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Original research

Bone Ongrowth of Contemporary Cementless Tibial Components: A Retrieval Analysis

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ABSTRACT

Background: Cementless total knee arthroplasty is gaining interest as total knee arthroplasty patients become younger, more active, and interested in long-term biologic fixation. New porous coatings have altered mechanical properties to improve bone osseointegration, although limited data exist on this topic. We measured the bone ongrowth on retrieved tibial trays to determine how demographic, radiographic, or implant design factors correlate with ongrowth.

Material and methods: Twenty retrieved trays were assessed from 3 designs: Zimmer NexGen Trabecular Metal (n = 9), Stryker Triathlon Tritanium (n = 6), and Biomet Vanguard Regenerex (n = 5). Exclusion criteria included revision for aseptic loosening or early postoperative infection. Ongrowth on the tibial components and on corresponding pegs (if accessible) was assessed. The amount of osseointegration was reported as the bone directly opposed to the surface divided by the available area for ongrowth. Radiographs were reviewed for alignment and regions of biologic fixation.

Results: Bone ongrowth covered $65\% \pm 19\%$ of the tibial tray surface and did not differ among manufacturers (P = .27). Medial pegs had less ongrowth than lateral pegs (39% vs 64%, P = .02). Vanguard medial pegs had less ongrowth than NexGen medial pegs (15% vs 61%, P = .03). Length of implantation was different between the NexGen (55 months) and Triathlon (24 months, P < .05) design only. Patient and radiographic data demonstrated no correlation with ongrowth.

Conclusion: An average 65% of the porous tibial tray surface had ongrowth at revision. These values are consistent with manufacturing claims for excellent bone ongrowth for newer porous coatings.

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Introduction

Cemented fixation is considered the gold standard for total knee arthroplasty (TKA) components with excellent long-term results [1-3]. The clinical challenge of treating young, active patients seeking TKA has reignited interest in cementless fixation because long-term failure rates of cemented TKA are higher in younger individuals [4]. In addition, the risk of aseptic loosening with a wellaligned cemented TKA in patients with obesity (body mass index [BMI] \geq 35 mg/kg²) is a concern [5] because the risk of aseptic

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loosening is doubled. Cementless implants provide the opportunity for biologic fixation that can prevent long-term loosening that accompanies failure of cement interfaces. Earlier cementless implants were promising; however, reports of early aseptic loosening and osteolysis halted their widespread adoption [6-9]. Retrieval analyses of the earlier generation cementless tibial components demonstrated less than 30% bone ongrowth [10,11].

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These earlier designs incorporated porous surfaces formed by cobalt-chromium sintered beads, titanium fiber metal mesh, cancellous-structured titanium, and titanium plasma spray [12]. Newer generations of implants using highly porous metals have been developed with the goal of improving osseointegration by increasing porosity, reducing elastic modulus, increasing the coefficient of friction, and thus attaining more rigid initial fixation [12,13].

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Table 1					
Patient demographics	and	reasons	for	revisio	n.

Demographics	$All \ (n=20)$	NexGen $(n = 9)$	Triathlon $(n = 6)$	Vanguard $(n = 5)$	P value
Age (y), mean (SD)	57.8 (8.3)	56.0 (10.4)	61.4 (4.6)	56.6 (5.5)	.474
BMI (kg/m ²), mean (SD)	30.2 (7.4)	33.5 (8.3)	29.3 (5.6)	25.4 (4.3)	.161
Length of implantation (mo), mean (SD)	39.5 (30.2)	55.1 (35.1)	23.5 (19.3)	30.4 (11.7)	<.05
Sex (male/female)	6M:14F				
Laterality (right/left)	12R:8L				
Reasons for revision					
Instability	8	7	1	0	
Arthrofibrosis	3	1	1	1	
Femoral aseptic loosening	3	2	0	1	
Metal allergy	5	0	2	3	
Late infection	1	0	1	0	

Post hoc comparisons showed differences in length of implantation between the NexGen and Triathlon groups (P < .05). P value < .05 denotes significance.

Studies examining these newer generation porous-coated tibial implants have demonstrated good short- and mid-term clinical outcomes and low failure rates equivalent to cemented components [14-17]. However, little information exists on the extent of bone ongrowth that is achieved with these contemporary designs. We evaluated the extent of bone ongrowth on retrieved cementless tibial trays to determine if patient, device, and radiographic parameters correlated with the extent of osseointegration.

Material and methods

Using our institutional review board-approved institutional implant retrieval system, we identified 25 contemporary cementless porous coated tibial trays implanted between 2000 and 2019. Exclusion criteria were defined as either an implant that failed due to aseptic loosening of the tibial component or a short-term infection revised within 1 month of implantation leading to the elimination of 5 revised implants. The remaining 20 implants spanned 3 designs: Zimmer NexGen Trabecular Metal (Warsaw, IN; n = 9), Biomet Vanguard Regenerex (Warsaw, IN; n = 5), and Stryker Triathlon Tritanium (Mahwah, NJ; n = 6) tibial baseplates. Patient demographics and clinical data including age at index surgery, BMI, sex, length of implantation, laterality, and reason for revision were collected using electronic medical records (Table 1). Design information, such as pore size, porosity of the tibial tray, and how they are manufactured can be found in Table 2. Radiographs were used to determine tibiofemoral alignment, tibial mechanical axis alignment, and to check for any zones of radiolucency [18] in both anterior-posterior and lateral views.

To avoid destructive testing of these implants, we mapped the bone ongrowth of the tibial tray using a visual assessment method with light microscopy under 20X magnification [19]. Implants were retrieved from the pathology department after they had been fixed in 10% formalin for 24 hours. Implants were then soaked in 10% bleach for 20 minutes before they were rinsed, cleaned with a soft brush and detergent, and left to air dry.

Implants undergo an initial visual inspection (E.B., R.P.) to build confidence in defining regions of bone compared with fibrous material. Unidentifiable regions of uncertainty were found in only 3 of 20 implants; the remaining 17 implants had thick layers of bone directly apposed to the surface of the tray. To confirm the presence of calcified bone in the uncertain regions, small particles of adherent tissue were removed from the implant, embedded, stained using picrosirius red, and analyzed under fluorescence microscopy. If the tissue was considered fibrous, it was not included in the damage mapping as it was not calcified bone attached to the tibial tray.

Pictures of the inferior surface of each implant were taken using a digital microscope under 5X magnification (Keyence Corporation, Osaka, Japan) and, as mentioned previously, analyzed under a standard light microscope (Wild Type 376,788 Microscope; Wild Heerbrugg, Heerbrugg, Switzerland) at 20X magnification to identify regions of interest [19]. Additional photographs were taken to capture the geometry and surface area of the corresponding pegs if pegs were included on the inferior surface as part of the design. A trained research engineer and orthopedic fellow performed the analysis, assessing the implants and coming to a consensus of where bone was across the tibial tray (and using the microscopy analysis in 3/20 cases). Implants were mapped by 1 of the 2 graders only.

Adobe Photoshop (Adobe Systems Inc, San Jose, CA) was used to define 3 regions of interest: bone, damage from removal (consistent with damage done during surgical removal of the tray from the underlying bone), and total surface area (Fig. 1). The overall surface of the implant (without the keel and pegs) was outlined by hand, as were regions of bone and damage for each implant. ImageJ (National Institutes of Health, Bethesda, MD) was used to calculate threshold and the percent area of bone and damage from removal across the total surface area [19]. The extent of osseointegration was reported for 20 tibial trays and 18 corresponding pairs of pegs.

Bone ongrowth (%) was defined as the percentage of the bone across the surface available for ongrowth excluding the damaged region. Damage from removal regions was evident on all but 2 of the implants, and this measure allowed for normalization of bone ongrowth percentage to what was observed on the implants at the time of revision. Damaged regions were likely caused using a surgical saw or osteotome at removal from well-fixed components; however, we are unable to confirm what was removed at revision

Table 2			
Design characteristi	s of implants	included i	n the study.

Design name	Manufacturer	Material	Pore size (average)	Porosity (max possible)	Manufacturing method
Regenerex	Biomet	Titanium alloy	300 µm	67%	Additive manufacturing
Trabecular metal	Zimmer	Tantalum	440 μm	80%	Thermal deposition
Tritanium	Stryker	Titanium alloy	400-500 μm	65%	Additive manufacturing

Implants are manufactured from different materials and have different specifications for manufacturing.



% Bone Ongrowth =
$$\frac{Bone}{Surface - Damaged Region}$$

Figure 1. Tibial trays were each mapped for 3 regions of interest: (1) Surface available for bone ongrowth; (2) bone attached to the surface; and (3) damaged regions caused by revision surgery (unable to define as bone). Below the images is the equation for bone ongrowth. Each implant was studied under 20× magnification using a visual light microscope, and regions were defined by hand using Adobe Photoshop and quantified using ImageJ.

and, therefore, excluded the damaged region from the total surface area of the tibial tray.

Statistical analysis

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Patient demographics were compared using an analysis of variance with post-hoc pairwise comparisons to observe differences within groups. The extent of bone ongrowth was compared among tray designs and between peg laterality using an ANOVA with Holm-Sidak pairwise comparisons. A *P* value less than 0.05 denoted statistical significance. Linear regressions for BMI, length of implantation, and patient age at surgery were used to determine if patient factors influenced the extent of bone ongrowth. Statistical analyses were performed using SigmaPlot (Systat Software Inc., San Jose, CA).

Results

The average extent of bone ongrowth calculated using digital image analysis was $65\% \pm 19\%$ of the available surface, across the 3 implant designs (Table 3). No differences were found among manufacturers (P = .27). In the 18 retrieved implants with pegs, we observed a larger percent ongrowth on the lateral pegs when compared with the medial pegs ($64\% \pm 26\%$ vs $39\% \pm 31\%$, respectively; P = .02). Peg analysis confirmed that the medial peg on the

Table 3

Bone ongrowth percent for tibial tray and corresponding pegs.

Biomet Vanguard had significantly less bone ongrowth than the medial peg on the Zimmer NexGen (15% vs 61%, P = .03). No differences existed among manufacturers for bone ongrowth on the lateral pegs (P = .16).

Damage from removal regions, identified as areas of iatrogenic damage from revision surgery, were visible in all but 2 of the 20 implants analyzed. Damaged regions were not included in any analysis, although these regions are relevant to report in that we were unable to assess them for bone ongrowth. The average damaged area across all implants was 13%, ranging from 0 to 39%. Among the 3 designs, Zimmer baseplates had an average of 5% of the surface area damaged, Biomet 19%, and Stryker had the highest area at 20%.

Age at implantation, age at explantation, and BMI did not differ among the 3 implant designs (P = .474, .67, and .161, respectively; Table 1). Holm-Sidak comparisons found that the Triathlon had a lower length of implantation than the NexGen (P < .05) only. The average length across all groups was 39 months. NexGen components were implanted for an average of 55 months, Biomet for an average of 30 months, and Stryker components for 24 months.

Linear regressions for patient age at implantation, length of implantation, and BMI were not significant, although each factor was modeled to contribute 8% to 17% of the variability observed for bone ongrowth extent (P > .05 for all; bone ongrowth vs age at implant, $r^2 = 0.08$; bone ongrowth vs length of implantation, $r^2 =$

Variable	Implant	Ν	Mean	Std. Dev.	Range		P value
					Min.	Max.	
Tibial Tray, bone ongrowth %	NexGen	9	72.2	13.2	52.4	95.6	
	Triathlon	6	64.4	21.7	33.7	89.5	
	Vanguard	5	54.3	25.0	15.9	75.5	
	Total	20	65.4	19.1	15.9	95.6	.27
Lateral peg, bone ongrowth %	NexGen	7	78.0	16.1	43.8	99.0	
	Triathlon	6	68.8	14.0	50.0	87.5	
	Vanguard	5	40.0	33.9	0	100	
	Total	18	64.3	26.9	0	100.0	.16
Medial peg, bone ongrowth %	NexGen	7	61.2	23.1	21.1	94.1	
	Triathlon	6	33.3	26.7	0	75.0	
	Vanguard	5	15.0	24.2	0.0	62.5	
	Total	18	39.1	31.2	0.0	94.1	.03

One-way ANOVAs were used to define differences as P < .05 significant. Two pairs of pegs were unavailable for analysis. The results for the medial pegs were significantly different between the Vanguard and NexGen designs using Holm-Sidak pairwise method.

Bolded P value indicates the significant variable of the one way ANOVA.

0.17; bone ongrowth vs BMI, $r^2 = 0.10$). Radiographic analysis confirmed that all implants were well-aligned and had minimal zones of radiolucency across the tibial plateau. The average tibial tray alignment was 1.7° varus (range: 3.4° valgus- 7.8° varus), and the average tibiofemoral alignment was 1° valgus (range: 8.4° valgus- 8.8° varus). Radiolucent lines were present in zones 1 and 2 [17] in 3 implants although only one had $\leq 30\%$ bone ongrowth.

Discussion

Our results demonstrate a moderate percentage ($65\% \pm 19\%$) of bone ongrowth across contemporary highly porous cementless tibial trays, specifically with 1 tantalum (NexGen) and 2 titanium (Vanguard and Triathlon) implants. The observed extent of bone ongrowth for these components is substantially higher than previously reported values for Trabecular Metal Monoblock (tantalum) and Miller-Galante I (titanium) tibial trays (21% and 27%, respectively) [10,11], suggesting a greater degree of biologic fixation and the potential for greater stability and durability in a clinical setting.

Early series of cementless TKAs demonstrated concerns for aseptic loosening and osteolysis associated with the tibial component [6-9]. Avoiding these complications depends on obtaining good early stability to minimize micromotion at the bone-implant interface, thus allowing osseointegration of the tibial tray. Micromotion of <50 microns is associated with successful bony ongrowth, whereas motion >150 microns is associated with failure of ongrowth [20,21]. Designs of contemporary implants have focused on using novel manufacturing processes to increase the coefficient of friction with the goal of increasing initial stability. thus reducing micromotion. These newer porous coatings also have increased porosity to allow for improved osseointegration. With the rapidly evolving field of additive manufacturing, parameters such as coefficient of friction and porosity can be adjusted as well as the location of the porous surface on the baseplate, keels, and pegs. These design improvements would not be possible without the recent advancements in 3D printing and additive manufacturing techniques.

These differences between earlier and contemporary porous structures could account for the increased extent of bone ongrowth demonstrated in our study. The variation in elastic modulus within designs did not impact the bone ongrowth observed. The Triathlon has a relatively higher elastic modulus (106-115 GPa) than the NexGen and Vanguard (2.5-3.9 GPa, respectively) designs [12], although there were no differences in the amount of bone ongrowth across the 3. While there are benefits from adjusting design parameters, our study exemplified that bone ongrowth was consistent within designs regardless of these differences. Adjusting design parameters could affect the initial stability of implants with these coatings because of differences in deformation at the bonecoating interface during impaction of the implant in the operating room. In addition, these differences could affect ongrowth through stress shielding of the underlying bone caused by the dissimilar stiffnesses of the baseplate (as determined in part by the elastic modulus of the porous structure on the underside) within each design. Earlier porous coatings made by sintering together cobalt-chromium alloy beads (cobalt alloy beads having an elastic modulus of 200GPA) demonstrated that localized stiffness differences adversely affected local biological fixation [22].

Adjuvant fixation devices such as pegs are used to enhance initial fixation in cementless TKA, and increased bone ongrowth onto pegs was previously demonstrated [22]. We found increased ongrowth around lateral pegs compared with medial pegs in all 3 implant designs. Regional variation in bone density in the proximal tibia is well described, with increasing stiffness in the medial plateau in varus osteoarthritic knees due to sclerotic subchondral bone [23]. Cancellous bone in osteoarthritis undergoes significant microarchitectural changes with resultant degradation in bone quality, which could compromise its ability to osseointegrate [24]. Mechanical and biological changes in arthritic bone on the medial tibial plateau could explain the relative decrease in medial peg ongrowth observed in our study. Both the Triathlon and Vanguard pegs are smaller in surface area and are intended to provide stability, rather than ongrowth. Despite this, we felt it important to report bone ongrowth at the peg interface as cases of catastrophic failure have been reported at the peg-baseplate junction, leading to tibial collapse due to overingrowth of the pegs, specifically in the NexGen design [25]. We did not have any such failures in our cohort of implants.

Patient factors including age at index surgery, BMI, sex, length of implantation, laterality, and reason for revision were not strongly associated with the extent of bone ongrowth, which is consistent with previous literature [11]. While the number of patients in our investigation is likely underpowered to investigate fully the impact of these confounding factors, our results support the notion that the extent of osseointegration is primarily dictated by the local environment at the bone-implant interface.

Our study has limitations. We examined retrieved components that were explanted because of failure; therefore, by definition, the demonstrated bone ongrowth is not necessarily in the context of clinical success. If anything, our results tend to underestimate the extent of bone ongrowth that occurs in successful nonrevised cases. This underestimation of bone was partly affected by the regions of damage through the fixation surfaces by instruments used in revision surgery: this was observed on all but 2 implants. However, our results are normalized, and the 3 designs were not different in extent of bone ongrowth, confirming all 3 designs as viable options for cementless fixation. Owing to our small sample size, we were unable to match the implants for patient factors such as BMI, length of implantation, sex, reason for revision, or age at implantation. While we noted a marked difference in the length of average implantation time among the 3 designs studied (NexGen with 55 months, Biomet with 30 months, and Stryker with 24 months), due to the small sample size, we were unable to account for this difference in our data analyses. Therefore, we compared implant design cohorts. While matching could have eliminated confounding variables, nonetheless, reporting on our earliest subset of contemporary cementless knees is clinically important. An additional limitation was that we did not perform destructive testing to observe the extent of osseointegration using microscopy methods such as scanning electron microscopy or serial milling. This will be the objective of future research with larger sample sizes per implant group as we collect more retrieved implants over time. Finally, while we examined the extent of bone ongrowth, we did not assess whether this correlated with clinical success. However, successful fixation in metaphyseal tibial sleeves has been demonstrated with only 14.7% bone ongrowth [19]. The exact amount of osseointegration necessary for a successful outcome in primary TKA is yet to be determined. In addition, preoperative varus alignment may result in more sclerotic bone medially and potentially less bony ongrowth in this region of a cementless tibial component. There is also variability in how surgeons address this issue, with some surgeons resecting additional tibia to allow exposure of more cancellous bone and less sclerotic bone and some surgeons drilling holes in the sclerotic bone to potentially allow improved fixation. Furthermore, newer technologies, such as robotic assisted surgery, allow surgeons to add a few degrees of varus to the tibial resection for varus knees, therefore, resecting more of the sclerotic bone medially. Unfortunately, we do not have preoperative radiographs on all the patients in this study cohort, nor do we have intraoperative information from the primary surgery

where we could reliably comment on the operative techniques that were used, so we recognized these issues as additional limitations.

In conclusion, our findings demonstrate a high percentage (64%) of bone ongrowth of contemporary cementless tibial trays, including increased ongrowth on the lateral pegs. Newer highly porous designs may be more effective at achieving the initial stability required to maintain a low micromotion environment while bony ongrowth occurs by providing a level of porosity conducive to osseointegration. Continuing retrieval analysis and reports on clinical outcomes of these implants in higher numbers will further elucidate their performance capabilities. Nonetheless, cementless TKA using contemporary implants presents an attractive option to achieve long-term biologic fixation.

Conflicts of interest

T. M. Wright receives royalties from Exactech and Lima, receives research support as a principal investigator from Lima, and is a board member in OREF Research Grant Committee, AJRR Data Committee, and Knee Society Education Committee. G. Westrich receives royalties from, is a paid consultant for, and receives research support as a principal investigator from Stryker and Exactech; is in the speakers' bureau of/gives paid presentations for Ethicon; and is a board member in Eastern Orthopedic Association.

For full disclosure statements refer to https://doi.org/10.1016/j. artd.2021.12.007.

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