Optimization of a Compliant Tibial Stem for Total Knee Arthroplasty

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Disclosures: Alex-Upfill Brown, Brandon T. Peterson, Jonathan B. Hopkins, Nelson F. Soohoo, and Tyler R. Clites are co-founders of FleX Orthopaedics Inc. and inventors on a UCLA-owned patent (WO2023108094A1).

INTRODUCTION: The volume of total knee arthroplasty (TKA) procedures in 2019 exceeded 480,000 and is expected to increase annually by 4.4% to a projected volume of nearly 3 million by 2060 [1]. Although TKA is generally viewed as a successful surgical operation, with reported patient satisfaction rates of 80% [2] and ten-year survival rates of over 90% [3], revisions are common. In fact, 10-20% of TKA patients require a revision operation within 20 years [4]. Among the numerous causes for revision TKA, the most common modes of non-infectious failure are aseptic loosening, joint instability, and polyethylene wear [5]. Over-constraint of the tibial component has been shown to exacerbate these problems: an implant that does not accommodate internal tibial rotation will have increased contact stress between the resurfaced femoral condyles and the tibial insert, creating more, larger particulate wear. Those contact forces and moments are transferred to the stem/keel of the tibial component, creating higher shear stress at the bone-implant interface. There is an established theoretical foundation that redesigning the tibial component to include rotational compliance about the tibia's long axis should eliminate over-constraint, thereby reducing both bearing wear and interfacial stress and prolonging implant lifespan [6]. One way to implement this rotational compliance is to use a "mobile bearing" to allow the tibial insert to rotate freely with respect to the tibial tray. However, mobile bearings necessarily introduce an additional articulating surface between the backside of the tibial insert and the tibial tray, which serves as a new source of particulate wear. As such, mobile bearings have not shown any significant improvement in survivorship or complication rates compared to conventional, over-constrained bearings [6].

As an alternative to conventional mobile bearings, we present a *compliant* tibial stem that accommodates rotational deformation about the tibia's long axis without introducing additional wear surfaces (Fig 1A). The stem is built around a compliant mechanism, which achieves motion via elastic deformation of flexible elements rather than rubbing or sliding of bearing surfaces; this has the potential to reduce polyethylene wear and increase longevity of TKA.

METHODS: The stem's central mechanism is designed to accommodate relatively large deformations about a single axis while supporting large compressive loads along that same axis. Before beginning our optimization process, we parameterized the mechanism design into 8 key geometric features (Fig 1A). We fixed blade number (16), inner diameter (14 mm), and post diameter (12 mm) based on manufacturing and geometric constraints. The remaining parameters were then swept independently through a finite element analysis (FEA) solver (Abaqus, Dassault Systems, 2023) to characterize the effect of each parameter on maximum stress within, and rotational stiffness of, the compliant mechanism. Loads for the FEA sweep were selected from the average directly-measured internal joint loads from instrumented knee implants during walking [7]. Deformations were selected from published knee joint kinematics [8,9].

Once we understood how each parameter affects stress and stiffness, we ran a brute-force optimization of the 5 swept geometric parameters to produce a compliant mechanism architecture with the lowest possible i) rotational stiffness and ii) maximum stress under worst case loading and deformation during level-ground walking (2000 N in compression, 10° in internal-external rotation, and a 23 Nm transverse moment). Based on published bone sizes from cadaver studies [10], we constrained our optimization to the largest tibial stem that would not require resection of cortical bone in the median proximal tibia; this corresponds to a flexure blade length of 55 mm and a maximum outer diameter of 28 mm. We then iteratively tuned the implant parameters in FEA until a minimum was observed in stiffness and maximum stress. After optimization, full loading trajectories for walking, stair ascent, and stair descent were applied to the optimized design, to ensure that the design would not exceed the fatigue strength of Ti-6Al-4v (484 MPa) at any point during the loading cycle. To validate model predictions, we additively manufactured several stem geometries, and evaluated their mechanical performance (stiffness and failure loads) on a 6 degree-of-freedom serial manipulator robot (KUKA, Augsburg, Germany).

RESULTS: Under the peak walking loads used for optimization, the optimized implant saw a maximum stress of 371.6 MPa, which provides a safety factor of 1.51 on the fatigue stress of Ti-6Al-4v. The mechanism's stiffness was 0.435 Nm/deg, which corresponds to a maximum interfacial torque of 2.61 Nm at peak angular deflection and load during walking. Maximum stress in the implant during walking, stair ascent, and stair descent were all below this fatigue stress as well (Fig 1B). The worst load case occurred during stair descent, with a maximum stress of 454.1 MPa. Additive manufacturing of the mechanism proved difficult, and the implant prototypes had visible warping and defects in the blades. Despite these imperfections, benchtop performance of the prototypes was qualitatively similar to model prediction in both stiffness and blade deformation. Rotational stiffness increased with increasing compressive force. Under 2000 N of compressive force, the implant prototype did not fail until it had been rotated by 52º, which is more than twice the modeled range of motion (and more than 5x what is necessary to support gait). Failure was non-catastrophic, such that no sharp edges or metal shards were created.

DISCUSSION: We show that a compliant tibial stem design can accommodate the internal-external rotation of the tibia during walking, stair ascent, and stair descent without failing to fatigue. Our design will benefit from additional optimization of the parameters that we fixed (blade number, inner diameter, and post diameter), which will likely allow us to shrink the total envelope. The next step toward translation of this new technology is to fabricate the compliant stem using conventional subtractive techniques, which are much more robust than 3D printing, and validate fatigue performance under cyclic loading.

SIGNIFICANCE/CLINICAL RELEVANCE: The compliant tibial stem has the potential to reduce particulate wear and bone-implant interfacial shear stress, which would increase the lifespan of TKA implants and reduce revision rates.

REFERENCES: [1] Shichman I et al. [2] Bourne RB et al. [3] Fort-Rodriquez DE et al. [4] L. E. Bayliss et al. [5] Thiele K et al. [6] M. Capella et al. [7] Bergmann G et al. [8] Lafortune MA et al. [9] Komnik I et al. [10] Cristofolini L et al.

IMAGES AND TABLES:

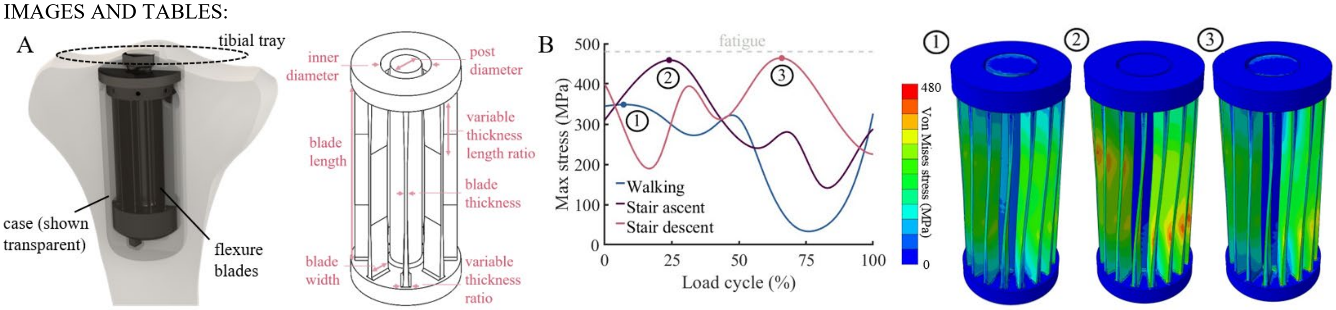

Figure 1. A) Compliant mechanism design with labeled geometric parameters. B) Maximum stress throughout the load cycle for walking, stair ascent, and stair descent for the optimized compliant tibial stem design. FEA contour plots are shown for the worst load case for each task.