NeoMold: A 3D-Printed Customizable Ear Mold for Congenital Ear Differences in Neonates

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Project Goal

Problem

Approximately 1 in 6000 newborns are born with congenital ear deformities, with Hispanic, Native American, and Asian-Pacific Islander communities being disproportionately affected [1]. The most common types of deformities include prominent ear, Stahl's ear, and lidding (Fig. 1) [2]. Children with outer ear deformities are at a higher risk of experiencing psychosocial distress [3].

Current solutions to correct ear deformities have many limitations, as summarized in Table 1. To properly correct outer ear deformities non-surgically, diagnosis and treatment within 2-6 weeks of birth is crucial. This limited time window is difficult to meet for the underserved communities most affected. Ear molding devices are also often marked up and are not customizable to each patient. Surgical correction is considered an aesthetic plastic surgery, which is often expensive and paid out of pocket.

Figure 1. Prominent ear, Stahl's ear, and lidding deformity (left to right) [4]

Current Solutions	Strengths	Limitations
Reconstructive surgery	viable beyond 2-6 weeks, standard treatment [5]	expensive, invasive, surgical complications [5]
EarWell (non-surgical molding)	highly effective (>90%), early initiation [5]	aggressive, bulky, dislodgement, poorly tolerated [4]
EarBuddies (non-surgical molding)	accessible to public, easy management [6]	skin irritation, unmonitored, low effectiveness [6]

Table 1. Current solutions for correcting congenital outer ear deformities and their associated strengths and limitations

Goals

1. Create a customizable ear mold to non-surgically correct outer ear deformities in neonates within the first 2-6 weeks of birth
2. Optimize the ear mold to reduce costs and manufacturing time and maximize comfort

Impact

With a 3D-printable ear mold customized to each individual newborn, lower manufacturing time and cost and improved ease of use for non-physicians will increase timely, economic, and geographic accessibility to non-surgical ear deformity correction.

Project Design

Newborn is diagnosed with outer ear deformity → Practitioner/ parent performs 3D ear scan → Develop CAD model of patient-specific ear mold device (Fig. 2) → 3D-print ear mold device (Figs. 3, 4) → Ship 3D ear molding device to practitioner/ parent → 1. Attach back splint around ear 2. Fold cuffs to shape helical rim

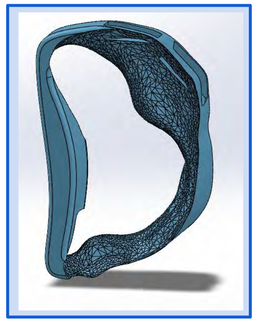


Figure 2. CAD model of back splint of ear mold.

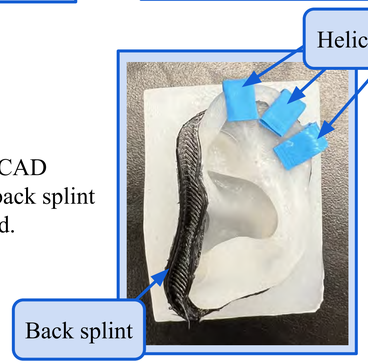


Figure 3. Top view of first prototype: 3D printed back splint and 3 helical rim cuffs (stainless steel wrapped in Chinchilla flexible filament) on adult silicone ear model.

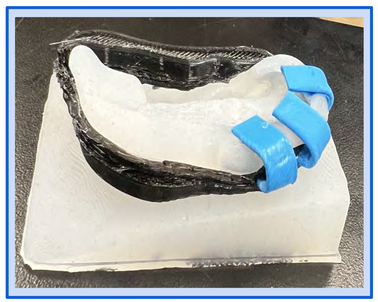


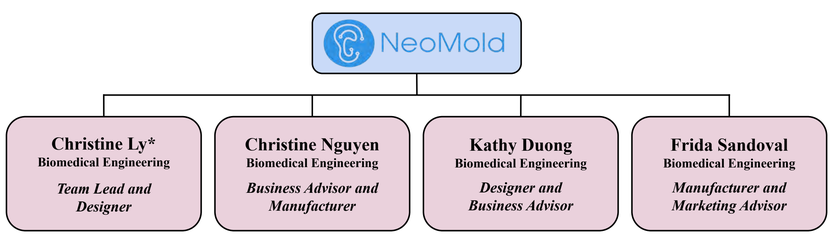
Figure 4. Right view of first prototype on adult silicone ear model.

Device Verification and Validation

User Need	Design Requirement	Applicable Standard(s)	Design Verification	Design Validation
Short application time	Application Time < 10 minutes	ISO 14971, ISO 13485, IEC 62366	Measure time to apply ear mold on ear model	Physician application
Easy application	Average rating of 3 or higher for ease of use	ISO 14971, ISO 13485, IEC 62366	Collect ratings after subject applies ear mold to ear model	Physician application & usability testing
Cuffs do not dislodge from back splint	*Glue joint strength ≥ EarWell adhesive strength	ISO 14971, ASTM F04.15, ISO 13485	Free body diagrams Instron testing until failure	Simulation testing
Cause little to no skin irritation & ulcerations	Use biocompatible material	ISO 14971, ISO 10993, ASTM F04.15, ISO 13485	Pressure measurements and mapping Literature review	Simulation testing Physician application
Quick manufacturing	< 1 week turnaround	ISO 14971, IEC 62366, ISO 16142, ISO 13485	Measure time to design and manufacture	Measure time to design, manufacture, and ship ear mold to physician

** Testing in progress*

Team Organizational Chart



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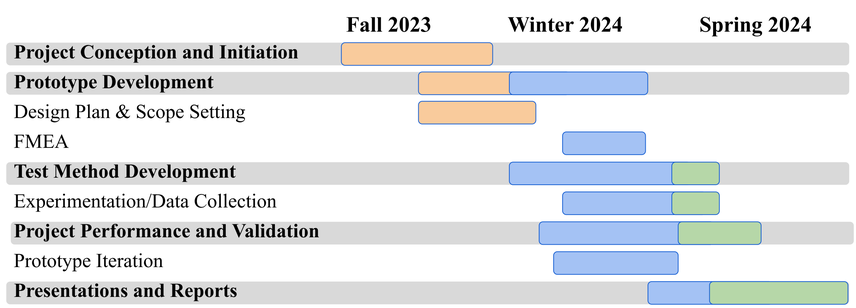
Timeline



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