Bone mineral and migratory patterns in uncemented total knee arthroplasties

A randomized 5-year follow-up study of 38 knees

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We measured the amount of bone mineral in the medial tibial condyle 1 week postoperatively, after 1 year and after 4–5 years in 38 arthrotic knees randomized to a Freeman-Samuelson hydroxyapatite-coated (FS HA) or a Miller-Galante II (MG II) total knee arthroplasty. Clinically excellent results were recorded in both groups after 5 years. At the last follow-up, the overall decrease in bone mineral was 26%, as measured by triple-energy X-ray absorptiometry. The decrease was larger in FS HA knees than in MG II knees after 4–5 years, indicating stress-shielding of the proximal tibia. Radiostereometry at 1 and 5 years showed smaller maximum total point motion, maximum subsidence and varus or valgus tilt in the FS HA group. There was a tendency towards a reversed relationship between subsidence and change in bone mineral after 1 year, but not after 4–5 years. Distal fixation of the stem in the Freeman-Samuelson hydroxyapatite-coated (FS HA) components might explain the more pronounced loss of bone mineral in the medial tibial condyle.

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Uncemented prosthetic fixation relies on stability and bone ingrowth for long-term endurance. The extent of this process influences the load distribution between the tibial component and the underlying bone, and consequently affects bone remodeling. A decrease in the amount of bone mineral beneath the tibial tray has been reported in several studies (Hvid et al. 1988, Petersen et al. 1994, 1995, Levitz et al. 1995). After 2 years, this decrease has amounted to 11%–14% in uncemented and cemented total knee arthoplasties (Hvid et al. 1988, Petersen et al. 1995). The amount of bone mineral is closely correlated to, among other things, the compressive strength of trabecular bone (Hansson et al. 1980, Hvid et al. 1985). These mechanical properties are important for the immediate postoperative, as well as the long-term stability. In the long term, localized bone resorption beneath the tibial tray might result in loss of both structural and mechanical support proximally, causing fatigue fractures of the stem of the implant or migration of prosthetic components (Taylor 1997). We found no reports on the connection between bone mineral losses and prosthetic fixation in the mid-term follow-up. We performed this randomized trial to investigate the relationship between the amount of bone mineral in the proximal tibia and migration of the tibial component in uncemented total knee arthroplasty.

Patients and methods

33 patients (38 knees, mean age 67 (56–73) years, 23 women) with grades III–V osteoarthrosis according to Ahlbäck (1968) were included in the study (Table 1). The patients were part of a larger cohort stratified to an uncemented Freeman-Samuelson hydroxyapatite (FS HA) or a Miller-Galante II (MG II) total knee arthroplasty. This study in-

Table 1. Patient demographics

	Male/female (knees)	Uni-/bilateral surgery	Deceased
FS HA	6/14	16/2	2
MG II	5/13	12/3	0

cluded 51 knees in 45 patients. Due to limited resources at the laboratory for bone mineral measurements, only 38 of these knees were included in the bone mineral study. Prior to the operation, consecutive patients admitted for surgery were randomized, after informed consent, by the minimization method (Pocock 1983). The randomization was based on age (< 65 years, ≥ 65 years), weight (< 75 kg, ≥ 75 kg), degree of deformity (< 10°, ≥ 10° varus or valgus deformity), gender and smoking habits (yes/no). 13 patients had unilateral arthrosis, 16 had bilateral arthrosis and 4 had generalized arthrosis.

The FS HA total knee arthroplasty was inserted in 20 knees. The undersurface of the components and the straight anchorage stem of this prosthesis are grit-blasted. On the tibial undersurface, a hydroxyapatite layer is plasma-sprayed (thickness 150–250 μm, porosity 15–20%, pore size < 50 μm, Ra = average roughness 5.1 (SE 0.66 μm). The articular design is a semiconstrained "roller in a through" system.

The MG II prosthesis, inserted in 18 knees, includes a flat articulating surface and a smooth surface, fluted tibial stem. The tibial base plate is inclined 10° posteriorly and the stem has a posterior angle of 10° in relation to the plate. A fiber mesh (porosity 50%, pore size of 350 μm) made of commercially pure titanium is attached to the undersurface of the tibial component. In both tibial designs, four cortical screws were used to improve initial fixation. The posterior cruciate ligament was retained. Full weight bearing was allowed after 6 weeks.

Clinical data were collected prospectively. The Hospital for Special Surgery (HSS) score was calculated (Insall et al. 1976). Alignment was measured preoperatively and after 1 year on long-leg standing (Hip-Knee-Ankle-angle = HKA) and on standard radiographs. On the standard radiographs, the normal alignment was defined as 6° ± 3° valgus alignment.

During the operation the plastic insert in the tibial component and the proximal tibia were prepared with spherical tantalum markers for later radiostereometric analysis (RSA) (Ryd 1986, Kärrholm 1989). Repeated RSA examinations were done up to 5 years after the operation. In this presentation, migration between the postoperative (within the first week) and the 1- and 5-year examinations are accounted for. Rotations of the tibial component about the three principal planes of the body's cardinal axes and translations of peripheral points were evaluated (Nilsson and Kärrholm 1993). The translation measurements of the peripheral points were based on five standardized positions on the edge and one in the center of the plastic insert. Maximum Total Point Motion (MTPM), maximum subsidence and absolute values of rotations about the cardinal axes are stated.

The amount of bone mineral below the medial condyle of the tibia was determined in the first postoperative week and after 1 year and 4–5 years. Triple-energy X-ray absorptiometry (TXA) was used for this measurement. This particular TXA method employs a permutation technique where 23 photon energies, between 35 and 57 keV, are utilized in a continuous X-ray spectrum as the photon source (Swanpalmer et al. 1998a, b). The results were expressed as bone mineral areal mass (BMD) in g/cm^2. The bone volume measured was cylindrical and had a diameter of 8 mm. The examined leg was placed in a device designed to secure the limb in the same position at each follow-up measurement. In the FS HA knees, the region of interest was located between the stem and the distal end of the medial peg. In the MG II knees, a corresponding region at the same distance (2 cm) from the tibial tray was selected (Figure 1). We used fluoroscopy to obtain reproducible locations and avoid interference with the screws. The in vivo precision of the bone mineral measurements was determined to be 3.4 (0.57–6.36)% (Swanpalmer et al. 1998b).

2 patients died 35 and 53 months after the index operation for reasons not related to the surgery. No patient was lost to follow-up.

Statistics

The reproducibility of the bone mineral determinations was expressed as the coefficient of variation (CV) which is defined as CV = SD/mean. All statistical methods are indicated in the text. Two-tailed tests were performed.

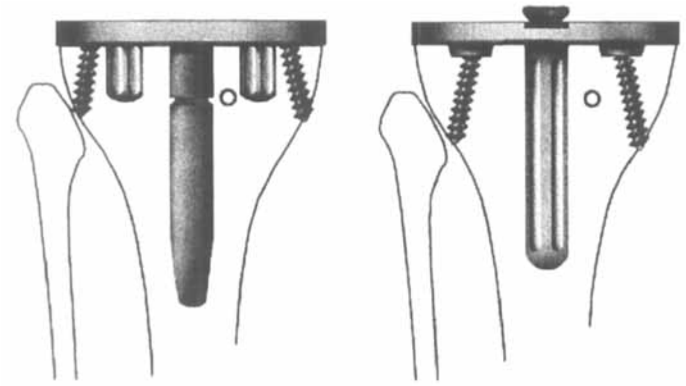

Figure 1. Schematic drawing of the area for bone mineral measurements in the FS HA prosthesis (left) and the MG II prosthesis (right).

Results

There were no clinical outcome differences between the two groups. The mean HSS score was 93 in both groups at the 5-year follow-up. All patients had a good or excellent result.

The preoperative hip-knee-ankle (HKA) alignment varied from 163° to 200° (< 180° = varus). 6 knees had valgus alignment and 25 knees had varus alignment preoperatively. 16 knees had a preoperative varus alignment corrected to valgus alignment (i.e., decreased load on the medial condyle) and 5 knees had a preoperative valgus alignment corrected to neutral or varus alignment (i.e., increased load on the medial condyle) after surgery. At 5 years, 13 of 18 FS HA (72%) and 2 of 18 MG II (11%) tibial components had condensation of trabecular bone in close apposition to the stem, indicating bony fixation ($p < 0.001$, Fisher's exact test).

When all patients were evaluated, the decrease in BMD with later follow-ups was statistically significant ($p < 0.001$, Friedman test) (Table 2). In the FS HA and MG II knees, the amount of bone mineral had decreased by 29% and 15% at 1 year, respectively. After 4–5 years, the decreases in the 2 groups were 36% and 15% (FS HA vs. MG II; $p = 0.02$, repeated measures ANOVA). 2 patients in the FS HA group had an extremely pronounced loss of bone mineral (1 year, 75% and 57%; 4–5 years, 94% and 90%).

Postoperatively, men had more bone mineral than women ($p < 0.001$, Mann-Whitney test). 1 week after surgery, patients with preoperative valgus alignment had less bone mineral in the proximal medial tibia than those with varus deformity (varus/neutral/valgus: $p = 0.009$, Kruskall-Wallis test; varus vs. valgus deformity: $p = 0.002$, Mann-Whitney test).

Between the postoperative and the 4–5-year follow-ups, knees with increased load on the medial condyle showed a smaller relative change of bone

Table 2. Mean BMD postoperatively (g/cm^2), percentage change in BMD compared to initial postoperative value and range for different groups in the cohort

	Postoperatively g/cm^2		1 year %		4–5 years %	
All patients [a]	0.74	(0.34–1.43)	-22	(-75–25)	-26	(-94–22)
FS HA [b]	0.75	(0.42–1.35)	-29	(-75–19)	-36	(-94–11)
MG IIb	0.72	(0.34–1.43)	-15	(-41–25)	-15	(-44–22)
Male	0.97 [c]	(0.58–1.43)	-16	(-40–6)	-17	(-34–-2)
Female	0.64 [c]	(0.34–1.01)	-25	(-75–25)	-29	(-94–22)
Preop varus	0.81 [d]	(0.41–1.43)	-26	(-75–25)	-35	(-94–-2)
Preop neutral	0.67 [d]	(0.42–0.92)	-14	(-47–19)	-13	(-44–22)
Preop valgus	0.49 [d]	(0.34–0.81)	-15	(-35–9)	-4	(-28–11)
Decreased load	0.90	(0.58–1.43)	-22	(-63–6)	-25 [e]	(-58– -2)
Increased load	0.54	(0.34–0.92)	-13	(-47–19)	-4 [e]	(-26–4)

[a] $p < 0.001$, Friedman test, [b] $p = 0.02$, repeated measures ANOVA,
[c] $p < 0.001$, Mann-Whitney test, [d] $p = 0.01$, Kruskall-Wallis test,
[e] $p = 0.02$, Mann-Whitney test.

Table 3. MTPM (mm) and maximum subsidence (mm) at 1 and 5 years, mean (range)

	MTPM 1 year	MTPM 5 year	Max subsidence 1 year	Max subsidence 5 year
FS HA	0.53 (0.2–1.9)	0.65 (0.2–1.3)	-0.24 (0.2– -1.7)	-0.23 [a] (0.1– -1.0)
MG II	0.67 (0.3–1.6)	0.87 (0.4–1.9)	-0.52 (0.4–1.9)	-0.64 [a] (0.1– -1.7)

[a] p= 0.01, Mann-Whitney test

Table 4. Mean rotations (degrees) about the 3 cardinal axes at 1 and 5 years (range)

	Anterior or posterior tilt 1yr	Anterior or posterior tilt 5yr	Inward or outward rotation 1yr	Inward or outward rotation 5yr	Varus or valgus tilt 1yr	Varus or valgus tilt 5yr
FS HA	0.34 (0–2.1)	0.38 (0–1.5)	0.38 (0–1.2)	0.47 (0–1.5)	0.28 (0–1.3)	0.17 [a] (0–0.5)
MG II	0.42 (0–1.0)	0.69 (0–2.2)	0.25 (0–1.1)	0.26 (0–0.5)	0.27 (0–0.9)	0.35 [a] (0–0.9)

[a] p = 0.04, Mann-Whitney test

mineral, compared to those whose load was expected to be decreased (p = 0.02, Mann-Whitney test).

Radiostereometric evaluation revealed an initial migration in terms of MTPM and maximum subsidence in both designs of prostheses. The FS HA knees stabilized thereafter, whereas the migration in the MG II knees continued. At 5 years, the FS HA knees had less migration with regard to MTPM and maximum subsidence (FS HA vs. MG II at 5 years: p = 0.2 (MTPM) and p= 0.01 (maximum subsidence), Mann-Whitney test) (Table 3). The FS HA prostheses tended to be more stable as regards anterior or posterior tilt and varus or valgus tilt throughout the study. At 5 years, there was a significant difference in varus or valgus tilt (p = 0.04, Mann-Whitney test) (Table 4).

At 1 year, there was an inverse relation between changes in BMD and the value of maximum subsidence ($R^2 = 0.16$ $p = 0.03$, linear regression). Cases of increased subsidence tended to lose less bone mineral. No corresponding relation was found after 4–5 years.

Discussion

To our knowledge, TXA has not been used previously to measure changes in BMD around joint arthroplasties. The precision agreed with previous studies using dual-photon absorptiometry (DPA) (1.4–4.7%) (Madsen et al. 1994, Petersen et al. 1995, Swanpalmer et al. 1998b), but was slightly lower than for DXA (1%) (Swanpalmer 1998). TXA (expressed as the standard error of the estimate, SEE = 1.2%) has, however, been shown to be more accurate than DPA (SEE =10%) and DXA (SEE =9%) (Swanpalmer 1998). In addition, the amount of bone mineral in the three-tissue-compartment system (bone mineral, lean soft tissue and adipose tissue) can be uniquely determined by the use of TXA (Swanpalmer et al. 1998a, b).

The amount of bone mineral beneath the medial and lateral tibial condyles is closely related to the femorotibial angle (Hvid et al. 1988, Levitz et al. 1995, Petersen et al. 1995). Previous studies of patients with gonarthrosis have shown that the bone is more dense and sclerotic in the medial tibial condyle in a varus malaligned arthrotic knee (Hvid 1988, Madsen et al. 1994). This was verified by our postoperative measurements. In addition, our finding that changes in the load on the medial condyle influence the amount of bone mineral in this region agrees with earlier reports (Hvid et al. 1988, Petersen et al. 1995). In primary gonarthrosis varus malalignment is commoner than valgus malalignment. Furthermore, in most patients the compressive load transmitted across the knee is, on the medial side as a result of the adduction moment (Harrington 1983, Andriacchi et al. 1986). On the basis of these observations and the choice of only one region of interest, we assumed

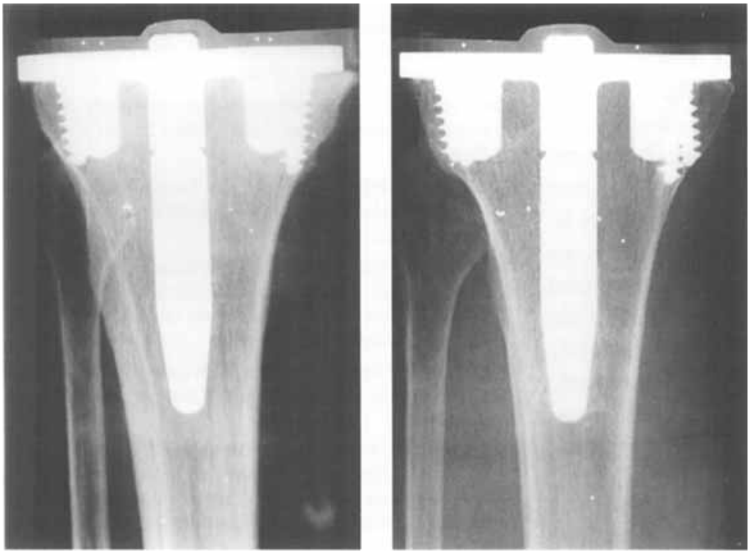

Figure 2. The FS HA prosthesis postoperatively (left) and after 5 years (right), displaying the condensation of trabecular bone in close contact with the stem.

that the bone remodeling activity should be more pronounced medially and selected the region for this longitudinal study.

A decrease in the amount of bone mineral after total knee arthroplasty has been reported (Hvid et al. 1988, Petersen et al. 1994, 1995, Levitz et al. 1995). The amount of the decrease is more pronounced beneath the condyle, where the load is reduced when malalignment is corrected (Hvid et al. 1988, Petersen et al. 1995). After 1 and 3 years, Petersen et al. (1995) found an average bone mineral loss of 8% and 22% in patients operated on with uncemented PCA prostheses due to arthrosis. Hvid et al. (1988) studied patients with arthrosis and rheumatoid arthritis, operated on with a cemented total condylar knee, including an all-polyethylene tibial component. After 2 years, decreases of 11% and 32% in the amount of bone mineral were noted in the two groups of diagnoses, respectively. We found an overall decrease of 26% after 4–5 years. However, the amount of bone mineral was reduced by 15% in the MG II group and 29% in the FS HA group after 1 year. The MG II prostheses stabilized thereafter, but the FS HA prostheses continued to lose bone. These divergent patterns could be explained by differences in the quality of the fixation. The FS HA prosthesis has a rough structure on the titanium alloy central stem. Bony apposition around the stem could induce proximal stress-shielding in the condylar region, whereas the MG II prostheses, with a smoother stem, subsided more, resulting in increased contact and load transfer between the tibial tray and the bone (Figure 2).

Petersen et al. (1994) found a positive relation between preoperative BMD and MTPM after 6 weeks and 1 year. We found no such correlation, but a correlation was found between the change in BMD and distal migration. Stable components in terms of subsidence revealed less bone mineral after 1 year. Decelerating migration in the MG II group after 1 year, influence of other factors such as variations in the patient's activity after the first postoperative year and differences in implant stiffness might explain why this relation had disappeared at the last follow-up.

Bone mineral loss in the proximal tibia is a concern for aseptic loosening in uncemented tibial components. However, the FS HA tibial components were more stable with regard to micromotion evaluated by RSA. Earlier stable fixation in hydroxyapatite-coated, unlike in to titanium devices has been shown in several animal studies (Søballe 1993, Gottlander 1994). This has also been found clinically at 2 and 6 months in a study of 51 total knee arthroplasties (Regnér et al. 1994). Tibial components supported with a central stem are more stable than unstemmed components in in vitro studies (Volz et al. 1988, Yoshii et al. 1992). The addition of hydroxyapatite coating to the undersurface of the tibial component in the FS HA prosthesis may further promote early fixation. This will facilitate apposition of bone to the tibial undersurface and around the stem. Distal fixation of the stem will unload the bone beneath the tibial tray, resulting in stress-shielding, which previously has been observed in vitro with stemmed components (Bourne and Finlay 1986). This has repeatedly been observed around the proximal part of the rigidly fixed uncemented femoral component in total hip arthroplasty (Engh et al. 1992). Whether this sign is part of a failure scenario might be questioned. The risk of stem fracture and difficulties treating the osteoporotic bone and even bone defects during a subsequent revision procedure has, however, been debated (Engh et al. 1992, Huiskes 1993). To avoid these problems, we think it desirable to avoid implants associated with stress bypass due to distal fixation. The use of a shorter, smooth-surfaced, fluted or partially coated stem in uncemented total knee arthroplasty may be one solution, provided that such an implant would not jeopardize the long-term fixation.

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