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Is There A Difference in Bone Ingrowth in Modular Versus Monoblock Porous Tantalum Tibial Trays?

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Abstract

Contemporary total knee designs incorporating highly porous metallic surfaces have demonstrated promising clinical outcomes. However, stiffness differences between modular and monoblock porous tantalum tibial trays may affect bone ingrowth. This study investigated effect of implant design, spatial location and clinical factors on bone ingrowth in retrieved porous tantalum tibial trays. Three modular and twenty-one monoblock tibial trays were evaluated for bone ingrowth. Nonparametric statistical tests were used to investigate differences in bone ingrowth measurements by implant design, spatial location on the tray, substrate depth and clinical factors. Modular trays ($5.3 \pm 3.2\%$) exhibited higher bone ingrowth than monoblock trays ($1.6 \pm 1.9\%$, $p=0.032$). Bone ingrowth in both designs was highest in the initial 500 μm from the surface. Implantation time was positively correlated with bone ingrowth for monoblock trays.

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Introduction

Although cemented fixation is considered the gold standard for total knee arthroplasty (TKA) [1, 2], some cementless tibial components have been clinically successful [3–8]. Revision reasons of first generation cementless tibial components include tibial loosening, particle migration through screw holes, and particle induced osteolysis [9–13]. New materials and cementless designs have been proposed to address loosening due to stress shielding and breakdown of the cement mantle [14]. One of these new coatings, made of tantalum, is designed with a high porosity (75–85%), with the intent to increase bone ingrowth. It has favorable frictional properties ($\mu = 0.88$) to reduce micromotion between the bone and tray, and a low elastic modulus (2.5–3.9 MPa) to reduce stress shielding [15–17].

There are two types of NexGen® (Zimmer, Inc., Warsaw, IN) porous tantalum tibial trays that are currently clinically available. The monoblock design consists of a porous tantalum ingrowth surface with an ultra-high molecular weight (UHMWPE) bearing surface compression molded into it and two hexagonal porous tantalum pegs for initial stability. This monoblock design was intended to prevent backside wear, which may reduce long-term UHMWPE particle burden [18, 19]. An alternate design, the porous tantalum modular component, consists of a titanium alloy modular tray with a porous tantalum layer that also includes two hexagonal pegs. This design includes a central boss (small circular peg) in the central posterior of the tray that is used with a lock down screw.

Several clinical studies and one registry study of the porous tantalum tibial tray have shown no cases of tibial loosening [18, 20–22]. In a recent study using the Finnish registry with seven year follow up there were no reported revisions due to aseptic loosening in 1143 patients with a monoblock porous tantalum tibial tray [18]. Studies of porous tantalum tibial trays have shown stabilization of components at 2 and 5-year follow-ups despite high initial migration [20–22]. There have been only two retrieval studies of porous tantalum monoblock tibial trays to-date. One case study showed preferential bone ingrowth in the peg compared to the tray region [23]. The second study evaluated bone ingrowth of seven monoblock tibial trays, however no preferential bone ingrowth was detected [24]. No study has examined the bone ingrowth performance between the modular and monoblock porous tantalum tibial trays.

The effect of implant design (modular vs monoblock), spatial location within an implant and implantation time or other clinical factors on bone ingrowth into porous tantalum tibial trays implants remain unknown. Therefore, the goal of this study was to investigate in vivo bone ingrowth in retrieved monoblock and modular porous tantalum tibial trays implants. The first objective of this study was to determine the effect of implant design and spatial location within a porous tantalum tibial tray on bone ingrowth. The second objective was to determine if implantation time or patient factors correlated with bone ingrowth.

Materials and Methods

Porous tantalum tibial trays (NexGen® Trabecular Metal™; Zimmer Inc, Warsaw, Indiana) were retrieved during revision surgery under an IRB-approved multicenter retrieval

program. Between 2003 and 2014, 4 modular tibial trays (2 CR-Flex and 2 LPS-Flex) and 41 monoblock tibial trays (8 CR-Flex and 33 LPS-Flex) were collected. All of the tibial trays were revised following primary surgeries, except for one modular and one monoblock tibial. Clinical data consisting of age, height, weight, implantation time and reason for revision were obtained for each patient (Table 1). Revision operative reports were reviewed to verify the reason for revision and if loosening was noted by the treating surgeon.

The tibial trays were implanted for 1.9 ± 1.2 years (modular), 1.0 ± 0.3 years (monoblock: CR-Flex) and 2.5 ± 2.7 years (monoblock: LPS-Flex). The average age of patients at implantation was 59 ± 4 years (modular), 53 ± 6 years (monoblock: CR-Flex) and 57 ± 10 years (monoblock: LPS-Flex). The average weight of the patients was 169 ± 18 lbs (modular), 210 ± 32 lbs (monoblock: CR-Flex) and 227 ± 53 lbs (monoblock: LPS-Flex). The patients in this study had a largely mildly to moderately active lifestyle as determined by UCLA activity score (Table 1). The modular CR-Flex tibial trays were revised for tibial loosening (n=1, 50%) and unresurfaced patella (n=1, 50%). The modular LPS-Flex tibial trays were revised for infection (n=1, 50%) and stiffness (n=1, 50%). The monoblock CR-Flex components were revised for instability (n=3, 37.5%), malalignment (n=2, 25%), arthrofibrosis (n=1, 12.5%), infection (n=1, 12.5%) and internal rotation of tibial component (n=1, 12.5%). The reasons for revision of the monoblock LPS-Flex components were instability (n=15, 45.5%), infection (n=5, 15.2%), femoral loosening (n=4, 12.1%), pain (n=2, 6.1%), periprosthetic fracture (n=2, 6.1%), tibial subsidence (n=2, 6.1%), arthrofibrosis (n=1, 3.0%), femoral component overhang (n=1, 3.0%) and tibial loosening (n=1, 3.0%).

Out of the collection, 3 modular (1 CR-Flex and 2 LPS-Flex) and 21 monoblock (3 CR-Flex and 18 LPS-Flex) implants were selected to be analyzed for bone ingrowth. One modular tray was excluded as it was collected after a fourth revision surgery. The selected tibial trays were implants from primary surgeries with favor given to the trays that were retrieved together with their pegs (in some cases, the pegs are left in the patient). One monoblock and one modular tibial tray revised for tibial loosening were excluded for bone ingrowth analysis. Seven of the monoblock tibial trays with associated pegs were analyzed and reported in a previous study [24]. The original study lacked power ($p=0.28$) to investigate differences in bone ingrowth due to spatial location (central, lateral, medial and peg). The current study increased the power ($p=0.82$) for the spatial location analysis and also allowed for comparison of design (modular vs monoblock). Analyzed trays were implanted for 1.8 ± 1.5 years (modular), 1.3 ± 0.2 years (monoblock: CR-Flex) and 1.9 ± 1.5 years (monoblock: LPS-Flex). The implantation time, patient age, weight and UCLA score were not different between the overall collection and the analyzed implants (Table 2). The three analyzed modular components were revised for infection, pain and stiffness. The analyzed monoblock CR-Flex components were revised for instability (n=2, 66.6%) and malalignment (n=1, 33.3%). The reasons for revision of the analyzed monoblock LPS-Flex were instability (n=9, 50%), infection (n=3, 16.7%), femoral loosening (n=2, 11.1%), pain (n=2, 11.1%), femoral component overhang (n=1, 5.6%) and periprosthetic fracture (n=1, 5.6%).

The process for sample preparation and bone ingrowth measurements have been previously described [24]. Briefly, each implant was dehydrated using increasing graded alcohols,

embedded in polymethylmethacrylate (Polysciences and Sigma-Aldrich) and sectioned using a diamond wafering saw (Isomet 1000, Buehler, Lake Bluff, Illinois). Each section was ground flat, polished, sputter-coated and imaged using a scanning electron microscope (SEM, XL30 ESEM FEG, FEI, Hillsboro, Oregon and Supra 50 VP, Zeiss Peabody, Massachusetts) in backscattered electron mode. Six sections were analyzed from each tibial tray (2 medial, 2 central and 2 lateral) in addition to one central section for each available peg.

The bone ingrowth analysis consisted of an assessment of the bone area/pore area (BA/PA), extent of ingrowth, maximum depth of ingrowth and evaluation of the bone area/pore area by zone. BA/PA was defined as the fraction of available pore space within the porous coating that was occupied by bone. It is calculated by dividing the bone area (BA) divided by the pore area (PA). The extent of bone ingrowth is a topological quantification of the distribution of bone ingrowth across the surface of the implant. The surface of the implant was divided into 1mm increments, in which each section was assessed for evidence of bone ingrowth penetrating into the surface of the implant. The extent of ingrowth was calculated as the number of sections with ingrowth divided by the total number of sections and expressed as a percentage. The maximum depth of ingrowth was defined at the deepest point where bone was observed in the porous tantalum substrate. Maximum depth was expressed as a percentage of the full available depth of the substrate. The zones for BA/PA depth analysis were defined by depth as: zone 1 (0–500µm, superficial zone), zone 2 (500–1000µm) and zone 3 (1000µm - full depth).

Following bone ingrowth analyses, five of the monoblock tibial trays were randomly chosen and histologically analyzed for presence of fibrous and bone tissue. For each implant, one section from the central, lateral and medial was histologically analyzed. Sections were ground down to 50 µm, polished and stained using Toluidine Blue and imaged under transmitted light microscopy at 5 and 10× using a Zeiss Axioplan (Zeiss, Oberkochen, Germany) microscope camera. Sections were analyzed to note location of regions with fibrous tissue or bone ingrowth.

Nonparametric statistical tests were used to investigate differences in BA/PA, extent of ingrowth and maximum depth by design (modular versus monoblock), spatial location within the implant (central, lateral, medial and peg) and depth (Related – Friedman's Analysis of Variance by Ranks, Independent – Kruskal-Wallis Test). Post-hoc Dunn tests were completed for subsequent pairwise comparisons. Spearman's rank order correlation was used to identify correlations between continuous variables (implantation time, patient age, height, weight, UCLA Score - activity level, BA/PA, extent of ingrowth and maximum depth). The level of significance chosen for all statistical analyses was $p < 0.05$. All statistical tests were performed using PASW Statistics package (Version 19.0.0; IBM, Chicago, IL).

Results

BA/PA was different between for the modular and monoblock implants. The total BA/PA from the modular tray sections ($5.3 \pm 3.2\%$) was higher when compared to the monoblock tray ($1.6 \pm 1.9\%$, $p = 0.032$, Figure 2A). However, for the other bone measurements there was

no difference between the modular and monoblock tray (extent: $p=0.239$ and maximum depth: $p=0.127$). The pegs of the modular and monoblock components were not different for bone ingrowth measurements (BA/PA: $p=0.766$, extent: $p=0.655$ and maximum depth: $p=0.456$, Figure 2A–C).

Bone ingrowth into the porous tantalum tibial trays differed based on location. The bone ingrowth in the modular and monoblock tibial trays was highest in zone 1 (0–500 μm) of the tray sections. For example, BA/PA in the modular component trays was higher in zone 1 ($9.1\pm5.3\%$) compared to zone 3 ($2.3\pm2.2\%$, $p=0.043$, Figure 1). For the modular trays, there was no difference between the tray and pegs for total BA/PA ($p=0.896$), extent ($p=0.145$) and maximum depth ($p=0.241$). Total BA/PA was higher in the pegs ($2.8\pm2.5\%$) than the central tray ($1.0\pm1.3\%$, $p=0.019$, Table 3) for the monoblock components. The monoblock peg had a higher extent of bone ingrowth and maximum depth than all the tray locations (Table 3). BA/PA in monoblock trays was higher in zone 1 ($4.6\pm5.4\%$) compared to zone 2 ($2.0\pm2.7\%$, $p=0.002$) and zone 3 ($0.5\pm0.7\%$, $p<0.001$). One modular tray component had bone ingrowth spanning the full depth of the porous tantalum substrate (Figure 3A). However, none of the monoblock components had bone spanning the full depth of the tray. There were 4 monoblock implants that had tibial tray sections that did not have any bone ingrowth while only one peg section had no bone ingrowth. Bone growth in the pegs was predominantly seen on the periphery (Figure 3B). The five histologically assessed monoblock implants showed dense fibrous tissue in the center of the peg and in the tray where bone was limited. The tray showed the highest amount of bone ingrowth located in zone 1 (0–500 μm), with fibrous tissue spanning the full depth of the porous tantalum substrate (Figure 4A). For the pegs, bone was located on the outer periphery and fibrous tissue was prevalent throughout the center region (Figure 4B).

For the monoblock tibial tray, implantation time was correlated to total BA/PA (Spearman's $\text{Rho}=0.547$, $p=0.01$), extent of ingrowth (Spearman's $\text{Rho}=0.488$, $p=0.025$) and maximum depth (Spearman's $\text{Rho}=0.497$, $p=0.022$). There were no correlations between clinical or patient factors and bone ingrowth measurements for the monoblock tibial trays. For the modular tibial trays, bone ingrowth did not correlate with implantation time and clinical factors.

Discussion

Highly porous metallic surfaces have been developed to address aseptic loosening of hip and knee components. The potential advantages of porous tantalum include enhanced initial fixation and retention of bone stock through reduced stress shielding. Porous tantalum is used in cementless fixation due to its increased porosity, coefficient of friction and decreased elastic modulus. Retrieval analysis studies of porous tantalum tibial trays have been limited [23, 24]. The aim of this study was to examine some possible factors that may affect bone ingrowth in retrieved porous tantalum tibial trays. We found that retrieved modular tibial trays had a higher percentage of bone area/pore area (BA/PA) than the monoblock trays. We also found that BA/PA was highest in the superficial layer (zone 1) of the tibial tray implants. Bone ingrowth measurements correlated with implantation time for monoblock tibial trays but not the modular tibial trays.

This study had several limitations. We were able to collect a large number ($n=41$) of monoblock tibial trays; but only a small number ($n=4$) of modular tibial trays. Our retrievals were not retrieved post-mortem and therefore may not be representative of a well-functioning component. The revision procedure can potentially tamper with the amount of observed ingrown bone in the substrate due to mechanical damage. Finally, the time of implantation for these cohorts of retrieved implants is short-term where only 5 implants analyzed for bone ingrowth were implanted greater than 3 years. The strengths of our study include the largest number of porous tantalum monoblock tibial trays to be analyzed. This allowed us to investigate the effect of spatial location within the implant (central, lateral, medial and peg) and clinical factors on bone ingrowth.

Our reported BA/PA ($5.3 \pm 3.2\%$) for modular tibial trays was lower than a previously reported retrieval study of sintered titanium mesh (9.5%) [25], but similar to two postmortem studies that investigated cancellous-structured titanium ($6\% \pm 2$) [9] and sintered cobalt-chromium beads (6%) [26]. Additionally, one study that evaluated 34 cementless tibial components from various manufacturers reported an average of 3% BA/PA [27], which was lower than our reported BA/PA. The BA/PA for the monoblock tibial trays was lower than these studies [9, 25, 27]. We found the tibial tray extent of bone ingrowth (modular: $29 \pm 13\%$ and monoblock: $22 \pm 18\%$) to be similar to a retrieval study of sintered titanium mesh ($27\% \pm 16$) [25], but lower than previous postmortem studies that evaluated cancellous-structured titanium ($73\% \pm 17$) [9]. Differences in BA/PA between porous tantalum and historical porous coatings may be due to porosity, substrate depth and measurement techniques. To account for differences in porosity, each BA/PA can be scaled or multiplied by its porosity (ex: modular BA/PA*porosity = 5.3×0.75). After scaling, the amount of bone in the porous tantalum modular trays (4.0%) is lower than the sintered titanium mesh (4.3%), but higher than the cancellous-structured titanium (3.1%) and sintered beads (2.4%). The scaled BA/PA for the porous tantalum monoblock (1.2%) is lower than the three historical coatings (sintered titanium mesh, cancellous-structure titanium and cobalt chromium beads). Measured bone ingrowth for tibial trays was lower than three historical porous coatings; however this reflects the greater substrate porosity and depth. BA/PA in the modular tibial trays was higher than the monoblock tibial trays. This is an initial finding as only 3 modular components were available for analysis. The difference in the number of modular compared to the monoblock components may be due when the FDA cleared each component. Modular tibial trays were cleared in 2007, while the monoblock tibial trays were cleared in 2002. It should be noted that the depth of the modular coating is 1.2 mm versus the monoblock coating which is 2.6 mm. BA/PA in Zone 1 was not different ($p=0.106$) between modular and monoblock trays. There could be differences in tray stiffness between these two designs that could affect bone ingrowth.

Bone ingrowth into the porous tantalum tibial trays differed based on location. BA/PA in the modular and monoblock tibial trays was highest in the superficial layer of the tray sections (zone 1; $0-500$ um). BA/PA was higher in the pegs than the central monoblock tray sections. A previous study of sintered titanium mesh [25] showed higher BA/PA in the pegs than the tray, similar to our monoblock tray findings. A case study of a porous tantalum tibial tray also showed a higher amount of bone ingrowth into the pegs compared to the tray sections [23]. Taken together, these findings suggest that future porous tantalum coatings may not

need to be as thick, as bone was preferentially located in the superficial layer (zone 1). It remains unclear why bone ingrowth was higher in the pegs than central tray regions. It may be due to the fact that the two hexagonal pegs are used for initial fixation instead of the screws that were used in previous designs. The tight initial apposition of the pegs to the bone may preferentially bias bone ingrowth into the pegs.

Bone ingrowth into the porous tantalum tibial trays did not correlate with patient factors, similar to a previous study [25], though bone ingrowth into the monoblock porous tantalum tibial trays was positively correlated with implantation time. In a previous study of sintered titanium mesh shells, implantation time was shown to be a significant factor of bone ingrowth [28]. This trend was not seen when the same group analyzed bone ingrowth into sintered titanium mesh tibial trays [25]. Similar to previous studies [25, 28], patient factors did not correlate with the amount of bone ingrowth. However, one clinical study of porous tantalum tibial trays has showed cases of subsidence linked to specific patient factors (tall, heavy, male) [29]. Bone ingrowth did not correlate to implantation time for the modular trays, this may be due to the limited number available for analysis.

In conclusion, our study supports that the bone ingrowth focused primarily in superficial 500 μ m (zone 1) of short-term porous tantalum tibial trays is suitable for solid fixation. The BA/PA highest in the superficial 500 μ m (zone 1) may provide the opportunity to reduce the thickness of the porous layer thus conserving more bone in future designs. We present the amount of bone ingrowth necessary for solid fixation from 24 short-term porous tantalum tibial trays, in which none were revised for tibial loosening. Instability was the highest reason for revision for the monoblock components. One potential limitation of monoblock component is that the insert thickness cannot be modified after implantation. This could contribute to a higher rate of instability in monoblock components. The findings of our study are specific to porous tantalum tibial trays and may not be representative of other cementless designs. A number of clinical trials are underway that may provide further information on the comparative performance between the monoblock and modular components. Future studies could include a blinded randomized controlled trial of uncemented vs cemented TKA in regards to outcomes and bone ingrowth. This may be difficult as a large number of knees may be necessary to power this study. Determination of the amount of bone ingrowth necessary for long-term (>10 years) fixation of implants will yield further insight into the clinical performance of porous tantalum implants.

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Fig. 1.

Fig. 1A–C (A) Grayscale image of a monoblock tantalum porous tibial tray converted to color showing bone area/pore area (BA/PA). White/green is the porous tantalum substrate, gray/orange is the bone and black is the pore area. (B) BA/PA zonal analysis showing the measured zones. (C) An example of extent of ingrowth with 7 increments out of 9 having bone ingrowth. (D) An example of maximum depth of bone ingrowth measurement. The porous tantalum substrate is white/green, the bone is gray/orange and the black is the pore area.

Fig. 2.

Fig. 2A–C Comparison of modular tibial tray sections to monoblock tibial tray sections for (A) Bone area/Pore area, (B) extent of ingrowth and (C) average maximum depth.

Fig. 3.

Fig. 3A–B Back-scattered electron SEM images of (A) a modular tibial tray section and (B) a porous tantalum peg. Note: Bone ingrowth is located on the periphery of the peg and full ingrowth into the modular tray section. The porous tantalum substrate is white, the bone is gray and the black is the pore area.

Fig. 4.

Fig. 4A–B Light microscopy images of (A) monoblock tibial tray with fibrous tissue ingrowth into the full depth of the substrate (5×) and (B) peg with dense fibrous tissue in the center and bone on the periphery (10×). The sections were stained with toluidine blue. The mineralized bone is light blue and fibrous tissue is dark blue.

Table 1

Clinical information for the porous tibial tray cohorts. Values are expressed as mean±SD, with range in parentheses.

Implant Type	Implantation Time (Y)	Patient Age (Y)	Weight (Lbs)	UCLA Scores
Modular (N=4)	1.9±1.2 (0.3–3.2)	59±4 (55–63)	169±18 (144–185)	4±2 (3–6)
Monoblock CR-Flex (N= 8)	1.0±0.3 (0.6–1.4)	53±6 (46–63)	210±32 (162–270)	3±1 (2–4)
Monoblock LPS-Flex (N=33)	2.5±2.7 (0.2–12.8)	57±10 (36–78)	227±53 (122–330)	5±2 (2–10)

Table 2

Clinical information for the porous tibial tray cohorts analyzed for bone ingrowth. Values are expressed as mean $\pm$ SD, with range in parentheses.

Implant Type	Implantation Time (Y)	Patient Age (Y)	Weight (Lbs)	UCLA Scores
Modular (N=3)	1.8 $\pm$ 1.5 (0.3–3.2)	58 $\pm$ 4 (55–63)	178 $\pm$ 9 (168–185)	5 $\pm$ 1(4–6)
Monoblock CR-Flex (N= 3)	1.3 $\pm$ 0.2 (1.1–1.4)	55 $\pm$ 3 (53–58)	204 $\pm$ 15 (186–213)	4
Monoblock LPS-Flex (N=18)	1.9 $\pm$ 1.5 (0.2–5.5)	58 $\pm$ 11 (36–78)	217 $\pm$ 50 (122–300)	5 $\pm$ 2 (2–10)

Table 3

Bone ingrowth measurements based on location and implant type. Values are expressed as mean±SD, with range in parentheses.

Modular Implants			
Location	BA/PA Total (%)	Extent (%)	Maximum Depth (%)
Central	4.1±3.1 (1.4–7.5)	37±16 (19–48)	41±35 (14–80)
Lateral	5.3±2.7 (2.2–6.9)	25±14 (9–34)	69±26 (41–91)
Medial	6.4±7.0 (2.0–14.5)	26±15 (16–43)	43±43 (15–93)
Peg	2.1±0.4 (1.9–2.4)	50±4 (48–53)	47±38 (20–73)

Monoblock Implants			
Location	BA/PA Total (%)	Extent (%)	Maximum Depth (%)
Central	1.0±1.3 ^c (0.1–5.0)	20±23 ^a (0–87)	22±21 ^b (0–72)
Lateral	1.8±1.9 (0.1–6.3)	25±22 ^a (0–76)	35±23 ^c (0–90)
Medial	2.1±3.2 (0.1–14.1)	21±21 ^a (0–88)	33±22 ^c (0–71)
Peg	2.8±2.5^c (0.3–10.0)	51±25^a (15–95)	62±24^{b,c} (23–100)

There were no differences between tray locations and the peg.

Bone area/pore area is denoted as BA/PA.

Comparison a, b and c were made between implant locations (central, lateral and medial and peg).

Bone area/pore area is denoted as BA/PA.

Bone measurements in bold were significantly higher than others and are denoted by the following:

^a = p < 0.001

^b = p < 0.01

^c = p < 0.05