Novel ‘Compliant’ Implanted Ankle-Foot Prosthesis in a Caprine Model

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INTRODUCTION: Severe ankle-hindfoot pathology is a devastating problem, causing severe limitations to patient mobility and quality of life. Surgical options are limited for these patients, especially in the setting of bone loss. One option includes tibio-talo-calcaneal fusion; however non-union may occur in up to 30% of cases necessitating multiple procedures, and possible amputation [1,2]. For some, the pain is so severe or the limitations of fusion are significant enough that they *opt* for amputation [3,4]. Patients are therefore forced to choose between improved functional outcomes or preservation of their limb. To restore function and preserve the limb, we have developed a novel implantable ankle-foot endoprosthesis, consisting of a central compliant (i.e., flexible) mechanism that is inherently stable and frictionless. The central innovation is an inverted cross-axis pivot (x-pivot) (Fig. 1a) that guides rotation of the joint via the deformation of thin metal blades [5]. This eliminates all loaded rubbing and sliding of surfaces, and therefore has the potential to dramatically reduce wear debris, which contributes to aseptic loosening [6,7]. Given the unique geometry and function of the implant, we developed a goat animal model to understand *in vivo* performance of a novel compliant ankle endoprosthesis, with respect to soft tissue response and implant mechanics.

METHODS: The ankle implant was designed based on measurements from pre-operative goat XRs. Goat gait biomechanics data were used to estimate joint reaction forces (JRF) and range of motion (ROM) during ambulation [8]. Finite element analysis (FEA) was used to validate an implant geometry capable of fitting within the goat ankle envelope and accommodating expected loads (Abaqus, Dassault Systems, 2019). The implant was 3D-printed in Titanium 6Al-4V. Covers, which were designed to block subcutaneous tissues from contacting deforming blades, were custom made from sintered porous high-density polyethylene (pHDPE) (Anatomics Pty Ltd). The surgical plan, including proximal and distal fixation methods, was designed over the course of multiple cadaver dissections. The procedure and post-operative care was carried out in accordance with approved UCLA institutional animal care and use committee (IACUC) protocol, ARC-2021-014. Two animals were included in our study, with an implant redesign performed between experiments. Range of motion measurements and XR were obtained at regular intervals. Gross pathology and histopathology were performed to examine local soft tissue response.

RESULTS: The mechanism was designed to support an estimated JRF of 360 N (1x bodyweight) and a total ankle ROM of 50 degrees (Fig 1A,B). Based on osseous ankle dimensions, the outer geometry was constrained 20mm medial to lateral and 35mm anterior to posterior (Fig1C). FEA showed that this design could support gait loads with a safety factor of 1.1x within yield stress. For Goat 1, surgical implantation when smoothly. During scheduled imaging at post-operative day (POD) 8, we noted the implant blades had failed mechanically. The lateral outer blade was plastically deformed, and the medial outer blade had fractured at its midpoint; the central blade appeared slightly twisted, and was locally buckled on one side near its midpoint (Fig 2A,B). The animal subject was euthanized at POD 42. The joint was able to articular through its full 50-degree range, and the skin envelope was intact and showed no irritation, erosion, extrusion, or open wounds. We redesigned the implant and conducted an FEA study of several potential loading scenarios. We compared the predicted stress distributions with the specific failure mechanics we observed. From this analysis, we determined that the failure was most likely caused by a large *valgus* moment applied to the hoof. Our simulations predict that valgus torque would put the medial outer blade in compression and lead it to buckle and fail catastrophically. Also, this force loads the central blade in torsion, causing local buckling on one side. We made multiple designs changes, the most important of which involved the addition of a hard-stop “track” for the tibial stem. The surgical implantation in Goat 2 was uncomplicated. During the scheduled imaging section on POD 15, we observed that the implant was slightly loose in axial rotation; it was determined that this occurred at the Morse taper (Fig 1A). The incision healed well without erosion or irritation. The implant remained intact and retained its full range of motion throughout the experiment (Fig 2C,D). Goat 2 was euthanized on POD 141. Post-mortem dissection of the implant revealed diffuse fibrosis within the implant, however the scar tissue deformed readily within the implant as it moved such that range of motion was not restricted (Fig 2E,F). Histological analysis showed no signs of ulceration or soft tissue breakdown over the implant. Comparing the diameter of the four anterior tendons (t1 through t4) in representative sections, we found no evidence atrophy or wear, with no significant differences in mean tendon diameter compared to the contralateral side (Fig3 G,H, p=0.95,0.97,0.11,0.37).

DISCUSSION: Our preliminary short-term results are highly encouraging showing good soft tissue response to the novel geometry and good soft tissue integration into the pHDPE covers. One of the primary takeaways from this study was the dangerous potential for unexpected out-of-plane loads to damage the implant blades. Although the first implant failed mechanically, a redesign of the implant to address out-of-plane load prevented yielding or failure in the second goat. Wear testing is planned to evaluate performance of the central mechanism as well as interaction with the pHDPE covers. Compliant mechanisms have the potential to revolutionize orthopaedic implants by eliminating wear debris and providing inherent constraint – thereby dramatically increasing implant lifespan and function – and providing durable alternatives to amputation.

SIGNIFICANCE/CLINICAL RELEVANCE: Severe ankle-hindfoot pathology presents a challenging problem without a clear surgical solution. Towards developing a novel compliant ankle-foot endoprosthesis to preserve both limb and function, in a caprine model we demonstrate excellent soft tissue tolerance and highlight the importance of accounting for off-axis loading in implant design.

REFERENCES: [1] Crawford et al. (2014); [2] Asomugha et al. (2016); [3] Doukas et al. (2013); [4] METRC (2021); [5] Hopkins and Culpepper (2010); [6] Ho et al. (2021); [7] Stratton-Powell et al. (2021); [8] Clites et al. (2019)

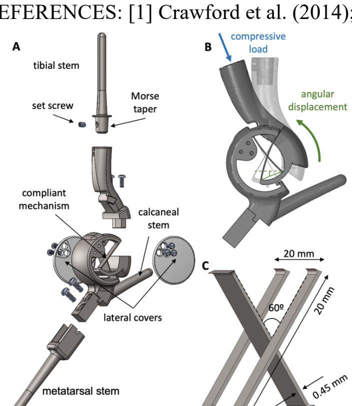

Figure 1. Design of implant

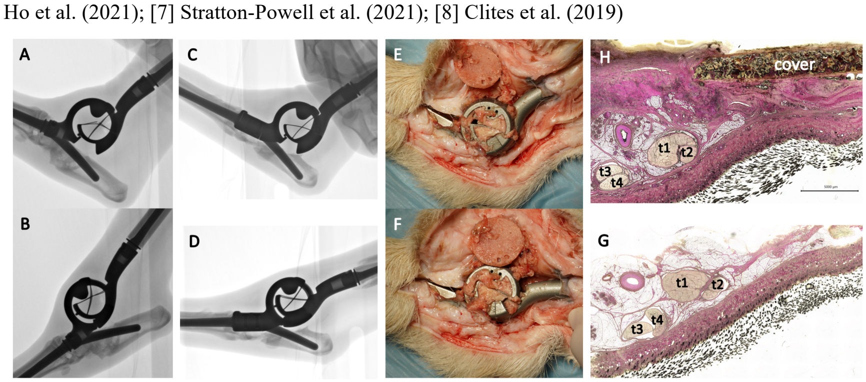

Figure 2. Radiographs, gross pathology and histopathology