Transdermal Implant Fail-Safe

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Introduction:

The world or orthopedics and prosthetics is constantly growing and changing. A relatively new design for amputees is the osseointegrated or transdermal implant. This implant is connected to the remaining portion of the patient's bone, and then protrudes out of the patient's skin to connect to a prosthetic. This eliminates the need for a traditional socket prosthetic, which causes many irritations for patients.
The transdermal implant requires a fail-safe device to connect between the implant and prosthetic in order to protect patient bone when the prosthetic experiences hazardous bending moments or torques.
Other fail-safe designs currently exist on the market, but there is a lack of research due to the fact that the technology is so novel. Therefore, there is much room for improvement in the fail-safe designs.

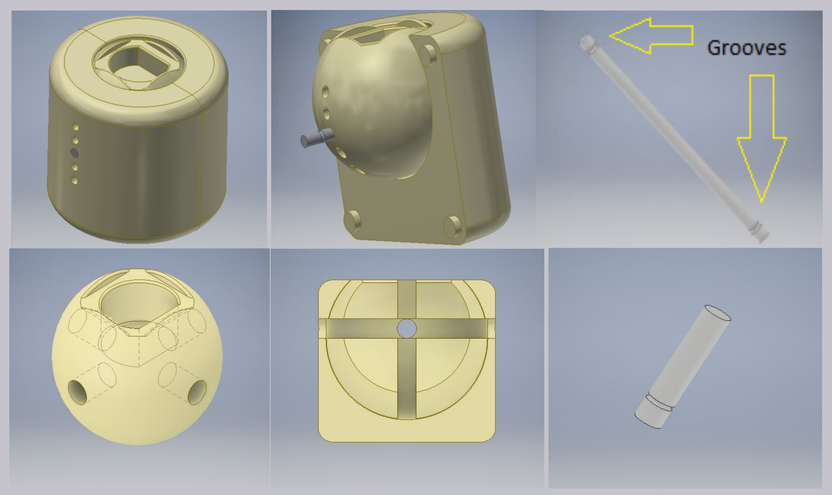
The Trine University team partnered with Zimmer Biomet, an orthopedic company located in Warsaw, Indiana, to design and manufacture a new fail-safe design that will ideally function better than the existing designs and promote use of transdermal implants.

Design Process:

Team was encouraged to brainstorm at least 15 ideas and combine concepts from best designs.
Team met with Zimmer Biomet mentors multiple times to determine potential issues within design before settling on a design and beginning the manufacturing process.

Final Designs:

Ball-in-socket design and shear pin design were combined as seen in the Figures below for final design.



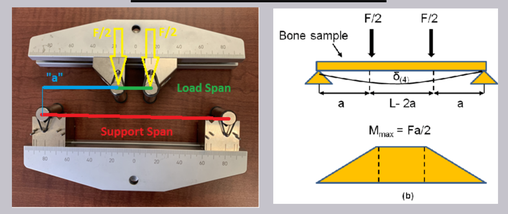
Manufacturing:

- 3D Nylon Models printed at Zimmer Biomet
- Shear pins manufactured on lathe at Trine
- Instron Machine adaptor manufactured on lathe and mill at Trine

Testing:

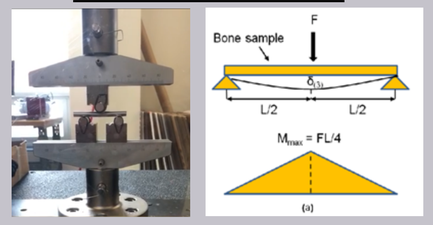
Bend compression testing of the shear pin component was required to determine the bending moment that the device would activate. Studies suggested that femurs with transdermal implants would fracture at 100 N*m bending moments, which served as the target value for testing.

Four-Point Bend Test



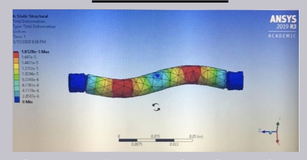
The goal of this testing was to develop a procedure for four-point bend compression testing of the shear pins for the improved fail-safe design. Due to the samples bending into contact with the fixtures before fracture and equipment failures, a switch to three-point bend testing was made for the next round of testing.

Three-Point Bend Test



The purpose of this testing procedure was to conduct a 3-point bend test on aluminum A360, steel, and brass metal rods of the relatively same diameter to pick the optimal material choice for the shear pins that will be used for the final Zimmer Biomet fail-safe design.

ANSYS Test



ANSYS testing was used to replicate the bending moment forces on the shear pins at the grooves

Results and Discussion:

Table 1 and Table 2 show the results of the four-point bend and three-point bend test respectively. The nylon and aluminum samples in Table 1 fell well below the 100 N*m bending moment target; however, the high-speed steel samples in Table 2 provided tremendous results under three-point bend loading conditions.

Table 1: Four-Point Bend Test Results

Specimen	Shaft Diameter [mm]	Groove Diameter [mm]	Maximum Load [N]	Max Bending Moment [N*m]
1 (Nylon)	7.62	N/A	1933.74	11.6
2 (Aluminum)	9.25	6.02	3198.96	19.2
3 (Aluminum)	9.35	6.66	5047.80	30.3

Table 2: Three-Point Bend Test Results

Specimen	Rod Diameter (mm)	Maximum Load (N)	Max. Bending Moment (N*m)
High-Speed Steel 1	8.0264	7931.98779	99.14984738
High-Speed Steel 2	8.0264	8100.75146	101.2593933
High-Speed Steel 3	8.0264	7975.48926	99.69361575
Aluminum A360 1	9.4488	≈ 5000*	62.5
Aluminum A360 2	9.4488	≈ 5000*	62.5
Aluminum A360 3	9.4488	5442.30322*	68.02879025
Brass 1	6.4008	≈ 1162.7738 *	14.5346725

Conclusion:

Osseoinegrated transdermal implants could be the future of prosthetics to serve the over 1.2 millions patients in the United States that suffer from limb loss. Transdermal implants have the capability of replacing traditional prosthetic approaches if an effective fail-safe can be developed that protects the amputee patient's bone from damaging forces that typically occur as a result of falls. Initial testing of the shear pin component feature of this design showed promise in meeting the requirements of an effective fail-safe. With COVID-19 cutting the testing efforts short, further testing of this design could lead to a product that may one day be produced for transdermal amputee patients across the globe.

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