Caprine animal model of a novel ‘compliant’ implanted ankle-foot prosthesis

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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. One option includes tibio-talo-calcaneal fusion; however non-union may occur in up to 30% of cases necessitating multiple procedures, and possible amputation. For some, the pain is so severe or the limitations of fusion are significant enough that they *opt* for amputation. Patients are therefore forced to choose between improved functional outcomes or the preservation of their limb. To restore function and preserve limb, we have developed a novel implantable ankle-foot prosthesis, consisting of a central compliant (i.e. flexible) mechanism that is inherently stable and frictionless. The central innovation is an inverted cross-axis pivot (Figure 1A) that allows for range of motion by deformation of thin metal blades. This eliminates all loaded rubbing and sliding of surfaces, and therefore has the potential to dramatically reduce wear debris, which contributes to aseptic loosening. Given the unique geometry and function of the implant, it remains an open question how the surrounding tissues will respond. We developed a goat animal model of the implant to evaluate the local soft tissue response, as well as the impact of scar tissue formation on implant function. Here, we discuss the design and development of the implant, our modeling of implant performance, and *in vivo* results from our animal studies.

METHODS:

Goat implants were designed based on measurements from pre-operative goat XRs (Figure 1B). Goat gait biomechanics data were used to estimate joint reaction forces (JRF) and range of motion (ROM) during ambulation. Finite element analysis (FEA) performed in Abaqus (Dassault Systemes, 2019) was used to optimize implant geometry to accommodate expected loading. 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) by Anatomics Pty Ltd (Melbourne, Australia). Proximal and distal fixation methods and surgical approach were 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. Passive ROM measurements were made at 1, 2, 4 and 6 weeks post-op. Sacrifice occurred at 6 weeks; gross pathology and histopathology were performed to examine local soft tissue reaction, integration of covers and integrity of anterior tendons running over anterior barrel of implant.

RESULTS:

The central mechanism was designed support an estimated joint reaction force of 360 N (1x bodyweight) and an ankle ROM of 25 degrees in both dorsiflexion and plantarflexion. Based on measured goat ankle dimensions, the outer geometry of the implant was constrained 20mm medial to lateral and 35mm anterior to posterior. FEA showed that this design could support gait loads with a safety factor of 1.1x within yield stress. Surgical implantation went smoothly, with no immediate complications other than difficulty cementing the calcaneal stem (Figure 1C). Imaging on POD 7 showed the stems were well fixed without signs of loosening. Immobilization was discontinued on POD 14 as incision was healing well without dehiscence. Measured passive ankle ROM at 1, 2, 4 and 6 weeks was consistently 105-160 degrees (absolute tibio-metatarsal angle). On gross examination at POD 42, the surrounding soft tissues had healed well with no signs of extrusion (Figure 1D). The pHDPE covers appeared well integrated. There was scar tissue present throughout the central mechanism, but this did not appear to limit range of motion. Anterior tendons appeared healthy with no signs of fraying, tendon sheathes remained intact. Histopathology showed fibrous integration of pHDPE covers with minimal inflammatory response.

Figure 1 – Preliminary design of human implanted ankle-foot prosthesis(A) and corresponding components of goat device(B) with XR from first animal showing implanted goat devicein vivo (C) and well healed soft tissue envelope at POD 42 (D).

DISCUSSION AND CONCLUSION:

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. Wear testing is planned to evaluate performance of the central mechanism as well as interaction with the pHDPE covers. Based on these promising early results, we will study the longer-term impact of scar tissue formation in future animal studies. 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 alternatives to unnecessary amputation.