Published in final edited form as:

Med Eng Phys. 2021 July ; 93: 1–7. doi:10.1016/j.medengphy.2021.05.011.

Virtual implantation technique to estimate endoprosthetic contact of percutaneous osseointegrated devices in the tibia

Carolyn E. Taylor^{b,c}, Heath B. Henninger, PhD^{b,c}, Kent N. Bachus, PhD^{a,b,c}

^aDepartment of Veterans Affairs, 500 Foothill Drive (151), Salt Lake City, Utah, United States of America

^bDepartment of Orthopaedics, University of Utah, 590 Wakara Way, Suite A100, Salt Lake City, Utah, United States of America

^cDepartment of Biomedical Engineering, University of Utah, 36 S Wasatch Drive SMOB 3100, Salt Lake City, Utah, United States of America

Abstract

Percutaneous osseointegrated (OI) devices have an endoprosthesis attached to the residual bone of an amputated limb, then pass permanently through the skin to be connected to the distal prosthetic componentry outside of the body. Whether the bone-anchoring region of current OI endoprostheses are cylindrical, and/or conical, they require intimate bone-endoprosthesis contact to promote stabilizing bone attachment. However, removing too much cortical bone to achieve more contact leads to thinner and, subsequently, weaker cortical walls. Endoprostheses need to be designed to balance these factors, namely maximizing the contact, while minimizing the volume of bone removed. In this study, 27 human tibias were used to develop and validate a virtual implantation method. Then, 40 additional tibias were virtually implanted with mock cylindrical and conical bone-anchoring regions at seven residual limb lengths to measure resultant bone-endoprosthesis contact and bone removal. The ratio of bone-endoprosthesis contact to bone volume removed showed the conical geometry had more contact area per volume bone removed for all amputation levels ($p < 0.001$). In both mock devices, cortical penetration of the endoprosthesis at 20% residual length occurred in 74% of cases evaluated, indicating that alternative endoprosthesis geometries may be needed for clinical success in that region of bone.

1. Introduction

Percutaneous osseointegrated (OI) endoprosthetic systems are used to attach exoprosthetic limbs to the residual bone of an amputated limb. The endoprosthesis placed in the medullary canal is attached to a load-bearing percutaneous post which connects to the distal exoprosthetic componentry outside the body. This procedure is still in its infancy, with only six types of percutaneous OI devices in use worldwide [1, 2]. Each takes a different engineering approach to secure the endoprosthesis in the bone. One design creates

Corresponding Author: Kent Bachus, kent.bachus@hsc.utah.edu, 590 Wakara Way, Room A100, Salt Lake City, Utah, 84108, USA.
Competing interests: None declared.

Ethical approval: University of Utah and Salt Lake City Institutional Review Board #11755.

static compression between a distal collar and proximal anchored intramedullary plug (Compress^{TM}, Zimmer-Biomet, Warsaw, IN) [3]. The remaining five systems use press-fit or threaded fixation to create intimate bone-endoprosthesis contact with a surface that encourages bone attachment without the use of bone cement: Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA, Integrum, Molndal, Sweden), Integral Leg Prosthesis (ILP, Orthodynamics, Lubeck, Germany), the Osseointegrated Prosthetic Limb (OPL, Permedica S.p.A., Milan, Italy), Intraosseous Transcutaneous Amputation Prosthesis (ITAP, Stryker Orthopaedics, Kalamazoo, MI), and the Percutaneous Osseointegrated Prosthesis and Percutaneous Osseointegrated Docking System (POP and PODS, DJO Surgical, Austin, TX) [2]. These devices use an OI facilitating surface with a cylindrical profile, conical profile, or combination of the two.

While the array of percutaneous OI endoprostheses have shown promising clinical outcomes with transfemoral patients [4, 5], five of the six (OPRA, OPL, ILP, ITAP, Compress^{TM}), have been used clinically for transtibial patients [2, 5]. However, continued reports of aseptic loosening in these patients [6] indicate that endoprosthesis designs may need to be reconsidered for transtibial devices.

To achieve stabilizing OI, the bone attachment region of percutaneous OI endoprostheses requires intimate bone-endoprosthesis contact. It has been shown that host bone more than 50 μm away from the endoprosthesis cannot bridge the interface before the formation of fibrous connective tissue [7], making it the most important region to match the bone-endoprosthesis interface. For systems that use press-fit fixation, a conical taper allows for a tight fit in the medullary canal. The only purely conical bone attachment region is in the POP/PODS device. This system also has the shortest porous coated region (3 cm) to allow placement in short residual limbs and minimize bone resection if endoprosthesis revision is necessary [8]. The ILP and OPL use a similar press-fit approach, but with a curved cylindrical geometry and combination of conical and cylindrical geometries, respectively, and have a much longer bone attachment region (up to 18 cm) [1, 5].

In orthopaedics, virtual implantation is used to preoperatively template endoprostheses prior to surgery [9–12], improving patient outcomes when implemented correctly [13]. Virtual implantation utilizes a computer generated endoprostheses placed into a 3D reconstruction of the patient's bone or joint for non-invasive, optimization of surgical techniques. It can assess endoprosthesis designs by determining the estimated amount of contact between the bone and endoprosthesis and the amount of bone removal necessary to achieve that contact. Bone-endoprosthesis contact serves as a predictor of bone attachment, and bone removal could contribute to cortical thinning and lead to compromised cortical integrity [14]. Utilizing virtual implantation to assess percutaneous OI designs in the tibia could help predict fit and avoid aseptic loosening.

The tibia has a unique anatomic morphology with an hourglass shaped medullary canal that has thin cortex on the proximal and distal ends and thicker cortex in the middle [15]. Each region presents its own challenges and may require unique approaches. Unlike the humerus where we see a consistent medullary flare as you move proximally [16], the tibia has a distal convergence, diaphyseal straight region, and proximal flaring [15]. The previous approaches

that allow for a single, scaled endoprosthesis for any residual limb length are likely not the best for the changing nature of the tibia. Virtual implantation allows us to see which endoprosthesis geometry is more amenable to the entire tibia, to see if direct translation of endoprosthesis designs from other anatomical locations is possible.

There were two goals of this study. The first was to develop and validate a virtual implantation method with accuracy less than or equal to 1 mm compared to surgical implantation, in agreement with the clinical axial CT resolution of 1 mm slice thickness. The second was to use the virtual implantation technique to examine the fit of cylindrical and conical endoprosthesis geometries and measure resultant bone-endoprosthesis contact, and bone removal after virtual implantation into the medullary canal of the tibia. Mock cylindrical and conical endoprostheses were evaluated to most directly compare 1-to-1 by controlling for length and diameter. We hypothesized the ratio of contact to unit of bone volume removed would be higher, and therefore more favorable, for the conical geometry at distal amputation lengths, the cylindrical for the mid-tibia shaft, and there would be no difference between the geometries for proximal lengths.

2. Methods

2.1 Validation of Virtual Implantation Procedure

Deidentified fresh frozen human tibia were obtained from a national tissue source (United Tissue Network, Phoenix, AZ; Science Care, Phoenix, AZ). The use of cadaver tissue was deemed exempt by both the University of Utah Institutional Review Board, and the Salt Lake City Veterans Affairs Medical Center, (protocol #11755). A paired, two-means power analysis ($\alpha = 0.05$, power = 0.8, effect size = 0.6) of variation in mean cortical thickness of the tibia was conducted to determine the sample size necessary to capture cortical thickness variation in the population as this is an important measure in endoprosthesis fit. Mean cortical thickness at adjacent residual lengths of 20, 35, 50, 65, and 80% estimated a maximum population of 25 specimens (50 to 65% was omitted because there was not a statistical difference in cortical thickness between these lengths) [15]. A total of 27 fresh-frozen, unpaired tibias were selected for validation procedures.

Axial CT scans were collected (Siemens SOMATOM Definition Flash scanner, 120kVp, 100mAs, 512×512 acquisition matrix, 1-mm slice thickness). CT scans were reconstructed to generate 3D models (MIMICS v21.0, Materialise, USA, Plymouth, MI) at three points during the surgical process of implanting an endoprosthesis with conical geometry: 1) isolated intact bones with soft tissue removed, 2) after amputation at the 40% residual length (Figure 1) [15], and 3) after surgical placement of the endoprosthesis but before final impaction. Scan 1 was segmented using semi-automatic thresholding to identify cortical and medullary boundaries. This segmentation was decimated and smoothed to reduce aliasing artifact by performing three smoothing iterations using a smooth factor of 0.5 (MIMICS) [15]. Scan 2 aligned the previous segmentation to the bone in this scanner and cropped the segmentation at the distal osteotomy using thresholding around the distal end. Scan 3 also aligned the segmentation from scan 1 to the bone but utilized thresholding to edit the prepared endosteal surface and crop around the distal osteotomy. Residual length was defined as the distance between the average height of the tibial plateau and tibial plafond

where percent length is measured proximal (0%) to distal (100%) [15]. A 40% residual length was selected based on the optimal length of a below knee amputation (15 cm from the medial knee joint line [17], where the average length of the tibia is 36.95 cm [15]).

Each tibia was prepared according to surgical instructions provided by the medical device manufacturer for POP/PODS systems (DJO Surgical, Austin, Texas) including reamer, planar, and broach instrumentation as detailed by Drew et al. [18]. These steps dictated alignment and sizing of the endoprosthesis system, which were the target parameters to validate in this study.

The intact bone models from each CT scan were aligned to a global coordinate system defined by proximal anatomical landmarks [15]. 3D reconstructions of the amputated and surgically prepared bone were then globally aligned by surface fit to the intact tibia to reduce influence of alignment variation using the Global Registration function in 3-Matic (v13.0, Materialise, USA, Plymouth, MI). The amputated, but not surgically prepared, reconstruction then underwent a virtual preparation procedure. Here, a conical model matching the proximal and distal diameter and length of the broach used in surgical preparation was coaxially aligned to the tibial shaft axis [15] at the centroid of the distal medullary canal. The tibial shaft axis was defined by the inertial axis of the medullary canal from one medial-lateral proximal plateau width down the shaft from the origin and terminating at 50% residual length [15]. The distal osteotomy planar was aligned perpendicular to this axis. This object was then subtracted from the 3D reconstruction to simulate the final surgical preparation of the bone.

2.1.1 Validation Data Analysis—A part comparison analysis of the most distal 3 cm region of interest was conducted between the virtual and surgical preparations (3-Matic). This region reflects the prepared bone that would come in contact with the OI facilitating surface of the endoprosthesis. This part comparison determined the RMS error of the Euclidean distance between each node of the two surfaces revealing the error between the virtual and surgical preparation procedures. The target of this validation was to achieve alignment agreement at or below CT voxel resolution of 1 mm.

2.2 Virtual Implantation

An additional 20 deidentified tibia specimen pairs (40 bones) were selected to undergo virtual implantation. For this analysis, fully intact CT scans of each bone were virtually implanted at 20, 30, 40, 50, 60, 70, and 80% residual length according to the previously described procedure (Section 2.1) followed by final virtual implantation of the cylindrical and conical geometries, independently (Figure 1). The metaphyseal regions were excluded as this would either not support the stack-up of an exoprosthesis limb above the ankle at the distal end, or would not allow for knee function in very short residual lengths [15]. This resulted in a total of 560 virtual implantations with 40 trials in each residual length.

The average diameter of the medullary canal at the distal osteotomy dictated endoprosthesis size. This matched the size used in more than 70% of the cases involved in validation analysis and always fell within 1 mm diameter of the indicated endoprosthesis from the cadaver surgery. Simplified cylindrical and conical endoprosthesis geometries were modeled

for testing. Both designs were 3 cm in length to maintain consistency to compare only the influence of shape, and both had the same distal diameter. The conical geometry had a 2 degree taper as it progressed proximally (Figure 2).

2.2.1 Virtual Implantation Data Analysis—The percent bone-endoprosthesis contact and the percent bone removed during implantation were calculated using surface and volume measurements in 3-Matic. Bone-endoprosthesis contact was calculated as the percent of all possible contact with the endoprosthesis surface. Bone removed was the volume of bone intersecting with the endoprosthesis as a percent of total volume of the original region of interest. The ratio of these two values indicates the amount of bone-endoprosthesis contact per unit volume removed. Because bone contact and bone removal are subject to slight variations in diameter and taper angle, the ratio was used to better compare the results of these two endoprosthesis geometries. Changes in cortical thickness were also analyzed around this region of interest using a custom Matlab script that calculated cortical morphology in transverse cross-sections [15]. The maximum and minimum cortical thickness for the region of interest were measured. All cross sections were normalized to bone length and collected in 1% increments. The 3 cm region of interest resulted in approximately 7% bone length.

All implantations that had the endoprosthesis penetrate the cortex at any point were removed from population analysis and analyzed separately. A two-tailed, independent t-test with significance level of 0.05 was used to compare between male and female populations for each residual length. The statistical difference between the cylindrical and conical endoprosthesis at a given residual length was determined using a two-tailed, paired t-test with significance level of 0.05. For bone removal and contact area, this was a single value comparison for each residual length. For cortical thickness measurements, this comparison was completed for each percent bone length involved in the region of interest for a total of 7 discrete comparisons per implantation level.

For cases with endoprosthesis penetration through the cortex, the surface area of the endoprosthesis that was on the external surface of the bone was recorded. An independent t-test was used to compare between the cylindrical and conical surface area that penetrated the cortex.

3. Results

3.1 Validation of Virtual Implantation Procedure

Specimens used for validation included 15 male, 14 female, 14 right, 15 left, and mean age 37 years (range 15–87 years). Surface comparison between surgically prepared specimens and virtually prepared models revealed an average RMS error between surfaces (range) of 0.25 mm (0.17 – 0.32 mm, Figure 3). Most of the disagreement between surfaces occurred at the distal end of the bone. This region was influenced most by the 1 mm slice thickness of the scans and associated stair-step artifact created at the distal osteotomy.

3.2 Virtual Implantation

Specimens used for virtual implantation included 20 male, 20 female, and mean age 31 years (range 16–64 years). All virtual implantations where cortical penetration did not occur showed statistically different bone-endoprosthesis contact and bone removal between the cylindrical and conical shapes ($p = 0.008$, Table 1). Overall, the cylinder had more bone-endoprosthesis contact at the expense of more bone removal. The ratio of bone-endoprosthesis contact to bone removed showed statistically more contact per volume of bone removed in the conical endoprosthesis for all residual lengths ($p = 0.001$, Table 1). Statistical differences were observed in the ratio of contact per volume removed for both the conical and cylindrical geometries between male and female specimens at the 60, 70, and 80% residual length ($p = 0.04$, Table 1). Additional differences were observed in bone removed at the 60, 70 and 80% residual length for the cylindrical geometry ($p = 0.03$, Table 1) and at 60 and 70% residual length for the conical geometry ($p = 0.03$, Table 1).

Cortical penetration occurred in more than 70% of all virtual implantations at 20% residual length (Table 2, Figure 4). The cylindrical design at 80% residual length also had a high rate of cortical penetration (50%). This was not matched by the conical shape which only had 20% of cases with cortical penetration (Table 2). The anatomic region of cortical penetration was also observed. For every case that this occurred at the 20 and 30% residual length, penetration was observed on the medial and/or lateral sides (Figure 4). This was also true for the majority of penetration cases at 70 and 80% residual length, except 9 cases where there was penetration on the posterior side. The most common location for penetration was on the medial side of the bone.

After virtual implantation, the cylindrical and conical endoprosthesis designs had statistically different maximum cortical thickness from 50–80% residual lengths ($p = 0.025$, Figure 5). At 40% residual length, maximum cortical thickness was statistically different in the distal region of interest (35, 38–40% residual lengths, $p = 0.035$, Figure 5). At 30% residual length, maximum cortical thickness was statistically different for only 27% residual length ($p = 0.035$, Figure 5).

4. Discussion

The goals of this research were first to develop and validate a virtual implantation method, and second to use virtual implantation to measure resultant bone-endoprosthesis contact and bone removal after virtual implantation of cylindrical and conical endoprosthesis geometries into the medullary canal of the tibia. We applied the practice to simplified cylindrical and conical geometries as these are the primary strategies in use today for percutaneous OI. The virtual implantation protocol replicated endoprosthesis placement within CT voxel resolution of 1 mm. We hypothesized that the distal, mid, and proximal regions would favor the conical, cylindrical, and neither shape, respectively, with the ratio of bone contact to amount of bone removed. Instead, the conical endoprosthesis design had a more favorable ratio for all residual limb lengths resulting in more bone-endoprosthesis contact per unit of bone volume removed ($p = 0.001$).

The ratio of bone-endoprosthesis contact to bone removal gives a more objective idea of the design efficiency by providing a value for how much contact is achieved per unit volume of bone removed. We recognize that matching the distal diameters of the shapes biases the cylinder to remove more bone volume. However, we did not expect a difference for the proximal region where the medullary flare does not allow either geometry to make contact with the proximal endoprosthesis. Additionally, we thought the cylinder would better perform in the mid-diaphysis where the medullary canal is relatively straight and the cortex is much thicker. Instead, we saw that the conical geometry was more efficient for the entire bone in achieving more bone-endoprosthesis contact per unit bone volume removed (Table 1).

Though results point to utilization of a conical shaped endoprosthesis to optimize the relationship between stability and structural compromise, neither provides satisfactory results for short (20%) residual lengths. With cortical penetration occurring in 74% of total trials at this length, bone-endoprosthesis contact less than 10%, and bone removal of more than 75%, the typical endoprosthesis geometries would not result in successful clinical outcomes. It may be possible to achieve some bone-endoprosthesis contact with a smaller diameter that doesn't protrude through the outer cortex (Figure 4), but this was not examined here, nor in accordance with surgical instructions or the virtual implantation procedure validated in Section 3.1. Size selection is made on a subject-specific basis to achieve the best surgical preparation and fit, but using the average diameter of the medullary canal to dictate endoprosthesis size fails with short residual limbs. An alternative endoprosthesis geometry, like the elliptical cross-section geometry (Figure 4) used in a sheep model, should also be investigated for these short residual limbs [19]. When aligned properly, an endoprosthesis with elliptical cross-section would penetrate further into the thicker cortex at the anterior and posterior sides while still achieving some contact with the thin medial and lateral sides without penetrating the outer cortex (Figure 4). However, if this isn't aligned in this manner, the elliptical cross-section may increase the risk of penetration and result in less contact with more bone removed.

Very short residual limbs may not be candidates for percutaneous OI attachment. Amputations proximal to the tibial tuberosity (~9% residual length [15]) would compromise knee function making it unlikely that the tibia would be preserved. Since the tibial tuberosity location is approximately the midpoint of the patellar tendon insertion, it is likely that an amputee with only 20% residual limb would be the most proximal amputation to maintain knee function and still be a candidate for OI attachment. The findings of this study suggest that a custom device design or surgical approach may be necessary for these patients. Additionally, very long residual limbs may need further resection to accommodate attachment of a prosthetic foot. Low clearance prosthetic feet have approximately a 65 mm build height and the PODS device has a minimum build height beyond the distal osteotomy to a prosthetic attachment of 100 mm (including the endoprosthesis, percutaneous post, and prosthetic adapter terminating in a male pyramid). With an average ankle height of 81 mm [20], and average tibia length of 370 mm [15], the longest residual limb possible would be approximately 75%. This would make the 80% residual length evaluated here irrelevant until a shorter stack-up can be designed.

Cortical penetration of the endoprosthesis occurred in different regions for proximal versus distal cases. In the proximal 20 and 30% residual lengths, penetration primarily occurred at the distal osteotomy. Because the cylindrical and conical geometries had the same distal diameter, both geometries penetrated the cortex when one did. In long residual limbs of 70 and 80% residual lengths, penetration primarily occurred at the proximal end of the region of interest because of the inverted funnel shape of the bone and medullary canal. For this reason, incidences of cortical penetration were much higher for the cylindrical geometry. Therefore, a tapered conical design is especially beneficial for long residual limbs to match the converging nature of the bone at this region while maintaining a large distal diameter to maximize contact.

Minimum cortical thickness was impacted more than maximum for every amputation level (Figure 5). The largest change in maximum cortical thickness occurred at the proximal end of the 80% residual length where there was an average 0.7 and 1.2 mm decrease for the cylindrical and conical designs, respectively. In contrast, the average decrease in minimum cortical thickness at the proximal end of the 80% residual length of 2.7 and 2.2 mm for the cylindrical and conical designs, respectively (Figure 5). Considering the intact minimum cortical thickness at this level is only 3.1 ± 0.5 mm, this creates an extremely thin region in the bone. Cortical thickness is associated with structural stability and support of the device, and a very thin cortex has decreased structural stability [18]. Endoprosthetic placement was biased towards areas where the cortex was already thin. As a result, it is important to consider the thinner cortical regions of the tibia when evaluating locations for endoprosthesis placement as these will be primarily affected no matter what design approach is used.

A major limitation of this study is that the virtual implantation procedure was only validated on a conical device due to the availability of these surgical components to study personnel. Though we predict similar final accuracy for the cylindrical shape, this has not been confirmed. Additionally, the intent of this investigation was to evaluate the fit of the shape in the tibia and not a specific design, so length and diameter were controlled to better compare these geometries. There are no clinically used cylindrical endoprostheses that are only 3 cm long. Longer endoprostheses would, in theory, give more bone-endoprosthesis contact. However, this would include more regions of the highly variable tibia morphology forcing either more bone removal or gaps between the bone and endoprosthesis surface making size selection less dependent on the distal medullary diameter. We recognize that this study did not validate the size selection of the cylindrical geometry, but made the decision to match the distal diameter of the cylindrical and conical endoprostheses modeled because we were able to validate this on the conical geometry. This decision most closely matches the relationship that we predict when implanting these devices in bone. The ratio of bone contact to bone removed was used to mitigate the inherent bias that came from this decision.

5. Conclusion

This research has formulated, validated, and utilized a method of virtual implantation of transtibial endoprostheses. The fit of two primary endoprosthesis designs (cylindrical and conical) were analyzed based on simplified models of current devices. The results of this

investigation indicated that a conical endoprosthesis shape for transtibial percutaneous OI attachment of exoprosthetic limbs is more efficient and applies to a wider range of residual limb lengths compared to the cylindrical design. However, this implantation approach fails with both geometries for very short amputations of approximately 20% residual limb length. This research has provided a framework for virtually implanting percutaneous OI endoprostheses to assess their fit in the tibia.

Acknowledgements

This work was supported in part with resources at the Salt Lake City Veterans Affairs Medical Center, with research funding from the US Department of Veterans Affairs Rehabilitation Research and Development Service under Merit Review Award #I01RX001246, with funding from the US Army Medical Research and Materiel Command under contract #W81XWH-15-C-0058, and with resources at the University of Utah Department of Orthopaedics. The content of this research does not necessarily reflect the position or the policy of the funding sources, and no official endorsement should be inferred.

Abbreviations:

OI	osseointegration
OPRA	osseointegrated prostheses for the rehabilitation of amputees
ILP	integral leg prosthesis
OPL	osseointegrated prosthetic limb
ITAP	Intraosseous Transcutaneous Amputation Prosthesis
POP	percutaneous osseointegrated prosthesis
PODS	percutaneous osseointegrated docking system
CT	computed tomography

References

1. Zaid MB, O'Donnell RJ, Potter BK, Forsberg JA. Orthopaedic Osseointegration: State of the Art. *J Am Acad Orthop Surg.* 2019;27(22):e977–e85. Epub 2019/06/11. doi: 10.5435/JAAOS-D-19-00016. [PubMed: 31181031]
2. Hoyt BW, Walsh SA, Forsberg JA. Osseointegrated prostheses for the rehabilitation of amputees (OPRA): results and clinical perspective. *Expert Rev Med Devices.* 2020;17(1):17–25. Epub 2020/01/15. doi: 10.1080/17434440.2020.1704623. [PubMed: 31931635]
3. McGough RL, Goodman MA, Randall RL, Forsberg JA, Potter BK, Lindsey B. The Compress(R) transcutaneous implant for rehabilitation following limb amputation. *Unfallchirurg.* 2017;120(4):300–5. Epub 2017/03/10. doi: 10.1007/s00113-017-0339-9. [PubMed: 28275847]
4. Hoellwarth JS, Tetsworth K, Kendrew J, Kang NV, van Waes O, Al-Maawi Q, et al. Periprosthetic osseointegration fractures are infrequent and management is familiar. *Bone Joint J.* 2020;102-B(2):162–9. Epub 2020/02/06. doi: 10.1302/0301-620X.102B2.BJJ-2019-0697.R2. [PubMed: 32009427]
5. Thesleff A, Branemark R, Hakansson B, Ortiz-Catalan M. Biomechanical Characterisation of Bone-anchored Implant Systems for Amputation Limb Prostheses: A Systematic Review. *Ann Biomed Eng.* 2018;46(3):377–91. Epub 2018/01/13. doi: 10.1007/s10439-017-1976-4. [PubMed: 29327257]
6. Haque R, Al-Jawazneh S, Hoellwarth J, Akhtar MA, Doshi K, Tan YC, et al. Osseointegrated reconstruction and rehabilitation of transtibial amputees: the Osseointegration Group of Australia

- surgical technique and protocol for a prospective cohort study. *BMJ Open*. 2020;10(10):e038346. doi: 10.1136/bmjopen-2020-038346.
7. Bloebaum RD, Bachus KN, Momberger NG, Hofmann AA. Mineral apposition rates of human cancellous bone at the interface of porous coated implants. *J Biomed Mater Res*. 1994;28(5):537–44. Epub 1994/05/01. doi: 10.1002/jbm.820280503. [PubMed: 8027094]
  8. Webster JB, Bachus KN, Beck JP, Jeyapalina S, Drew AJ, Bloebaum RD. Osseointegration Research. In: PC Tepe V., editor. *Full Stride*. New York, NY: Springer; 2017. p. 167–93.
  9. Subburaj K, Ravi B, Agarwal M. Automated identification of anatomical landmarks on 3D bone models reconstructed from CT scan images. *Comput Med Imaging Graph*. 2009;33(5):359–68. Epub 2009/04/07. doi: 10.1016/j.compmedimag.2009.03.001. [PubMed: 19345065]
  10. Awadalla M, Al-Dirini RMA, O'Rourke D, Solomon LB, Heldreth M, Taylor M. Influence of varying stem and metaphyseal sleeve size on the primary stability of cementless revision tibial trays used to reconstruct AORI IIA defects. A simulation study. *J Orthop Res*. 2018;36(7):1876–86. Epub 2018/01/13. doi: 10.1002/jor.23851. [PubMed: 29327379]
  11. Wong KC, Kumta SM, Leung KS, Ng KW, Ng EW, Lee KS. Integration of CAD/CAM planning into computer assisted orthopaedic surgery. *Comput Aided Surg*. 2010;15(4–6):65–74. Epub 2010/09/21. doi: 10.3109/10929088.2010.514131. [PubMed: 20849368]
  12. Zampelis V, Flivik G. Custom-made 3D-printed cup-cage implants for complex acetabular revisions: evaluation of pre-planned versus achieved positioning and 1-year migration data in 10 patients. *Acta Orthopaedica*. 2020:1–6. doi: 10.1080/17453674.2020.1819729.
  13. Zeng C, Xing W, Wu Z, Huang H, Huang W. A combination of three-dimensional printing and computer-assisted virtual surgical procedure for preoperative planning of acetabular fracture reduction. *Injury*. 2016;47(10):2223–7. Epub 2016/07/04. doi: 10.1016/j.injury.2016.03.015. [PubMed: 27372187]
  14. Jeyapalina S, Beck JP, Bachus KN, Chalayan O, Bloebaum RD. Radiographic evaluation of bone adaptation adjacent to percutaneous osseointegrated prostheses in a sheep model. *Clin Orthop Relat Res*. 2014;472(10):2966–77. Epub 2014/02/22. doi: 10.1007/s11999-014-3523-z. [PubMed: 24557934]
  15. Taylor CE, Henninger HB, Bachus KN. Cortical and medullary morphology of the tibia. *Anat Rec (Hoboken)*. 2020. Epub 2020/06/26. doi: 10.1002/ar.24479.
  16. Drew AJ, Tashjian RZ, Henninger HB, Bachus KN. Sex and Laterality Differences in Medullary Humerus Morphology. *Anat Rec (Hoboken)*. 2019;302(10):1709–17. Epub 2019/04/17. doi: 10.1002/ar.24138. [PubMed: 30989818]
  17. Khan MA, Javed AA, Rao DJ, Corner JA, Rosenfield P. Pediatric Traumatic Limb Amputation: The Principles of Management and Optimal Residual Limb Lengths. *World J Plast Surg*. 2016;5(1):7–14. [PubMed: 27308235]
  18. Drew AJ, Taylor CE, Tashjian RZ, Chalmers PN, Henninger HB, Bachus KN. Initial stability of a percutaneous osseointegrated endoprosthesis with proximal interlocking screws for transhumeral amputees. *Clin Biomech (Bristol, Avon)*. 2020;72:108–14. Epub 2019/12/22. doi: 10.1016/j.clinbiomech.2019.12.005.
  19. Jeyapalina S, Beck JP, Bachus KN, Bloebaum RD. Cortical bone response to the presence of load-bearing percutaneous osseointegrated prostheses. *Anat Rec (Hoboken)*. 2012;295(9):1437–45. Epub 2012/07/19. doi: 10.1002/ar.22533. [PubMed: 22807281]
  20. Tomassoni D, Traini E, Amenta F. Gender and age related differences in foot morphology. *Maturitas*. 2014;79(4):421–7. doi: 10.1016/j.maturitas.2014.07.019. [PubMed: 25183323]

Figure 1: Residual lengths.

Residual lengths at 10% intervals of the bone length used for virtual implantation. Both cylindrical and conical endoprosthesis designs were modeled for each residual length. Bone length was defined by the average tibial plateau height to average tibial plafond height [15].

Figure 2: Endoprosthesis geometry.

Geometric profile of cylindrical (left) and conical (right) endoprosthesis geometries. Both were 3 cm tall with matching distal diameter. The conical endoprosthesis had a 2 degree taper angle to the proximal end which had a diameter corresponding to the average diameter of the medullary canal. This proximal diameter ranged from 9 – 30 mm.

Figure 3: Validation part comparison.

Part comparison of virtually and surgically prepared bones. Heat map (right) indicates distance (mm) between nodes of the two shapes representing excess bone in the surgical preparation (+) and excess bone in the virtual preparation (-). Only the region of interest (distal 3 cm) was analyzed as this is the region where bone implant contact is used to facilitate osseointegration in this endoprosthesis design.

Figure 4: 20% Residual Length Cross Section.

Cross-sectional view of the cortex at 20% residual length. The *blue* circle shows the average diameter of the medullary canal. The center point is the centroid of the endosteal surface. Due to the irregular shape of the medullary canal at this length, the endoprosthesis would extend through the cortex at some locations. The *black* circle shows a possible approach that undersized the endoprosthesis to preserve cortical thickness at the expense of bone contact. In *white*, another alternative approach would be to design an endoprosthesis with elliptical cross-section that may be better suited for these short residual limbs.

Figure 5: Changes in Cortical Thickness.

Maximum (top) and minimum (bottom) cortical thickness measure for intact bone (grey), cylinder implantation (red) and conical implantation (blue). Each graph represents an independent residual limb length for virtual implantation. Distal osteotomy occurs at 10% intervals starting at 30% (right of each graph).

* Indicates significant difference between cylinder and cone performance over the entire region of interest.

Table 1:

Endoprosthesis fit summary

Mean±SD		Cylindrical			Conical		
Residual Length (%)	Endoprosthesis Maximum Diameter	Contact (%)	Bone Removed (%)	% Contact / % Removed	Contact (%)	Bone Removed (%)	% Contact / % Removed
COMBINED (N = 40)							
20	26±3	37.6±5.9	7.4±1.0	5.1±0.7	30.6±4.2	5.4±.7	5.7±0.6
30	19±2	52.5±8.2	9.6±3.0	5.9±1.6	42.5±6.8	6.8±2.2	6.7±1.8
40	15±2	66.8±9.0	8.6±2.7	8.4±2.2	49.4±6.7	5.3±1.9	10.3±2.8
50	12±1	80.4±7.8	10.0±3.1	8.8±2.9	63.9±9.9	6.0±2.2	11.9±4.1
60	11±1	87.0±6.6	12.2±3.7	7.7±1.9	73.9±7.3	7.6±2.7	10.5±2.8
70	12±2	95.4±4.3	19.7±5.6	5.2±1.4	86.7±6.8	13.1±4.1	7.2±2.1
80	16±2	98.6±3.5	35.2±8.4	3.0±0.9	96.7±3.5	28.4±8.2	3.7±1.3
MALE (N = 20)							
20	27±2	36.8±7.5	7.2±1.1	5.2±0.8	30.5±5.0	5.3±0.8	5.8±0.7
30	20±2	53.2±8.3	9.5±2.9	6.0±1.8	42.7±7.0	6.6±2.0	6.9±2.0
40	15±2	66.3±9.3	8.3±2.9	8.7±2.6	49.5±7.5	5.1±2.0	10.7±3.1
50	12±2	79.3±9.3	9.5±3.5	9.5±3.6	63.6±12.3	5.8±2.4	12.7±5.3
60	11±1	86.6±5.5	10.8±3.3 *	8.5±1.9 *	73.0±6.7	6.7±2.3 *	11.7±2.8 *
70	12±2	94.2±4.4	16.9±4.8 *	6.0±1.4 *	84.7±7.0	11.0±3.5 *	8.3±2.2 *
80	16±2	99.3±1.5	32.2±8.5 *	3.3±1.0 *	97.1±3.1	26.1±8.3	4.2±1.6 *
FEMALE (N = 20)							
20	25±3	38.9±3.0	7.4±0.6	5.0±0.5	30.8±2.6	5.7±0.5	5.5±0.6
30	18±3	51.7±8.2	9.7±3.3	5.7±1.5	42.2±6.7	6.9±2.3	6.5±1.6
40	14±2	67.8±8.9	9.0±2.5	7.9±1.7	49.7±5.9	5.5±1.9	9.7±2.3
50	12±1	81.5±6.0	10.5±2.8	8.2±1.7	64.3±7.0	6.2±2.0	11.1±2.4
60	11±1	87.6±7.4	13.4±3.6 *	6.9±1.5 *	74.6±7.8	8.4±2.8 *	9.6±2.3 *
70	12±2	96.5±4.0	22.6±5.0 *	4.5±0.9 *	88.6±6.2	15.1±3.7 *	6.1±1.2 *
80	16±2	97.6±5.3	39.8±6.2 *	2.5±0.5 *	86.2±3.9	30.9±7.5	3.3±0.7 *

Data excludes any conditions with endoprosthesis penetration through the cortex.

All comparisons between cylindrical and conical geometries revealed statistical differences for the whole population (p 0.008).

* Statistical differences between male and female populations (p 0.04).

Table 2:

Summary of cases with cortical penetration of the endoprosthesis

Mean (Range)	Cylindrical		Conical	
Residual Length (%)	Number of Cases (N, N=40 total)	Endoprosthesis Cortical Penetration (%)	Number of Cases (N, N=40 total)	Endoprosthesis Cortical Penetration (%)
20	30	9.0 (0.2 – 23.0)	29	6.3 (0.3 – 20.6)
30	8	8.1 (0.6 – 17.1)	8	5.0 (0.4 – 13.5)
70	1	1.0	0	NA
80	20	6.8 (0.0 – 15.7)	8	3.7 (1.3 – 10.1)

Data includes conditions only where cortical penetration occurred. The percent of endoprosthesis surface penetrated is the total portion of the endoprosthesis surface that has penetrated through the outer cortex.

All comparisons revealed significant differences (p 0.02).