Orthopedic Surgical Training Model for AGN1 Local Osteo-Enhancement Procedure (LOEP)

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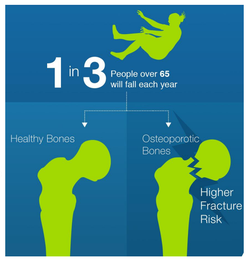
Introduction

Background:

- Approximately 200 million women are affected by osteoporosis, a metabolic disease in which the bone material becomes porous and fragile.
- Nearly 1.6 million of osteoporotic patients suffer from hip fractures leading to 50% rate of depression and loss of mobility.[1]



Agnovos' Solution:

- The AGN1 synthetic biomaterial is used to replace and restore functionality to the diseased bone.
- In the local osteo-enhancement procedure (LOEP), AGN1 is injected into the femoral head of the patient, where it hardens to reduce the fragility of the bone and increase bone density.[2]

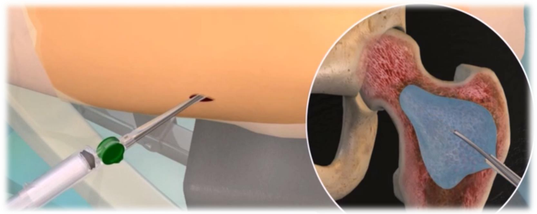


Figure 1. Injection of AGN1 into the femur head of an osteoporotic patient during LOEP.

Problems of Current Surgical Model in the Market:

- Expensive (approximately $70 per model)
- Difficult to stabilize in fixed position during procedure
- Not watertight (cannot recreate LOEP irrigation and suction steps)
- Not reusable

Objectives

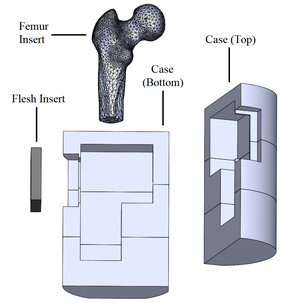
- To design and create a surgical training model that is cost-efficient, easy to use, and reusable to simulate the LOEP procedure

Ethical Implications

- Our training model must ensure user proficiency for orthopedic surgeons so that they can provide the best care for their patients
- Our training model must accurately imitate real cadaver conditions in order to prevent medical complications during real-time procedures

References:
1. Facts and Statistics. (2017). Retrieved from https://www.iofbonehealth.org/facts-statistics
2. Shaul, J., et al. (2017). Resorbable AGN1 Biomaterial Confers Biomechanical Integrity to Osteoporotic Cadaveric Femurs. Retrieved from http://www.ors.org/Transactions/63/1342.pdf

Design Concept



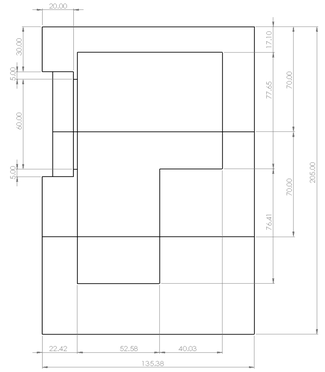


Figure 2. The three components of our model. The case is reused for multiple training sessions and the femur head and flesh insert are replaced with each use. The case dimensions are provided on the right.

Results

Materials Testing:

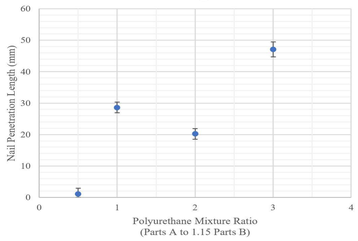


Figure 3. Foam nail-weight impact test results. Increasing the ratio of A to B when mixing the polyurethane foam solutions yielded more brittle foam results. Having less than the recommended 1:1.15 ratio yielded foam that was too spongy and deformed easily. Triplicate samples analyzed for each ratio.

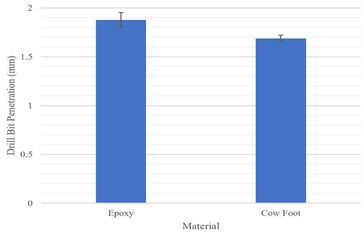


Figure 4. Epoxy timed drill penetration test results for t = 10s. The epoxy was determined to be an acceptable representation for the trabecular layer of bone, as the drill bit penetrated a similar distance in both sets of trials. Triplicate samples analyzed for each ratio.

LOEP Tutorial App Design:

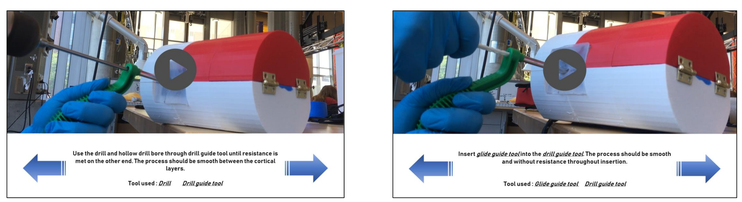


Figure 5. The companion application features a stepwise video demonstration and descriptions of steps, with links to the tools used in each step.

Cost Analysis:

Item	Item Part Unit	Item Cost
3D Printed Leg Casing	1	$50.55
Hinges (Casing)	2	$2.60
Silicone rubber (Skin)	1	$1.17
Humimic Medical Gel (Muscle)	1	$6.00
Epoxy Resin Coating (Outer Bone)	1	$4.37
Polyurethane Foam (Inner Bone)	1	$0.53
Padding (Bone)	1	$0.20
Total		**$65.42**

Table 1. Aside from the skin, muscle, outer bone, and inner bone components, all other parts are reusable. Thus, the total cost of a model after the initial production cost would be $12.07.

Methods

Prototype Development:

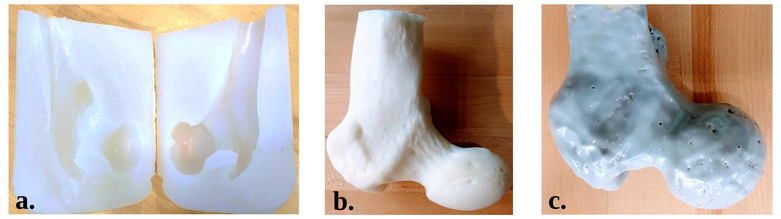


Figure 6. (a) Silicone rubber mold developed using an anatomical femur bone model. (b) Polyurethane foam used to create inner bone for femur model using the optimal 2:1 (A:B) ratio. (c) Epoxy resin applied to polyurethane foam for outer bone coating.

Testing Methods:

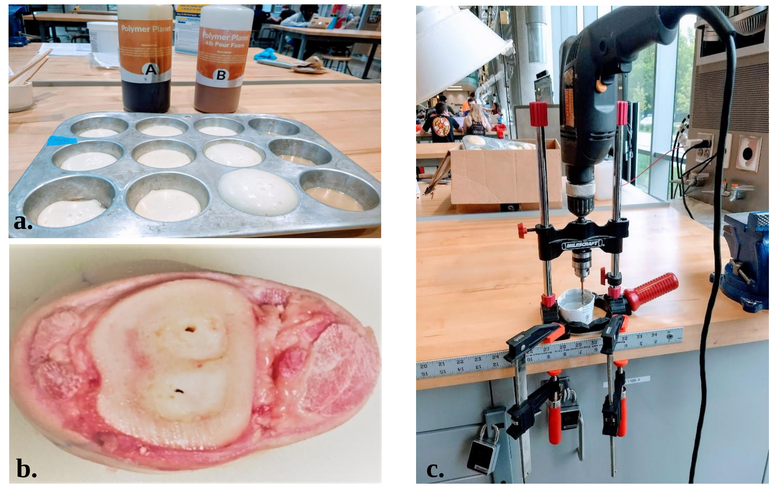


Figure 7. (a) Polyurethane foam ratio testing for inner bone composition of osteoporotic patients. (b) Cow bone used for inner and outer bone comparison testing. (c) Drill test conducted on epoxy resin coating for outer bone composition of osteoporotic patients.

Future Work

- Expand surgical applications of training model to other bone-related procedures such as hip replacement surgery
- Expand tutorial app to monitor time taken to complete procedure

Conclusions

Model Performance:

- Our training model meets the requirement of being low-cost: the $12.07 cost of our bone and muscle insert is much lower than the $60 figure associated with the custom Sawbones model.
- The app provides an intuitive walk-through of the training procedure, and the case allows the bone and flesh inserts to be replaced easily.
- Trainees are able to carry out the irrigation step of the LOEP procedure using our waterproof femur head.