

3D Printing of the Temporal Bone for Surgical Simulation

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Problem

Otolaryngology (ENT) residents and surgeons perform over 16 million procedures each year in the United States. These procedures require high fidelity training models to gain knowledge of the anatomy and properties of the bone for various temporal bone procedures.

Training tools for these surgeries are essential to the advancement of the field, as current training modalities are expensive, difficult to source and often do not accurately mimic haptic properties of temporal bone.

Background

- Temporal bone encompasses the middle and inner portions of the ear.
- It is responsible for important physiological functions (ex. hearing, balance).
- Procedures are high-risk and require specific technical skills due to the complex anatomy of the bone and the surrounding soft tissue.

Figure 1: Anatomy of the temporal bone

- Current training models include cadaver bones, which are expensive and difficult to source.
- There is a gap in the market for a surgical simulation platform that is low cost and high efficacy.

Objectives

Our model provides a way to scale and more easily produce temporal bone models while addressing the high-cost of these models for surgical residents to learn Otolaryngology procedures on accessible, durable models at a high standard of quality for seamless transition from training to real life surgery.

Table 1: Project stakeholder analysis

Stakeholders	Outcomes
Patients	Improved patient outcomes
Surgical residents	Increased quantity of training models
Surgeons	Higher surgeon skills & confidence
Hospitals	Economic relief

Final Prototype

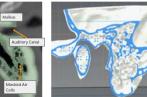


Figure 2: Temporal bone model in right side (left), isometric (middle), and frontal (right) views

Our temporal bone model is 3D printed out of PETG (Figure 2) and is generated from a patient-specific CT scan (Figure 3).

It contains an internal, open-cell triangular lattice structure (Figure 4). Epoxy resin serves as the continuous matrix, filling the open space in the lattice to form our composite material (Figure 5).





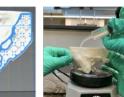


Figure 3: complex anatomical Figure 4: Internal lattice structure features are preserved generated on FabPilot

Figure 5: Resin is injected into the 3D structure

Our prototype is:

- 1. Less expensive than conventional temporal bone simulation platforms
- 2. Accurately resembles the mechanical properties of temporal bone
- 3. Anatomically accurate
- 4. Adaptable and can be made patient specific

Demonstration and Material Testing



Figure 5: Compression testing Figure 6: of PETG cube sample for yield Microhardness strength and elastic modulus indentation of PETG

Figure 7: Drilling through temporal bone model with otologic drill and diamond burr

Table 2: Mechanical comparison of final prototype to cadaver bone

Material	Yield Strength (GPa)	Microhardness (HV)	Compressive Modulus (GPa)
Final Prototype	.0454±.011	14.854±.430	1.24±.066
Temporal Bone	0.042 ± 0.019**7	12.2 - 34.6 HV *6	3.30 - 9.65 *6

Surgical Simulation Results

Table 3: Surgeon Results				
Survey Category	Material Score	Score	Comparison	
Haptic Response	3.75	5	Identical	
* *	3	4	Very Similar	
Drill Time/Speed	3	3	Similar	
Auditory Response	3	2	Very different	
		1	Unlike	
Dust Generation	4.5	"It's a great training tool, a lot of this is		
Color	2.875			
Usefulness for learning drilling technique	4.75	muscle memory nice physical and mental exercise for drilling." Dr. Philip Zapanta, GW University of Medicine Associate Professor of Surgery, Otolaryngology Residency Program Director		
Usefulness for simulating surgery	4			
Overall likeness	3.5			

Pathway to Market

Manufacturing Costs

Considering labor cost, machine upkeep, and raw materials we were able to design a bone that is up to 17x cheaper than cadaver specimens.

Fable 2: Cost breakdown of model			
Cost Breakdown	Cost (\$)		
Material Cost	3.97		
Production Cost	37.12		
Total Cost	\$41.09		

Reimbursement and Regulatory Pathway

- Since our model is purely to train surgeons and residents, it is unlikely that the cost will be reimbursed as a training platform.
- The model may be classified as a Class I device and not be subject to 501(k) clearance or premarket approval.

Patentability

- In order to be patentable, our solution must be novel, useful, and nonobvious. Novel: No other existing patents that use similar technology as ours Useful: Provides valuable training for surgical residents
- Nonobvious: Innovative composite material rather than solid, pure material

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References