Design and validation of a compliant tibial stem for total knee arthroplasty

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INTRODUCTION: Despite the ten-year success rates of total knee arthroplasty (TKA), cyclic loading of these rigid implants creates inherent limitations to implant longevity. Over-constrained loading is even more problematic, because it causes increased interfacial stress at both the bone-implant and bone-cement interfaces, and accelerates wear of articulating materials. Both processes contribute to aseptic loosening, which almost always involves the tibial component and is the leading cause of TKA revision in the United States. While prior innovations have emerged to address loosening– e.g. highly cross-linked polyethylene, press-fit implants, anatomic implant positioning – long-term revision rates remain at 18%. We have developed a component design that incorporates compliance ("flexibility") into the tibial tray to reduce interfacial stresses at both interfaces. This component is built on the caged hinge, which is a frictionless, compliant mechanism that permits rotation about one axis via elastic deformation. When incorporated into the stem of a knee prosthesis, the caged hinge would allow for internal-external rotation while remaining strong in axial tension. Furthermore, because there is no rubbing or sliding in the mechanism, this design has the potential to eliminate particulate wear. In this work, we present the development of a compliant TKA stem. We first discuss an analytical model for predicting the caged hinge response to typical human knee loads, and then verify this model in finite element analysis (FEA) and benchtop testing.

METHODS:

We performed FEA (ABAQUS, Dassault Systemes, 2019) to simulate the mechanism's response to different loading conditions derived from instrumented knee prostheses and published biomechanical analyses. For each loading condition, we swept across five defining geometric parameters: blade length (20-60 mm), width (5-20 mm), thickness (0.1-0.5 mm), distance to center of the blades (7-20 mm), and number of blades (Fig. 1A). As a preliminary material for the implant we selected Titatium-6Al4v (Ti64), which is known for its high yield strength, excellent fatigue properties, and biocompatibility. Maximum stress values were extracted and recorded from FEA simulations of each implant configuration (Fig. 1B). Additionally, stiffness of the mechanism was computed and recorded based on FEA simulations. Multiple designs were additively manufactured in Ti64, with stiffness and performance assessed in a benchtop model using our KR-210 robot (KUKA, Augsburg, Germany).

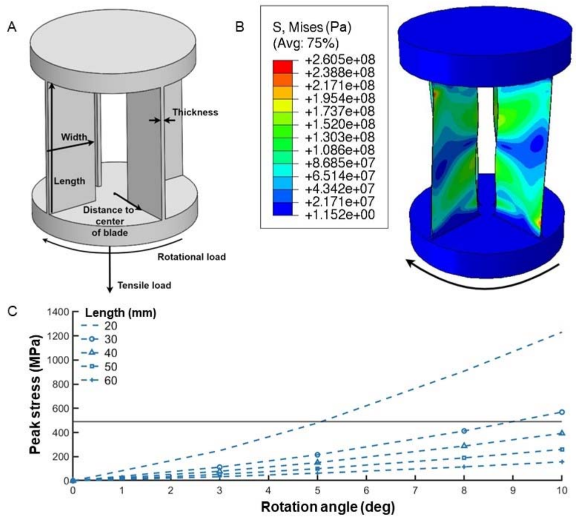
RESULTS:

FEA results were used to generate an analytical model of peak stress based on the caged hinge's response to different loading conditions. Error between analytical model predictions and FEA results was less than 5%. The analytical model produced a design space of configurations capable of withstanding 50 years of typical knee loading conditions before fatigue failure. FEA confirmed that peak stresses under combined rotational and tensile loads associated with walking and stair-climbing were below the fatigue stress limit (490 MPa) of Ti64 to achieve 4.6x10^7 cycles, which corresponds to approximately 50 years of 2,500 cycles per day (Fig. 1B). We selected one feasible configuration and performed an in-depth analysis of the effect of varying blade length on peak stress (Fig. 1C). Our analysis demonstrated that peak stress was below the 490 MPa fatigue threshold for all tested designs with blade lengths greater than 35 mm (Fig. 1C). A prototype compliant stem was fabricated and tested on the KUKA; stiffness and absolute failure loads were consistent with FEA model predictions.

DISCUSSION AND CONCLUSION:

Our results show that a caged-hinge that fits within the envelope of the proximal tibia can support typical knee loads. Depending on the configuration, up to 20 total degrees of internal/external rotation can be supported, which exceeds that seen from the biological knee during gait. Our future work will involve cyclic wear testing of several implant designs on a wear simulator, as well as experimentally characterizing interfacial stresses and micromotion at the bone-implant interface. Compliant mechanisms are unique in their ability to provide frictionless motion, enabling applications across multiple joints and pathologies. Increasing orthopaedic implant compliance has the potential to reduce aseptic loosening and prolong implant longevity.

Figure 1: A.) Example caged hinge showing geometric parameters and loads. B.) FEA stress results for a caged hinge rotated at 10°. C.) Maximum stress of a caged hinge rotated at different angles, varying only blade length.


A
Thickness
Width
Length
Distance to center of blade
Rotational load
Tensile load
B
S, Mises (Pa)
(Avg: 75%)
+2.605e+08
+2.388e+08
+2.171e+08
+1.954e+08
+1.737e+08
+1.520e+08
+1.303e+08
+1.086e+08
+8.685e+07
+6.514e+07
+4.342e+07
+2.171e+07
+1.152e+00
C
Length (mm)
20
30
40
50
60
Peak stress (MPa)
Rotation angle (deg)
0
200
400
600
800
1000
1200
1400
0 1 2 3 4 5 6 7 8 9 10