Design Document

Ariadne: Onsite Pediatric Earmold Fabrication

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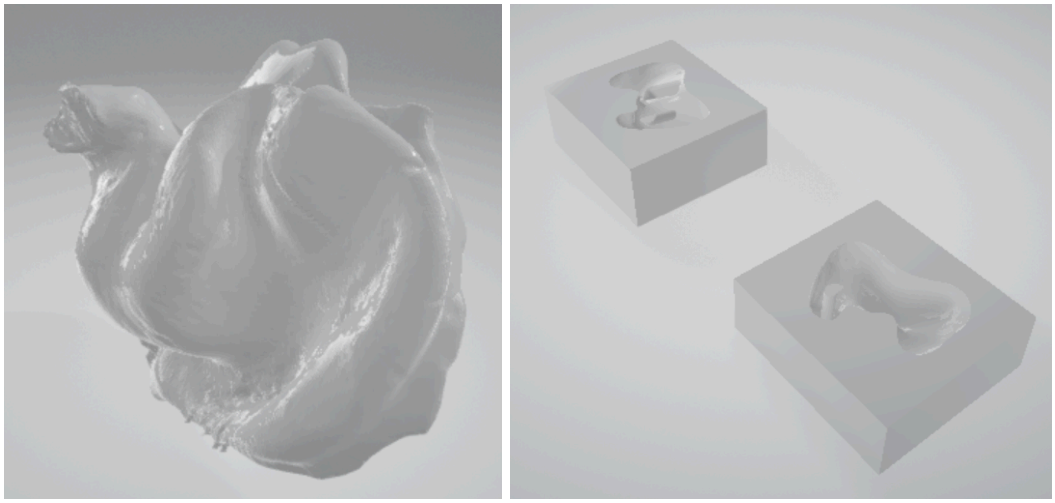

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Ariadne: Onsite Pediatric Earmold Fabrication

Written on 5/20/24 by Kayla Vallecillo and Armaan Priyadarshan . Edited on 5/22/24 by Erica Dong and Ethan Zhou.

Ariadne's onsite pediatric earmold fabrication methods are motivated by an effort to address the inconvenient process of acquiring replacement pediatric earmolds. The earmold manufacturing process is unnecessarily convoluted, lengthy, and expensive, causing inconvenience for quickly developing pediatric patients who use hearing aids and need to replace their earmolds often (Anderson & Madell, 2014). This issue may be addressed by developing a short-term pediatric earmold fabrication that aims holistically to improve efficiency and user-based ease of acquisition. Ariadne aims to do just that: reconstruct existing earmold fabrication methods to provide easily adoptable, efficient, onsite pediatric earmold fabrication systems that are centered on the comfort of children with hearing loss.

The developed fabrication process is designed for implementation in hospitals and medical centers, easing process adoption by developing an instructional guide and a clear, detailed set-up describing how this process may be implemented for medical professionals. In developing a design that is implemented in medical facilities, the fundamental issue experienced by children and adults alike who use assistive hearing devices can be minimized and addressed. The proposed process is centered on developing child-friendly and biocompatible earmolds while introducing the logistical components of its fabrication process and implementation in medical facilities.

Purpose of this Document

This design document aims to present the final prototype and outline the product development process that the Ariadne team has pursued throughout the 3-month project timeline. Through design, development, testing, and efficiency evaluation of the following fabrication

process “prototypes,” the team was able to successfully develop and present a final design that addresses many of the product requirements and demonstrates the implementation of a short-term, pediatric onsite earmold fabrication process aimed at reducing the convoluted nature of replacement earmold acquisition experienced by children and adults which hearing loss.

Background

Hearing loss is a prominent birth defect amongst newborns, affecting their ability to perceive sound from an early age and potentially impacting their development. About 2 to 3 out of every 1,000 children in the United States are born with a detectable level of hearing loss in one or both ears (CDC, 2010). More than 90% of deaf children are born to hearing parents. Approximately 15% of American adults (37.5 million) ages 18 and over report some trouble hearing (Blackwell et al., 2014). Hearing loss can affect a child's ability to develop speech, language, and social skills (CDC, 2019). Early intervention and access to appropriate medical and educational resources are crucial to address this issue.

One of the leading forms of addressing the challenges posed by hearing loss is the hearing aid. A hearing aid is a small electronic device worn in or behind the ear. It makes some sounds louder so that a person with hearing loss can listen, communicate, and participate more fully in daily activities (NIDCD, 2022). Whether engaging in conversations, enjoying music, or navigating noisy environments, hearing aids empower individuals to overcome the barriers posed by hearing impairment.

However, major problems arise when considering a fundamental part of the hearing aid: the earmold. The earmold is the part of a hearing aid that sits precisely within the ear canal and the surrounding outer structure, the concha. It channels amplified sound from the electronics via

a tube into the eardrum (Clason, 2023). For this reason, it is crucial for earmolds to perfectly fit their users to permit the stable flow of sound and maximize comfort.

Poor-fitting earmolds result from many factors, mainly growth and development. When a child outgrows the earmold, the amplified sound leaks through a gap around it. When received by the hearing aid microphone, it is further amplified and sent back to the earmold, escaping from the gap again and causing feedback. This feedback generates a high-pitched and high-intensity noise (known as whistling, screeching, or howling), irritating the user (Bustamante et al., 1989). A poorly fitted earmold could also press against parts of the ear, causing sores. As a result, children are less likely to wear the hearing aid if the earmold does not fit.

When children outgrow their earmolds, they need to get a replacement. This process, however, can be lengthy or unpredictable, leading to delays in procuring the necessary device for the child's optimal hearing (Anderson & Madell, 2014). This waiting time, along with the manufacturing expense, makes it challenging for families to promptly address the evolving needs of their child with hearing loss.

The existing process for earmold manufacturing is unnecessarily convoluted and inadequate. The patient first visits the hospital, and an audiologist has to take an impression of the outer ear. Then, the impression must be shipped to an offshore manufacturing company, which uses it to create the correct earmold. The patient must wait weeks before revisiting the hospital to collect the newly manufactured earmold. In case of a misfit, the whole process must again be repeated, leading to another waiting period filled with discomfort and hindrance.

Summary of Market Research

Written on 5/21/24 by Kayla Vallecillo and Ethan Zhou. Edited on 5/22/24 by Erica Dong and Armaan Priyadarshan.

The pediatric earmold fabrication landscape primarily consists of existing privatized fabrication processes, in which patients acquire new earmolds by shipping an ear impression taken at a medical facility. These impressions, such as those taken by over-the-counter (OTC) products such as the EZ Ear Impression Kit, can be used to order a new earmold from a separate earmold manufacturer (EZ Ear Impression Kit, n.d.). This process often involves 3-4 weeks of waiting time, potentially posing a risk to child development and comfort in the case of replacing broken, dysfunctional, or unusable earmolds and hearing devices. In addition to this common process of ordering and acquiring replacement earmolds several weeks after an initial request, existing solutions developed by previous research and organizations emphasize rapid, user-centric earmold fabrication.

One such example, which proposes same-day custom earmold fabrication, showcases an innovative and precise approach, utilizing high-precision Einscan-SE for 3D scanning, CARL for real ear measurements, digital manipulation through Blender, and earmold 3D printing with Recreus FilaFlex 70A, which combines the benefits of flexibility, durability, and skin compliance. Despite this method's advanced technological approach, FilaFlex 70A is not suitable for children, who need smaller and softer ear molds that the 3D printer may struggle to create, and the material is not fully approved for medical use (Talarico, 2021).

3DP4ME, a nonprofit organization dedicated to providing 3D-printed hearing aids to struggling communities worldwide, aims to address the global hearing loss crisis by leveraging advanced technology to create custom-fit hearing solutions primarily for groups in the Middle East. The process utilized by this organization involves 3D ear scanning, printing and assembly, and fitting with an expert audiologist. Accompanying this process is an emphasis on documenting the patient and family experience through interviews, photoshoots, private speech

therapy, and continued support and maintenance after the service. 3DP4ME offers accessible and patient-centric care through its high-quality process and materials yet fails to offer consistent and expandable earmold fabrication solutions (3DP4ME - Give the Gift of Hearing, n.d.).

In addition to existing earmold fabrication methods demonstrated by previous research and deployment at an organizational level, OTC hearing devices, such as the Lexie B2 Plus Self-Fitting Hearing Aids, offer short-term yet highly-priced hearing loss solutions. Powered by Bose, this product is designed for adults aged 18 or older with perceived mild-to-moderate hearing loss. The hearing device is rechargeable and includes an accompanying app with customizable features (volume, sound clarity, background noise) and rubber domes to fit into the client's ear (*Lexie B2 Plus self-fitting OTC hearing aids*, n.d.). While the product offers a solution that does not necessitate the use of earmolds or a custom fit, there are still limitations with scope, cost, and function. Primarily, its limitations lie in its functionality for children, as well as the use of rubber domes, which are generally less likely to create a perfect seal in the ear canal, leading to feedback or whistling noises and negative impacts on the hearing aid's overall sound quality. The hearing aid would be rendered ineffective if used with children or others whose ear canal shape changes.

Through thorough research into the existing solutions and methods for short-term, child-centric, onsite, and easily accessible earmold fabrication, the Ariadne team has identified critical points that need to be referenced in the introduced designs.

Preliminary Designs

Written on 5/18/23 by Erica Dong and Ethan Zhou. Edited by Kayla Vallecillo and Armaan Priyadarshan on 5/21/23.

With the objective of fulfilling the needs identified in the contextual research, the following section outlines several preliminary designs that were developed initially and adjusted

to align with the iterative nature of the design and prototyping process. As the Ariadne team grew more familiar with the tools used to design and develop the earmolds, several preliminary designs were expanded to account for the various techniques used to cast and mold earmold structures. An additional preliminary design related to structural prediction aims to aid in the fabrication processes tested, a separate objective from the other design objectives, which aim to reform and improve the onsite earmold fabrication process.

Design #1: Impression-based 3D-Printed Earmold Fabrication

This design first takes a custom ear impression from the patient using the EZ Ear Impression Kit, although any ear impression device can be used. This ear impression is cured and scanned with the Artec Spider or another 3D scanning technology. The scan is cleaned with Artec Studio and processed into an earmold design with Cyfex Secret Ear Designer, with automatically built-in channels for the hearing aid. The design is exported as an STL and directly printed using a resin printer.

Figure 1: 3D-printed custom earmolds from a resin printer; ring (left) and full shell (right) designs are shown.

Design #2: Structural Prediction RNN Model

This design constitutes part of the fabrication process involving the prediction of ear canal developments. It aims to use machine learning in the form of a recurrent neural network model to infer how the earmold design will change for patients over time. Its implementation uses Python and TensorFlow. A

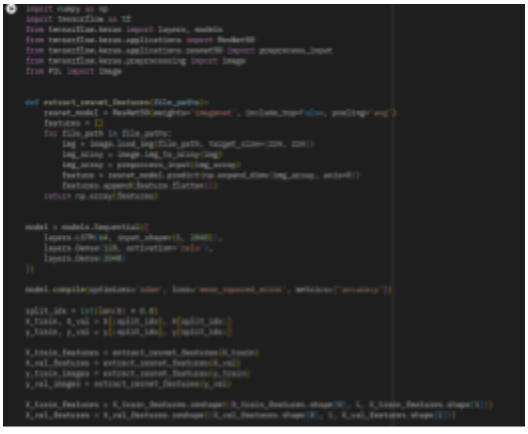

Figure 2: Model implementation within Google Colab with Python and TensorFlow

database of ear canal growth over time is first imported into the program. This data was collected from 224 infant participants at the Chawama Clinic in Lusaka, Zambia. It contains sequential, timestamped images of each infant's ear canal across a developmental period (Simukanga et al., 2021). Using a pre-trained ResNet model, pairs of images to subsequent images were converted into encodings of image features that are usable for training. From there, formatting is applied to create a dataset, which is fed into and used to train a recurrent neural network.

Design #3: Impression-based Silicone Injection Earmold Fabrication

Design #3 utilizes an impression-based earmold structure to generate a hollow resin shell for silicone injection. This design follows a similar scanning, modeling, and meshing process to Design #1 but differs in the injection process. First, the user must obtain an ear impression using an OTC kit such as the EZ Ear Impression Kit or another medically or commercially-sourced product. Once the ear impression is obtained, the user can scan the ear impression using the handheld Artec Spider 3D scanner. The scan is cleaned with Artec Studio and processed into a shell cast design with Cyfex Secret Ear Designer, with automatically built-in channels for the hearing aid. The shell is printed using a 3D resin printer, as a filament 3D printer would need support structures for the complex hollow structure. Next, a high-viscosity biocompatible silicone is injected into a small opening atop the casted structure. The shell is cracked or peeled open to reveal the customized silicone earmold within once the curing process has finished.

Figure 3: Shell cast 3D-printed with a resin printer and filled with silicone.

Build Steps

Written on 5/21/24 by Erica Dong and Kayla Vallecillo. Edited on 5/22/24 by Ethan Zhou and Armaan Priyadarshan.

Ear Impression Taking

The EZ Ear Impression Kit was used to take an impression of the ear. A foam stop selected based on the ear canal size was inserted around the second turn of the patient's ear canal.

Figure 4: Injecting the ear impression material into a patient's ear. The string of the foam stop can be seen hanging out.

The two parts of the impression material were thoroughly mixed until they became a solid, continuous color. The material was filled into a syringe; it was pushed until there was one-eighth of an inch left of space at the tip of the syringe to minimize air bubbles. The syringe was inserted into the patient's ear canal, and the impression material was injected. After 10 minutes, after the impression was fully hardened, it was taken out.

Ear Impression 3D Scanning

The first step of converting the ear impression into a 3D mesh file was placing it on the turntable for scanning. The Artec Spider, a handheld 3D scanner, was connected with the Artec Studio software on a nearby computer, pointed at the ear impression, and activated. The turntable was slowly turned to give the scanner a full view of the impression, and progress was monitored on the computer. The scan was then trimmed manually, cleaned, and smoothed using the automatic tools "Remove small bodies" and "Register" provided by Artec Studio. Finally, it was exported as an STL file for use in the next steps of the process.

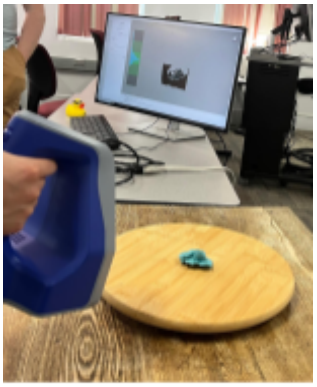

Figure 5: Artec spider being pointed at the ear impression, with Artec Studio in the background.

Earmold Cast Design and Fabrication

The ear impression STL was imported into Cyfex Secret Ear Designer and a template was configured with the target design and original ear direction (left or right). The box cast design was chosen, and the software automatically parsed and processed the ear impression scan into an earmold design.

Next, this earmold design was inverted and converted into a hollow box cast by again choosing a template from the software. This cast design was exported from Cyfex Secret Ear Designer as an STL. Autodesk Fusion was used to slice and reposition the box for ease of printing and casting.

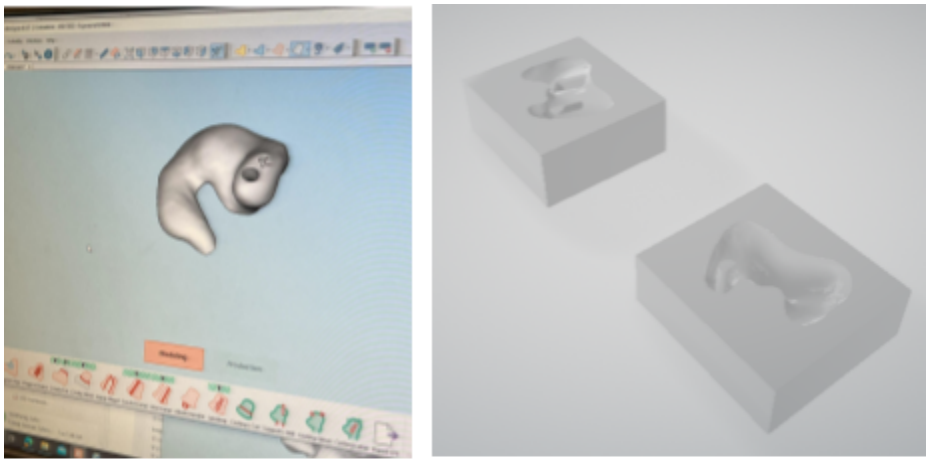

Figure 6: Earmold design generated by Cyfex Secret Ear Designer (left) and final box cast design file, ready for 3D printing (right).

Finally, the box cast was imported into UltiMaker Digital Factory and 3D-printed using an Ultimaker FDM 3D printer, although any 3D printer of sufficient fidelity can handle the design. The open design allows for easier printing with the filament printer due to its ability to easily remove supports, in contrast with some previous designs. The only post-processing required was removing a few supports.

Figure 7: 3D-printed box casts for injection.

Earmold Fabrication Through Silicone Injection

First, the two parts of the box mold were sprayed with mold release, specifically from Mann Release Technologies, to allow for easy removal of the silicone after curing. Then, the two parts were aligned and bound with tape. High-viscosity biocompatible silicone, specifically the Ecoflex Platinum Cure Silicone Rubber, was procured, along with a scale and a small cup. This silicone required mixing equal parts of yellow and blue liquids to cure. For precision, the scale was used to pour the same weights of yellow and blue liquids into the small cup. A popsicle stick was used to mix the liquids thoroughly. The silicone mixture was put into a syringe and injected into the top of the box cast with a built-in funnel. Additionally, the cast was put into a pressure pot connected to a Bostitch air compressor to eliminate air

Figure 8: Materials used for silicon casting.

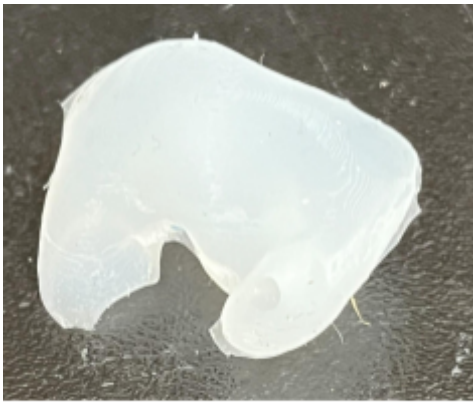

Figure 9: Silicone earmold produced from box cast.

bubbles, allowing for a more consistent and effective product. A timer was set for 3.5 hours, the approximate curing time of the resin, after which the tape was undone, and the earmold was safely extracted from the cast.

Design Studies

Written on 5/20-21/23 by Kayla Vallecillo and Armaan Priyadarshan. Edited by Erica Dong and Ethan Zhou on 5/21/23.

Design Study #1: User-Earmold Compatibility

Purpose. The purpose of this design study was to both qualitatively and quantitatively analyze the compatibility between the generated earmold designs and their users. In gathering tools to analyze the performance of each earmold in relation to its user-centric facets, the solution presented can be explicitly designed to provide the most comfortable and compatible user experience. Considering that our product centers primarily upon its application in pediatric healthcare, with applications to growing children, user-centric comfort evaluations are essential in producing a product that allows the child to develop and reduce the risk of device-related injury properly.

Variables. To determine the effectiveness, when centered upon comfort and compatibility with the user, we created a short quantitative comfort response form, which uses the following variables to generate a compatibility score:

- Independent Variables
  - The fabricated earmold: The earmold differs in characteristics based on the fabrication method used.
- Dependent Variables
  - Fit: how “snug” the earmold fits in the ear. Insufficiency in fit is defined as being too tight or too loose for the user.

- Hardness: how close the earmold is to being comfortable in relation to hardness. Discomfort may be caused by an earmold that is too hard or soft for the users' preferences.
- Weight: how close the earmold is to being comfortable in relation to weight. Discomfort caused by weight may be caused by an earmold that is too heavy or too light for the users' preferences.
- Durability: how durable the earmold is in relation to its ability to remain in its original/similar condition during and after physical activity or physical stress.

A limitation of the variables utilized in this testing and compatibility scoring process is that the tests conducted are primarily based upon the preferences of the tested individual, which may differ from those impacted by its implementation in pediatric healthcare. This research should be re-conducted at a larger scale and among a more specific or applicable group to ensure that this product, when expanded, best aligns with the needs of the user.

Materials. The materials used in this design study include the earmolds generated from each tested fabrication process and an object or set of objects that approximates the mass of its user. Within its applications in pediatric healthcare, the approximate weight of the object used was 48 lbs. The Cincinnati Children's Hospital provided this weight as the midpoint of a range of weights for children aged six years old, a group this product aims to support. This weight, used in earmold stress testing, is essential in determining the earmold's durability in preparation for high-force impacts or falls that the child may experience during active periods.

Methodology. The methodology below was used to conduct the design study:

1. Place the generated earmold in the patient's ear opening. Prompt the patient to complete the earmold compatibility survey by ranking fit, hardness, and weight in relation to earmold comfort.

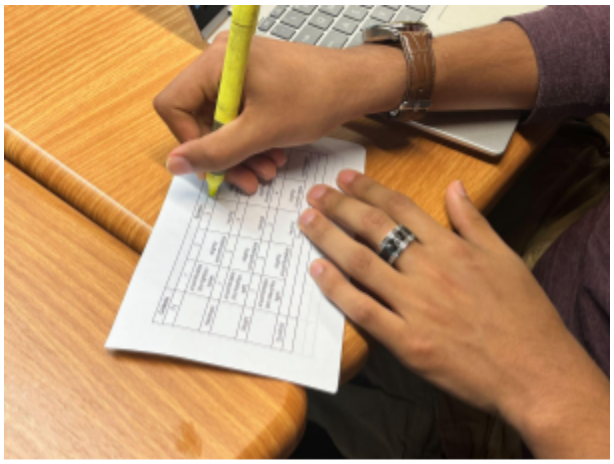

Figure 10: Patient completes earmold compatibility survey.

2. Place a heavy object that simulates the patient's weight on top of the earmold for 3-5 seconds. Fill the survey's respective durability section with the results of the test. If the earmold breaks, cracks, or faces irreversible structural damage, the test counts as a failure. Otherwise, the test was passed.
3. Sum the listed scores of each earmold test. The highest possible score an earmold prototype can receive is 20 points, whereas the minimum score is 3. An ineffective earmold is one that possesses a compatibility score of less than 10. Higher scores or scores which near the maximum value of 20 are generally considered better quality according to patient-centric feedback. Analysis may be conducted by analyzing which fabricated earmolds generate the highest compatibility scores relative to each other.

Tests. Tests regarding earmold compatibility using the developed survey were conducted for each earmold design. The compatibility survey template can be seen below.

Table 1

Earmold compatibility survey template.

Criteria	**Scores**				
Fit	1	2	3	4	5
	uncomfortable (too tight/too loose)	slightly uncomfortable	neutral	slightly comfortable	comfortable
Hardness	1	2	3	4	5
	uncomfortable (too hard/too soft)	slightly uncomfortable	neutral	slightly comfortable	comfortable
Weight	1	2	3	4	5
	uncomfortable (too heavy/too light)	slightly uncomfortable	neutral	slightly comfortable	comfortable
Durability	Pass = 5				
	Fail = 0				

When conducting these tests for each fabricated earmold, the scoring for each comfort parameter in Table 2 was recorded.

Table 2

Earmold compatibility scoring data.

Criteria	Design 1 - Concha	Design 1 - Ring	Design 3 - Shell Ring	Design 3 - Box 1	Design 3 - Box 2	**Design 4 - Box 3**
Fit	2	1	1	4	4	5
Hardness	2	2	3	5	5	5
Weight	4	4	5	4	4	4
Durability	5	5	0	5	5	5
Total	**13**	**12**	**9**	**18**	**18**	**19**

Analysis. When conducting this survey on each fabricated earmold with the test patient, scores were generated regarding the comfort and compatibility of the earmold. Figure 12 expresses the compatibility score comparison for each tested earmold.

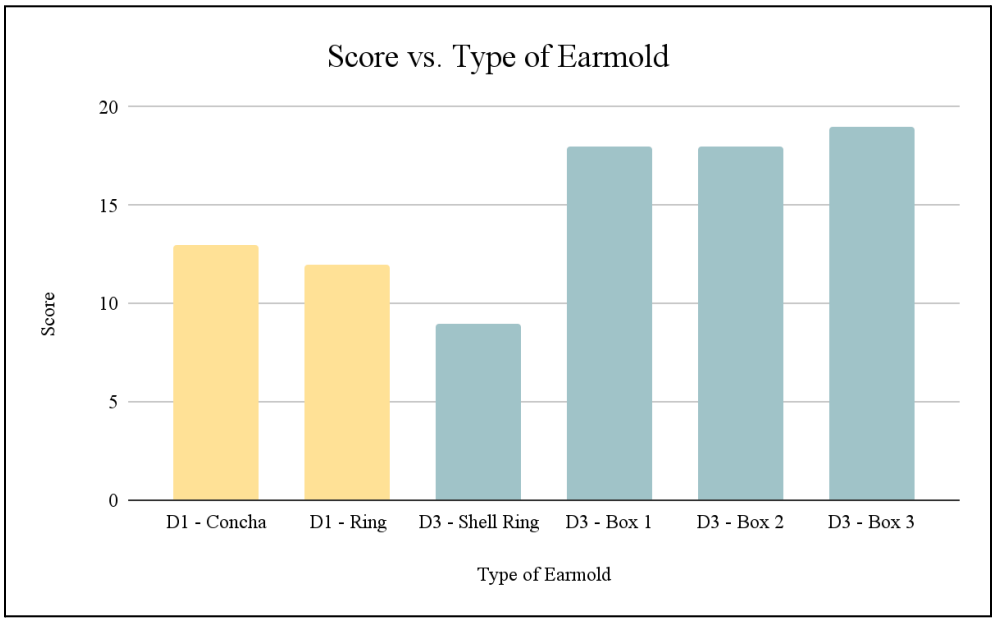

Figure 11: Score comparisons for each tested earmold

From the data gathered during this testing process, the third attempt at utilizing a box cast for the silicone-injected earmolds had the highest compatibility score of 19 with the tested patient. This third iteration of the box cast design utilized a pressure cooker to minimize air bubbles within the silicone earmold and significantly increased smoothness and reduced air pockets within the earmold's structure. The patient described during testing that this design was smoother and appeared to be more filled in than the previous box attempts. These improvements resulted in its designation as the highest-performing fabricated earmold due to its ability to maintain conditions after durability testing and due to its highest reported comfort levels in relation to hardness, fit, and weight.

Conclusions. The objective of this design study was to analyze the compatibility of the earmolds fabricating during our prototyping and testing process with the patient. Using a compatibility survey which generates a score based on the hardness, fit, weight, and durability of the earmold, it was determined that the earmold that was most compatible with the tested patient was the third attempt at silicone earmold fabrication using the box casting method. To further improve the validity and applicability of these results, further testing should be conducted with children and patients with hearing loss.

Design Study #2: Space-Time Efficiency of Fabrication Process

Purpose. The purpose of this design study is to evaluate the efficiency of each proposed fabrication process in relation to time and cost. Through performing an analysis of the spatial and time-related costs of the proposed fabrication methods, the processes proposed with each design may be taken into consideration as the final design is selected. Considering the three proposed preliminary designs, there are three fabrication methods that best align with each respective design. The first utilizes 3D resin printing to create hard, durable earmolds. The second involves utilizing 3D resin printing or 3D plastic printing to create hollow molds for silicone injection. The last proposed fabrication consideration involves integrating a structural prediction model to replace the initial impression-taking steps for both fabrication methods. With the objective of analyzing the space-time efficiency of each proposed fabrication process, this design study will propose several solutions and evaluations for each design.

Variables. Several variables were used to measure the space-time efficiency of the proposed fabrication methods.

- Independent Variables

- ➢ The proposed fabrication method: space-time efficiency will differ between each proposed fabrication method.

❖ Dependent Variables

- ➢ Time: time of each step in the process and overall time for fabrication time per earmold unit is dependent upon the proposed fabrication method. Effective earmold fabrication methods are those which do not exceed 5 hours of fabrication time, allowing the patient to request and receive a new earmold within the same day.
- ➢ Space: the space taken up by the onsite earmold fabrication site will depend upon each fabrication method. Generally, it is recommended that this fabrication site does not exceed 90 square feet in area, which is a common area for medical treatment rooms. Effective earmold fabrication methods within this context are those which do not exceed this area requirement and which can be flexibly configured depending upon the medical facility.

While the variables presented can be quantified through units of time and occupied space, the primary goal of this design study is to analyze timing for each fabrication method and introduce and determine possible layout and integration strategies for its applications in medical sites.

Materials. The materials used in this design study include the materials used for each proposed and iterated fabrication method as well as mobile devices to keep track of passing time while tests were conducted. The materials used for each fabrication method are detailed below.

❖ Design #1: Impression-based 3D-Printed Earmold Fabrication

- ➢ Ear Impression Kit - EZ Ear Impression Kit

- ➢ 3D Scanning Technology - Artec Spider 3D Scanner
- ➢ Earmold Design Automation Software - Cyfex Secret Ear Designer
- ➢ 3D Printer/Stereolithography printer & resin filament

❖ Design #2: Structural Prediction RNN Model

- ➢ Supply of longitudinal ear canal structure data - used a database of images which are referenced in the Preliminary Designs section.
- ➢ Software and tools for model development - TensorFlow, Python, ResNet

❖ Design #3v1: Impression-based Silicone Injection Earmold Fabrication (Shell Cast)

- ➢ Ear Impression Kit - EZ Ear Impression Kit
- ➢ 3D Scanning Technology - Artec Spider 3D Scanner
- ➢ Earmold Design Automation Software - Cyfex Secret Ear Designer
- ➢ 3D Printer/Stereolithography printer & resin filament
- ➢ Biocompatible Silicone - EcoFlex 00-30
- ➢ Silicone Release Agent - Mann Release Technologies Ease Release

❖ Design #3v2: Impression-based Silicone Injection Earmold Fabrication (Box Cast)

- ➢ Ear Impression Kit - EZ Ear Impression Kit
- ➢ 3D Scanning Technology - Artec Spider 3D Scanner
- ➢ Earmold Design Automation Software - Cyfex Secret Ear Designer
- ➢ 3D Printer & PLA filament
- ➢ Biocompatible Silicone - EcoFlex 00-30
- ➢ Silicone Release Agent - Mann Release Technologies Ease Release
- ➢ Pressure Pot - Bostitch 150 psi, 6 gal Pressure Pot

These materials were utilized in the fabrication process for each proposed design. During this design review, each proposed fabrication method is considered through the time and space-related costs of its implementation. The materials used will directly influence the amount of time it takes to fabricate each earmold as well as the space necessary to store the listed materials.

Methodology. To conduct a thorough analysis of the space-time costs of the earmold fabrication processes. Below is the analysis methodology for time analysis:

- Break down each fabrication method into several steps. Each step should introduce a new task which, once completed, can be considered as a time addition which adds to the total time for the analyzed process.
- Comparisons between processes may be drawn by evaluating which processes take the least amount of time. Time, in minutes, is considered an additional component of each proposed design which can be used to make evaluations and determine which proposed design should be implemented into the final design.

The following methodology can be utilized to evaluate the space efficiency of each earmold fabrication process:

- Space efficiency of the proposed earmold fabrication methods can be determined through several techniques. This first technique involves evaluating which materials are used in each fabrication method and whether a configuration can be produced that fits within the required room area of 90 sq ft.
- Considering that materials overlap between fabrication methods, the quantity of additional materials for each fabrication method which are deemed outside of the consistent materials (impression kits, scanner, software) can be summed. Whichever

fabrication method holds the highest quantity of additional "substantial" materials, or materials which require additional space rather than storage in shelving/pre-built storage locations, can be considered less efficient.

Space efficiency is primarily a quantity and space expenditure-based approach which involves discussion and qualitative evaluation prior to selecting a final design. This method, which relies on generalized assumptions and the evaluator's perceptions, has been deemed as an effective evaluation method due to its ability to account for a wide variety of material sizes and facility sizes. For example, 3D printers can be sized at drastically different levels, from tabletop printers to full, industrial-sized printers. To account for this variety as well as a variety in spatial capacity depending upon the implementation location, generalized quantitative reasons can be exercised. Space efficiency can be considered a matter of passing sizing requirements as well as reducing overall spatial expenditures (adding a significant addition, such as an additional mechanism or printer). The final design selection will be primarily based upon its implementation in standard medical treatment rooms and adaptability to varying facility sizes.

Tests. Breaking down each proposed earmold fabrication process in steps and approximating the time recorded for each step results in the total time calculations in Table 3 for each design.

Table 3

Expected time cost for each of the designs.

Proposed Designs	Design 1: Impression-based 3D-Printed Earmold Fabrication	Design 3: Impression-Based Silicone Injection Earmold Fabrication (Shell Cast)	Design 3: Impression-Based Silicone Injection Earmold Fabrication (Box Cast)	Design 3: Impression-Based Silicone Injection Earmold Fabrication (Box Cast w/ pressure pot)

Process Steps and Respective Times (min)	Take Impression	15	Take Impression	15	Take Impression	15	Take Impression	15
	Scan, Process, Export Impression	20	Scan, Process, Export Impression	20	Scan, Process, Export Impression	20	Scan, Process, Export Impression	20
	Generate Automated Earmold	10	Generate Automated Earmold	10	Generate Automated Earmold	10	Generate Automated Earmold	10
	Print & Cure Earmold	60	Print Resin/PLA shell	60	Print Box Cast	90	Print Box Cast	90
	Test for Patient Comfort	15	Prepare for Injection	7	Prepare for Injection	7	Prepare for Injection and Set Up Pressure Pot	10
			Inject Silicone & Cure	180	Inject Silicone & Cure	180	Inject Silicone & Cure	180
			Remove Earmold & Test for Patient Comfort	15	Remove Earmold & Test for Patient Comfort	15	Remove Earmold & Test for Patient Comfort	15
Total Time (min)	120		307		337		340	

Analysis. As demonstrated in Table 3, time for per-unit earmold fabrication is dependent upon the method being tested. Of the tested processes, Design 1, which directly prints hard, resin earmolds, took the least amount of time with 120 minutes, or 2 hours of total fabrication time. Design 3, which utilizes a silicone injection in a box mold and pressure pot for minimization of bubbles, had the longest fabrication period of 340 minutes, or 5 hours and 40 minutes. As the final design is being determined through an evaluation process detailed in our engineering matrix, the time per unit can be used as a measure of the process' time-related effectiveness. Figure 13 visually expresses this distribution of time for each process design when compared relatively to one another.

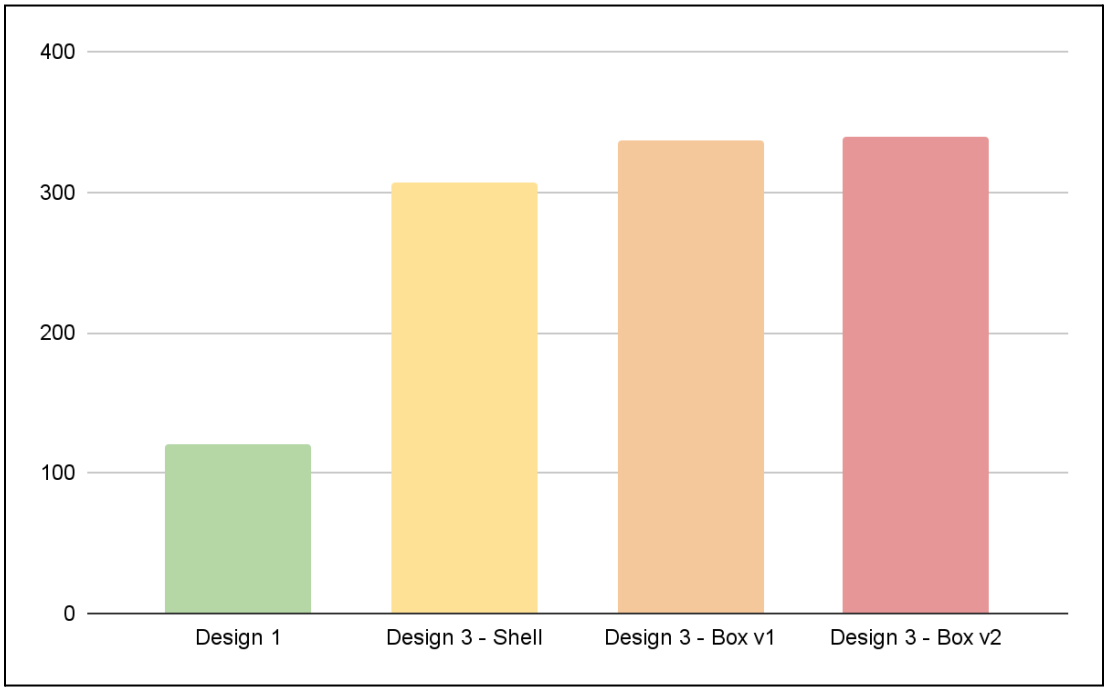

Figure 12: Relative time for each proposed fabrication process.

To evaluate spatial efficiency of each fabrication process, a design layout of fabrication implementation in a 90 square foot medical treatment room can be visualized in Figure 14.

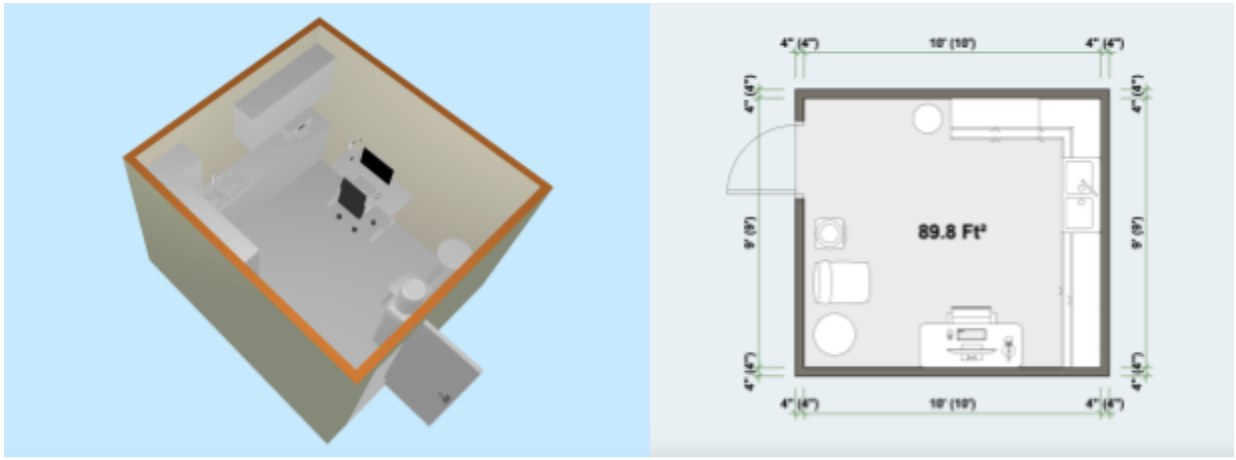

Figure 13: 3D visualization (left) and 2D floor map (right) of a potential setup for the design process.

This proposed fabrication “lab” set-up proposes a kitchen-style workspace, where the patient is offered a sitting place for comfort testing, the medical professional is offered an office configuration with a computer, chair, and stereolithography or conventional 3D printer. In

addition, the room offers an abundance of shelving and storage for the materials necessary for printing, injection, and curing of the earmold. The fabrication of the earmold can be flexibly arranged depending on the fabrication location and requires little spatial volume to fabricate.

All fabrication processes passed the area requirement and can be easily implemented into medical facilities with existing shelving, working space, access to water, and computers. When considering the impacts of spatial expenditures which exceed the common materials, fabrication methods which use silicone injection require additional materials. Further, Design #3v3, which utilizes a pressure pot and silicone box injection scheme to fabricate each earmold, requires an additional spatial expenditure of the pressure pot in relation to the other proposed methods.

Conclusions. When evaluating the space-time efficiency of each proposed fabrication method, Design #1, which utilizes fast-paced resin printing to produce solid earmolds, is the most effective in relation to the time of fabrication per unit and the spatial expenditures of its implementation in a medical facility. While this design performed best within these facets, the final design will be determined by considering the results of all design studies, including user compatibility and ease of implementation.

Design Study #3: Accuracy of Structural Prediction ML Model

Purpose. This design study aims to evaluate the efficacy of the proposed machine learning model for sequential prediction of earmold upsizing. The model was trained and evaluated using a validation set and then benchmarked with regard to accuracy, a traditional ML metric that denotes the number of correct predictions out of the number of total predictions. This accuracy value was used in conjunction with other facets of the model, such as the relevance of training data, model scope, and scalability, to establish a comprehensive evaluation of the model and determine its feasibility and place within our system.

Variables. There was one variable that was used predominantly in this design study

- Accuracy: Accuracy is the number of true positives and true negatives divided by the total number of examples. As in the name, it denotes how accurately an ML model performs on a set of data.

Materials. The materials mainly included what was used in the original design. These are as follows

- Google Colaboratory - Google Colab was used as a development environment for the training and testing of our model.
- Python - Python was used as the programming language due to the ease of implementation it provides for ML applications.
- Pillow - Pillow is an image-processing library in Python that was used to load images from the dataset into the program.
- TensorFlow - TensorFlow was the ML framework used to process the dataset, create the model, train the model, and benchmark.

Methodology. The methodology for training and benchmarking the model was as follows:

1) Load all the images of ears into a dictionary sorted by the patient's ID. Proceed to sort the images within each dictionary sequentially by time based on the timestamp provided in the filename. Create training examples by mapping each image to its subsequent image.
2) Initialize a pre-trained ResNet model via TensorFlow. Use this model to create feature embeddings for the image pairs and gather these embeddings into a dataset. Use an 80-20 split to create a training set and validation set.

3) Define a neural network architecture to be trained with an LSTM layer with 64 units, a dense layer with ReLU activation and 128 neurons, and another dense layer with 2048 neurons. Fit the model on the established dataset.
4) Observe the accuracy of the model, reported across epochs.

Tests. The final reported accuracy of the model was 61.79%.

Analysis. The model's accuracy was not bad, considering the complex nature of the task and the simplicity of the model architecture. While the reported accuracy does not meet the ideal expectations for deployment, it serves as a baseline for future improvements.

Conclusions. The study's findings indicate that while the model achieves a certain level of accuracy, there is significant room for improvement. The current accuracy of 61.79% suggests that the model can correctly predict the next stage of earmold upsizing more often than random chance, but it is not reliable enough for practical use. Further refinement of the model architecture, augmentation of the dataset, and additional feature engineering are necessary to enhance performance. Future iterations should focus on increasing the model's complexity and leveraging more sophisticated techniques such as data augmentation, transfer learning with more specialized pre-trained models, and hyperparameter tuning to achieve better results.

Engineering Matrix

Written on 5/21/24 by Ehtan Zhou. Edited on 5/21/24 by Erica Dong.

The following engineering matrix does not include the machine learning model due to it following different requirements, having nothing to compare the model to, and the model not being effective in general.

Table 3

Engineering matrix evaluation of prototypes. Each criteria is evaluated out of 10, then multiplied by its weight.

Criteria	Weight	Shell Cast	Box Cast	3D Printed
The fabricated earmold must be well-fitting and comfortable for the patient.	10	5	10	7
The earmold fabrication system must not take more than a 90 sq ft area, making it suitable for an onsite location.	9	10	10	10
Each earmold must cost at most $100 to fabricate.	10	9	8	10
The earmold must be made of soft, biocompatible material.	10	10	10	7
The earmold must be durable enough to support continuous pressure from at least 50 lbs.	7	8	10	8
The user can independently conduct the process with no more than 7 hours of training.	8	7	8	10
The necessary devices and software must cost at most $5000.	6	4	5	7
The process shall include a training manual.	4	0	10	0
A new earmold must be able to be fabricated in under 5 hours.	6	6	6	10
Total Points	**700**	**502**	**610**	**568**

Prototyping Process

Written on 5/21/24 by Erica Dong and Armaan Priyadarshan . Edited on 5/22/24 by Kayla Vallecillo and Ethan Zhou.

The first prototype, the directly 3D-printed earmold, was quick and efficiently made. However, it had a glaring weakness, that being the comfort of the patient. As the printed material was rigid and inflexible, the earmold stretched the patient's ear instead of creating a snug fit, resulting in discomfort. Additionally, for a child patient, the target audience of this design, a hard

earmold would be unsafe for physical activity; if the child were to hit or fall on their ear, a rigid structure could pose a serious threat.

The next prototype, the RNN predictive model, was not effective at predicting ear canal growth, with only a 62% accuracy, which is far too low for medical purposes. Additionally, the dataset used to train the model was unsuitable. Although a better, more comprehensive dataset was found, IRB approval is still pending, so we were unable to use it for our model. Due to these challenges, we decided to focus more on the fabrication subsystem.

The third prototype, the shell cast, took longer to print due to its complex structure and required a resin printer. A cast was chosen as soft silicone material could be injected to create a soft earmold, resolving the main issue from the first prototype. Extra time was also needed for casting the silicone earmold. We encountered several difficulties with this prototype. Due to the shell's complex structure, a severe amount of air bubbles built up, which we were unable to eliminate. The structure also caused issues in the injection process due to having to continuously hold the shell in place. Also due to the shell's complex structure, the cast had to be broken for the final earmold to be taken out. This was a tedious process that damaged the earmold inside, which was already fragile due to all of the bubbles. All of these obstacles culminated into a flimsy and uncomfortable earmold unsuitable for pediatric patients.

The fourth prototype, the box cast, enabled a simpler 3D print that did not require a resin printer, making it more accessible. The box structure also enabled removal of the earmold without damaging the cast and risking damage to the earmold. In order to eliminate bubbles, several iterations of this prototype were taken.

In the first iteration of box casting, the resulting earmold was very soft and had the desired general structure. However, the surface was rough, and there was an unwanted divot in

the back of the hearing-aid canal, which could cause some problems with sound passage and amplification. These two issues were likely caused by the buildup of air bubbles while curing, which caused imperfections.

In the following iteration, an air vent was drilled for air bubbles to escape while curing. The resulting earmold was similar to the previous iteration; however, it exhibited much smoother features, and the hearing aid canal was much more precise, with no visible defects. However, some of the silicone leaked out of the air vent while curing, resulting in a noticeable hole in the earmold.

In the final iteration, no air vent was drilled, but the mold was placed in a pressure pot. The result was smooth, with no noticeable holes or gaps. This final iteration of box casting became out final design.

Final Device Summary

Written on 5/21/24 by Erica Dong and Kayla Vallecillo . Edited on 5/22/24 by Ethan Zhou and Armaan Priyadarshan.

The final design is the following earmold fabrication process:

1. Take an ear impression from the patient and let it cure.
2. Scan the ear impression, post-process the scan with the digital scanner's accompanying software, and export it as an STL.
3. Import the ear impression scan and design the earmold box cast with Cyfex Secret Ear Designer and a mesh manipulation software such as Autodesk Fusion.
4. Print the box cast with a 3D printer of any type.
5. Put together the box cast, prepare the silicone for injection, and prepare the pressure pot.
6. Inject the silicone into the box cast and let cure.
7. Remove the earmold and test for patient comfort.

More details of each step, as well as process pictures, are included in the Build Steps section. As a note, the aim of this project was to design a process, not a specific device. The innovation lies in optimizing over time, space, and money to enable earmold fabrication at the hospital site, rather than the creation of the earmold itself. Hence, the description of the final design is focused on the process of earmold fabrication.

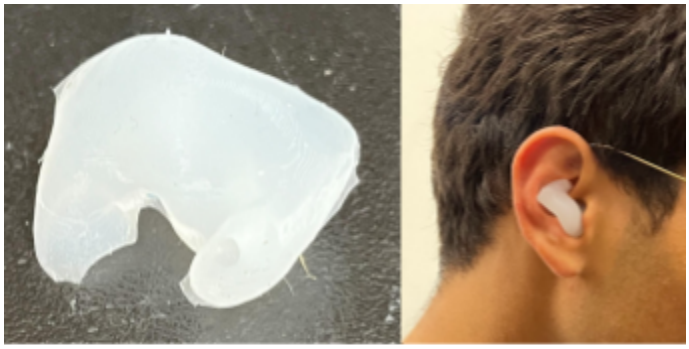

Figure 14: Example of a silicone earmold produced from the final design (left) and the earmold in the patient's ear (right).

According to Table 2, the final design has the highest patient comfort and fit score. Based on Table 3, the total time to carry out this process is 340 minutes, or 5.67 hours. The entire setup can be fit in a space of 89.8 sq ft, as seen in Figure 13. The overall budget for a hospital to set up the process is around $17,800, as described in Appendix A. After initial setup, the main costs will come from yearly software licensing renewals; filaments for 3D printing—the casts will be one-time usage, so cheap material can be used; ear impression materials; silicon material; miscellaneous casting supplies including syringes and mold release; and electricity.

Overall, the design is very effective in fulfilling our Level 1 requirements as well as most Level 2 and 3 requirements. Regarding Level 1 requirements, the final earmold is well-fitting and comfortable, soft and safe for skin, and does not cost very much to manufacture. The process also does not take too much space, making an onsite fabrication system at a hospital feasible.

Regarding Level 2 requirements, the earmold is durable and the process is not too convoluted, mainly consisting of taking impressions, operating various hardware and software tools, and making casts, so it is not difficult to learn. Unfortunately, the final cost of the system,

at around $17,800, significantly exceeds the target cost of $5,000. However, most hospitals should still be able to afford such a system, especially considering the increased convenience and elimination of the middleman, and due to common medical devices frequently being even more expensive.

Regarding Level 3 requirements, a detailed instructions manual for setting up and maintaining the system was created. Although the time limit of 5 hours for a new earmold was not reached, the estimated time of 5.67 hours is very close, and remains much lower than the weeks that the conventional earmold refitting process would take.

Materials

The following materials are used for the design, first listing the general category that can be used, then the specific material we used, if needed.

- Ear impression materials (including impression material, a syringe, and foam plugs) - EZ Ear Impression Kit
- 3D scanner and corresponding software - Artec Spider and Artec Studio
- Earmold designing software - Cyfex Secret Ear Designer
- Mesh manipulation software - Autodesk Fusion
- 3D printer, corresponding material/filament, and corresponding software - UltiMaker Filament 3D Printer, white plastic filament, and UltiMaker Digital Factory
- Silicone release spray - Mann Release Technologies Mold Release
- Tape
- Syringe
- Soft, skin-safe silicone - Ecoflex Platinum Cure Silicone Rubber
- Pressure pot

- Air compressor - Bostitch Air Compressor

CAD Files

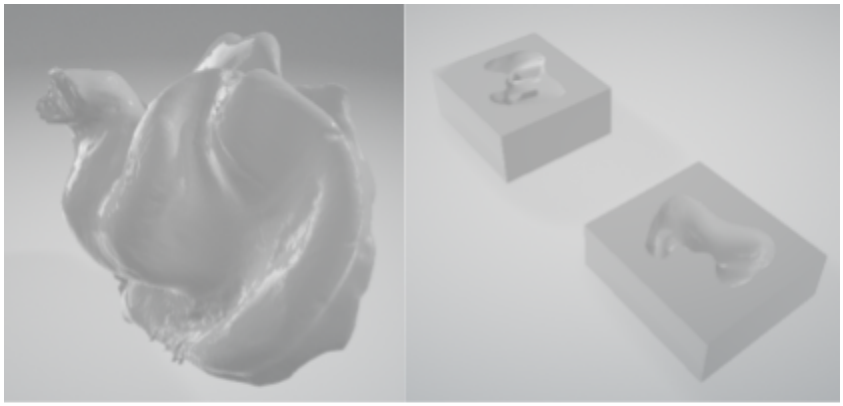

Figure 15: CAD files for the original ear impression scan (left) and the generated earmold box cast (right)

These CAD files will be slightly different for each patient, as their internal ear structure will vary.

Final Requirements Matrix

Table 4

Requirements matrix for final design.

#	*Level*	*Requirement Type*	*Requirement Statement*	***Impression-based Silicone Injection Earmold Fabrication (v2 - Box Mold)***
1	1	Functional	The fabricated earmold must be well-fitting and comfortable for the patient.	Pass
2	1	Physical	The earmold fabrication system must not take more than a 90 sq ft area, making it suitable for an onsite location.	Pass
3	1	Cost	Each earmold must cost at most $100 to fabricate.	Pass

4	1	Physical	The earmold must be made of soft, biocompatible material.	Pass
5	2	Physical	The earmold must be durable enough to support continuous pressure from at least 50 lbs.	Pass
6	2	User	The user can independently conduct the process with no more than 7 hours of training.	Pass
7	2	Cost	The necessary devices and software must cost at most $5000.	Fail
8	2	Documentation	There must be a logbook that is regularly updated with progress.	Pass
9	3	Documentation	The process shall include a training manual.	Pass
10	3	Cost	A new earmold must be able to be fabricated in under 5 hours.	Fail

Future Work

Written on 5/21/24 by Erica Dong. Edited on 5/22/24 by Kayla Vallecillo, Ethan Zhou, and Armaan Priyadarshan.

Next steps for this design involve further optimizing the process by experimenting with different earmold casting designs that require different amounts of material, and exploring more 3D printing strategies. For example, a smaller earmold would require less silicone to cure, but more cast material to be printed. This effect leads to certain tradeoffs in time, product robustness, and cost. Varying the 3D printing strategies, such as resin printing versus filament printing, and differing support structures, have a similar tradeoff effect.

Balancing cost, quality of materials, and time is also a tradeoff that must be investigated further. Directly 3D printing silicon is feasible, but the materials required are much more expensive and less accessible. Similarly, higher quality casting and earmold material would be

desirable for a more effective process, but these materials also cost more than generic silicon and plastic.

Potential other areas of exploration include finding a more efficient method of 3D scanning the ear canal and formalizing a system for adjusting the earmold design based on client feedback, which is essential for real-world implementation of this system. The predictive model could also be revisited once IRB approval for a better dataset is obtained. Despite these areas for improvement, our final design is already robust and has the potential to truly improve the comfort and development of children with hearing aids.

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Appendix A

Bill of Materials

Material	Vendor	Quantity	Cost ($)
EZ Ear Impression Kit	E.A.R. Inc.	1	$34.95
Artec Spider*	Ebay	1	$9,500
Cyfex Secret Ear Designer**	Cyfex	1	Quoted
Autodesk Fusion**	Autodesk	1	$680/year
UltiMaker FDM 3D Printer*	Amazon	1	$6,950
White PLA Filament*	Amazon	1	$24.99
Mann Release Technologies Mold Release*	Amazon	1	$22.27
Tape *	Amazon	1	$9.99
Syringe*	Amazon	1	$0.07
Pressure pot*	Amazon	1	$260
Bostitch Air Compressor*	Amazon	1	$289
		Total	$17,771.27

**These materials were donated or loaned, so costs are estimates and material identification is general.*

***This software was obtained for free with a student license, so enterprise costs are generally unknown.*

Appendix B

Tools

Many of these are included in Appendix A as well.

Name	Purpose
3D Printer	Printing the cast
Cyfex Secret Ear Designer	Designing the earmold cast
Autodesk Fusion	Slicing the box cast
Artec Studio	Postprocessing the ear impression scan
UltiMaker Digital Factory	Preparing the STL for 3D printing
Pressure Pot	Eliminating bubbles while the earmold is curing
Canva	Designing fair poster
Google Slides	Making fair poster