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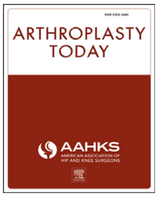

Original Research

Personalizing Revision Tibial Baseplate Position and Stem Trajectory With Custom Implants Using 3D Modeling to Optimize Press-fit Stem Placement

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ABSTRACT

Background: A common tibial construct for revision total knee arthroplasty includes a long diaphyseal engaging press-fit stem. Due to tibial canal bowing, compromises are often necessary to match patient anatomy when choosing stemmed implants. The objective of this study is to determine through 3-D modeling whether current implant press-fit options appropriately fit patient anatomy, or whether an alternative angle between the stem and baseplate could increase the cortical engagement of long press-fit tibial stems.

Methods: Preoperative computerized tomography scans from 100 patients undergoing TKA were imported into an image-processing software program. Three-dimensional models were created with tibial stems placed at a fixed perpendicular angle and a custom angle to the revision tibial baseplate. Stem diameter, depth, offset, and contact surface area were measured and analyzed between the 2 groups.

Results: Significantly more cortical contact, larger stem diameter, and smaller offset of the custom keel from the center of the baseplate were associated with free custom tibial stem placement vs a fixed perpendicular baseplate-stem interface ($P < .001$). Statistically significant differences were also found between different patient demographics.

Conclusions: Custom free-angle stem placement allows for increased stem diameter and cortical contact of press-fit tibial stems compared to existing constructs that must interface with the baseplate at a 90-degree angle. Current revision tibia implants limit fixation of tibial press-fit stems and often mismatch with patient anatomy. Alternative ways to fit patient anatomy may be beneficial for patients with extreme mismatch. In the future, custom keel angles may help to resolve this problem.

Introduction

The demand for revision total knee arthroplasties (rTKAs) has increased dramatically with the growing number of total knee arthroplasties (TKAs) being performed yearly [1,2]. Common indications for rTKA include complications such as infection, instability, component malposition, fracture, and aseptic loosening [3,4]. rTKAs Have been shown to have an overall high rate of survivorship, up to 90.6% over 10 years; however, a major reason for revision knee arthroplasty failure is aseptic loosening of the tibial baseplate [5]. Regarding tibial reconstruction, there are currently 2 stem fixation options: cemented stems and uncemented press-fit stems. Cemented tibial stems while using a cone are gaining popularity because of the ease of matching patient anatomy, but there are many surgeons who still prefer using press-fit tibial

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stems. Press-fit stems engage with the cortical bone in the diaphysis and align the baseplate to be perpendicular with the trajectory of the diaphysis. They may also bypass deficient or damaged bone and allow for the possibility of bony ingrowth or on-growth onto the stem [6,7]. In some revisions for infection, surgeons may prefer to use cemented stems to allow for antibiotic elution. On the other hand, cemented stems may be easier to use as they are not confined by the location of the diaphysis, and a short stem can float in the metaphysis and gain fixation with cement. A downside is that because the stem engagement in the diaphysis is not directing baseplate alignment, the tibial baseplate can be placed into malalignment, especially if there is significant bone loss on the tibial surface.

When surgeons discuss optimal fixation, the concept of zonal fixation is often used to better understand fixation of revision components. The 3 zones for fixation are the epiphysis or joint surface, the metaphysis, and the diaphysis. Fixation in at least 2 of these 3 zones is recommended to provide solid long-term fixation [8]. With long-stem press-fit prostheses, this fixation is usually obtained at the diaphysis as well as, to some degree, at the joint surface. Addition of a tibial cone may assist in providing metaphyseal fixation to augment stability in short-stem cemented prostheses but does not appear to significantly decrease micromotion during loading in long-stem press-fit constructs [9]. The long-term survivorship of press-fit stems compared to cemented short-stem prostheses has been shown to be similar with regard to the need for revision for aseptic loosening, and press-fit stems also have the advantages of improved longitudinal prosthesis alignment and easier extraction if revision is required [7,10,11].

There are various methods to optimize the cortical engagement of press-fit stems with a wide range of options for stem length and diameter and the use of offset couplers which give further options for the placement of the keel with respect to the optimal position of a press-fit stem. In uncemented prostheses, the stems are often offset in order to accommodate the canal position relative to the tibial tray [12]. However, mismatch between the trajectory of the intramedullary canal and the center of the metaphysis can cause components to be malpositioned, even with the use of offset stems [13]. The current stem constructs remain at fixed angles with the baseplate and are confined by specific offset sizes. There are different options for offset with different commonly used implants (Table 1) [14]. These stem positions are limited to only a single angle that the stem makes with the baseplate to try to achieve diaphyseal engagement. Many surgeons who conduct significant numbers of revisions attempt to not use offset couplers because of the difficulty in stem extraction if further revisions are needed, which further limits the use of press-fit stems. The press-fit stem designs currently available are not ideal for many patients' anatomies and may also contribute to failure if actual diaphyseal engagement is not achieved [15].

Our hypothesis is that a large majority of patients would have malaligned tibial components if press-fit stems (reamers) were used to set the tibial baseplate cut, as is done now both with press-fit and cemented tibial components. Additionally, we wanted to see what the ideal angle of the tibial stem would be to the baseplate and where a keel would ideally be on the baseplate in order to best match patient anatomy. We hypothesized that a custom tibial baseplate and keel can be designed to accommodate personalized placement of a tibial stem (this will be referred to as free-angle-placed stem) to better engage the tibial diaphysis in a true press-fit design. In this study, we analyzed the placement of press-fit stems in rTKA procedures by using 3D modeling to customize the stem trajectory and the stem's interface with the tibial baseplate. We compared this press-fit position with the best-fit position of current options for tibial stems with a fixed angle with the based plate and options for offset couplers.

Material and methods

Preoperative computerized tomography (CT) scans were selected from patients undergoing TKA and imported into the image-processing software package Simpleware ScanIP 3D (Mountainview, CA) to perform image processing. Patient-specific models were created, including the proximal and distal tibia. Image processing was conducted as follows: The DICOM files of the knee joint and ankle joint were imported, and the cropping and resampling tools were used to reduce background noise and focus on the region of interest. Segmentation of the images was done using the threshold tool to create an initial mask of the greyscale values representing bone. The proximal tibia and proximal fibula were separated from surrounding constructs into individual masks using the split regions tool. A morphological close function was performed on each mask, and a mask flood fill tool was used to separate the intramedullary canal from the outer cortex. A recursive Gaussian filter was used to smooth out the model and remove bone islands and scatter. The above outlined steps were repeated for the CT scan of the same patient's ankle joint to segment the distal tibia, distal fibula, and talus. The voxel dimensions of the models were 0.65 mm × 0.65 mm × 0.65 mm.

To model the tibial cut, a slice view of the coronal plane was enabled using the 3D clipping tool. The mechanical axis of rotation was created using a centerline from the intercondylar eminence of the proximal tibia through the midpoint of the talar dome. The centerline was rotated 90 degrees across the y-axis, then placed perpendicular to the mechanical axis of a rotation. A landmark was placed on the highest lateral portion of the tibia, and the line perpendicular to the mechanical axis was aligned for the tibial cut. The shape-to-shape measurement tool was used to ensure proper placement of the tibial cut 9-9.5 mm inferior to the highest lateral point of the proximal tibia. The portion of the tibia superior to the measured line was removed to model the tibial cut (Fig. 1).

Zimmer Biomet (Warsaw, IN) NexGen Wedge Tibia base plates of appropriate size were placed perpendicular to the mechanical axis with their rotation centered at the junction of the middle and medial thirds of the tibial tubercle. A 10-mm-diameter Zimmer Biomet tibial stem was aligned with the baseplate to analyze fixation of current press-fit stem placements (Fig. 2).

Primitives were created in ScanIP in the shape of cylinders to model tibial stems. Stems with diameters ranging from 8 to 20 mm and lengths ranging from 160 to 220 mm were placed in the intramedullary canal. One of these stems was placed perpendicular to the mechanical axis of the tibia with freedom to move uniaxially (fixed perpendicular). This stem, if it did not align with the conventional location of the tibial baseplate keel, would require an

Table 1
Common implants.

Manufacturer	Knee system	Offset
Smith and Nephew	Legion Revision Knee System	2 mm, 4, mm, and 6 mm
Zimmer	Persona Revision Knee System	Straight, 3 mm, and 6 mm
Stryker	Triathlon Revision Knee System	Up to 6 mm maximum

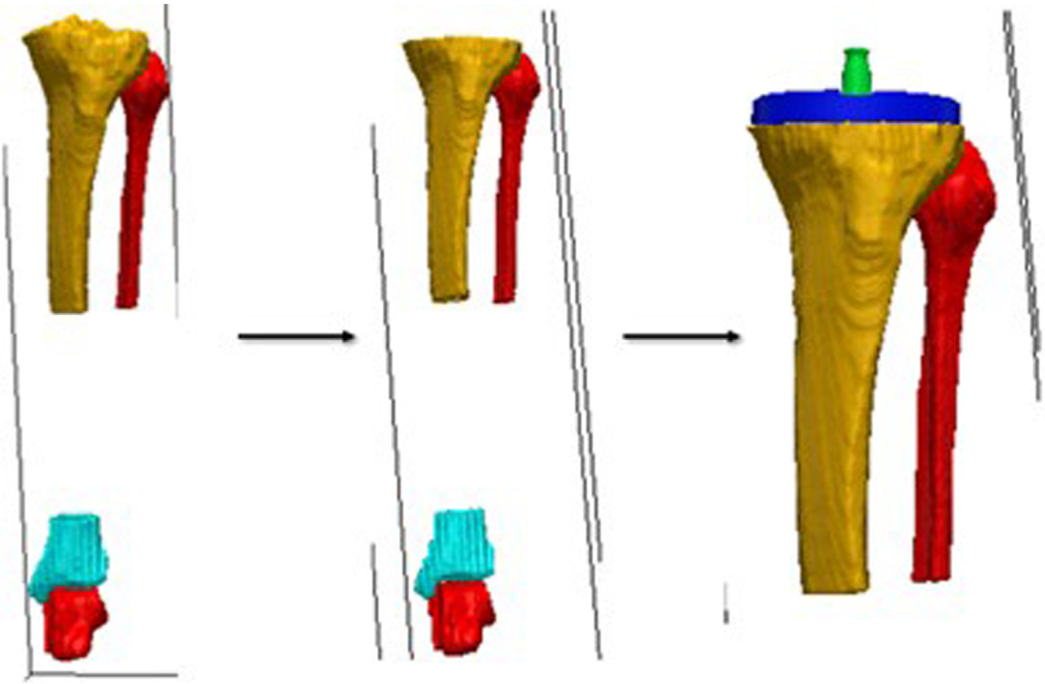

Figure 1. Three-dimensional models created in the Simpleware ScanIP software, shown from left to right at the stages of image segmentation, tibial cut, and implant placement.

offset coupler. Another stem was placed into the isthmus at an angle with which it represents the most ideal press-fit fixation in the diaphysis (free angle). Coronal, sagittal, and axial plane views in ScanIP were used to determine optimal stem size and placement for each setup. Measurements were taken for the stems using the Simpleware ScanIP software and compared to the conventional placement.

Finite element analysis (FEA) was performed in 3 representative sample patients. FEA reporting standards of Erdemir et al. are used here [16]. Patient 1 had height and weight of 62 inches and 61.2 kg, patient 2 was 65 inches and 88.5 kg, and patient 3 was 70 inches and 122.5 kg, respectively. A digital mask was created using ScanIP, combining the proximal tibia and fibula into 1 model. Base plates and stems were chosen in consultation with orthopedic surgeons with greater than 5 years of postfellowship experience. Fixed stems were put in place, as given by the manufacturer. Free stems were created moving the point of entry medially by approximately 2 mm and angling the entry slightly anteriorly to create variability. The stem and tibial base plates for each model were combined, modeling them as a single unit. Material properties of this implant

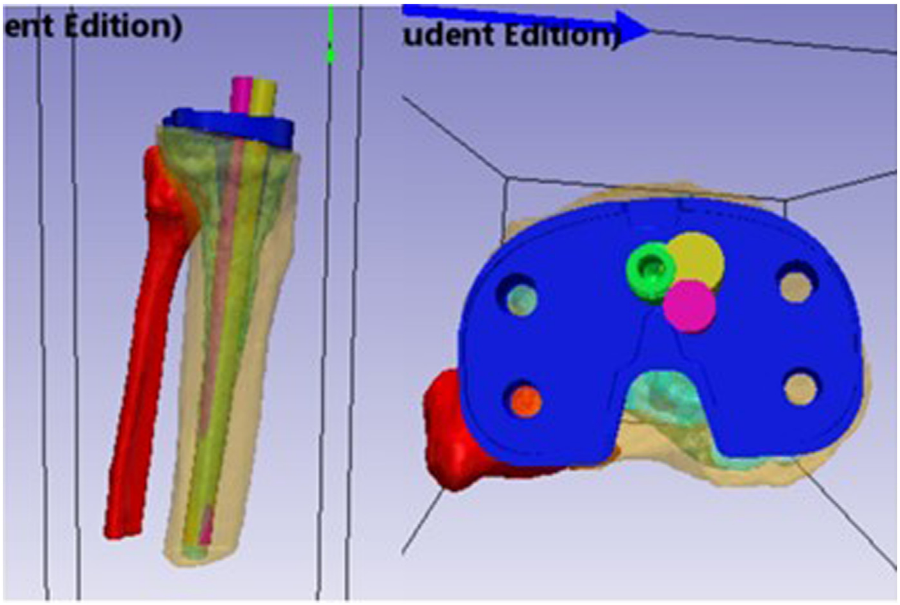

Figure 2. Implant placement. Three-dimensional models of a conventional placement without offset stem (green), a fixed perpendicular placement stem (pink), and a free-angle-placement stem (yellow) created in the Simpleware ScanIP software. Models are shown in the sagittal and axial planes on the left and right, respectively.

Table 2
Demographics.

Patient characteristic	Count (%) of mean and range
Male	51 (51%)
Female	49 (49%)
Mean age (range)	66 y (34-89 y)
Mean height (range)	67 in (59-83 in)
Mean BMI (range)	30.5 kg/m^2 (20.5-48.1 kg/m^2)

BMI, body mass index.

were a titanium alloy (Ti-6Al-7Nb) with a density of 4.52 g/cc, Young's Modulus of 105 GPa, and Poisson's ratio of 0.32 [17,18].

Material properties were modeled for trabecular bone by taking the grayscale value of each voxel between 0 and 1000 in the femur mask and creating 5 bins of increasing grayscale value [19]. Each bin's average grayscale value was converted by ScanIP into an apparent density value calibrated to an aluminum rod (of known density 2.7 g/cc) scanned by the same CT scanner. The 2 points of (−1000, 0 g/cc), the known grayscale value at 0 g/cc density, and (2082, 2.7 g/cc), the resulting grayscale value of the aluminum rod (4 grayscale values of the aluminum rod were taken and averaged), were obtained. These points were entered into ScanIP for the grayscale to apparent density conversion. Once obtaining the apparent densities for each of the 5 bins, an established equation for converting apparent density to Young's Modulus, given by Morgan et al. and multiplied by 1.28 to account for side-artifact errors (equation given below), was used [20,21].

$$E = (1.28)(8,920\ \rho_{apparent}{}^{1.83})$$

Cortical bone, in contrast, was modeled as a separate bin consisting of a uniformly stiff material with the Reilly and Burstein Young's Modulus value of 17,000 MPa for all voxels greater than a grayscale of 1000 [19,22]. Poisson ratios were given by Goodheart et al. with trabecular bone being 0.3 and cortical bone being 0.46 [23].

The models were meshed using tetrahedral quadrilateral curved elements of a side length of 3 mm. Contacts were established between the implant and the bone with a frictional coefficient of 0.35 [24]. Using the Abaqus software (Dessault Systèmes, Waltham, MA) the models were fixed at the distal end of the tibia and fibula. The load of each patient's weight was applied across the nodes of the superior surface of the tibial base plates to simulate load in standing.

Results

One hundred and twelve scans were initially gathered for analysis. However, 12 scans were unable to be used due to insufficient inadequate imaging depth of the distal tibia, leaving 100 scans of knees of 49 females and 41 males with a mean age of 66 years that were included in the analysis (Table 2). Statistically significant differences were found for the stem diameter, stem depth, stem offset, and contact surface area between the fixed perpendicular-placement stems and the free-angle-placement stems (Table 3).

Free-angle-placement stems demonstrated increased stem diameters, stem depth, and contact surface area, as well as decreased stem offset in comparison to fixed perpendicular placement stems. The mean stem diameter increased by 2.0 ± 0.92 mm when a free-angle-placement stem was used in place of a fixed perpendicular placement stem for patients (13 ± 1.9 mm vs 11 ± 2.2 mm, $P < .001$) (Table 3, Fig. 3). In addition to stem diameter, the depth of the stem into the intramedullary canal where it made cortical contact increased from 65 ± 26 mm to 150 ± 19 mm when a perpendicular placement stem was swapped out for a free-angle-placement stem ($\Delta = 80 \pm 29$ mm, $P < .001$). Tibial stem depth refers to the combination of the visible stem within the intramedullary canal and the stem running through the tibial keel. For example, a stem depth of 80 mm consists of a 31-mm tibial keel plus 49 mm of visible stem beneath the keel.

Stem offset from the center of the baseplate was 9.5 ± 4.5 mm for the fixed perpendicular placement group and 6.6 ± 3.0 mm for the free-angle-placement group. Significantly decreased offset was found for free angle placement ($\Delta = -2.9 \pm 5.2$ mm, $P < .001$). FEA on existing models showed free-angle-placement stems exhibiting greater contact surface area with the cortex than the fixed perpendicular stems (650 ± 570 mm^2 vs 350 ± 370 mm^2, $P < .001$).

Comparing differences between fixed perpendicular placement stems and free-angle-placement stems between men and women, statistically significant results were found for the correlation between patient height and decrease in stem offset with a free-angle-placement stem.

The taller group of patients was found to have a greater decrease in stem offset between the free-angle-placement stem and the fixed perpendicular stem than the shorter group of patients ($\Delta = -4.0 \pm 5.5$ mm vs $\Delta = -1.9 \pm 4.8$ mm, $P = .042$) (Table 4). Free-angle-placement analyses identified differences between men and women and patients shorter and taller than the median height of 67.75" (Table 5). Anterior contact angle refers to the angle between the tibial stem and the coronal plane in the anterior direction. Medial contact angle refers to the angle between the tibial stem and the sagittal plane in the medial direction (Fig. 3). Men were found to have a greater stem diameter than women (13 ± 1.8 mm vs 12 ± 2.0 mm, $P = .046$) while taller patients were found to have a larger stem diameter (12 ± 1.8 mm vs 13 ± 1.9 mm, $P = .0003$) and less medial angular offset with the baseplate (89 ± 1.7 degrees vs 90 ± 1.7 degrees, $P = .033$). Free and fixed stems had approximately the same peak von Mises stress at the distal tip (Table 6). The heavier the patient is, the more the von Mises stress differed between the free and fixed stems.

Discussion

This study demonstrated that if a press-fit stem is used to determine the tibial baseplate orientation, as is done routinely in revision knee replacements, then the tibial baseplate will often be malaligned. This 3D analysis was able to demonstrate that a stem placed at a free angle and allowed to accurately align with the tibial

Table 3
Summary of stem changes in all patients (n = 100).

Measurement	Fixed perpendicular placement (mm)	Free-angle placement (mm)	Absolute change mean (mm)	*P* value
Stem diameter	11 ± 2.2	13 ± 1.9	2.0 ± 0.92	$P < .001$
Stem depth	65 ± 26	150 ± 20	80 ± 29	$P < .001$
Stem offset	9.4 ± 4.5	6.5 ± 3.0	−2.9 ± 5.2	$P < .001$
Contact surface area	350 ± 370 mm^2	650 ± 570 mm^2	380 ± 430 mm^2	$P < .001$

P values less than .05 were considered statistically significant.

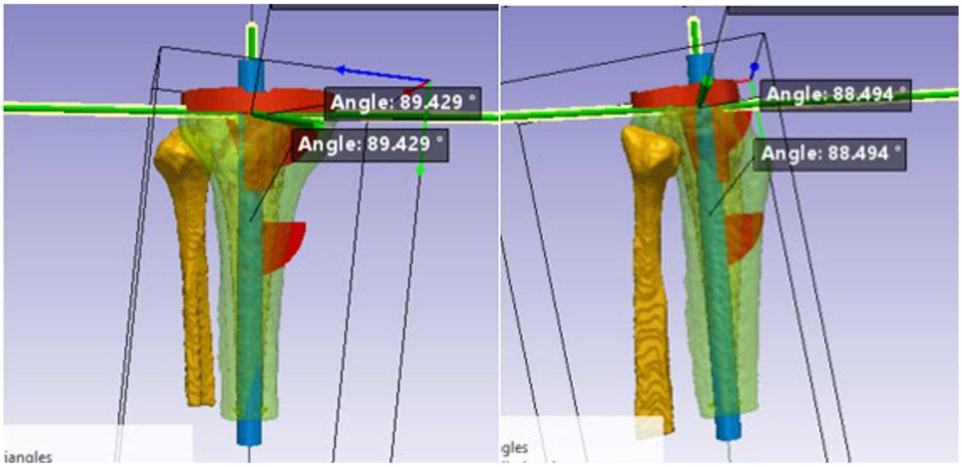

Figure 3. Measurements: coronal and sagittal plane views of anterior and medial contact angles found for a free-angle-placement stem. Angles were measured between the centerline of the stem and lines perpendicular to the coronal and sagittal planes.

diaphysis angle and location improved cortical contact, stem diameter, and length when compared to a fixed perpendicular stem. Follow-up FEA revealed similar stresses near the tip of the stem in normal weights, but stresses diverged in heavier patients. With a maximum offset coupler of +6 mm offered in rTKA guides, 79 of the 100 patients in this study would not be adequately compensated with a fixed perpendicular stem combined with an offset coupler [25]. In contrast, free-angle stem placement decreases the need for offset couplers. It also should be considered in patients who have a large degree of mismatch between tibial diaphysis and mechanical alignment of the tibia and who may not be appropriate candidates for press-fit revision tibial components. Because of the large degree of mismatch, we do recommend getting full-length standing films preoperatively for all patients who a surgeon is considering using a press-fit tibial component on.

A notable limitation of this study was that we were unable to evaluate imaging of the entire lower extremity. To protect the patients from excess exposure to radiation, instead of acquiring full-length tibia scans, separate CT scans of the knee joint and ankle joint were taken and combined in the image segmentation software with a portion of the distal tibial shaft missing between the 2 scans. Several studies had to be excluded because tibial diaphyseal bone was missing to obtain accurate measurements. In addition, the generalizability of the results is limited by the relative homogeneity with regard to patient demographics such as ethnicity and race. Further research is also needed to see whether these data would be different in more diverse demographics. An additional limitation of this study is that it is all done based on modeling and not being tested on patients' anatomy. While this would not be possible at this stage, it does pose a problem because patients' bone quality may change the amount able to be reamed and the direction of the reamer. Additionally, the ability to use a custom press-fit revision tibia is just a theoretical solution to an ongoing problem of alignment in revision TKA. For future directions of the project, mechanical testing of custom tibial keels printed at an angle must be conducted to ensure they have similar properties to limit fatigue stress in comparison to standard tibial keels positioned at 90 degrees. What it does do is draw focus that this is a complex problem and present potential future solutions and allow surgeons to further question what the correct implant for their patients is.

This study supported that free placement of stems allows a larger diameter and increased cortical engagement when compared to the fixed perpendicular stem placement. Gobba et al. demonstrated that patients' anatomical characteristics can create conflicts in rTKA procedures with longer stems as they may not be well aligned within the tibial canal [26]. This study further supports this finding but uses a larger sample size and 3D models [26]. Another study found alignment to be a major technical challenge with press-fit stem design constructs but determined that increased engagement of the diaphysis with the long press-fit stems facilitates more accurate alignment [27]. Our study shows that improving alignment of the press-fit stem via a free-angle design can reduce the severity of this limitation. These results should be taken into account when considering the press-fit stem

Table 4
Correlation analyses between fixed perpendicular placement and free-angle placement stems.

Measurement	Sex		
	Men (n = 51)	Women (n = 49)	*P* value
Change in stem diameter (mm)	2.0 ± 0.93	2.0 ± 0.93	.96
Change in stem depth (mm)	83 ± 28	77 ± 29	.32
Change in stem offset (mm)	−3.1 ± 5.5	−2.7 ± 5.0	.75
Change in contact surface area (mm^2)	330 ± 350	440 ± 500	.18
	Short vs tall patients Patients 59-68" (n = 50)	Patients 68-83" (n = 50)	*P* value
Change in stem diameter (mm)	2.0 ± 1.0	2.0 ± 0.81	.87
Change in stem depth (mm)	78 ± 28	81 ± 30	.62
Change in stem offset (mm)	−1.8 ± 4.8	−4.0 ± 5.5	**.042**
Change in contact surface area (mm^2)	380 ± 460	390 ± 390	.95

P values less than .05 were considered statistically significant and denoted in bold.

Table 5
Free-angle placement analyses.

Measurement	Men (n = 51)	Women (n = 49)	*P* value
Stem diameter	13 ± 1.8	12 ± 2.0	**.046**
Anterior contact angle with baseplate	91 ± 2.3	91 ± 2.1	.98
Medial contact angle with baseplate	90 ± 1.8	89 ± 1.7	.29
Offset direction	6.5 ± 2.9	6.6 ± 2.6	.85
	Patients 59-68” (n = 50)	Patients 68-83” (n = 50)	*P* value
Stem diameter	12 ± 1.9	13 ± 1.9	**.0003**
Anterior contact angle with baseplate	91 ± 2.1	91 ± 2.3	.85
Medial contact angle with baseplate	89 ± 1.7	90 ± 1.7	**.033**
Offset direction	6.4 ± 2.7	6.8 ± 2.8	.43

P values less than .05 were considered statistically significant and denoted in bold.

diameter, length, and offset for use when performing rTKA procedures based on patients’ characteristics and anatomical features.

This experiment provides new insight into the relationship between the potential for customized press-fit tibial stem/baseplate designs and opportunity for improved cortical engagement in revision total knee replacement. A study tested the use of custom-made porous titanium cementless metaphyseal cones as an alternative approach for complicated knee revisions [28]. Through the use of biomechanical testing and FEA, as well as clinical follow-up analysis, the report found that the customized cones provided better biomechanical support than off-the-shelf constructs, and no complications were seen within the sample group [28]. While this research is focused on customized cones and cemented tibial stems, there is little existing research that examines the use of a custom tibial stem combined with a custom base plate for a fully custom press-fit design in rTKA procedures. However, the results and methodology from this research should be considered when assessing which indications are best suited for a custom-made implant and how to design a biomechanical study into fully customized press-fit stem construct designs.

Conclusions

This study demonstrates that in a majority of patients, the use of a long press-fit stem to set alignment would result in malalignment of tibial component in revision TKA. Additionally, this study shows that if free-angle placement of stems is able to be done, then this would exhibit a larger stem diameter, longer stem length, increased cortical engagement, and smaller offset than fixed perpendicular placement press-fit tibial stems. Upon 3D modeling assessment of the free-angle placement of stem, we found that taller patients tend to fit larger-diameter press-fit stems, while shorter patients tend to have greater medial angular offset. Better and longer cortical engagement can be achieved with a press-fit stem through the use of a custom baseplate and stem construct with custom keel placement. With standard, non–patient-specific press-fit stems, a small but quantifiable risk of periprosthetic fracture has been described [29]. It is important for surgeons to recognize this when selecting implants, and in these patients with a large degree of mismatch, a cemented tibial component with a cone may be the best choice of implants that currently exist. We propose developing patient-specific 3D tibial baseplates and custom keel placement with free-angle stem placement for rTKA, as the free-angle design improves the cortical fit of the prosthesis and could be an effective way to obtain a more stable, customized construct for patients in whom revision knee arthroplasty is indicated. These implants would need to be further developed and undergo biomechanical testing.

Table 6
Three case studies of patients used in the FEA with height (in) and weight (kg) demographics as well as peak von Mises stresses (MPa) near the distal tip of the implant for fixed and free stems.

Patient	Height (in)	Weight (kg)	Fixed (MPa)	Free (MPa)
1	62	61.2	23.78	18.56
2	65	88.5	13.70	18.22
3	70	122.5	29.46	46.17

Conflicts of interest

J. Bernstein is a paid consultant for DePuy Synthes and is an American Association of Hip and Knee Surgeons Young Arthroplasty Committee member, American Joint Replacement Registry Young Physician Committee member, and is an American Academy of Orthopaedic Surgeons Hip Knee Adult Reconstruction Evaluation Committee member. D. Wiznia is a paid consultant for Intellijoint. G.-C. Lee is a paid consultant for Stryker, Corin, and Heron Therapeutics; receives research support from Smith & Nephew, DePuy, and KCI Acelity; is in the editorial or governing board of Journal of Arthroplasty, Clinical Orthopaedics and Related Research, Journal of Bone & Joint Surgery, and The Bone & Joint Journal; and is a Knee Society Technology Committee member. All other authors declare no potential conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2022.08.011.

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