—— Cemented
– – – Uncemented

Factors influencing bone remodeling

Age, body weight, and stem size did not influence the bone changes in either prosthetic group. Women with uncemented prostheses developed more bone atrophy (*P* 0.03) and cortical hypertrophy (*P* 0.04) than did men. Men with cemented stems developed more ectopic bone than women (*P* 0.009).

Discussion

This appears to be the first randomized radiographic comparison of bone remodeling around cemented and uncemented femoral stems. The bone changes around cemented stems demonstrated in this series confirm studies on well-fixed asymptomatic cemented femoral components (Küsswetter et al. 1984, Thomas et al. 1986, Iwasaki 1987, Comadoll et al. 1988). Considera-

Figure 3A. Uncemented stem 3 weeks and 2 years postoperatively. Bone atrophy Grade 3 and radio-opaque double line in level 1 are apparent.

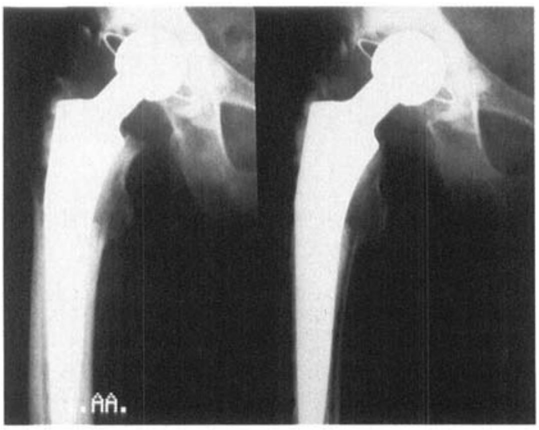

Figure 3B. Cemented stem 3 weeks and 4 years postoperatively. Bone atrophy Grade 4 has developed.

Figure 3C. Uncemented stem 3 weeks and 2 years postoperatively. Distal cortical hypertrophy reaching up in level 3 is visible, but there is no proximal bone loss or double line formation.

ble loss of bone is seen in the calcar region, and some cortical atrophy in the subtrochanteric region is also frequent. Our study indicates that this remodeling around well-bonded cemented stems reached a maximum 3–4 years after implantation. This is in line with the results of a histomorphological study on retrievals carried out by Jasty et al. (1990).

Standard radiographs furnish a rather insensitive measurement of bone changes (Poss 1992). The application of dual photon absorptiometry (McCarthy et al. 1991) may offer more accurate assessment of bone loss, but this method was not available for ordinary clinical use when we started the study. West et al. (1987) conclude, however, that reliable information can be obtained from prospective quantitative densiometric analysis of femoral radiographs under controlled conditions, as in our study. In a newly published study Kilgus et al. (1993) found good accordance between the bone changes measured by dual energy X-ray absorptiometry and by radiographs.

Finite element analysis of cemented and uncemented stems with similar design features have shown that uncemented stems create more proximal stress shielding and more distal stress transfer than cemented stems do (Huiskes 1990). The very low incidence of distal cortical hypertrophy around cemented stems found in this and other series (Ritter and Fechman 1988) confirms the finite element analyses. The relatively high incidence of proximal bone atrophy around cemented stems in our series opposes the theory that predicts a higher proximal stress transfer around cemented stems compared to uncemented stems. We have used a rough method in quantifying bone loss, but our findings confirm the results from the retrieval study by Torchia and Ruff (1990) and from a recent in vitro study by O'Connor and Harris (1992), who surprisingly found that strain reduction was greater for cemented stems.

Maloney et al. (1991) found more ectopic bone in patients with uncemented THA compared to those who received cemented stems and uncemented sockets. Their explanation was that the increased distribution of bone debris or marrow elements locally could lead to stimulation of heterotopic ossification. Our study did not confirm these findings.

The uncemented Zweymüller stems studied in this series seemed to be well bonded, since no subsidence, no complete radio-opaque double line or pedestal formation were seen. Lintner et al. (1988) found in an autopsy study of 3 asymptomatic Zweymüller prostheses total osseointegration of 1 stem; around the 2 other stems a border of connective tissue was seen in the proximal segment, whereas osseointegration had occurred more distally. They explained the border of connective tissue by the fact that the distance between preexisting bone and metal is very wide proximally, thus preventing the bone tissue from growing quickly onto the metal surface. In our study the radio-opaque double line, which we believe represents a layer of soft tissue between the metal and a secondary sclerotic bone shell, was not visible on the 3-week and 4-month radiographs. Our explanation of the proximal double line is therefore that the implant elasticity of a distally well-bonded stem creates proximal micromovements during loading. It is unlikely that the proximal double line represents radiographic loosening, since the hip pain score was similar to that in cases without any radiolucent line.

Cortical hypertrophy around the distal part of the uncemented press-fit stems, which has been reported with a frequency as high as 66 percent (Amstutz et al. 1989), is thought to be an indication of distal stress transfer to the cortical bone. Histologic examination of autopsied cases has confirmed that the distal hypertrophy is not associated with loosening (Lintner et al. 1988). Thus, one can hypothesize a net transfer of bone from the trochanteric region to the proximal femoral shaft around the uncemented stems, whereas cemented stems lose bone proximally, without any rebuilding distally, resulting in more net bone loss.

The proximal bone loss due to stress shielding around uncemented femoral stems can potentially have severe effects (Brown and Ring 1985). The design and stiffness of the stem, and the type and extent of the surface texture are factors which influence the adaptive bone response (Sumner et al. 1992). We found, like Rosenberg (1989), that the resorptive phenomena appeared to stabilize by 3–4 years. A stabilization of the bone loss was also demonstrated in animal retrieval studies (Bobyn et al. 1990, Maistrelli et al. 1991). Particulate debris generated from acetabular loosening may be another cause of resorptive changes than altered stress distribution (Harris 1992). In our series, wear debris could hardly have caused bone atrophy as the follow-up was relatively short and only 3 cups loosened.

Phillips et al. (1990) claim that patients with uncemented stems have a low margin of safety for rotational loosening, and the recent report by Kim and Kim (1992) stresses the poor initial support as a cause for stem loosening. The conical-rectangular design of the Zweymüller stem provides it with optimal preconditions for primary stability until bone ingrowth has occurred. The entire stem has a surface roughness of 3–5 µm which appears to offer the same good condition for bony tissue to grow onto the implant as onto a porous coated surface (Zweymüller et al. 1988). Coating of the whole stem length is, however, a matter of controversy, and several of the uncemented stems currently in use are coated only proximally. The incidence of bone atrophy due to stress shielding in patients with proximally coated stems (Rosenberg 1989, Galante et al. 1991) seems to be the same as we found. We conclude therefore that the risk for bone atrophy around fully-coated osseointegrated uncemented press-fit stems has been overestimated; the remodeling process tends to be self-limited, and the net bone loss seems to be less than that around cemented stems.

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