Production of a Custom Middle Ear Prosthesis Using Bone Cement

Brandon Kamrava BS, Steven Zuniga MD, Yah-el Har-el PhD, Pamela Roehm MD PhD

Objectives

Introduction: Partial ossicular prostheses (PORPs) are used to reconstruct the ossicular chain by connecting the stapes capitulum to the tympanic membrane, malleus or both. While use of PORPs is common, they do not allow full closure of the air-bone gap and can extrude or become displaced. Our team has previously developed a 3D, adjustable model of the incus to produce custom prostheses for patients who would normally require an ossiculoplasty in order to circumvent drawbacks noted with current PORP technology. However, due to limitations of current technology, we are unable to directly print a prosthesis in biocompatible material. In this study we have explored the utility of using a custom 3D printed form to manufacture a silicon mold which is subsequently used to cast a custom prosthesis with otologic bone cement.

Methods: To verify the production methods, three variations of the novel incus replacement prosthesis were developed: one with normal anatomical proportions, and two with exaggerated morphologies. Using a 3D printer, each model variant was produced at scale in VeroWhitePlus photopolymer (Stratasys, Eden Prairie, MN). From these prints, silicon molds were set under centrifugation for removal of microair bubbles. Molds were then filled with OtoMimix® Bone Cement (Olympus America, Center Valley, PA) to produce hydroxyapatite prostheses. Mass and morphology were then measured. Additionally, the maximal force for breakage of the incus long process was measured on manufactured hydroxyapatite prostheses. Four incudes were extracted from cadaveric temporal bones and were similarly assessed to provide control data.

Results: 4 prostheses of each incus variant were produced through casting, providing a total of 12 manufactured prostheses (Figure 1). Morphological measurements on average differed by 0.037% (S.D. 2.70%). The average mass of all manufactured prostheses was
26.67mg (S.D.= 5.85mg). The average force for breakage was 0.54N (S.D = 0.16N). Mass of cadaveric incudes on average was 30.71mg and average force of breakage was greater than 4.85N.

Conclusions: The novel manufacturing methods we have developed allow for the accurate morphological production of middle ear prostheses. OtoMimix® bone cement was used for this testing due to its qualities of setting very rapidly with minimal processing requirements. Breaking force of novel middle ear prostheses manufactured with this method is less than that of cadaveric incudes. Future studies will determine if breaking force measurements on freshly harvested incudes are similar to those of cadaveric fixed incudes. We will also determine if breaking force is an essential component of incudal replacement design that affects performance and durability for long-term use using both modeling and fresh tissue studies.

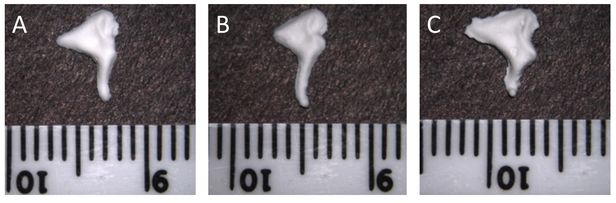

Figure 1. Manufactured prosthesis produced from OtoMimix®.
Three incus variants were produced in this study, normal variant (*A*), extended long-process and shortened short-process variant (*B*), and shortened long-process and extended short-process (*C*). Each prosthesis was produced through placement of OtoMimix® bone cement into formed molds and placed under pressure for 24 hours. Once extracted from the molds, care was taken to remove flashing, although not all could be removed as evidenced by the sample in (*C*). Ruler lengths are in mm.

Methods & Results

In SolidWorks 2017 (Dassault Systems, Waltham, MA), three variations of the prosthesis were produced: one with normal anatomical proportions, and two with exaggerated morphologies. Models were printed in VeroWhitePlus on a Objet500 Connex3TM 3D printer (Stratasys, Eden Prairie, MN). Using PlatSil® Gel-25, molds were produced at 200RCF at 21°C for 60 min for reduction of air bubbles. Molds were cast with OtoMimix® Bone Cement (Olympus America, Center Valley, PA) and removed from molds after 24 hours. Manufactured prostheses were then assessed for mass and morphological measurements. Additionally, the maximal force for breakage of the incus long process was recorded via an ElectroForce 3200 mechanical tester (TA Instruments, New Castle, DE). Four incudes were extracted from cadaveric temporal bones and were similarly assessed to provide control data.

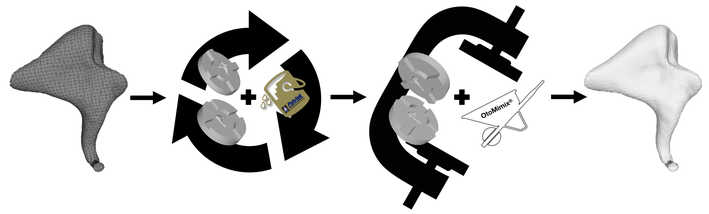

Figure 2. Graphic illustration of the Production Process for Creating Novel Ossicular Prostheses.
The procedure designed by our team to create each prosthesis can be divided into 4 critical steps. First, using computer-aided design, adjustments to the modeled incus are made to create the intended morphologic specimen. The modified model is then divided in two and 3D printed into two separate templates, each representing one half of the incus. In the next step, silicone gel is placed over the templates. Gel and templates are then centrifuged at 200g for 60 minutes at 21ºC. Templates are removed from the molds, which are now a negative impression of the incudal models. Cured negative molds are cast with bone cement (OtoMimix®) and placed in a vice (10N) to cure overnight. Subsequently, the cast material is removed yielding the final prostheses.

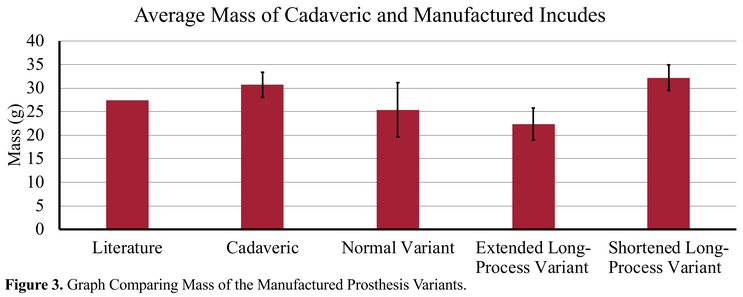

Figure 3. Graph Comparing Mass of the Manufactured Prosthesis Variants.
The mass of the OtoMimix® prostheses was measured, as well as the mass of the extracted cadaveric incudes. Additionally, the literature mean[2] of incudes masses was recorded. Error bars are included in the graph demonstrating the standard deviation, which was not recorded in the literature.

Results Continued

Prosthesis variants were 3D printed from which silicon negative molds were produced. From these negative molds, 4 prostheses of each iteration were cast using bone cement, yielding a total of 12 manufactured prostheses (Figure 1). Average percent difference were calculated, with negative values indicating manufactured prostheses measurements less than those of the 3D models. Morphological measurements of the normal incus variant demonstrated an average percent difference between 3D model and the manufactured model to be -0.79%, with a minimum of -9.59%, maximum 8.91%, and standard deviation of 3.84%. For the two variants, the average percent differences were 0.41% and 0.50%, with minimums of -4.75% and -13.74%, maximums of 8.68% and 4.63%, and standard deviations of 3.39% and 4.01%. The average mass of all manufactured prostheses was 26.67mg, with a minimum of 18.94mg, maximum of 35.71mg, and standard deviation of 5.85mg (Figure 3). The average force for breakage was 0.54N, with a minimum of 0.31N, maximum of 0.91N, and standard deviation of 0.16N. For comparison, the mass of cadaveric incudes on average was 30.71mg and average force of breakage was greater than 4.85N.

Table 1: Anatomic Outcomes of Production of a Normal Variant Incus Prosthesis

Model	Short Process Length (mm)	Articulating Surface Height (mm)	Maximum Length of Incus (mm)	Angle of Axis (degrees)	Functional Length (mm)	Interprocess Length (mm)	Max Force to Breakage (mN)
CAD	4.767	2.274	6.692	65.745	4.132	5.567	n/a
Prosthesis Mean	4.658	2.269	6.609	67.159	3.994	5.578	57.225
Prosthesis Min	4.553	2.056	6.500	63.032	3.905	5.487	35.531
Prosthesis Max	4.720	2.399	6.722	71.600	4.108	5.783	92.517
Prosthesis S.D.	0.065	0.137	0.080	3.051	0.082	0.120	25.173

Table 2: Anatomic Outcomes of Production of a Extended Long-Process and Shortened Short-Process Variant Incus Prosthesis

Model	Short Process Length (mm)	Articulating Surface Height (mm)	Maximum Length of Incus (mm)	Angle of Axis (degrees)	Functional Length (mm)	Interprocess Length (mm)	Max Force to Breakage (mN)
CAD	4.014	1.885	6.960	65.197	4.668	5.680	n/a
Prosthesis Mean	4.087	1.772	7.137	65.686	4.806	5.732	50.369
Prosthesis Min	3.958	1.626	6.927	62.952	4.704	5.635	31.503
Prosthesis Max	4.185	1.860	7.240	67.809	4.884	5.784	67.232
Prosthesis S.D.	0.088	0.090	0.127	1.814	0.073	0.057	12.791

Table 3: Anatomic Outcomes of Production of a Shortened Long-Process and Extended Short-Process Variant Incus Prosthesis

Model	Short Process Length (mm)	Articulating Surface Height (mm)	Maximum Length of Incus (mm)	Angle of Axis (degrees)	Functional Length (mm)	Interprocess Length (mm)	Max Force to Breakage (mN)
CAD	5.033	2.794	6.496	70.769	3.492	5.867	n/a
Prosthesis Mean	5.178	2.806	6.488	70.336	3.448	5.934	57.743
Prosthesis Min	4.939	2.668	6.305	67.407	3.426	5.746	49.486
Prosthesis Max	5.470	3.005	6.714	72.609	3.462	6.122	65.828
Prosthesis S.D.	0.197	0.124	0.147	2.171	0.014	0.173	5.787

Table 1, 2, & 3. Summary of Manufactured Prostheses Anatomic Features.
Three incus variants were produced with OtoMimix® bone cement. After production, each prosthesis was imaged under stereotactic microscope. Images were used to measure critical anatomic aspects. In each table, the first row provides the lengths of the computer aided design (CAD) model used to create the prostheses. Comparison of the prosthesis measurements to the CAD measurements provides insight into the accuracy of the production process. In the final column, the average force of breakage of the long process was measured.

Contact

Pamela Roehm, MD, PhD
Temple Head and Neck Institute
3509 N. Broad Street; Boyer Pavilion, 6th Floor
Philadelphia, PA 19140
pamela.roehm@tuhs.temple.edu
215-707-3665

References

1. Yu H, He Y, Ni Y. PORP vs. TORP: a meta-analysis. *Eur Arch Otorhinolaryngol*. 2013;270:3005-3017. doi:10.1007/s00405-013-2388-1
2. Kamrava B, Roehm PC. Systematic Review of Ossicular Chain Anatomy: Strategic Planning for Development of Novel Middle Ear Prostheses. *Otolaryngol Head Neck Surg*. 2017;157(2):190-200. doi:10.1177/0194599817701717
3. Kamrava B, Gerstenhaber JA, Amin M, Har-El Y-E, Roehm PC. Preliminary Model for the Design of a Custom Middle Ear Prosthesis. *Otol Neurotol*. 2017;38(6):839-845. doi:10.1097/MAO.0000000000001403
4. Schuenke M, Schulte E, Schumacher U. External Ear: Auricle, Auditory Canal, and tympanic Membrane. In: MacPherson BR, Stefan C, eds. *Thieme Atalas of Anatomy. Head, Neck and Neuroanatomy*. 2nd ed. New York: Thieme; 2016:139.