Enhanced Fixation Hip Implant

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Abstract

The Enhanced Fixation Hip Implant (EFHI) addresses hip implant failure as a result of stress shielding induced aseptic loosening in the proximo-lateral region of the femur. This complication occurs in the majority of Total Hip Arthroplasty (THA) patients after an average of 10-15 years of use. Bone resorption from stress shielding is a prominent problem since the prosthetic prevents normal physiological loads from being applied to the nearby bone cells. Bone cells require cyclic loading to maintain their structural integrity. A lack of load stimulus to the bone cells can cause bone resorption. This project aims to design a novel hip prosthetic that incorporates a fixation mechanism within the femoral component that will redirect load into the bone instead of the prosthetic. The device design utilizes pins housed within the prosthetic. Once implanted in the femur, the pins are manually extended to penetrate surrounding bone. This interaction reintroduces loads into the bone like those that a normal hip joint experiences, thereby reducing stress shielding within the bone stalk and should delay aseptic loosening. Computational analysis considering stainless steel and titanium alloy (Ti) verified that the device is predicted to function properly in accordance with device specifications. Further mechanical testing using a stainless-steel prototype will be conducted to verify and validate the device design and function.

Introduction

Every year, roughly 450,000 Americans undergo THA. While these hip implants are considered durable and efficient, the average functional lifespan is only about 10-15 years.[2] The average patient age is decreasing; therefore, the relatively short implant lifespan leads to more revision surgeries to replace the failing implant. One common cause of implant failure is femoral aseptic loosening.[1] Aseptic loosening can occur due to osteolysis induced by stress shielding of the bone cells surrounding the femur proximal ends. Bone resorption from stress shielding is a prominent problem since the prosthetic prevents normal physiological loads from being applied to the surrounding bone cells.[3] Bone cells require cyclic loading to maintain their structural integrity and a lack of load stimulus to the bone cells causes bone resorption. If bone cells do not experience a minimum loading amount, they will not be able to remodel based on Wolff's Law. When implemented, a more robust device such as the EFHI could provide patients with a longer lasting hip implant. It may delay the need for revision procedures in younger patients and allow older patients to keep walking without joint pain since revision surgeries cannot be tolerated.

Design Inputs

To address aseptic loosening, the EFHI must distribute applied loads to the femur such that stress shielding is minimized. The bone-prosthetic interface can be classified into 7 different regions (Figure 1). Zones 1 and 7 tend to have the largest differences in microstrain magnitude when comparing intact femur loading and implanted femur loading, therefore, the EFHI will address this issue by reintroducing loads into those two regions.[3]

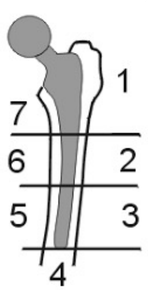

Figure 1: Bone-prosthetic interface zones

The intention is to provide a long-lasting hip implant that does not induce bone loss. There are several design inputs for the EFHI. Stress shielding must be minimized in zones 1 and 7 by achieving at least 200 microstrains to the surrounding bone. The device must be able to carry the applied loads during clinically allowed normal daily activities. Stair-climbing is the most intensive daily activity that uses the maximum accepted load of 4243N. The device must also withstand daily activities over decades worth of loading cycles. The device must also exhibit a pull-out strength of at least 2250N and must maintain its position in the femur at a 23Nm torque. The device was tested computationally to verify the specifications. Most requirement validation is done in tandem with verification testing.

Design Solution

The final design solution includes a screw mechanism to push out wedge shaped pins housed in the actual hip implant. The prototype includes seven 10mm wide by 5mm thick wedged-shaped pins. The pins are housed in the stem lining by zones 1 and 7, and once the femoral component is implanted, a ¼"-20" screw is placed into the hollow lining. When the screw is turned, the back end of the pin will get pushed on and the ejected pin tips will apply load into the trabecular bone. The screw is shaved down at the bottom end to a hemisphere to fit the device. The tapered screw end will simultaneously push out the pins as the screw is driven down. This specific screw design will prevent any micromotion occurring within the implant and minimize possible damage to the pins. The reintroduction of load into these areas will result in an increase in life expectancy by reducing stress shielding.

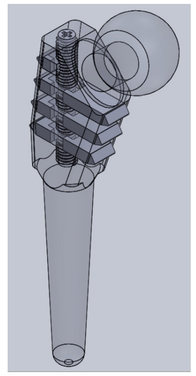

Figure 2: EFHI prototype

Testing

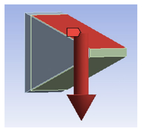

Figure 3: Force applied to pin.

Testing was completed using ANSYS Workbench (Figure 3). A simplified model was used by inserting a single pin into a block of trabecular bone. The total force was dividing to apply the appropriate force for one pin for each test. Stainless steel and titanium alloy were tested to predict device and bone behavior. To verify minimized stress shielding in the bone, the maximum principal elastic strain was determined by applying 362.2N in compression to one pin as found in literature. Microstrains greater than 200 reach about 2.26mm away from the pin (Figure 4). The pin will reintroduce load into the bone since this reaches the minimum specified value.

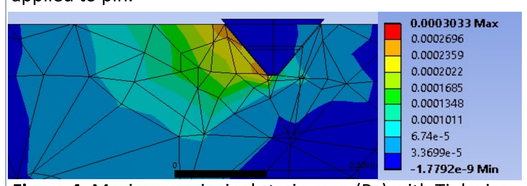

Figure 4: Maximum principal strain map (Pa) with Ti device.

Assuming equal force distribution on all 7 pins, 4243N was divided to apply 606.14N to one pin to test the device's ability to withstand stair-climbing. Young's Modulus of Ti alloy is about 200% higher than maximum stress on the Ti device so it should withstand force required to climb (Table 1).

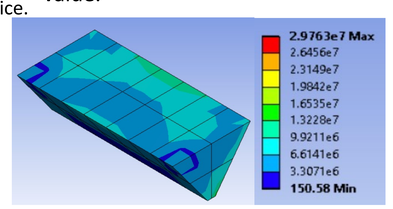

Figure 5: Equivalent stress map (Pa) on Ti pin during stair climbing

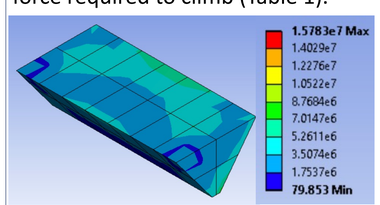

Figure 6: Equivalent stress map (Pa) on Ti pin during pull-out test

A force of 321.4N was applied in tension to one pin by dividing the standard pull-out strength of 2250N amongst the 7 pins. It was found that there is not enough stress placed on the device to break it during standard pull-out strength (Figure 6).

Since the device must be able to withstand a torque of 23Nm within the bone, a force of 670N was calculated to apply in the –x direction. It was found that the maximum stress on the pin is much lower than the Elastic Modulus, therefore, the device will not break in torsion.

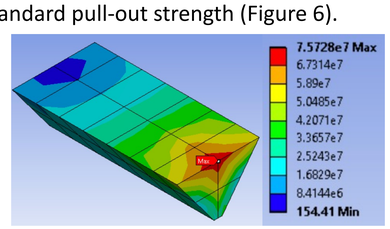

Figure 7: Equivalent stress map (Pa) on Ti pin in torsion

Test	Titanium alloy	Stainless Steel	% Diff $\sigma_{max,Ti}$ and $E_{Ti\ alloy}$	% Diff Pin $\sigma_{max,Ti}$ and Pin $\sigma_{max,SS}$
Stair-climbing	27.8 MPa	30.4 MPa	199.898	8.93
Pull-out strength	4.69 MPa	9.55 MPa	199.983	68.26
Torsion	75.7 MPa	78.3 MPa	199.721	3.377

Table 1: Maximum equivalent stress on Ti and stainless-steel pins during different computational verification tests. % difference between Young's Modulus of Ti alloy and maximum stress on Ti pin. % difference between the maximum stresses of both materials.

Stainless steel had higher maximum equivalent stresses for the three tests than the titanium alloy did since it is a stiffer material. The percent difference comparing the titanium alloy stress and Elastic modulus is about 200% for all activities, thus the device will not crack or break under too much stress for the various necessary tests. The percent difference comparing the device material is low for stair-climbing and torsion tests, therefore, both materials are comparable. Pull-out strength may not be comparable since stainless steel was about 68% higher than titanium alloy.

Verifying whether the device could withstand decades of loading cycles would require a hydraulic testing frame and an SN-curve for fatigue, which is unavailable.

Many validation tests for the design input requirements were done simultaneously with the verification activities by confirming industry standard practices. Typical validation of a hip implant would entail implantation into a cadaver to test range-of-motion, axial and compression testing, and wear and fatigue.

Conclusions

- Although prototype is of 630 stainless steel, it is comparable to a standard material of titanium alloy
- Microstrains of 200 are seen in the bone when force applied to pin resulting in enough redirected load to reduce stress shielding
- Device is predicted to withstand normal daily activities, standard pull-out strength, and standard torsion testing
- Bone is not projected to break under stress from the implanted device even after implantation.
- Further mechanical testing is required to fully verify the device

References

[1] Delauney C. et al. Clin Orthop Relat Res. 2013; 471(12): 3863–3869
[2] Evan JT, et al. Lancet. 2019; 393: 647–654
[3] Cilla M, et al. J Orthop Res. 2017; 35(11): 2534-2544.

Acknowledgements

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