Design and Validation of an Implanted Ankle-Foot Prosthesis for Severe Ankle and Hindfoot Pathology

Brandon Peterson, Alexander Upfill-Brown[1], Jonathan B Hopkins[2], Nelson Fong SooHoo[3], Tyler R Clites
[1]David Geffen School of Medicine At UCLA, [2]University of California, Los Angeles, [3]UCLA

INTRODUCTION:

The pain and disability caused by severe ankle-hindfoot pathology are so extreme, and current treatment options so limited, that patients and clinicians often *choose* to amputate the dysfunctional but otherwise viable limb. After numerous surgeries to stabilize and heal the distal tibia, talus, and calcaneus bones, patients in these severe cases are forced to decide between extensive ankle-hindfoot fusion and amputation. While tibio-talo-calcaneal arthrodesis allows patients to retain their limb, these extensive fusions are associated with poor functional outcomes. Amputation actually provides better function than arthrodesis, even when using a conventional spring-like prosthesis, but comes at the cost of losing a limb. Unfortunately, total ankle replacement is not typically an option for these patients, because current implants rely on a healthy talus for robust integration and intact ligaments for stability, both of which are typically compromised in these severe cases. In light of these limited options, there is an urgent unmet need for a treatment option that restores function and preserves the biological limb. To meet this need, we propose an implanted ankle-foot prosthesis that attaches to the tibia, midfoot, and calcaneus, and provides ankle rotation through the deformation of frictionless, compliant (i.e., flexible) blade flexures. The implant is inherently stable, has no articulating surfaces, and lies fully beneath the skin. Herein, we provide finite element analysis (FEA) illustrating performance of the device, which is made of Titanium 6Al-4V (Ti64), under expected walking loads. We also discuss mechanical characterization of a physical prototype on a robotic testbench. Preliminary results suggest this technology has the potential to restore joint function without sacrificing the limb.

METHODS:

We first used a custom analytical algorithm to generate an implant geometry that both supports ankle joint loads and fits within the anatomical envelope of the ankle. Expected loads and range of motion (ROM) during level walking and activities of daily living (ADLs) were extracted from published biomechanics studies (Figure 1). We evaluated and refined the preliminary design in FEA (Abaqus, Dassault Systems, 2019) by simulating peak stresses and rotational stiffness during the target joint loads. This FEA model was also used to evaluate stability in reaction to out-of-plane inversion/eversion and internal/external rotational loads. Our design objective was to keep peak stresses in the implant below 490 MPa, which corresponds to a fatigue lifetime of 4.6×10^7 cycles or approximately 50 years of 2,500 daily cycles. A physical prototype was 3D printed and evaluated for acute performance on an industrial robot arm (KUKA KR-210, Augsburg, Germany).

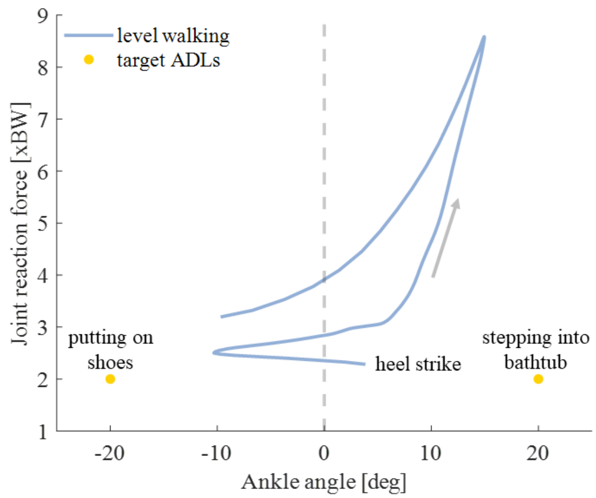
RESULTS:

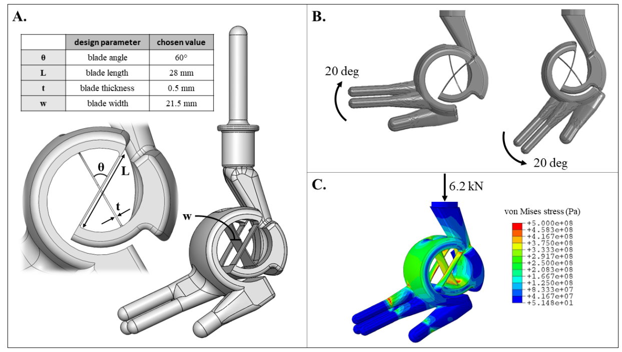
Our analytical algorithm produced a viable design for an ankle replacement with a 50-year fatigue life. The implant has a total width of 4 cm and diameter of 5 cm which, based on published CT measurements of the tibial plafond, fits comfortably within the ankle envelope. The algorithmically-optimized blade-flexure parameters are labeled in Figure 2A in the context of our chosen geometry. According to FEA, this implant design supports an unloaded ROM of +/- 20 degrees (peak stress 360 MPa) and a pure compressive load of 6200 N (peak stress 380 MPa), which corresponds to approximately 9x bodyweight. Under combined loads representative of level walking and ADLs, peak stresses remained within fatigue limits. Peak stresses also remained below fatigue limits under ISO standard off-axis loads. FEA results illustrating isolated range of motion and compressive loading are shown in Figures 2B-C. Benchtop validation of stiffness and acute failure showed a high level of agreement with FEA predictions.

Figure 1: Target joint mechanics for the ankle implant combine results adopted from previous studies including expected loads during the stance phase of level walking (Kim et al., Journal of Biomechanics, 2018) and ADLs associated with larger ROM (Hyodo et al., Brazilian Journal of Physical Therapy, 2017).

Figure 2: Proposed ankle implant geometry with blade flexure parameters (A), FEA deformation results showing ankle ROM (B), and FEA stress results under maximum compressive load (C).

DISCUSSION AND CONCLUSION: A preliminary design for an implanted, compliant ankle prosthesis capable of supporting walking loads for 50 years was validated through FEA and acute benchtop testing. Future work in cyclic-wear testing is necessary to appropriately assess implant fatigue lifetime. These results highlight the potential of this device to restore joint function while preventing unnecessary amputation in cases of severe ankle-hindfoot pathology.


level walking
target ADLs
Joint reaction force [xBW]
Ankle angle [deg]
putting on shoes
heel strike
stepping into bathtub
9
8
7
6
5
4
3
2
1
-20
-10
0
10
20


A.
design parameter
chosen value
θ
blade angle
60°
L
blade length
28 mm
t
blade thickness
0.5 mm
w
blade width
21.5 mm
θ
L
t
w
B.
20 deg
20 deg
C.
6.2 kN
von Mises stress (Pa)
+5.000e+08
+4.583e+08
+4.167e+08
+3.750e+08
+3.333e+08
+2.917e+08
+2.500e+08
+2.083e+08
+1.667e+08
+1.250e+08
+8.333e+07
+4.167e+07
+5.148e+01