Loss of Cement-bone Interlock in Retrieved Tibial Components from Total Knee Arthroplasties

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Abstract

Background Aseptic loosening continues to be a short- and long-term complication for patients with cemented TKAs. Most studies to this point have evaluated tibial component fixation via radiographic changes at the implant-bone interface and quantification of component migration; direct assessment of morphologic features of the interface from functioning TKAs may provide new information regarding how TKAs function and are fixed to bone.

Questions/purposes In a postmortem retrieval study, we asked: (1) What are the morphologic features at the cement-trabecular bone interface in retrieved tibial

components? (2) Do constructs with greater time in service have less cement-trabecular bone interlock? (3) Do constructs with more estimated initial interlock sustain more interlock with in vivo service?

Methods Fourteen postmortem retrieved tibial components with time in service from 0 to 20 years were sectioned and imaged at high resolution, and the current contact fraction, estimated initial interdigitation depth, current interdigitation depth, and loss of interdigitation depth were quantified at the cement-bone interface. Estimated initial interdigitation depth was calculated from the initial mold shape of the cement mantle that forms around the individual trabeculae at the time of surgery. Loss of interdigitation depth was the difference between the initial and current interdigitation depth.

Results There was resorption of trabeculae that initially interlocked with the cement in the postmortem retrievals as evidenced by the differences between current interdigitation and the estimated original interdigitation. The current contact fraction ($r^2 = 0.54$; $p = 0.0027$) and current interdigitation depth ($r^2 = 0.33$; $p = 0.033$) were less for constructs with longer time in service. The current contact fraction for implants with 10 or more years in service (6.2%; 95% CI, 4.7%–7.7%) was much less than implants with less than 10 years in service (22.9%; 95% CI, 8.9%–37%). Similarly, the current interdigitation depth for implants with 10 or more years in service (0.4 mm; 95% CI, 0.27–0.53 mm) was much less than implants with less

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than 10 years in service (1.13 mm; 95% CI, 0.48–1.78 mm). The loss of interdigitation depth had a strong positive relationship with time in service ($r^2 = 0.74$; $p < 0.001$). Using a two-parameter regression model, constructs with more initial interdigitation depth had greater current interdigitation depth ($p = 0.011$), but constructs with more time in service also had less current interdigitation depth ($p = 0.008$).

Conclusions The cement-trabecular bone interlock obtained initially appears to diminish with time with in vivo service by resorption of the trabeculae in the cement interlock region.

Clinical Relevance Our study supports the surgical concept of obtaining sufficient initial cement interlock (approximately 3 mm), with the acknowledgment that there will be loss of interlock with time with in vivo service.

Introduction

More than 600,000 TKAs are performed each year in the United States [11] and the number of joint arthroplasties is expected to increase to more than 3 million per year by 2030 [8]. TKA is a successful procedure providing substantial improvement in functional status and quality of life for patients. Even with this success, aseptic loosening continues to be a concern during the long term. The lifetime risk of revision continues to be large and recently was estimated to be 14.9% for males and 17.4% for females [21].

Substantial efforts have been made to improve long-term function of knee arthroplasties, particularly regarding knee kinematics, surgical alignment, cementing technique, and development of new polyethylene formations. Far less attention has been given to changes in cemented TKA fixation with in vivo service, and this generally has been limited to assessment of radiolucencies at the implant-bone interface [17]. There also is evidence that there are changes in bone density surrounding cemented tibial trays with in vivo service. Bone mineral density (BMD) measured during the initial 3 months after TKA showed a temporary decrease of 13% in BMD under the tibial tray [9]. Further, tibial tray components that have been cemented with a central stem or keel show a greater loss of BMD under the tray when compared with components that do not use a keel [10]. Based on these findings, Lonner et al. [10] suggested that proximal bone resorption may contribute to early implant loosening through loss of bony support under the tray. While the BMD measures of bone distal to the implants are likely important to the loosening process, there are no current estimates of the loss of mechanical

Table 1. Donor information for 12 postmortem retrievals and two laboratory-prepared constructs with 0 time

Donor	Time in service (years)	Sex	Age (years)	BMI (kg/m ²)	Implant manufacturer*: type	Stem or stem with keel	Cruciate retaining or posterior stabilized	Radiographic score (loose, possibly loose, well fixed)
A	0	Male	70	34.3	Stryker: Triathlon [®]	Stem/keel	Cruciate retaining	Well fixed
B	0	Female	67	36.4	Stryker: Scorpio [®]	Stem/keel	Posterior stabilized	Well fixed
C	1	Female	73	22.7	Biomet: Vanguard [®]	Stem/keel	Cruciate retaining	Well fixed
D	2	Female	73	22.7	Biomet: Vanguard	Stem/keel	Cruciate retaining	Well fixed
E	2.5	Female	82	36.5	DePuy: PFC [®] Sigma [®]	Stem/keel	Posterior stabilized	Well fixed
F	3	Female	84	24.1	Zimmer: NexGen [®]	Stem/keel	Posterior stabilized	Well fixed
G	5	Male	61	36.3	Stryker: Triathlon [®]	Stem/keel	Cruciate retaining	Well fixed
H	6.5	Female	83	23.7	Stryker: Scorpio [®]	Stem/keel	Posterior stabilized	Well fixed
I	9	Female	74	31.9	Zimmer: NexGen [®]	Stem/keel	Posterior stabilized	Well fixed
J	10	Male	78	18.4	DePuy: AMK [®]	Stem	Posterior stabilized	Well fixed
K	11	Female	69	22.5	Wright Medical: Advanced [®]	Stem/keel	Posterior stabilized	Well fixed
L	16	Female	65	31.4	Stryker: Duracon [®]	Stem/keel	Cruciate retaining	Well fixed
M	18	Female	87	NA	Zimmer: Insall-Burstein I [®]	Stem	Posterior stabilized	Possibly loose
N	20	Female	90	23.2	Zimmer: Insall-Burstein I [®]	Stem	Posterior stabilized	Well fixed

* Manufacturers include Stryker Orthopaedics (Mahwah, NJ, USA), Biomet Inc (Warsaw, IN, USA), Zimmer, Inc (Warsaw, IN, USA), and Wright Medical Technology, Inc (Arlington, TN, USA); NA = information not available.

interlock at the cement-bone interface. Quantifying the loss of interface fixation is important because failure is expected to occur at or near the interface, based on clinical evidence of progressive radiolucencies at this interface. From a biomechanics perspective, interfaces with more interlock between cement and bone are stronger [15]. Furthermore, clinical guidance suggests that approximately 3 mm of initial interlock between cement and bone is sufficient to obtain good clinical results [2]. However, it is not known whether the interfaces with better initial interlock maintain this interlock during the long term.

We therefore determined the morphologic features of the fixation at the cement-bone interface from en bloc postmortem retrieved TKA components. These implants were not obtained from revision surgery for a loose implant. We asked three questions: (1) What are the morphologic features of the interlock between the cement and trabecular bone in retrieved tibial components? (2) Do constructs with greater time in service have less interlock between the cement and trabecular bone? (3) Do the constructs with more estimated initial interlock sustain more interlock with in vivo service?

Materials and Methods

Specimen Preparation

Twelve fresh knees with postmortem-retrieved TKA components were obtained through the SUNY Upstate Medical University or Case Western Reserve University Anatomical Gift Programs. There was one bilateral set of knees (donor implants C and D). Donor time in service, sex, age, and BMI were documented along with details about the type of TKA (Table 1). In addition, the trabecular bone area fraction of the supporting bone bed was measured (details below) as an indicator of bone density. All components had metal-backed tibial components and all polyethylene inserts were of a fixed-bearing design. AP and lateral radiographs were obtained and were radiographically scored as well fixed, possibly loose, or loose by our arthroplasty surgeon (THI). Well-fixed implants had limited (< 2 mm thick) or no radiolucency between the cement-bone interface. Implants with radiolucencies greater than 2 mm in more than one zone were considered loose. Implants which had radiolucencies that did not reach the threshold of the 2 mm over two or more zones were considered possibly loose. For the 12 retrievals, one donor implant was possibly loose (donor M). No clinical data including knee scores and activity level were available.

Two additional Time 0 cadaveric constructs (donors A and B) were prepared in the laboratory using an approach that mimicked the intraoperative environment. The Time 0

Fig. 1A–B (A) Sagittal cuts are made in 10-mm intervals across the tibial tray surface. Slice 0 corresponds to the central axis of the tibial tray. (B) Morphologic features of the cement-bone interface are analyzed for the undersurface of the tibial tray and along the stem and keel.

constructs were meant to represent the state of the implant fixation immediately after surgery but before any biologic remodeling. Briefly, fresh proximal tibiae were stripped of the soft tissue and warmed to 37° C in a simulated blood analog solution [16]. The transverse tibial plateau and stem/keel cuts were made. Pulsatile lavage was used to prepare the bone bed. Polymethylmethacrylate (PMMA) cement (Simplex P®; Stryker Orthopaedics, Mahwah, NJ, USA) was mixed and applied using a cement gun to the cut surface, a spatula was used to spread the doughy cement and to apply pressure forcing the cement into the trabecular spaces, and the metal tibial component was pressed into place.

Sagittal cuts were made at 10-mm intervals (Fig. 1) with a water-cooled abrasive blade (IsoMet® 2000; Buehler Inc, Lake Bluff, IL, USA) and specimen faces were ground and polished (EcoMet® 6; Buehler Inc) to 1200 grit. Sections were prepared with von Kossa stain to add contrast to the bone and picosirius red stain to differentiate soft tissue. Seven transverse slices were imaged for each TKA implant using a custom reflected white light imaging system at high resolution (5.7 µm/pixel) over the entire surface of each section. Briefly, an x-y stage was synchronized with a digital camera (Spot RT™; Diagnostic Instruments, Sterling Heights, MI, USA) to take individual images (30 mm²) over the entire surface and the images were assembled in a composite image. This resulted in section images of up to 11,500 by 10,500 pixels (120 megapixels) with 32-bit color image depth. This approach allowed the histomorphometric survey of the entire implant interface at a very high resolution.

Evidence of Trabecular Resorption: Cement as a Trace Fossil

During cementation, doughy PMMA cement is pressed into the trabecular bone bed of the proximal tibia and cement flows around individual trabeculae, after which the cement polymerizes in place. As such, the cement creates a mold in

Fig. 2A–D (A) A 3-D reconstruction and (B) a reflected white light image of the cement-bone interface for Donor A, a Time 0 case, shows interlock between the trabeculae and the cement layer. (C) A 3-D reconstruction and (D) a white light image show the postmortem retrieval from Donor G, with 5 years in service. Trabecular resorption with some areas of bone remaining in the cement layer and some empty cavities are seen. One-millimeter bar scales are shown. (Stain, von Kossa stain and picrosirius red).

the shape of trabeculae. The observation that the contour of the cement boundary represents the shape of the bone at the moment when the cement hardens was first made by Charnley [3]. The cement-bone interlock region for the laboratory-prepared Time 0 specimens from micro-CT reconstruction (Fig. 2A) and reflected white light imaging (Fig. 2B) illustrates the infiltration of PMMA cement around the individual trabeculae. A distinct feature of the postmortem retrievals with in vivo service was the resorption of trabecular bone (Fig. 2C–D) leaving cavities in the cement layer, indicating locations where the trabeculae originally had existed [14]. This resorbed space is analogous to trace fossils from the field of paleontology where an imprint, such as a footprint, is formed into a substrate material that then fossilizes with time. In this work, we used the trace fossil approach to estimate the initial state of the cement-bone interface.

Morphologic Assessment

Four different morphologic measures were made at the cement-bone interface for all implant slices using the high-resolution images described above. Current contact fraction was determined using a stereology method; one hundred random lines were projected on each image (Fig. 3A). At each

point of intersection between the cement boundary and projected line, visual inspection was used to determine whether there was cement-bone contact at this interface. Points of cement-bone contact were counted and divided by the total number of intersections to calculate current contact fraction.

The initial interdigitation depth of cement into trabecular bone was determined by constructing a piecewise segmented line that followed the initial extent of penetration of trabeculae into the cement (Fig. 3B, top solid line) and a second line that followed the extent of cement penetration into the trabecular bone (Fig. 3B, bottom solid line). The average distance between the two lines was calculated using a local minimum point-to-point measurement algorithm (Image-Pro® Plus; Media Cybernetics, Rockville, MD, USA). The current interdigitation depth was calculated in a similar fashion except the segmented line followed the extent of penetration of the existing bone into the cement mantle (Fig. 3B, dotted line). Regions with complete resorption of interdigitated bone or having no evidence of initial interdigitation were considered to have 0 mm of interdigitated depth. The loss of interdigitation depth was calculated as a fractional measure using (initial – current interdigitation depth)/initial depth. A repeatability study was conducted for the current contact fraction and initial interdigitation measures using 10 repeat analyses of representative sections (Table 2).

The bone area fraction of trabecular bone below the tibial tray from the slices 20 mm medial and 20 mm lateral from the midline was calculated as a measure of trabecular bone density. A stereology grid with 0.3-mm spacing was created just distal to the extent of cement penetration and was extended distally for 5 mm. Trabecular bone area fraction was calculated by totaling the number of grid points in contact with bone divided by all points examined.

Fig. 3A–B A region of the cement-bone interface shows the interlock between cement (c) and bone (b). A region of resorbed bone space (r) also is seen. (A) Random rays are used for stereologic measure of contact fraction. White filled circles indicate points of cement-bone contact; gray-filled circles indicate points of cement-bone noncontact. (B) The current interdigitation depth and estimated initial interdigitation depth are measured using a line tracing algorithm.

Statistical Methods

To address Question 2, simple regression models were used to correlate current contact fraction, current interdigitation depth, and loss of interdigitation depth with time in service. A square-root transformation was performed on the data before performing the regression models. Data were fit to quadratic equations of the form: parameter = $(a * \text{time in service (years)}^{1/2} + b)^2$, where a and b were constants. This was done to better capture the nonlinear response of the data. A two-parameter linear regression model with current interdigitation depth as the dependent variable and initial interdigitation depth and time in service as independent variables was used to address Question 3. All statistical analyses were conducted using JMP 9.0 (SAS Institute, Cary, North Carolina, USA).

Results

Morphologic Features of Cement-Bone Interface in Postmortem Retrievals

Loss of trabecular interlock with the cement was a common feature for the postmortem retrievals, but the remodeled interfaces did have bony support, albeit over a small fraction (approximately 10%) of the cement surface. The supporting bone structure often was localized at discrete areas along the interface (Fig. 4A, arrows show regions of contact along the cut plane). Trabeculae often supported the cement as pedestals that formed gloves in apposition with the irregular cement surface (Fig. 4B–C). In regions where there was extensive bone resorption from the interlocked regions (Fig. 4D), there was often fibrous tissue formation along with condensation of bone at the interface between cement and bone. Numerous retrievals exhibited regions with evidence of no initial interlock between the cement and bone (Fig. 4E–F) as evidenced by the flat and uniform cement layer. It is not clear that the lack of interlock was attributable to inadequate cement pressurization to cause cement flow around a trabecular bone bed or the inability to penetrate dense, sclerotic bone. Along the periphery of the tibial tray, there was often a gap between the cement and bone (Fig. 4G) with interposing fibrous

Table 2. Repeatability study for curCF, inID, and curID

Outcome parameter	Mean	SD	95% CI	Standard error of mean
curCF (%)	23.9	3.0	22.0–25.8	0.95
inID (mm)	1.483	0.021	1.469–1.496	0.007
curID (mm)	0.633	0.012	0.625–0.640	0.004

curCF = current contact fraction; inID = initial interdigitation depth; curID = current interdigitation depth.

Fig. 4A–G Reflected white light images show the cement-bone interfaces from the postmortem retrievals. **(A)** Regions of cement-bone contact (shown with arrows) underneath the metal tibial tray were localized to small regions of the interface. **(B)** Regions of resorption of bone in the interdigitated region often were accompanied by regions with apposition between cement and bone. **(C)** A magnified region from Illustration **B** shows pedestal support of the cement by the supporting trabeculae. **(D)** Regions of extensive loss of interlock were common and these sometimes resulted in an interface with interposing fibrous tissue and condensation of trabecular bone. **(E)** Regions with no apparent initial interlock of the cement layer

sometimes were found with a fibrous tissue layer. **(F)** Regions with no initial interlock also were accompanied by apposition between cement and bone and no soft tissue layer. **(G)** The peripheral regions of the tibial tray often exhibited a gap between the cement and bone with interposing fibrous tissue and evidence of extensive bony resorption at the periphery of the tray. Sources for the images are **(A–C)** Donor H with 6.5 years of service, **(D)** Donor I with 9 years of service, **(E)** Donor L with 16 years of service, **(F)** Donor D with 2 years service, and **(G)** Donor G with 5 years service. (Stain, von Kossa and picrosirius red).

tissue and there was evidence of extensive bony resorption at the periphery of tray. The location of the initial tibial cut was evident from the trabecular mold shape in the cement layer (Fig. 4G, dashed line) indicated that this component had bone that interlocked with the cement at the edge of the tray at the time of surgery.

The trabecular bone area fraction just distal to the cement layer was 17.5% (95% CI, 11.0%–24.0%) and 13.6 (95% CI, 9.4%–17.8%) for the medial and lateral plateau sections, respectively.

Effect of Time in Service

The current contact fraction between cement and bone was less for tibial constructs with longer time in service ($r^2 = 0.54$; $p = 0.0027$) (Fig. 5A). The relationship between current contact fraction and time in service appeared to be nonlinear, with a reduction in current contact fraction from the initial Time 0 state ($40.9\% \pm 11.3\%$) (Table 3) to less than 10% after 10 years in service. The current contact fraction for implants with 10 or more years in service (6.2% ; 95% CI, 4.7% – 7.7%) was much less than for implants with less than 10 years in service (22.9% ; 95% CI, 8.9% – 37%). Similarly, the current interdigitation depth

for implants with 10 or more years in service (0.4 mm; 95% CI, 0.27 – 0.53 mm) was much less than implants with less than 10 years in service (1.13 mm, 95% CI, 0.48 – 1.78 mm). The estimated initial interdigitation depth was not related to time in service ($r^2 = 0.01$; $p = 0.74$) (Fig. 5B) with a mean depth of $1.45 \pm .68$ mm. This suggests that the amount of initial interlock obtained at the time of surgery did not change (for this limited sample of the TKA population) during the last 20 years. There were cases from the last 2 years with approximately 0.7 mm of initial interdigitation depth. The current interdigitation depth showed a decrease with time in service ($r^2 = 0.33$; $p = 0.033$), consistent with the current contact fraction results. For constructs with in vivo service, the average current interdigitation depth decreased to 0.63 ± 0.54 mm. The loss of interdigitation depth had a strong positive relationship with time in service ($r^2 = 0.74$; $p < 0.0001$) (Fig. 5C). With 10 or more years in service, the loss of interdigitation depth was approximately 75%.

Effect of Initial Interlock

Constructs with more estimated initial interlock did sustain more interlock with in vivo service, but there also was a

Fig. 5A–C The graphs show the (A) current contact fraction, (B) estimated initial interdigitation depth and current interdigitation depth, and (C) loss of interdigitation depth as a function of time in service. Specimens with greater time in service had less current contact fraction, less current interdigitation depth, and greater loss of interdigitation depth.

loss of interlock with time in service. The interaction between current interdigitation depth and initial interdigitation depth and time in service is shown as a contour plot (Fig. 6). Using the two-parameter regression model with current interdigitation depth as the dependent variable, the independent variables initial interdigitation depth (estimate = 0.68 mm/mm; $p = 0.011$) and time in service (estimate = -0.047 mm/year; $p = 0.008$) had significant contributions. Using this model, a construct with 3 mm of initial interdigitation depth would be predicted to have 1.9 mm of interdigitation at 5 years and 1.2 mm of interdigitation at 20 years. In contrast, a construct with only 1 mm of initial interdigitation depth would have 0.5 mm of interdigitation at 5 years and no interdigitation at 20 years.

This suggests that 3 mm of initial interlock may be sufficient for long-term fixation, while 1 mm of interlock may not.

Discussion

Interlock between cement and bone, achieved through adequate bone bed preparation and cement pressurization [17], is known to be important for obtaining good initial fixation of TKA implants. The morphologic changes that occur to the cement-bone interface of TKA implants with in vivo service have not been explored in detail and could provide information regarding the normal function and

Table 3. Descriptive statistics for donor information and curCF, inID, and curID

Parameter	Mean	SD	Minimum	Maximum
Time 0 cadavers (n = 2)				
Time in service (years)	0	0	0	0
Age (years)	68.5	2.1	67	70
curCF (%)	40.9	11.3	33	49
inID (mm)	1.67	0.29	1.47	1.87
curID (mm)	1.61	0.29	1.41	1.81
Postmortem retrievals (n = 12)				
Time in service (years)	8.7	6.5	1	20
Age (years)	76.8	9.2	61	90
curCF (%)	10.2	7.6	4.2	32.2
inID (mm)	1.45	0.68	0.63	3.0
curID (mm)	0.63	0.54	0.23	2.1

curCF = current contact fraction; inID = initial interdigitation depth; curID = current interdigitation depth.

Fig. 6 A graph shows the current interdigitation depth as a function of initial interdigitation depth and time in service. Specimens with more initial interdigitation depth ($p = 0.0011$) and shorter time in service ($p = 0.008$) had greater current interdigitation depth. Individual data points are shown as open circles.

conditions that might initiate a process of progressive loosening of these implants. Using a series of functioning postmortem retrieved knee implants, we found that constructs with greater time in service had less interlock between cement and bone, and constructs with more estimated initial interlock maintained more interlock with in vivo service.

Our study has several limitations. First, the sample population was from postmortem retrievals obtained from anatomic gift programs and there were various implant designs. However, all had metal-backed trays, and all were

cemented, albeit with different amounts of initial cement-bone interlock. Further, the general finding of loss of interlock was common to all postmortem retrievals. Details of the cement type, cementing technique used, and the viscosity of the cement at the time of application were not available, but the resulting interlock structure was quantified in detail. The initial interdigitation measurement was an estimate using the trace fossil concept. Error in estimated initial interdigitation was 0.06 mm, based on the difference between estimated initial and current interdigitation depth for the Time 0 constructs; Time 0 constructs would have no bony resorption. This postmortem retrieval study was not a time course study where changes in fixation could be evaluated during a period of service for each donor bone. Cement-bone interlock status was quantified only at time of retrieval, along with an estimate of the initial state of fixation. However, the use of these relatively rare postmortem retrievals provided the opportunity to directly measure the morphologic features of the interface for normally functioning components in a way that is not possible with clinical radiographs (where interlock is difficult to observe) or intraoperative retrievals (where the interface is likely damaged during removal).

Although our results show that implants with approximately 3 mm of initial interlock maintain the most interlock with in vivo service during the short term, our data were not conclusive regarding the long-term results of constructs with substantial (approximately 3 mm) initial interdigitation depth (Fig. 5). It would be helpful to study constructs with initial interdigitation depths of approximately 3 mm and long (15–20 years) times in service. Data were not available regarding functional status of each TKA implant; only radiographic evidence of fixation was available to assess these implants. There was one implant (donor M) that was possibly loose. Statistical analysis of the

results without this data point did not change the overall response regarding the contact fraction and interdigitation depth with time in service. Finally, there was one bilateral pair of implants in this study (donor C and D), both with short times in service (1 and 2 years). Removal of donor C or D from the statistical analysis did not change the overall response regarding the contact fraction and interdigitation depth with time in service.

The cement-trabecular bone interlock that is obtained initially with cementation of the tibial component appears to diminish with in vivo service by resorption of the trabeculae in the cement interlock region. The mechanism driving the loss of interlock between trabeculae and cement in the cemented tibial components is not clear, but there are several possible candidates. Polyethylene and cement particles are known to cause a macrophage-induced inflammatory response leading to osteolysis [12, 19]. Fluid-induced trabecular lysis attributable to pumping of fluid along the trabeculae-cement interface is another recently proposed mechanism [13]. Breer et al. [1] found demineralization of viable trabecular bone at the interface with cement from hip resurfacing arthroplasties. They hypothesized that trabecular bone loss may be attributable to a low pH environment at the implant interface, which causes dissolution of mineral locally. Monomer toxicity and thermal necrosis attributable to heat polymerization are additional factors that often are cited regarding loss of fixation at the cement-bone interface [12].

Constructs with greater time in service have less interlock and the resulting fixation for longer-term constructs (> 10 years) was limited, with cement-bone contact fractions of approximately 6% and interdigitation depths of approximately 0.4 mm. This appeared to be sufficient to support load transfer between the metal tibial tray and the proximal tibia, as these retrievals were from radiographically well-fixed components. The state of bony fixation with in vivo service for cemented tibial components has not been explored extensively. Draenert et al. [5] presented one example where there was good interlock between trabeculae and cement 9 months after implantation in at least one region for a cemented tibial tray. For a series of post-mortem retrieved cemented tibial components, the force required to pull off the tibial tray from the bone decreased with time in service [6]. In addition, the location of failure changed from the metal-cement interface for short-term implantation to the cement-bone interface for longer-term implantation. They concluded that the cement-bone interface became weaker with time in service. This finding is consistent with the current observation of loss of interlock and cement-bone contact with time in service, as this would affect the strength of the interface.

Constructs with more estimated initial interlock between cement and bone maintained more interlock with time in

service. The fractional loss of interdigitation depth appeared to depend primarily on the time in service. Implants with limited initial interlock might be expected to lose a greater proportion of the interlock, and this might explain cases where progressive radiolucencies develop with time.

In addition to the interlock between trabeculae and cement, the quality of the supporting bone bed also likely contributes to the success of the construct. The trabecular bone area fraction of bone distal to the cement layer (average of 15.6%) was less than reported for normal medial (21%) and lateral (17%) bone from the proximal tibia [4]. With osteoarthritis, the bone fraction has been shown to increase (25%), with the increase attributable to the presence of sclerotic bone [4]. The observation that the retrieval bone area fraction is decreased compared with normal and osteoarthritic subchondral bone suggests that the retrievals have a reduced ability to support load below the tibial tray. This may be compensated by load transfer along the stem and keel of the component.

From a clinical perspective, our study showed that it is important to obtain a sufficient level of initial cement-bone interlock because some loss of interlock can be expected owing to trabecular resorption with long-term in vivo service. There is some consensus in the clinical community that 3 to 4 mm of cement penetration is optimal for fixation of tibial TKA components [2]. This is based on the concept that cement penetration of at least 2 mm will interlock with at least one transverse trabeculae [20]. Additional penetration beyond 5 mm is thought to increase the risk of thermal necrosis [2]. Use of pulsatile lavage and pressurization of cement has been shown to reduce the initial occurrence of radiolucent lines at the cement-bone interface [17] and increase the amount of cement penetration into the trabecular bone bed [18]. In cases where there is sclerotic bone, drilling the cut surface has been advocated to allow penetration of the cement [2]. Even with careful preparation, the immediate postoperative contact fraction will likely be less than 100% because the intertrabecular spaces may contain some residual lavage fluid and marrow, and because the cement shrinks on curing [7]. Our study supports the concept of obtaining sufficient initial interlock, with the acknowledgment that there will likely be some loss of interlock with long time in service.

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