Do Porous Tantalum Implants Help Preserve Bone?

Evaluation of Tibial Bone Density Surrounding Tantalum Tibial Implants in TKA

Alicia K. Harrison MD, Terence J. Gioe MD,
Christine Simonelli MD, Penny J. Tatman MPH,
Mary C. Schoeller RT(R), CDT

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Abstract

Background TKA with conventional metal-backed tibial implants subjects the tibial metaphysis to stress shielding, with resultant loss of bone density.

Questions/purposes We hypothesized tibial bone mineral density in patients with porous tantalum (trabecular metal) tibial baseplates would (1) more closely parallel tibial bone mineral density in the nonoperative control limb and (2) be better maintained than in conventional historical controls. **Patients and Methods** We prospectively followed 41 patients (35 men, six women) 60 years of age or younger undergoing TKA with uncemented trabecular metal tibial

components. Patients underwent dual-energy xray absorptiometry scans of both proximal tibiae preoperatively and at 2 months, 1 year, and 2 years postoperatively. We determined bone mineral density in three selected regions of interest (Zone 1, between the pegs; Zone 2, beneath the pegs; Zone 3, directly below entire baseplate). Precision analysis revealed a precision error of 4% or less for each region of interest, indicating adequate power to detect bone mineral density changes of 8% or greater.

Results Bone mineral density percent change was different between the operative and nonoperative knees only in Zone 3 and only at 2 months. There was no change in bone mineral density in any zone in the nonoperative knee at any time. Only in Zone 3 did the bone mineral density decrease at 2 months in the operative knee.

Conclusions Trabecular metal implants appear to maintain tibial bone mineral density in a parallel fashion to the nonoperative limb in this population and better than historical controls.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at Minneapolis Veterans Administration Medical Center and HealthEast Osteoporosis Center, St Paul, MN.

A. K. Harrison, T. J. Gioe
Department of Orthopaedic Surgery, University of Minnesota
Medical School, Minneapolis, MN, USA

T. J. Gioe (✉)
Minneapolis Veterans Administration Medical Center
Section 112E, 1 Veterans Drive, Minneapolis, MN 55417, USA
e-mail: tjgioe@gmail.com

C. Simonelli, M. C. Schoeller
HealthEast Osteoporosis Center, St Paul, MN, USA

P. J. Tatman
HealthEast Research and Education, St Paul, MN, USA

Introduction

The number of TKAs performed in the United States continues to increase, with the rate of TKAs tripling from 1990 to 2002 [12]. The incidence of osteoarthritis of the knee is increasing in a younger patient population, with TKA more commonly performed for active patients in their 50s [13, 22]. These patients present multiple challenges for orthopaedic surgeons, as their activity level and life expectancy demand better long-term implant performance.

The surgical challenge and decreased survival of revision knee arthroplasty are well documented [2]. The severity of bone loss encountered at the time of revision arthroplasty plays a major role in the challenges faced with

revision TKA. Bauman et al. reported a 10-year survival rate of 75.9% for revision TKA with structural allograft for bone loss [2]. Others have reported a lower survival rate of revision TKA in younger patient populations [7, 23]. With the increasing number of younger patients receiving TKAs, the need for bone-preserving implants becomes clear [6].

Previous studies have documented the pattern of bone mineral density (BMD) changes about TKA implants, with some studies reporting a marked decrease in BMD beneath tibial baseplates of various designs [14, 21, 26]. This decreased BMD is presumably in response to altered stress concentration, which may be time and design dependent [5, 14, 15]. Implants with a lower modulus of elasticity approximating that of native bone may decrease or eliminate this bone loss.

Cementless tibial implants rely on bone ingrowth and remodeling around the implant for secure fixation and implant longevity. Tantalum has a unique modulus of elasticity similar to that of host bone [9]. Tantalum tibial implants therefore might result in increased loading of the bone in contact with the whole implant and minimize stress shielding seen about the tibial implant. As marked bone ingrowth has been observed at the time of revisions of this implant [11, 24], and because bone ingrowth presumably is related to durability, this sort of implant may result in fewer revisions for aseptic loosening. However, long-term survival of this implant has not been clinically confirmed.

We hypothesized tibial BMD in patients with porous tantalum (trabecular metal [TM]) tibial baseplates would (1) more closely parallel tibial BMD in the nonoperative control limb and (2) be maintained better than in conventional historical controls.

Patients and Methods

We considered patients younger than 62 years undergoing primary TKA between 2005 and 2007 as candidates for this study. During this time, we performed TKAs in 458 patients. We excluded patients with known metabolic bone disease, those taking medications affecting BMD such as bisphosphonates, calcitonin, and hormone replacement (calcium and vitamin D were not excluded), and those whose preoperative deformity was judged to require modular stems, augmentation, or a degree of constraint not offered in the studied design. Patients with a prior contralateral TKA were not excluded. During the study time 41 patients (35 men, six women) who met the criteria underwent TKA with an uncemented TM tibial component (Zimmer NexGen®; Zimmer Inc, Warsaw, IN) (Fig. 1) and cemented femoral and all-polyethylene patellar components. Two patients had a contralateral TKA before the study and one had staged bilateral TKAs performed during

Fig. 1 The uncemented tantalum TM tibial component used in the study (Zimmer Nex-Gen® TM) is shown.

Table 1. Patient demographics

Variable	Value
Number of patients	41
Age of patient preoperatively (years)*	56.0 ± 4.3 (42.9–62.6)
Number of males/females	35/6
Number of Caucasian/ African-American/Asian	37/3/1
Body mass index of patients preoperatively*	32.6 ± 4.4 (24.8–43.5)
Number of normal weight/ overweight/obese	2/10/29
Number with osteoporosis/ low bone mass/normal bone mass	0/16/24

* Values are expressed as mean ± SD, with range in parentheses.

the course of the study. Forty-two operative knees and 39 nonoperative knees therefore were available for analysis. Power analysis indicated 40 patients would be needed to detect a 35% difference in bone density (consistent with another study [15] and at a level that may be clinically relevant), assuming an alpha of 0.05 and a power of 80%. The mean age of the patients was 56.0 years (range, 42.9–62.6 years; SD, 4.3 years) (Table 1). IRB approval was obtained and all patients provided informed consent.

Standard operative techniques were used; the femoral component was aligned in 3° external rotation relative to the posterior condylar axis or in neutral rotation relative to the transepicondylar axis with use of an intramedullary guide, and the tibial cuts were aligned with an extramedullary system. All operations were performed by or under the direct supervision of the principal investigator or one of three other adult reconstructive surgeons, each of whom supervised similar numbers of procedures throughout this trial. We recognize tibial bone density is greatest closest to the joint and may vary as the implant is placed at differing levels from the joint line. Although it would be difficult to

ensure the implant was placed at the exact level in each patient, our surgical technique typically was based on a tibial resection of 0 to 2 mm below joint level of the most deficient compartment.

All perioperative and postoperative treatments were identical. All patients were allowed immediate postoperative weightbearing and progressed from using assistive devices as tolerated. Each patient received 24 hours of perioperative antibiotic prophylaxis and routine postoperative deep vein thrombosis (DVT) prophylaxis. Patients without additional risk factors for DVT or a history of DVT/pulmonary embolism received aspirin, 162 mg daily for 6 weeks. Patients with additional risk factors were given low-molecular-weight heparin until discharge and then treated with aspirin for 6 weeks. All patients also received mechanical prophylaxis with foot and ankle pneumatic compression devices until discharge.

Routine clinical followup included radiographs and validated scoring instruments (Knee Society score [10], WOMAC score [3], SF-36 score [17, 18]) at scheduled intervals of 2 weeks, 2 months, 6 months, and 1 and 2 years.

Patients underwent dual-energy xray absorptiometry (DEXA) scans of the bilateral proximal tibiae with designated precision knee software (GE Lunar Prodigy Advance[®], v.11.1; GE Medical Systems, Milwaukee, WI) preoperatively and at 2 months, 1 year, and 2 years postoperatively. Fourteen of the patients (12 men, two women) were measured three times while they were in the supine position, repositioning between scans, to calculate the coefficient of variation and determine precision error measurements. Three selected regions of interest (ROIs) (Zone 1, between the pegs; Zone 2, beneath the pegs; Zone 3, directly below the entire baseplate, encompassing Zone 1) (Fig. 2) were chosen to evaluate BMD using a standardized protocol. Additional ROIs were used to help align the composite template on the nonoperated knee using similar methodology to that used by Abu-Rajab et al. [1]. Lumbar spine and hip BMD values also were obtained preoperatively and at 2 years to characterize patients as having osteoporosis, low bone mass, or normal bone mass. Some patients did not return for their 1- and 2-year scan appointments despite frequent reminders and rescheduled appointments, leaving smaller data cohorts at these periods.

BMD and precision (reproducibility) analyses were completed using GE Lunar Prodigy Advance[®] (v.10.5) software. Fifteen patients had each knee scanned three times and BMD was calculated for each scan. The BMD precision error (reproducibility), which was measured using the root mean square method, ranged from 3.0% to 3.6% for each of the three ROIs, with a precision error of 2.8% for the three sites combined. As a result, BMD changes of 8% or greater for individual patients could be considered real changes and not artifacts of precision error.

Fig. 2A–B The ROIs are shown superimposed on (A) the nonoperative knee and (B) the operative knee. Zone 1 is between the pegs and is contained in Zone 3.

In comparison, age-related bone loss in trabecular bone is reportedly approximately 1% annually [16]. The percent change in BMD from the preoperative scans on the operative and nonoperative knees at the three designated ROIs to scans at 2 months, 12 months, and 24 months was analyzed using Student's paired *t* test. BMD preoperatively and at 2 months, 12 months, and 24 months also was compared for operative and nonoperative knees at the three designated ROIs using Student's *t* test or the Mann-Whitney test depending on the normality of the data, to determine if there were differences in BMD between the knees. Because of multiple comparisons in each zone, the Bonferroni correction method was used and *p* values less than 0.016 were considered significant. SPSS[®] v15.0 (SPSS Inc, Chicago, IL) was used for all analyses.

Results

The percent change in BMD was similar in the operative and nonoperative knees except in Zone 3 where it was reduced ($p = 0.001$) only at 2 months (Table 2). There was no change in BMD in the nonoperative knee for any ROI at any time. In Zone 1, the area between the pegs immediately beneath the baseplate, we found no change in BMD in the operative and nonoperative knees at any time (Table 3). In Zone 2, the region immediately beneath the pegs, we again found no change in BMD in the operative or nonoperative knee at any time (Table 4). Only in Zone 3 did the BMD decrease in the operative knee (Table 5). The mean BMD decreased ($p = 0.005$) in Zone 3 from 1.12 (SD, 0.19) preoperatively to 1.04 (SD, 0.22) at 2 months in the operative knee. There was no difference in BMD at 1 and 2 years in this ROI in the operative knee ($p = 0.06$ and $p = 0.136$, respectively).

Discussion

Bone loss or poor bone quality is a major concern for any orthopaedic surgeon performing revision TKAs. As an increasingly younger patient population undergoes TKA, the orthopaedic surgery community must consider techniques and implants that may preserve bone for a potential revision TKA. We sought to evaluate the BMD about a new uncemented tibial implant with a lower modulus of elasticity to determine if this implant might limit the stress shielding seen with more traditional tibial baseplates.

There are some limitations to this study. First, the majority of the participants were male, which, although

Table 3. Comparison of preoperative and postoperative BMD in Zone 1

Knee/time of measurement	Number	BMD value*	p Value [†]
Operated knee			
Preoperative	42	1.03 (0.22)	0.46
2 months	42	(0.24)	
Preoperative	34	1.03 (0.23)	0.35
12 months	34	0.98 (0.30)	
Preoperative	21	1.05 (0.28)	0.59
24 months	21	1.02 (0.34)	
Nonoperated knee			
Preoperative	39	1.04 (0.18)	0.94
2 months	39	1.04 (0.18)	
Preoperative	30	1.04 (0.18)	0.47
12 months	30	1.03 (0.19)	
Preoperative	18	1.05 (0.22)	0.26
24 months	18	1.01 (0.19)	

* Values are expressed as mean, with SD in parentheses; †paired t test; BMD = bone mineral density.

characteristic of a Veterans Administration Medical Center patient population, is not representative of other TKA populations. However, this controlled population did allow us to better control for variations in BMD based on age and gender. Second, no statements can be made regarding BMD changes beneath the TM tibial baseplate beyond 2 years. As survival of most TKA designs is excellent for the first few years after TKA, a longer-term evaluation might prove valuable. At least one longer-term followup study has shown BMD loss of as much as 36.4% at 8 years after TKA [14]. Third, BMD changes after TKA may be most pronounced (and therefore most clinically relevant) in

Table 2. Comparison in percent change in BMD for operative and nonoperative knees for all ROIs

ROI/times of measurement	Percent change in BMD*		p Value [†]
	Operated knees	Nonoperated knees	
Zone 1			
Δ between preoperative and 2 months	−0.6% ± 25.2%	0.6% ± 12.9%	0.08
Δ between preoperative and 12 months	−3.0% ± 27.3%	−1.2% ± 14.4%	0.75
Δ between preoperative and 24 months	2.0% ± 25.6%	−2.2% ± 10.0%	0.98
Zone 2			
Δ between preoperative and 2 months	−2.0% ± 15.8%	−0.8% ± 8.9%	0.36
Δ between preoperative and 12 months	−1.6% ± 13.6%	−0.7% ± 10.2%	0.78
Δ between preoperative and 24 months	0.2% ± 14.1%	1.7% ± 8.2%	0.62
Zone 3			
Δ between preoperative and 2 months	−6.7% ± 18.0%	−0.5% ± 9.6%	0.001
Δ between preoperative and 12 months	−8.4% ± 25.3%	−1.1% ± 11.3%	0.14
Δ between preoperative and 24 months	−6.6% ± 21.5%	−1.2% ± 9.6%	0.31

* Values are expressed as mean ± SD; †paired t test; BMD = bone mineral density; ROI = region of interest.

Table 4. Comparison of preoperative and postoperative BMD in Zone 2

Knee/time of measurement	Number	BMD value*	p Value [†]
Operated knee			
Preoperative	42	1.19 (0.20)	0.24
2 months	42	1.15 (0.22)	
Preoperative	34	1.19 (0.22)	0.35
12 months	34	1.17 (0.24)	
Preoperative	21	1.22 (0.25)	0.98
24 months	21	1.22 (0.28)	
Nonoperated knee			
Preoperative	39	1.20 (0.17)	0.42
2 months	39	1.19 (0.17)	
Preoperative	30	1.20 (0.18)	0.55
12 months	30	1.19 (0.18)	
Preoperative	18	1.23 (0.19)	0.30
24 months	18	1.20 (0.18)	

* Values are expressed as mean, with SD in parentheses; †paired t test; BMD = bone mineral density.

Table 5. Comparison of preoperative and postoperative BMD in Zone 3

Knee/time of measurement	Number	BMD value*	p Value [†]
Operated knee			
Preoperative	42	1.12 (0.19)	0.005
2 months	42	1.04 (0.22)	
Preoperative	34	1.12 (0.20)	0.06
12 months	34	1.02 (0.31)	
Preoperative	21	1.14 (0.24)	0.136
24 months	21	1.06 (0.31)	
Nonoperated knee			
Preoperative	39	1.12 (0.16)	0.52
2 months	39	1.11 (0.15)	
Preoperative	30	1.13 (0.15)	0.47
12 months	30	1.12 (0.17)	
Preoperative	18	1.12 (0.17)	0.47
24 months	18	1.10 (0.17)	

* Values are expressed as mean, with SD in parentheses; †paired t test; BMD = bone mineral density.

the distal femur [1, 14, 25, 26], but we did not examine this, as no tantalum ingrowth primary femoral component was available.

Accurately measuring and comparing bone density is challenging given the many variables that may affect bone density measurement and comparison. Osteoarthritis may alter the preoperative bone density of the operative and nonoperative knees, and pain secondary to osteoarthritis may limit the patient's weightbearing, likewise affecting

the bone density of either limb. Additionally, changes in anatomy and the weightbearing axis of the affected knee may increase density of the medial or lateral compartment in varus or valgus knees, respectively. Postoperatively, bone density may be affected similarly by weightbearing activity of patients and alterations in the mechanical axis of the limb. Finally, a potentially useful comparison to different TKA designs in the same patient was impractical as the sample size was small and the different implant design in the contralateral limb made zone modeling difficult. We acknowledge these limitations but believe the study population was too small to analyze multiple variables. Considering the logistics, patient commitment, and expense involved in this study of 41 patients (one of the larger single-design BMD studies), larger studies may prove impractical.

Quantifying BMD can be accomplished by numerous techniques such as ultrasound, quantitative CT, and DEXA. DEXA has the benefit of decreased radiation compared with CT. Also, recent software advances with DEXA technology allows for accurate measurement around arthroplasty implants. The software we used in this study to measure BMD can subtract the region occupied by the implant, measuring only the bone in question. The density is reported for the area as mg/cm², not as total density, effectively negating the area occupied by the implant pegs.

Because of the unique design characteristics of low modulus and excellent bone ingrowth, it has been suggested a monoblock TM tibial component may be associated with a lower rate of osteolysis and component loosening, thereby leading to improved implant survivorship. A recent midterm study of this implant showed stable components with no evidence of osteolysis or loosening in 125 arthroplasties at a minimum 5-year followup [19]. Additionally, a recent radiostereophotogrammetric analysis of this implant compared with a cemented tibial component showed cessation of subsidence after 3 months in the TM component, suggesting improved stability compared with previous metal-backed cementless designs [8].

Previous studies examining BMD surrounding TKA tibial components have shown variable changes, although comparisons are limited by varying followups and implant designs. Seitz et al. [25] reported a small decrease in uncemented tibial BMD 1 month postoperatively with a stemmed tibial component, with density returning to the immediate postsurgery level by 1 year. Bohr and Lund [4] reported a 15% decrease in BMD 6 months after surgery, which returned to 90% of the immediate postoperative level by 3.5 years after the operation. Levitz et al. [14] reported on seven patients followed for 8 years and observed inconsistent declines in tibial BMD in the first 6 weeks to 6 months after TKA, a return to the immediate postoperative density by 1 year, and a mean 36.4%

decrease in BMD of the proximal tibia 8 years after TKA. In a more recent study reviewing BMD beneath an uncemented tibial implant, Petersen found BMD decreased 22% at 3 years [20]. His study proposed alteration of the mechanical axis to a prearthrosis alignment may play a role in the decreased BMD noted postoperatively [20]. Unlike these previous studies, we found the BMD unchanged from the preoperative measurement in two of the three ROIs examined. We believe the unique properties of the TM tibial implant may be responsible for maintaining the BMD in Zones 1 and 2. The material characteristics of tantalum closely match that of bone (cancellous 10–1723 MPa; cortical 12,000–18,000 MPa) with a modulus of elasticity of 5200 MPa [9]. With biomaterial properties similar to that of host bone, stress shielding is minimized and load transfer across the implant should be more uniform. This may result in an increase in the loading of the bone in contact with the whole implant and minimize the stress shielding seen about the tibial implant that was reported in other studies [5, 14, 15].

Some studies have sought to determine the role design of the tibial baseplate (stemmed versus pegged) or method of fixation (cemented versus ingrowth) might play in the changes seen in BMD. Lonner et al. [15] and Bourne and Finlay [5] found centrally stemmed tibial components had a greater impact on stress shielding of the proximal tibia than those without stems or with short pegs. In another study, changes in BMD beneath cemented and uncemented stemmed baseplates were compared. The authors found no difference in BMD between the two methods of fixation [1].

The ROIs in our study were designed specifically for the implant in question. Zones 1, 2, and 3 were chosen because they might sustain stress shielding that could be clinically important with time. We believed Zone 3 was an especially important area as it represents all the bone immediately adjacent to and supporting the implant. The BMD in Zone 3 was seen to decrease substantially at 2 months in the operative knee. This is an interesting finding as Zone 3 includes Zone 1, with only the addition of small regions of bone outside the pegs, and Zone 1 did not have a similar decrease in BMD in the operative knee. As Zone 3 would include the more sclerotic medial/lateral plateau region characteristic of varus/valgus gonarthrosis, perhaps BMD decreases enough with the postsurgical removal of this bone to impact the ROI. Although the percent change in Zone 3 BMD from preoperatively to 2 months postoperatively differed between the operative and nonoperative knees, BMD did not increase with time in the nonoperative knee in this ROI. Possible explanations for this finding are diminished BMD with age or improved bilateral weight transfer after successful TKA. We also examined each ROI with time for each patient. Although the average BMD did not change in Zones 1 and 2 in the operative knee, we

found the BMD increased in some patients and decreased in others. This is consistent with other studies of BMD of the proximal tibia after TKA showing broad ranges in BMD with large SDs. Abu-Rajab et al. [1] reported SDs from 9.2% to 23.1% and Wang et al. [27] reported SDs from 8.8% to 14.1% with BMD percent changes ranging from –30.9% to +36.5%. Our study showed SDs from 9.0% to 32.1% and BMD percent changes ranging from –68.8% to +100.3%. This shows the importance of analyzing percent change in BMD rather than an absolute value and reflects the number of variables that may impact proximal tibial BMD.

The potential for implants that prevent stress shielding and therefore potential bone loss has long-term implications for arthroplasty revisions. Bone loss attributable to stress shielding in periprosthetic bone has been described in multiple studies involving the distal femur and proximal tibia [1, 5, 7, 12–14, 21, 23, 26]. Results of our study suggest BMD may be better preserved beneath a TM tibial baseplate compared with previous implant designs. Whether this will positively impact the anticipated TKA revision in the younger patient remains unanswered. Continued research of implants that minimize stress shielding and emphasize bone preservation is necessary as an increasingly younger patient population is considered for TKA.

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