Finite-element analysis of the influence of tibial implant fixation design of total ankle replacement on bone–implant interfacial biomechanical performance

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Abstract

Purpose: Implant loosening in tibia after primary total ankle replacement (TAR) is one of the common postoperative problems in TAR. Innovations in implant structure design may ideally reduce micromotion at the bone–implant interface and enhance the bone-implant fixation and initial stability, thus eventually prevents long-term implant loosening. This study aimed to investigate (1) biomechanical characteristics at the bone–implant interface and (2) the influence of design features, such as radius, height, and length. Methods: A total of 101 finite-element models were created based on four commercially available implants. The models predicted micromotion at the bone–implant interface, and we investigated the impact of structural parameters, such as radius, length, and height. Results: Our results suggested that stem-type implants generally required the highest volume of bone resection before implantation, while peg-type implants required the lowest. Compared with central fixation features (stem and keel), peripherally distributed geometries (bar and peg) were associated with lower initial micromotions. The initial stability of all types of implant design can be optimized by decreasing fixation size, such as reducing the radius of the bars and pegs and lowering the height. Conclusion: Peg-type tibial implant design may be a promising fixation method, which is required with a minimum bone resection volume and yielded minimum micromotion under an extreme axial loading scenario. Present models can serve as a useful platform to build upon to help physicians or engineers when making incremental improvements related to implant design.

Keywords
computational modeling, finite-element method, implant design, total ankle arthroplasty, total ankle replacement

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Introduction

Total ankle replacement (TAR) is a promising procedure for patients with end-stage ankle arthritis and regains popularity among foot and ankle surgeons in these decades. The fundamental rationale of TAR is to replace the damaged portion of tibial and talar bone with artificial implants, thus to relieve pain and restore ankle function. Implant loosening in tibia after primary TAR is one of the common postoperative problems in TAR, the incidence of which is in the

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range of 10.4–34%. Previous systematic review shows that implant loosening in the tibia is associated with implant structure, which may be reduced by refining design features to existing implants. Better implant structure design may reduce micromotion at the bone–implant interface and enhance the bone-implant fixation and initial stability, thus eventually prevents long-term implant loosening. For tibial components of total ankle implants, a variety of fixation configurations have been designed, and new implant designs are emerging. However, no total ankle implant showed a comparable long-term result of total knee or hip implants, and biomechanical studies of different TAR implant designs are lacking. The finite-element (FE) method is a valuable tool to investigate the mechanical characteristics at the bone–implant interface in joint implant research. FE models of the tibial bone–implant constructs (the assembly of resected tibial bone and the tibial component of TAR implant) were developed and validated in early studies but have not been applied in parametric design exploration of the fixation configuration above the tibial tray of TAR implant. Such studies are necessary to evaluate different tibial implant features and seek out the right structure design with the best performance.

In this study, we developed bone-implant FE models to investigate the effect of the fixation method on biomechanics at the bone–implant interface. The tibial components of existing TAR implants have primarily chosen four types of fixation configurations: stem, keel, bar, and peg type design. Then, we reconstructed these reference geometries from four commercially available ankle prostheses: Mobility (DePuy Synthes, Raynham, MA, US), Salto Taralis (Integra Lifesciences, Plainsboro, NJ, US), STAR (Stryker, Kalamazoo, MI, US), and Infinity (Wright, Memphis, TN, US) implants. Parametric analysis was conducted to evaluate the performance of different design factors, such as diameter, width, height, and length, and to find optimized implant design. A detailed understanding of these parameters will eventually enhance the performance of total ankle implants.

**Methods**

**Geometry reconstruction and model development**

The protocol of the study was approved by the ethics committee of our institution. The tibial fixation configurations above the tibia tray of four existing total ankle systems (geometry 1: Mobility, geometry 2: Salto Taralis, geometry 3: STAR, and geometry 4: Infinity) were reverse engineered, from which four reference geometries of the tibial fixation configuration were recreated in Rhino (McNeel, Seattle, Washington, USA) and were depicted in Figure 1. Parametric variations of the reference geometries of the tibial fixation configuration were generated, aligned, and assembled with a tibial tray extruded from the resection surface of the tibia with the same cross-sectional shape as the contact surface. (We use 3 mm as the thickness of all tibial trays, which was same as that of STAR implant system.) The parametric design table for the dimensions, such as length, width, and diameter of the fixation features, was listed in Table 1. Porous coating or cement was not modeled for simplification.
Table 1. Fixation type and simplification method, dimensions of fixation features, and TNG.

| Fixation type (FT) | Source implant (SI) | Simplified geometry (SG) | Dimensions of fixation features | Range (mm) | TNG |
|--------------------|---------------------|--------------------------|--------------------------------|------------|-----|
| 1 FT: Stem         | SI: Mobility        | SG: Sphere and truncated cylinder | Height ($H_S$) | $H_S = 4, 8, 12, 16, 20, 24, 28, 32$ | 20 |
|                    |                     |                          | The radius of the bottom surface ($R_b$) with a fixed radius of the top surface of the cylinder ($r_c$) | $R_b = 4, 6, 8, 10, 12, 14$ |     |
| 2 FT: Keel         | SI: Salto Taralis   | SG: Cylinder and cuboid  | Anterior–posterior length of the cuboid ($L_K$) | $L_K = 9, 12, 15, 18, 21, 24$ | 25 |
|                    |                     |                          | Height of the cuboid ($H_K$) | $H_K = 8, 12, 16, 20, 24, 28$ |     |
| 3 FT: Bar          | SI: STAR            | SG: Cylinders and cuboids | Radius of the cylinders ($R_b$) | $R_b = 2, 2.5, 3, 3.5, 4, 4.5, 5$ | 24 |
|                    |                     |                          | Anterior–posterior length of the cuboids ($L_b$) | $L_b = 8, 12, 16, 20, 24, 28$ |     |
| 4 FT: Pegs         | SI: Infinity        | SG: Truncated cylinders and cones | Radius of the cylinder ($R_c$) | $R_c = 3, 3.5, 4, 4.5, 5, 5.5, 6$ | 32 |
|                    |                     |                          | Minimum distance between two cuboids ($D_b$) | $D_b = 8, 10, 12, 14, 16, 18$ |     |
|                    |                     |                          | Height of the cuboids ($H_b$) | $H_b = 4, 5, 6, 7, 8, 9$ |     |

TNG: total number of geometries.
*The parameters of four reference geometries were in bold font.

Unlike hip or knee osteoarthritis, ankle osteoarthritis is mainly secondary to trauma. Thus, a younger population predominates in ankle osteoarthritis. To model the ankle anatomy of the young population, we collected images of the right ankle of a 24-year-old male volunteer under neutral position by computed tomography scanning (Sensation 64, Siemens Healthcare, Germany; slice thickness = 0.6 mm, pixel size = 512 x 512) and then, the tibial bone was segmented from this dataset using a medical image processing software (Mimics, Materialise NV, Leuven, Belgium). The recommended tibial bone resection level ranges from 5 mm to 11 mm among different implant systems. Thus, to keep consistency, the tibial bone was resected at 10-mm level superior to tibial plafond with the protection of medial malleolus under the guidance of senior foot and ankle surgeons (XM and CZ).

Model development

After obtaining the 3-D solid models of all bones, a further procedure, including meshing and material property assignment, was performed using 3-Matic (Materialise NV). The quadratic tetrahedral element with a maximum element length of 1.5 mm was used for a meshing purpose. Mesh size was defined by a mesh convergence study (see Supplemental Appendix 1). Element-based material assignments based on the empirical relationship from the literature for the implant geometries and bone were listed in Table 2.

Table 2. Material property assignment.

| Component                  | Young's modulus ($E$), MPa | Poisson's ratio |
|---------------------------|----------------------------|----------------|
| Tibia component           | 210,000                    | 0.3            |
| Bone (density ($\rho$)    | 19,000 ($\rho > 1.3$ g/cm³) | 0.3            |
| (dependent)               | 4773 ($\rho > 1.3$ g/cm³)  | 0.3            |
| $\rho = 0.022 + 0.00008456 *$ HU |                      |                |

FE models were analyzed in ANSYS workbench FE software (ANSYS, Inc., Pennsylvania, USA). Frictional interaction with a frictional coefficient of 0.5 was used at the bone and implant interface to characterize the initial unbounded condition. A fixed boundary condition was applied at the proximal surface of the tibial bone. A worst-case scenario force of five times body weight (3414 N) was applied uniformly at the distal surface of the tibial component. This loading condition was a maximum ankle joint force during walking, which was commonly used for ankle implant testing in documents of "Summary of safety and effectiveness" submitting to the US Food and Drug Administration. We chose the bone–implant interface micromotion as an indicator of initial stability. Previous studies showed small interface micromotion (40–100 µm) might induce osteolysis and aseptic loosening of the implant, while motions above 150 µm would promote the formation of fibrous tissue and jeopardize osseointegration at the bone–implant interface. The micromotion values at the bone–implant interface were calculated by the sliding
contact algorithm in ANSYS (ANSYS, Inc.).\textsuperscript{31,32} The structural contact variables “SlidingDistance” in ANSYS calculated the amplitude of total accumulated slip increments when the contact status was sliding\textsuperscript{33} that was the relative displacement of the contact elements as they were debonded from the target elements at the bone–implant interface. Besides, periprosthetic von Mises stress, principal strain, contact surface, and bone resection volume were analyzed. The modeling process was shown in Figure 2.

**Results**

A total of 101 models were generated. Peak micromotion, average and standard deviation of the bone resection volume, and the contact surface of each model were shown in Figure 3. Also, Figure 4 showed the contact pressure and micromotion contour plot of the reference geometries.

Generally, of all geometries, stem-type implants required the largest volume of bone resection before implantation, while peg-type implants required the least. Stem-, keel-, and bar-type geometries had a slighter small contact pressure (peak contact pressure for each geometry was 26.793, 24.631, and 24.281 MPa, respectively), and exhibited a high contact area (average contact area for each geometry was 1794.8 mm\(^2\), 1930.9, and 1855.5 mm\(^2\), respectively). Peg-type geometry showed the opposite (peak contact pressure was 29.151 MPa, and the average contact area was 1333 mm\(^2\)), but the difference in peak contact pressure among them was not remarkable. Compared with central fixation features (stem and keel), peripherally distributed geometries (bar and peg) were associated with lower initial micromotions, which were well below 100 μm. For each fixation configuration, contact pressure was concentrated in the out layer of the contact surface, and high
micromotion was located in the fixation structure or at the posterior–lateral corner of the surface under vertical loading.

As shown in Figure 5(a), the peak micromotion increased with the height for stem-type configuration. The peak micromotion reached a maximum of 153.76 μm. With the increase of the radius of the bottom surface of the cylinder ($R_S$) alone, peak micromotion elevated slightly. For $R_S$ with a fixed ratio of $R_S$ and $r_S$, its peak micromotion first increased and then decreased (Figure 5(b) and (c)).

The majority of stemmed implant exhibited a high micromotion larger than 100 μm, except those with a height lower than 12 mm.

The peak micromotion for varying geometry parameters of keel-type geometries was presented in Figure 6. No obvious trend was observed for micromotion when varying the length. Peak micromotion was in the range of 73.8–123.9 μm. However, as the height of the keel increased, peak micromotion first increased and then decreased. For the radius of the keel-type geometries, the peak and
micromotion slightly increased with the radius with or without a fixed ratio of $R$ and $w$, changing around 100 μm.

For bar-type geometry (Figure 7), peak micromotion was below 100 μm and showed the trend to increase with increasing radius ($R_B$), length ($L_B$), height ($H_B$), and distance ($D_B$) between two bars. It was expected, given that as the edge of bars extending into the trabecular bone with lower bone density, bone cannot support the implant well, resulting in an increasing sliding distance.

As shown in Figure 8(a) and (c), an increase in the radius of each peg ($R_P$), and the length of each anterior pegs ($L_P$) with a fixed ratio of $L_P$ and the length of each posterior pegs ($l_P$) was associated with increased peak micromotion. For the anterior–posterior slope of pegs ($A_P$), pegs with 45° of the slope had the lowest peak micromotion, 22.72 μm. Figure 8(d) and (e) illustrated the influence of peg arrangement and position offset at the anterior–posterior direction. Predicted peak micromotion was varying from 28.65 μm to 37.78 μm and no clear difference was observed among different numbers or positions of pegs.

**Discussion**

In this study, extensive FE simulations were employed to explore the design variation of tibial component fixation. The micromotions of 101 different tibial components from four reference geometries at the bone–implant interface were investigated. The reference geometries (i.e. stem, keel, bar, and peg type) are representatives of current commercially available TAR implants. The influence of different implant design features on micromotion at the bone–implant interface was then analyzed under vertical compressive load.

Our results suggested that the geometry of the tibial component had a significant impact on the micromotion at the bone–implant interface. We found the highest micromotion in stem-type implants, next to keel-type implants, followed by that in bar-type implants, the lowest micromotion was observed in peg-type geometries.

Central stem fixation design in TAR (such as Mobility (DePuy), INBONE II (Wright), and Buechel-Pappas Ankle System (Endotec, Inc, Orlando, FL, US)) was influenced a lot by experience in total knee arthroplasty. Stemmed tibial implant can help align the prosthesis and aid implant stability in the presence of bone deficit. Our results suggested that to preserve initial stability, the height of the stem should be lower than 12 mm, and higher stem exhibited large micromotion (Figure 5(a)). It was agreed with a clinical study showing that BP implant with a longer stem was associated with a higher implant loosening rate and revision rate compared to Mobility implant. However, a deep
Figure 7. (a) Peak micromotion in micrometer as a function of the radius of each bar ($R_B$), (b) peak micromotion as a function of the length of each bar ($L_B$), (c) peak micromotion as a function of the distance between two bars ($D_B$), and (d) peak micromotion as a function of the height of each bar ($H_B$).

Figure 8. (a) Peak micromotion in micrometer as a function of the radius of each peg ($R_P$), (b) peak micromotion as a function of the angle between pegs and the plate ($A_P$), (c) peak micromotion as a function of the length of each anterior pegs ($L_P$) with a fixed ratio of $L_P$ and the length of each posterior pegs ($l_P$), (d) peg arrangement, and (e) offset from reference peg position along the anterior–posterior direction.
intramedullary stem with a height higher than 32 mm (such as INBONE II implant with extra cylindrical segments) was not investigated in this study due to the limit of the current model geometry, which may make a difference to the result and should be investigated in future studies.

Both central keel type (such as Salto Talaris (Integra Lifesciences), Ankle Evolutive System (Zimmer Biomet, Warsaw, IN, US), and Agility (DePuy)) and parallel cylindrical bar type (such as STAR (Stryker), Box (MatOrtho Ltd, Leatherhead, Surrey, UK), trabecular metal total ankle (Zimmer Biomet)) fixation shared a similar biomechanical result and they had a lower micromotion compared with stem implants. Reduced peak micromotion was found in geometries with a short length, lower height, and smaller radius. It was noteworthy that extra-wide stem (Figure 5(c)), extra-long keel (Figure 6(a)), extra high keel (Figure 6(b)), and bar (Figure 7(d)) resulted in a decrease of peak micromotion, indicating that initial stability was achieved by large, deep, and wide fixation geometry anchored into cortical bone or high-bone-density trabecular bone proximal to the implant. However, such a fixation method required large bone volume resection.

Also, from an operative perspective, the surgical preparation for the implantation of stem, keel, and bar-type implants required creating an anterior cortical tibial window for insertion,15–17 which may jeopardize the integrity of tibial cortical bone, thus may weaken the support to the tibial implant.37 Alternative option38 is to place multiple cylindrical segments individually reaming through the talus from the plantar surface of the foot, which may endanger the blood supply of talus, causing talus necrosis.39 Thus, a small-sized, lower but thin stem, keel, or bar geometry was recommended to reduce initial interfacial micromotion.

Compared to the above three types of tibial implants, our data of peg design (such as Infinity (Wright), Cadence (Integra LifeSciences)) showed promising results. It required the least bone resection volume and yielded the lowest micromotion, thus promoted initial implant stability and reduced the risk of loosening. For peg-type design, shorter length, 45° of anterior–posterior slope, and shorter radius can reduce the micromotion. Also, results showed no impact of peg number and arrangement on the micromotion (as shown in Figure 8(d) and (e)). However, from the operative perspective, anteriorly positioned pegs were easier for implantation than that of posteriorly positioned.

Two design features of the tibial component were recommended by foot and ankle experts:34 decreased distal tibial bone resection and minimized disruption of the anterior tibial cortex. Higher distal tibial bone resection may waste large bone with high bone density resulting in poor initial stability and bring difficulty to future revision surgery.40 Our data also provided similar recommendations: for all types of fixation features, low and small size of tibial implants were recommended to use in surgeries to achieve better initial bone-implant fixation. Peg-type tibial implant also required no disruption of the anterior tibial cortex and seemed to be the most suitable implant design.

The current study has several limitations. Firstly, current models were not validated by experiments. However, bone-implant models have been widely used for implant design, and we verified our models by mesh convergence test. Comparative results of different design features can provide valuable information but should not be directly applied to clinical practice. And only one type of critical loading scenario was considered in this study. It is noticed that other types of loading conditions exist besides axial compressive load during gait,26 and multidirectional loading is likely to have bigger impacts in the ankle.41 However, a vertical load is a dominant joint force that the ankle would experience during normal walking, and a magnitude of five times body weight is nearly the maximum value it can reach. Therefore, to evaluate an ankle implant under extreme conditions, a vertical overload should be the first condition to be tested. Nevertheless, future studies need to account for real-life loading conditions over an extended period.

For simplification and consistency, only geometry above the tibial tray was evaluated in the present study. Current tibial trays were generated by extrusion from the resection surface of the tibial bone. Therefore, full coverage of tibial bone was achieved, and no underhang of the tibial component should be considered. Future research should be conducted to study the influence of different tibial tray design, position, and alignment.

Bone varied at different resection levels of distal tibia,42,43 but only one resection level was analyzed in this study. Besides, the bone material property of only one volunteer was used. Therefore, the impact of different recommended resection levels and between-subject variations of mechanical property should be considered in future studies. Lastly, only the interfacial micromotion was compared and discussed in this study. Although the related strain or stress parameters or bone remodeling phenomenon were all valuable for immediate postoperation and long-term clinical outcomes, they were beyond the scope of this work and should be considered in future studies.

The findings of this study may help guide the choice of ankle prostheses and inform future implant design, thus aiding surgeons in achieving better postimplantation outcomes through an enhanced understanding of what role geometric features of the implants play in preventing loosening. Developing these models is the initial step in building a platform to examine the impact of implant design (structure and material) by changing its geometric or material parameters under varying operating conditions instead of designing and performing complex experimental studies for implant design. It could be expanded to account for more design features or long-term effects during the osseointegration by adding more anatomic structures. Future attempts should be directed at developing methods
to enhance the accuracy and applicability for which the current model can serve as a template.

Conclusions
We have developed bone-implant FE models with a density-dependent material property to examine the impact of design parameters of the tibial component of TAR implant on bone-implant micromotion. Our results suggested that the initial stability of all types of implant design can be optimized by decreasing fixation size, such as reducing the radius of the bars and pegs and lowering the height. Peg-type tibial implant design may be a promising fixation method with a minimum micromotion, bone resection level, and no disruption on the anterior cortical bone under an extreme axial loading scenario. Such models can serve as a platform to build upon to help physicians or engineers when making incremental improvements related to implant design. Future integrated computational and experimental studies could guide the identification of key implant design specifications to maximize clinical performance.

Author contribution
The first three authors (JY, CZ, and W-MC) contributed equally to this work.

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