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Original Research

Off-the-Shelf Tibial Cone Sizes May Not Accommodate All Patients' Bone Morphology and May Lead to Cortical Breaches in Revision Total Knee Arthroplasty: A 3D Modeling Study

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A B S T R A C T

Background: In revision total knee arthroplasty, tibial cones have demonstrated improved longevity and reduced incidence of aseptic loosening. Several currently available “off-the-shelf” (OTS) cone systems may not have sizes to accommodate all patient bone morphologies.
Methods: Computed tomographies from one hundred primary total knee arthroplasty patients and dimensions of 4 OTS cones were obtained. Press-fit stems were positioned in 3D tibia models to fit the diaphyseal trajectory. Cones were positioned around the stem at 1, 6, and 13 mm resections measured from the trough of the medial tibial plateau, simulating proximal tibial cuts and bone loss. Tibias were examined for cortical breaching following modeled cone preparation.
Results: Increased rate of breaching was observed as size and depth of the cone increased. In 2/49 (4.1%) male and 19/46 (41.3%) female tibias, cones could not be positioned without breaching. No breaches were found in 22/49 (45.0%) male and 5/46 (10.9%) female tibias. For every 1 centimeter increase in patient height, odds of breaching decreased by 12% (odds ratio: 0.88, confidence interval: 0.84, 0.92). For every size increase in cone width, odds of breaching increased by 34% (odds ratio: 1.34, confidence interval: 1.28, 1.47). Placing cones deeper also increased breaching compared to the 1 mm cut.
Conclusions: In revision total knee arthroplasty, smaller OTS or custom tibial cones may be needed to fit a patient's proximal tibial geometry. This is especially true in patients not accommodated by the OTS cone sizes we tested, which impacted shorter patients and/or those with substantial bone loss requiring more tibial resection and deeper cone placement. Use of smaller or custom tibial cones should be considered where indicated.

Background

To optimize construct stability, a revision total knee arthroplasty (rTKA) should achieve fixation in at least 2 of the 3 fixation zones: the metaphysis, diaphysis, and the tibial plateau's proximal cut surface [1,2]. Both short cemented stems and long press-fit stems have been utilized to provide diaphyseal fixation [3]. Tibial cones are used to attain fixation in the metaphysis, and have been demonstrated to improve longevity, reduce incidence of aseptic loosening, and are often used in the management of bone loss [3].

Tibial cones are usually prepared around a reamer in the proximal tibia that aligns with the trajectory of the proximal tibia canal to increase bone engagement by the implant. The extent of bone engagement determines the surface available for bone ingrowth

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and is imperative to provide long term stability for an implant [4,5]. The optimal position and angle of press-fit stems to maximize stem bone fixation were demonstrated in our previous 3-dimensional modeling study [1]. Due to variations in patient anatomy, the trajectory of the reamer and, thus, the trajectory of the stem achieving optimal fixation may be off-axis with the patient's mechanical alignment [6,7]. On rare occasions, preparation of a tibial cone around a reamer with severe deviation from a patient's natural mechanical axis can manifest in cortical breaches intraoperatively, irrespective of the depth of tibial cut, size of cone used, or both. It is important to note that the presence of a cortical breach, where the cone pierces the cortex, does not mean that the cone will have poor fixation or that an intraoperative fracture occurs.

As revision and re-revision of total knee arthroplasty are becoming more prevalent, the need to ensure that manufacturers' tibial cones accommodate a variety of patients is essential. It is possible that tibial cones that are currently on the market are not refined to suit a wide range of patient anatomy [8]. The purpose of this study is to investigate whether current off-the-shelf (OTS) tibial cones can accommodate all patients, even those with unique anatomy. We hypothesize that several current OTS tibial cone sizes will not fit appropriately for a subgroup of patients and will result in a cortical breach.

Material and methods

Computed tomography (CT) scans were acquired preoperatively from 100 patients who required a primary total knee arthroplasty. CT scans were imported into a 3D image processing software, Simpleware ScanIP (Synopsys, Mountain View, CA). The scans and associated implant components were processed following methods outlined in Cooperman et al. [1] Demographics (age, sex, race, and height) of these patients were obtained through our hospital's medical record data analytics team. Four OTS tibial cones from one manufacturer, ranging from 30-50 mm wide and 30-35 mm in height (small: 30 mm × 30 mm, medium: 35 mm × 30 mm, large: 42 mm × 35 mm, and extra-large: 48 mm × 35 mm) were used. Implant measurements were approximated ± 2-3 mm from the actual specifications to protect the manufacturer's identity but provide the reader with important technical information. This was the only revision system we were able to obtain 3D models for, although we requested models from the 5 largest total joint replacement companies in the United States. As a part of the agreement to participate in this study, the name of the manufacturer and the specific dimensions of the implants are not to be disclosed. As the width of tibial cones increases, they become increasingly tapered, with the maximum circumference located closer to the tibial plateau. A researcher supervised by 2 orthopaedic surgeons with more than 5 years of postfellowship experience conducted the virtual cone implantation. The cones were manually centered around the press-fit stem and placed at a depth of 1 mm, 6 mm, and 13 mm, measured from the bottom of the baseplate for each scenario, with the medial tibial plateau serving as the level at which the proximal tibia was cut (Fig. 1). These resection depths were chosen to simulate minimal, moderate, and significant bone loss. For each patient, a total of 12 models centered around the stem were created corresponding to each cone size and depth combination. A binary outcome was assigned if the cone clearly perforates the cortex (0 for no breaching and 1 for breaching). Additionally, the study was stratified by sex to account for different bone morphologies affecting tibial cortical thickness.

Statistical analysis

The frequency of breaching at each of the 12 size and depth combinations were summarized using descriptive statistics. A repeated measures analysis model, generalized estimating equation (GEE), was implemented to determine the population-averaged effect of the demographic variables, the cone size, and depth of cone placement combinations on the frequency of breaching. All demographics, except for race, which was stated descriptively, were incorporated into the GEE model. The combination with the lowest rate of breaching was selected as the baseline reference for comparison. A marginal analysis model was used to analyze the differences in odds of breaching among the groups. Odds ratios (ORs) derived from the regression coefficients, probabilities, and 95% confidence intervals (CIs) were determined. All data analyses were performed using Stata 16.1 (StataCorp LP, College Station, Texas, USA).

Results

Patient demographics are summarized in Table 1. After the removal of 5 total age and height outliers, 49 male and 46 female proximal tibia CT scans were included in the analysis. Outliers were excluded if their age or height was greater than the third quartile or less than the first quartile by an amount that was at least 1.5 times the interquartile range. The rate of breaching at each combination stratified by sex is summarized in Table 2, showing that generally, females experienced cortical breaching more frequently than males. The lowest rates of breaching for males and females were 4% and 41%, respectively, for the small cone at the 1 mm resection, while the highest rates were 55% for males and 89% for females using the extra-large cone at the 13 mm resection.

Points of breaching for males and females are illustrated in a heatmap (Fig. 2). There was an area of concentration of perforation anteriorly, just medial to the tibial tuberosity for both males and females. Placement of the extra-large cone at 13 mm from the tibial baseplate resulted in perforation of the cortex immediately inferior to the lateral cortex of one male tibia. Posteriorly, the areas of

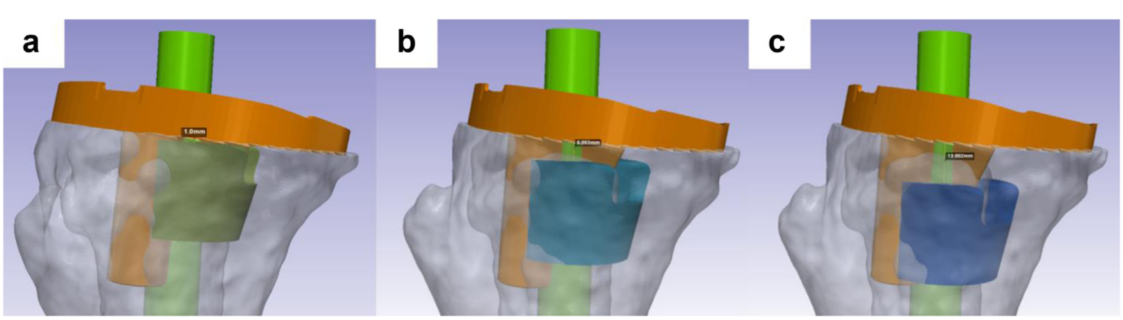

Figure 1. Tibial cones centered around a press-fit stem, placed at depths of (a) 1 mm, (b) 6 mm, and (c) 13 mm.

Table 1
Summary of demographics of patients included in this study.

Characteristic	Patients					
	All		Male		Female	
	Number	%	Number	%	Number	%
Patients enrolled	95	100	49	51.6	46	48.4
Age (years)						
Median	66		67		66	
Range	48-85		48-85		48-82	
Height (centimeters)						
Median	172.5		178.0		162.5	
Range	150-188		160-188		150-178	
Operative laterality						
Right	46	48.4	19	44.9	27	58.7
Left	49	51.6	27	55.1	22	41.3
Race						
Non-Hispanic White	78	82.1	43	87.8	35	76.1
Latino/Hispanic	6	6.3	1	2.0	5	10.9
Black	5	5.3	3	6.1	2	4.3
Asian	1	1.1	0	0	1	2.2
American Indian	0	0	0	0	0	0
Not reported	5	5.3	2	4.1	3	6.5

perforation for females were more equally distributed along the width of the proximal tibia just distal to the flare of the tibial plateau; however, there was still a greater tendency for perforations to occur medially. Conversely, posterior perforation for males was concentrated inferior to the tibial plateau, in line with the intercondylar eminence.

For 2 male tibias (4.1% of males) and 19 female tibias (41.3% of females), breaching resulted regardless of cone size used. Two male tibias also experienced breaching when the small cone was placed at the shallowest depth (1 mm), and 27 males (55.1%) experienced breaching when the extra-large cone was placed at the deepest depth (13 mm), resulting in a 1250% increase in breaching. Likewise, for female tibias, the incidence of breaching was lowest at 1 mm with the small cone (19/46; 41.3%) and highest when the extra-large cone was placed at 13 mm (41/46; 89.1%). This yielded a 216% increase in breaching when the smallest cone and depth combination was compared to its maximum counterpart. The mean height of females who experienced breaching with the small cone at the 1 mm resection was 159.3 cm compared to 165.6 cm in females who did not experience breaching using the same cone and depth. No breaching was found in 5 female tibias (10.9%) and 22 male tibias (45.0%).

The population-averaged GEE model found that greater cone size, increased depth of cone placement, and decreased patient height were significant predictors of breaching ($P < .001$) when all other factors were held constant and sex set to males (Table 3). For every stepwise size increase in cone width (from small to medium to large to extra-large), odds of breaching increased by 34% (OR: 1.34, CI: [1.28, 1.47]). Placing the cone 6 mm beneath the tibial baseplate increased the odds of breaching by 110% (OR: 2.10, CI: [1.93, 2.39]) compared to the baseline of 1 mm. In comparison, a cone placement of 13 mm in depth increased the odds of breaching by 494% (OR: 5.94, CI: [4.82, 8.06]. When cone size, depth of cone placement, age, and sex were held constant, for every 1 cm increase in patient height, the odds of breaching decreased by 12% (OR: 0.88, CI: [0.84, 0.92]). Controlling for all other factors, patient age ($P = .42$) and sex ($P = .29$) were not significantly associated with breaching. Although sex was not a significant predictor of breaching, the patterns of breaching exhibited by males and females were different (Fig. 3).

Table 2
Proportion of cortical breaches for each cone size and depth combination by sex.

Cone characteristics	Cone depth		
	1 mm	6 mm	13 mm
Cone size	Female		
Small	0.41	0.61	0.72
Medium	0.48	0.63	0.76
Large	0.52	0.65	0.85
Extra-large	0.54	0.67	0.89
Cone size	Male		
Small	0.04	0.14	0.20
Medium	0.10	0.16	0.27
Large	0.12	0.18	0.39
Extra-large	0.12	0.20	0.55

Discussion

In this study, we sought to investigate whether currently available OTS tibial cone sizes can fit appropriately in all patients or whether a subset of patients would not be able to accommodate the placement of an OTS cone. We found that shorter patient height, larger cone size, and deeper placement depth all contribute to an increased incidence of cortical breaching.

This study shows that a large proportion of shorter patients requiring a rTKA may benefit from cones that are smaller than those used in the study to ensure adequate metaphyseal fixation without cortical breaching. This would be especially true for small patients with significant bone loss, in which the cone needs to be placed more distal within the tibia. Of the 46 patients in our study who were up to 171.5 cm tall (150-171.5 cm), 19 (41.3%) could not accommodate any cone at any depth without breaching, compared to the 2 of 49 patients (4.08%) taller than 172 cm (172 and 188 cm) who encountered the same problem. We found that the lowest incidence of breaching was associated with the smallest cone placed at the shallowest depth (1 mm) from the baseplate, while the highest incidence was observed with the extra-large cone at 13 mm. More specifically, the odds of breaching increased as the width of the cone increased because larger cones have a greater area of contact with the bone, irrespective of depth of cone placement. Similarly, when a cone was placed deeper into the tibia, the circumference of the intramedullary canal decreased, making breaching more likely to occur.

The frequency of breaching for females and males are compared in Table 2. Despite sex not being a significant predictor of breaching

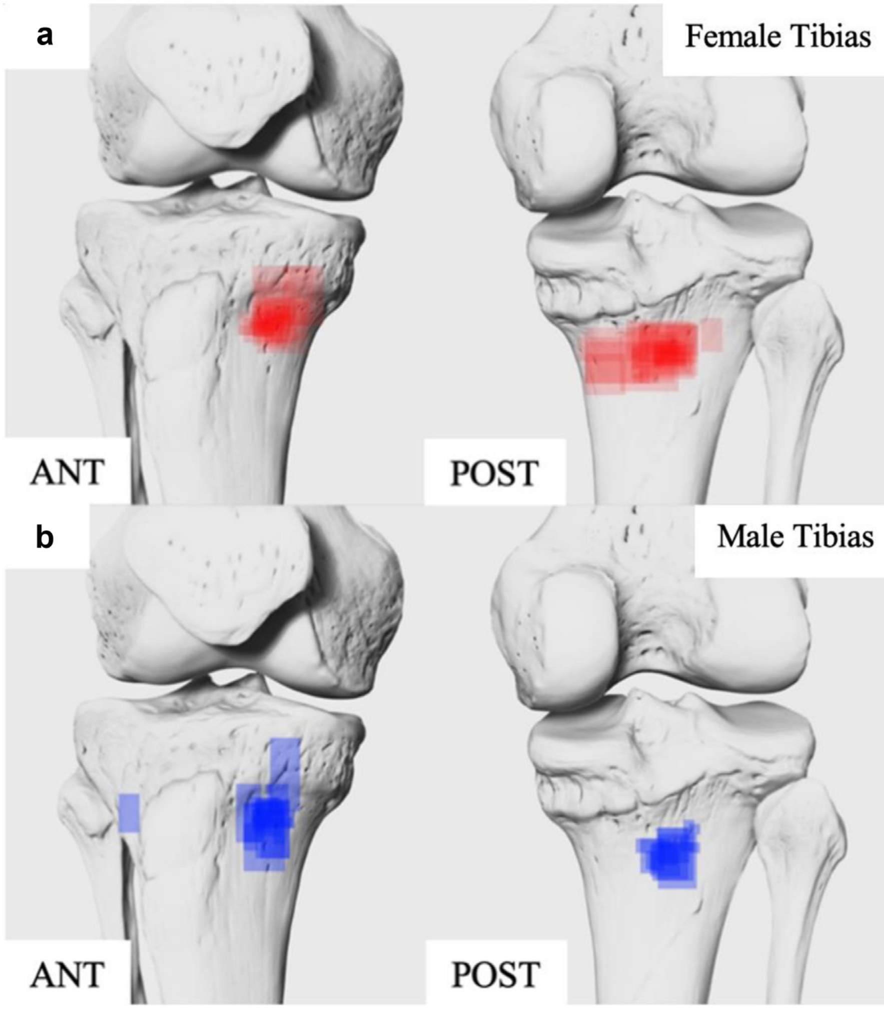

Figure 2. Heat map reflecting position of protruded implant in (a) females and (b) males from the anterior (ANT) and posterior (POST) views. The limits of each breach were inscribed within the perimeter of different sized rectangles, with at least one part of the breach coming in contact with each of the 4 sides.

in the GEE model, a noticeable pattern shows that males had a lower occurrence of breaching compared to females. The data demonstrated that 10.9% of females had no breaches compared to 45.0% in males, while 41.3% of females had breaches at all combinations compared to 4.1% in males. The smallest cone at the shallowest depth had a 55.1% chance of breaching in females, with only a 4.1% occurrence in males. Altogether, there were 290 breaches recorded in females and 125 breaches in male tibias across all combinations. This indicates both the availability of more combinations of cone size and depth that fit into male tibias appropriately and that several currently available OTS cone sizes from the same manufacturer or similarly sized cones from other companies are not optimized to fit into smaller sized tibias for patients undergoing rTKA. It has been previously described in the literature that there are morphological differences in the tibia according to sex such as the slope of the tibial plateau, cortical thickness, tibial size, and curvature [9-13].

Table 3
Odds ratio for each parameter of the generalized estimating equation describing odds of each variable influencing breaching.

Predictors	Odds ratio	95% confidence interval	*P*-value
Age	0.98	[0.95, 1.02]	.42
Sex (male)	1.61	[0.67, 3.89]	.29
Height (per 1 cm)	0.88	[0.84, 0.92]	<.001
Cone size	1.34	[1.28, 1.47]	<.001
Cone depth (per 1 mm)	1.16	[1.14, 1.19]	<.001

The marginal analysis produced by the GEE model demonstrated an increasing pattern in the odds of breaching for both sexes, albeit in a different fashion. For females, an increase in cone depth from 1 mm to 6 mm increased the odds of breaching more substantially than an increase from 6 mm to 13 mm; however, the opposite pattern was observed for males. In addition, females had higher adjusted odds of breaching in all combinations included in our study when compared to males. This is likely due to the difference in bone morphology and cortical thickness. Males have a greater tendency to have greater tibial bone mineral content, volumetric bone mineral density, and cortical area and thickness with greater periosteal circumference when compared to females of similar height and weight [14]. Therefore, use of larger cones and deeper cone placements will likely result in higher occurrences of breaching in female tibias. Likewise, as male tibias have a larger periosteal circumference, tibial cones are more likely to be able to fit at a deeper depth in males than females, providing additional stability. This signifies that as larger amounts of bone loss are seen in revision scenarios, the greater the need for smaller or custom cones in order to fit the patient's anatomy.

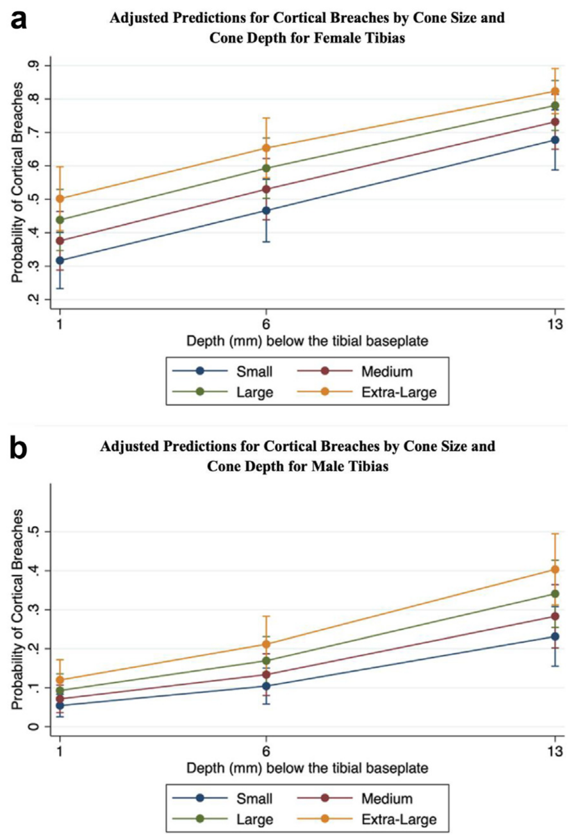

Figure 3. Comparing probability of breaching cones of varying width at different depths of placement between (a) females and (b) males.

This study on morphology-based differences in cone breaching, alongside known differences in bone morphology in the literature elucidates the lower risk of breaching when using smaller cones compared to larger cones, as well as the potential utility of using custom cones to prevent cortical breaching [9-13]. As patients undergoing rTKA already have substantial meta-diaphyseal bone loss often due to the explantation of the existing tibial baseplate or osteolysis, salvaging and preserving remaining viable bone is imperative. Therefore, in rTKA, OTS cones that allow tibial constructs to achieve at least 2 zones of fixation but perforate the cortex should be avoided [15]. The cones in our modeling scenario were placed in alignment with the custom press-fit stem, where the optimal angle was derived based on the patient's diaphyseal anatomy. Because the theoretical process of preparing these cones in our model is as described in the surgical technique provided by the manufacturer, we can infer that this is a good representation of how OTS cones fit into actual patients' anatomy.

While the examination of custom-fit cones is a relatively new concept, previous studies have shown promise for utilizing a patient-specific implant approach for cone design [15-17]. These studies have ranged widely from implementing a more elastic cone for improved press-fit [16] to models based on the contralateral knee [15], and custom press-fit intramedullary stems. Attempts at cementing stacked cones, such as in Spinello et al. [18] have been reported to be successful, but the process for how to do this can be somewhat variable. These studies have typically employed follow-ups for less than 5 years, constraining these studies to the short term; future directions should employ longer longitudinal approaches. Equally, as custom triflange cups are becoming an increasingly popular management option for severe acetabular bone loss or failed reconstructions, customizing tibial cones for tibial defects, unique patient anatomy, and complex revisions may be the solution where OTS cones of any size are not appropriate [19,20].

Limitations

The use of a GEE, which examines the population as a whole rather than looking at individual patients, is a limitation. Due to constraints with the dataset, a generalized linear mixed model was not possible. However, a GEE was deemed acceptable. Lack of an automated method when collecting measurement data was also a limitation, although our image processing software was able to display the necessary landmarks for accurate measurement. In addition, our image processing software does not have solid boundaries, which might otherwise provide resistance and path guidance to the entry of a cone. Additionally, some of the preparation of the cone intraoperatively can depend on whether the patient's bone is strong enough to ream into without fracturing or breaching, and this could not be assessed in the model, so potentially, some breaches may have tolerated a cone. Lastly, we did not consider a refresh cut when simulating the revision procedure; however, given that a refresh cut will ultimately result in deeper cone placement, our conclusion remains valid. As only one unique cone design from one manufacturer was used for this study, future studies should attempt to address this gap by considering smaller cones from other manufacturers in addition to custom-made cones. This concept should also be explored in cadaver or sawbone models to confirm our findings in future studies.

Conclusions

In rTKA, a certain subset of patients was not well accommodated by OTS cones, especially shorter patients and those who required a deeper cone due to substantial bone loss. Smaller cones or custom tibial cones for this patient population would lower the risk of cortical breaching. Given that we have demonstrated the need for more tibial cone options, further device development is required to engineer these cones as well as evaluate their safety, longevity, and instrumentation.

Conflicts of interest

J. Bernstein is a paid consultant for Depuy Synthes and Smith & Nephew and is a board/committee member of AAHKS, AAOS, EOA, and CT ortho society. D. Wiznia is a paid consultant for Globus and receives research support from Stryker Orthopaedics. All other authors declare no potential conflicts of interest.

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