Abstract

- 185,000 lower limb amputations each year with 80% reporting pain in the surrounding tissue.
- Pain is attributed to limb volume changes leading to prosthetic socket fit up issues.
- Currently a prosthetic is custom fitted for each amputee.
- Compression and Cylindrical loads to characterize material and fixation methods.
- Solution: Develop an implantable end pad (IEP) device that aids with the mobility and recovery for lower limb amputees. This product will allow patients to walk comfortably by protecting the soft tissue and bone.

Project Goals

1. Develop a computational model to prove the concepts of dampening and transferring of weight bearing loads back onto the skeletal structure.
2. Establish a fixation protocol and determine the necessary method of fixation that provides the maximum stability upon implantation.

End Pad Design

Bone Insertion Site

Concept Design

WEC Group Model

Revised Prototype

Computational Modeling

This SolidWorks® simulation provides press-fit constraints for an Finite Element Analysis (FEA) with a load applied to the bottom of the model and 2 axis fixation on the interior surface.

Material Characterization

Test samples were constructed using 0.5 diameter syringe tubes and stored until sample was cured. Upon curing, cylinders were cut to 1” in length per ASTM D6965. Cylinders were subjected to continuous deformation (.001 in/s) up to 70% strain during compression till failure tests. Modulus & stiffness were recorded. The second test subjected the cylinders to deformation by loads of 400 lbs over 100 seconds per cycle during continuous cyclic tests. Visual/Analytical analysis using environmental Scanning electron microscope (ESEM) and Instron data, respectively.

Material Comparison

- Advanced Polymer**
- Polycarbonate Polyurethane
- FDA approved for hip and spine implants
- Shore 80A durometer
- Modulus: 770 psi
- Processing: Injection molding

IEP Press Fit Compression

Results – ESEM Characterization

Results of compression testing on the Econ® 80A test samples yielded no discernable difference to the material both at low and high resolutions. Stress fractures, indicative of possible failure points were not found in both before and after image characterizations.

Results – Instron Analysis

This graph shows a comparative study of the stiffness of the two selected material durometers. The stiffness between samples (80A & 90A) is similar for approximately the first three minutes. However, a rapid increase in force applied onto the actuator in the 80A sample can be attributed to the larger swelling that occurred. The larger cross-sectional area that was created when being compressed placed a larger force onto the actuator throughout the constant displacement feed (.001 in/s until 70% strain).

Results – IEP Press Fit Compression

This graph displays the hysteresis loop for the 80A material after a cyclic loading test. Over the 10 cycle period it shows little deformation and a quick recovery time.

Discussion

- Based off results shown from computational modeling and material characterization, durometer 80A provided the best case for prototype development due to the recovery period and durability after mechanical simulation.
- Further testing is being prepared to complete prototype fixation characterization. Creep tests will indicate the ability to withstand natural weight bearing forces without plastic deformation.
- Stresses/pressure on prototype surface are comparable between SolidWorks® computational model and Vishay pressure film.
- Results indicate that the IEP will be able to handle the loads placed on it by the human body, but a redesign of the structure might be needed to prevent tearing of the insertion point’s walls.

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