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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. Three modular and twenty-one monoblock retrieved porous tantalum tibial trays were evaluated for bone ingrowth. Nonparametric statistical tests were used to investigate differences in bone ingrowth by implant design, tray spatial location, substrate depth and clinical factors. Modular trays (5.3 ± 3.2%) exhibited higher bone ingrowth than monoblock trays (1.6 ± 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.

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 potential for increased 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 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

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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 (lb)	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)

was detected [24]. No study has compared 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 tray 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 revising 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 lb (modular), 210 ± 32 lb (monoblock: CR-Flex) and 227 ± 53 lb (monoblock: LPS-Flex). The patients in this study largely had a 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, 12.11%), 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. The modular tibial tray revised for loosening was from a 4th revision surgery. 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, IL). 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 BA/PA 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 1 mm 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 (0–500 μm, superficial zone), zone 2 (500–1000 μm) and zone 3 (1000 μm – full depth).

Table 2
Clinical Information for the Porous Tibial Tray Cohorts Analyzed for Bone Ingrowth. Values are Expressed as Mean ± SD, With Range in Parentheses.

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