Bone mineral density changes of the proximal tibia after revision total knee arthroplasty. A randomised study with the use of porous tantalum metaphyseal cones

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Abstract

Purpose Forty patients were enrolled in a prospective randomised study using conventional method or “Trabecular Metal Cone” (TM Cone) (Zimmer inc., Warsaw, USA) for reconstruction of bone loss of the proximal tibia during revision total knee arthroplasty (rTKA). The aim was to evaluate changes in bone mineral density (BMD) at the proximal tibia.

Material and methods Thirty-six patients [median 67 years (range: 40–85 years)] received rTKA with NexGen® (Zimmer Warsaw, USA) revision system. Knee Society’s Knee Scoring System and the Anderson Orthopaedic Research Institute (AORI) bone classification was used. Changes in BMD were measured by dual energy X-ray absorptiometry (DEXA).

Results Knee and function score improved in both groups. No significant changes between the groups were found. Changes in BMD within the two groups were quite similar. Overall decreases in BMD of 0.1–5.4 % were found in both groups (ROI 1–6) postoperative to 12 months of follow-up, except that ROI 7 showed an increase in BMD (0.8–1.3 %). After 24 months of follow-up, an increase in BMD was found along the stem (ROI 2–5) of 1.9–6.3 %, with significant changes in the TM Cone Group (ROI 3, 4, 5). No significant changes in BMD between the groups were found.

Conclusions The bone remodelling pattern was almost the same in the two groups after two years.

Introduction

Total knee arthroplasties (TKA) have an overall ten-year survival probability far above 90 % [1]. The major causes of TKA failure are aseptic loosening, pain without loosening of components, instability, deep infection, and polyethylene wear. The exchange of an infected or loose TKA is often complicated by a considerable bone loss in the proximal tibia caused by polyethylene particle disease, stress shielding, bone necrosis from infection or due to removal of the prosthesis.

The aim of rTKA is to achieve well-fixed components, and to restore normal joint-line level and flexion-extension stability. Reconstruction of the bone defect is essential for the durability of the fixation. There exists well established agreement as to the surgical management and treatment of smaller bone loss of the proximal tibia [2]. Management of severe bone loss is dependent on the degree and location of the defect. Options are cement filling, use of metal augmentation, bone grafting or in severe cases mega prostheses [3].

A new porous Tantalum biomaterial shaped as a cone is now commercially available in different sizes under the trademark “Trabecular Metal Cone” (TM Cone) (Trabecular Metal, TM, Zimmer, Warsaw, IN). It is designed and developed for reconstruction of bone loss in the proximal tibia during rTKA. Tantalum is well documented as a highly biocompatible material through its high resistance to corrosion and little immunogenic response in host tissue [4]. With the appearance of porous Tantalum similar to cancellous bone, porous tantalum has the advantage to allow osseointegration [5], while filling out bone defects and tolerating physiological loads (Fig. 1). Preliminary clinical results evaluating the use of porous Tantalum in general [6] and as TM Cone [7] have been encouraging.

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Fig. 1 Reconstruction of bone defects in proximal tibia with TM Cone

Changes in bone mineral density (BMD) can be measured by dual energy X-ray absorptiometry (DEXA) [8]. No studies measuring changes in BMD of the proximal tibia after rTKA have previously been published. Studies on BMD changes in the proximal tibia after primary TKA have shown a significant decrease in BMD, sometimes reaching 20–36 %, independent of measuring technique (DEXA, CT bone densitometry, dual photon absorptiometry) [9]. However, some studies have shown an unchanged BMD [10] or even a small increase [11].

The aim of this study was to measure quantitatively using DEXA the adaptive bone remodelling of the proximal tibia and tibial shaft after rTKA and in a prospective randomised design evaluate the difference in remodelling pattern after rTKA with or without the TM Cone.

Material and methods

Forty ($n=40$) consecutive patients scheduled for rTKA from November 2005 to January 2008 were included in a prospective, randomised study. All patients had severe bone loss of the proximal tibia or were considered candidates for that after surgical removal of the tibial component. After oral and written informed consent had been obtained, the patients were randomised to receive surgical treatment reconstructing the tibial bone defects using the TM Cone (A) or without TM Cone using conventional technique (B). All patients who were selected for the study agreed to participate. By a computer-generated block-randomisation (four patients in each block), 40 numbered envelopes were allocated a note with A (TM Cone) or B (conventional=NO TM Cone), and sealed by an independent laboratory technician. The day before surgery, when the indication for the operation was finally set, the surgeon opened the sealed

envelope to see which type of reconstruction the patient had been allocated. The same surgeon performed all operations. The study was approved by the local ethical committees [the Scientific Ethical Committee of Københavns and Frederiksberg Kommuner (KF 01 276195)]. All Patients gave informed consent prior to inclusion into the Study.

Four patients were excluded: One patient was excluded because it was decided peri-operatively to change the surgical procedure and use another type of implant. Two patients were excluded after three months of follow-up because of death and recurrent infection requiring additional revision surgery. One patient was excluded because of poor quality of DEXA scans. Thus, 36 patients [female/male=17/19, mean age 67 years (range: 40–85 years)] were left for the study and 17 received a Trabecular Metal™ Cone (Table 1). Twenty-four of the patients had at least two previous TKA operations performed on the affected knee prior to inclusion in the study, and the rest of the patients had undergone one previous TKA operation. Ten patients had two-stage revision surgery, including at least three months of immobilisation of the affected limb. Fourteen patients were revised because of aseptic loosening, six because of instability, two because of PE-wear and four because of pain. Primary osteoarthritis was the major primary disease leading to the first TKA (Table 1).

The NexGen® (Zimmer Warsaw, USA) revision system was used in all cases: Rotating Hinge Knee ($n=5$), Legacy®Knee-constrained condylar ($n=25$) and Legacy® Knee-Posterior stabilised ($n=6$) (Table 1). Stems with or without off-set tibia and femur implants were used. The mean tibia stem diameter was 14 mm (10 mm–18 mm) and mean stem length was 110 mm (100 mm–155 mm). The mean femur stem diameter was 18 mm (14 mm–24 mm) and the mean stem length was 110 mm (100 mm–155 mm). 17 patients had femoral augmentation, seven patients had both tibial and femoral augmentation, and one patient had only a tibial augmentation, whereas 11 patients did not receive any augmentation. Five All Poly Patella (NexGen® Zimmer) implants were used.

The Knee Society's Knee Scoring System [12] was performed preoperatively and with follow-up after one year. Bone loss defects in the proximal tibia were classified according to the Anderson Orthopaedic Research Institute (AORI) bone classification [13]. Evaluation of preoperative radiographs showed five T3 bone loss defects and 31 T2b defects (Table 1). The final classification of bone defects was not changed reviewing the postoperative radiographs.

Measurements of BMD (g/cm^2) were performed by DEXA using a Norland XR-46 (Norland Corp. Fort Atkinson, WI, USA) bone densitometer in the coronal plane of the limb with a scan speed of 45 mm/s using the research scan option. Scans were performed of the proximal tibia and along the tibial shaft

Table 1 Demographic, clinical and operative data

	Total	TM Cone	NO TM Cone
<i>N</i>	36	17	19
Age [years]	67 (40–85)	65 (46–78)	67 (40–85)
Sex (M/F)	19/17	12/5	7/12
Body mass index	30 (21–46)	27 (21–36)	30 (25–46)
Primary disease			
Primary arthrosis	27	14	13
Secondary arthrosis	5	1	4
Rheumatoid arthritis	1	0	1
Sequelae after fracture	1	0	1
Haemophilia	2	2	0
Knee score			
Preoperative	37	40 (4–69)	34 (0–57)
One year	76	79 (39–100)	73 (17–99)
Two year	73	76(20–100)	70(20–100)
Function score			
Preoperative	24	19 (0–70)	25 (0–70)
One year	57	56 (5–90)	58 (15–80)
Two year	58	58 (5–91)	58 (15–90)
Prosthesis type			
Rotating hinge	5	4	1
Constrained condylar	25	10	15
Posterior stabilised	6	3	3
Cause of revision			
Aseptic loosening	14	7	7
Pain	4	2	2
Instability	6	3	3
PE-Wear	2	0	2
Deep Infection	10	6	4
Duration of surgery			
Mean	174 min	193 min	151 min
Range	(85 – 355) min	(135–355) min	(85 – 250) min
Bone defects tibia (AORI)			
T2	31	14	17
T3	5	3	2

in close relation to the tibial component (pixel size 1.0 mm×1.0 mm). Furthermore, scans of the distal tibia and fibula just above the ankle joint were performed bilaterally (pixel size 0.5×0.5 mm). All scans were performed by the same laboratory technician with the patient lying flat on their back, the knee extended and with the ankle in a neutral position pointing straight up. Postoperative scans were performed within the first two weeks after surgery and with follow-up after three, six, 12 and 24 months.

A custom-made software was used for analysis of DEXA scans [14]. The software allows measurements of BMD in close relation to orthopaedic implants, by exclusion of pixels considered by the software as metal. The software allows

a variable metal exclusion threshold to be set by the physician. The metal exclusion threshold was set at 4.5 g/cm² in this study.

On the computerised scan plots seven regions of interest (ROI) were selected for measurements of BMD of the proximal tibia and tibial shaft: the lateral tibial condyle (ROI 1), the medial tibial condyle (ROI 2), an area at the level of conjunction of the tibial component and the stem (ROI 3), three ROI along the tibial stem (ROI 4–6), and a distal area below the stem of the tibial component (ROI 7) (Fig. 2). In the distal tibia and fibula one ROI was selected one centimetre above the ankle joint line.

The precision of the BMD measurements was measured from double scans of the proximal tibia in 11 patients. Double scans were done consecutively on the same day with full repositioning of the patient and a break of five minutes between the scans. The mean precision was calculated in both groups for all ROI and expressed as the mean coefficient of variation (CV) in each ROI.

For statistical analysis SPSS statistical software 17.0 was used. The coefficient of variation [$CV = (SD/mean) \times 100\%$] was calculated to evaluate the precision of the BMD measurements in the various ROI. CV is given together with range and 95 % confidence limits (95 %-CL). The changes in BMD are given as the mean percent change together with total range and standard deviation (SD). For evaluation of the intra-group changes 95 %-CL were calculated (t-test for paired data). The potential differences in BMD changes between groups were evaluated using unpaired t-test.

Since no previously published studies evaluating the changes in BMD of the proximal tibia following rTKA existed when the study was planned, we used the SD from a recently published two-year follow-up study [11], where measurements of BMD were performed of the proximal tibia in patients with uncemented primary TKA. In that study a relatively large difference in SD (5.59 %–12.40 %) were found in the different regions of interest (ROI) used for BMD measurements, and our sample size calculations were based on an average SD from four different ROI of 7.53 %. We planned to be able to measure a significant difference (minimal relevant difference) between the two groups of 10 %, and with a type 1 error of 5 % and a type 2 error of 10 % the calculated sample size was $n=11$ in each group.

Results

The average precision for measurements of BMD in the various ROI in close relation to the tibial components of the two study groups was 3.6 % and 2.1 % for respectively the TM Cone and NO TM Cone group (Table 2).

After two years of follow-up the measured clinical effect of the rTKA ($n=36$) showed that the average knee and

Fig. 2 The 7 ROIs. **a.** DEXA scan with TM Cone (Right tibia), **b.** without TM Cone (Left tibia)

function score improved from 37 to 73 ($p=0.005$) and from 24 to 58 ($p=0.005$) respectively. An identical improvement ($p=0.0005$) of the knee and function scores were observed also in both individual study groups (Table 1), and no statistically significant difference between the improvements of the knee score ($p=0.36$) and function score ($p=0.97$) was found between the TM Cone and NO TM Cone groups. Surgical times using the TM Cone were

significantly longer ($p=0.004$) than that of the conventional method with an average time difference of 42 minutes (Table 1).

Changes in BMD within the two groups were quite similar. Overall decreases in BMD of 1.0–5.4 % was found in both groups (ROI 1–6) postoperative to 12 months of follow-up, except for ROI 7 which showed an increase in BMD (0.8–1.3). After 24 months of follow-up an increase

Table 2 Precision expressed as mean CV (%) with range and 95 %-CL

Study group	n	ROI 1 Lat	ROI 2 Med	ROI 3 Distal	ROI 4 Stem1	ROI 5 Stem2	ROI 6 Stem3	ROI 7 dstem	All ROI
TMC									
Mean	5	7.1	8.9	1.4	2.3	2.5	1.4	1.4	3.6
Range		2.30–11.80	1.90–19.90	0.30–2.90	0.80–4.20	0.80–4.40	0.94–2.00	0.05–2.83	1.4–8.9
95 %-CL		2.71–11.45	–0.80–18.68	0.06–2.65	0.63–4.0	0.55–4.48	0.88–1.88	–0.0034–2.81	0.7–6.5
NO TMC									
Mean	6	2.0	2.3	2.9	1.7	1.8	2.8	1.2	2.1
Range		0.09–3.80	0.08–8.30	1.20–4.50	0.09–4.5	0.05–4.40	0.15–5.20	0.59–2.98	1.2–2.9
95 %-CL		0.43–3.57	–1.02–5.58	1.41–4.29	–0.31–3.70	0.20–3.45	0.82–4.70	0.30–2.19	1.6–2.6

Table 3 Changes in BMD of the proximal tibia and tibial shaft around the rTKA

	BMD (g/cm^2) Postoperative TMC	BMD (g/cm^2) Postoperative NO TMC	Δ BMD [%] 0–3 months TMC	Δ BMD [%] 0–3 months NO TMC	P	Δ BMD [%] 0–6 months TMC	Δ BMD [%] 0–6 months NO TMC	P	Δ BMD [%] 0–12 months TMC	Δ BMD [%] 0–12 months NO TMC	P	Δ BMD [%] 0–24 months TMC	Δ BMD [%] 0–24 months NO TMC	P
ROI 1														
Mean	1.440	1.501	-3.7	-0.4		2.1	0.3		-1.0	0.5		-1.6	1.32	
Range	1.160–1.990	1.175–1.929	-14.7–8.6	-11.0–7.9	0.15	-14.0–22.3	-17.7–22.1	0.62	-15.0–15.2	-11.8–18.5	0.62	-24.1–17.7	-13.7–12.2	0.45
SD	0.20	0.21	6.9	5.6		11.8	8.9		8.3	8.0		13.5	7.7	
95 %-CL			-7.3 ; -0.0	-3.3 ; 2.4		-4.2 ; 8.4	-4.5 ; 5.0		-5.2 ; 3.3	-3.9 ; 4.9		-9.1 ; 5.8	-2.6 ; 5.3	
ROI 2														
Mean	1.493	1.578	-3.5	-1.1		-3.0	-1.4		-2.3	-1.8		4.2	4.0	
Range	1.266–1.984	1.258–1.174	-14.3–26.7	-11.8–11.7	0.40	-24.9–29.6	-17.5–106	0.66	-15.5–21.1	-15.1–10.1	0.88	-22.7–18.9	-14.0–19.6	0.95
SD	0.179	0.25	9.8	5.79		12.5	7.2		10.0	6.6		11.0	7.9	
95 %-CL			-8.7 ; 1.7	-4.1 ; 1.9		-9.6 ; 3.7	-5.2 ; 2.5		-7.4 ; 2.9	-5.5 ; 1.9		-1.9 ; 10.2	-0.1 ; 8.0	
ROI 3														
Mean	1.587	1.361	-0.8	-3.5		-2.5	-1.8		-1.5	-4.8		6.3	4.3	
Range	1.120–2.264	1.051–2.034	-12.3–16.0	-17.0–6.0	0.30	-15.7–9.9	-14.8–24.4	0.81	-15.0–15.6	-18.9–11.2	0.27	-8.8–21.7	-18.8–17.2	0.48
SD	0.31	0.27	7.6	6.9		7.6	9.3		9.0	7.0		7.5	8.6	
95 %-CL			-4.9 ; 3.2	-7.0 ; 0.1		-6.6 ; 1.5	-6.7 ; 3.2		-6.2 ; 3.1	-8.7 ; -0.9		2.2 ; 10.5	-0.2 ; 8.7	
ROI 4														
Mean	1.478	1.389	-2.9	-1.8		-3.3	-1.2		-4.3	0.5		5.4	4.6	
Range	0.985–2.184	1.069–1.820	-12.3–1.9	-13.8–8.0	0.55	-8.1–10.0	-9.2–10.1	0.24	-13.6–3.8	-13.5–22.8	0.07	-5.8–14.0	-6.6–35.0	0.80
SD	0.34	0.24	3.5	6.5		4.2	5.4		4.5	9.6		6.5	9.3	
95 %-CL			-4.8 ; -1.0	-5.2 ; 1.6		-5.5 ; -1.0	-4.1 ; 1.7		-6.7 ; -2.0	-4.8 ; 5.9		1.8 ; 8.9	-0.1 ; 9.4	
ROI 5														
Mean	1.667	1.578	-1.5	-3.2		-2.5	-0.8		-5.4	-4.0		4.5	1.9	
Range	1.228–2.376	1.214–1.840	-10.0–5.1	-18.0–5.4	0.36	-12.9–3.9	-7.2–7.5	0.32	-21.8–3.4	-21.8–5.4	0.56	-5.8–16.7	-5.9–9.2	0.17
SD	0.276	0.18	4.2	5.9		5.0	4.4		5.8	8.0		6.6	3.7	
95 %-CL			-3.8 ; 0.7	-6.2 ; -0.2		-5.2 ; 0.2	-3.2 ; 2.3		-8.4 ; -2.4	-8.4 ; 0.4		0.9 ; 8.2	-0.0 ; 3.8	
ROI 6														
Mean	1.775	1.677	-2.8	-4.0		-1.0	-0.4		-2.4	-2.1		2.0	-0.4	
Range	1.391–2.211	1.211–1.925	-19.2–3.1	-13.4–1.2	0.57	-9.6–6.4	-11.6–8.9	0.73	-13.4–6.1	-18.0–13.0	0.90	-7.6–12.7	-45.1–12.4	0.51
SD	0.22	0.18	-2.8	5.0		4.3	5.1		4.3	7.6		6.1	12.8	
95 %-CL			-6.1 ; 0.4	-6.6 ; -1.4		-3.3 ; 1.3	-3.2 ; 2.3		-4.6 ; -0.2	-6.3 ; 2.1		-1.4 ; 5.4	-7.0 ; 6.1	
ROI 7														
Mean	1.458	1.350	0.7	-0.1		0.9	0.8		1.3	0.8		-0.1	-0.9	
Range	0.947–2.085	0.775–1.653	-9.7–7.9	-7.6–8.7	0.62	-10.0–8.1	-10.4–13.3	0.97	-12.1–9.8	-11.7–17.2	0.84	-14.8–11.6	-11.1–10.7	0.73
SD	0.32	0.28	4.5	4.5		5.9	6.2		5.7	7.9		7.4	5.8	
95 %-CL			-1.7 ; 3.2	-2.4 ; 2.3		-2.3 ; 4.0	-2.5 ; 4.1		-1.6 ; 4.2	-3.6 ; 5.2		-4.2 ; 4.0	-3.9 ; 2.0	

in BMD was found along the stem (ROI 2–5) of 1.9–6.3 % with significant changes in the TM Cone Group (ROI 3, 4, 5). No significant change in BMD between the groups was found (Table 3).

BMD changes in the distal tibia of the operated extremity and contra-lateral distal tibia, showed an overall decrease in BMD after 24 months of follow-up (2 %, respectively, 1 %), with significant changes in the group of operated extremities (2.0 %, 95 %-CL: -0.0 %; -0.0 %). No significant changes between the two groups (TM Cone/NO Cone) was observed.

Discussion

Knee Society knee and function scores improved significantly (37 to 73 and 24 to 58) from approximately the same baseline values to the same level at two year of follow-up in both groups. The finding is consistent with Meneghini et al. [7] who followed 15 patients with rTKA with TM Cone for an average of 34 months earlier. They found an increase in Knee Society clinical score from 52 to 85 points (knee function scores not reported). Peters et al. [15] examined the clinical results of 47 rTKA with insertion of metaphyseal cemented femoral and tibial components with press-fit stems at a mean of 36 months of follow-up. They did not describe the extent of bone loss of the proximal tibia, but they found overall good to excellent results. Studies on clinical outcome after rTKA using structural bone grafting also report good results [16].

The reproducibility of our BMD measurements expressed as the average precision was in this study 3.6 % and 2.1 % for measurements in knees with and without TM Cone. This is consistent with other DEXA studies on BMD changes after knee replacement surgery, where the precision ranges from 0.9–8.3 % [10, 17, 18]. The slightly higher precision error in the TM Cone group was caused by a significantly higher CV for repeated measurements of the two proximal ROIs (ROI 1 and ROI 2). The area of ROI 1 and 2 are small which increases the CV [19].

Studies on BMD changes in the lower extremity after different physiological and traumatic influences are many. A decrease in BMD is often observed after immobilisation and reduced mobility, after ankle fractures, tibia shaft fractures and a postoperative decrease in BMD ranging from nearly unchanged to 27 % have been measured one year after TKA [10, 20, 21], THA [22] and osteotomy of the tibia [23].

Järvinen and Kannus [24] have described factors that are thought to be involved in the process of bone loss: the injury itself, the operative trauma and post-traumatic immobilisation. In our study, the initial decrease in BMD is probably due to the response of the organism to the surgical trauma and continued reduced mobility. All patients included in this study had a period before the rTKA of physical inactivity

because of the failed TKA. In addition ten patients had an additional period of immobilisation of the affected limb (spacer status in two-stage revision). These circumstances in combination with the cause of knee prosthesis failure (e.g. infection, wear) and previous surgery increase bone resorption resulting in initial low BMD values prior to rTKA. Entering the study with low BMD values could be an explanation for the fact that large decreases in BMD are absent due to the already depleted bone stock.

At 24 months of follow-up significant increase in BMD were found in ROI 3, 4 and 5 in the TM Cone group. Similar increase in BMD was also observed along the stem in the NO TM Cone group after 24 months but was not statistically significant. These results imply, that notable increased bone remodelling occurs along the tibial revision stem. In the literature, no published data from studies measuring BMD using DEXA after rTKA exists; however, experimental strain studies have been published. Completo et al. [25] performed an experimental quantification of strain shielding in the proximal synthetic tibia following rTKA. They tested the use of a revision tibial component with cemented (proximal and distal cementation) stem (13 mm×60 mm) and press-fit (proximal cementation) stem (14 mm×115 mm) of the proximal tibia. They found that the cemented stem induced a pronounced stress shielding effect of the proximal tibia close to the base plate of the tibial component, while the press-fit stem showed a minor effect of strain shielding along the stem. Both the cemented and press-fit stems transferred load to the bone at the tip of the stem. We believe that the results of the experimental stain study of the press-fit stem model are in good agreement with the bone remodelling pattern found in our study with a moderate increase in bone stock along the stem in both groups.

This is the first published study on BMD changes after rTKA. The bone remodelling pattern was almost the same in the two groups and no significant difference in changes in BMD between the groups was found. The Bone remodelling pattern is probably due to the strain forces along the stem.

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