

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

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

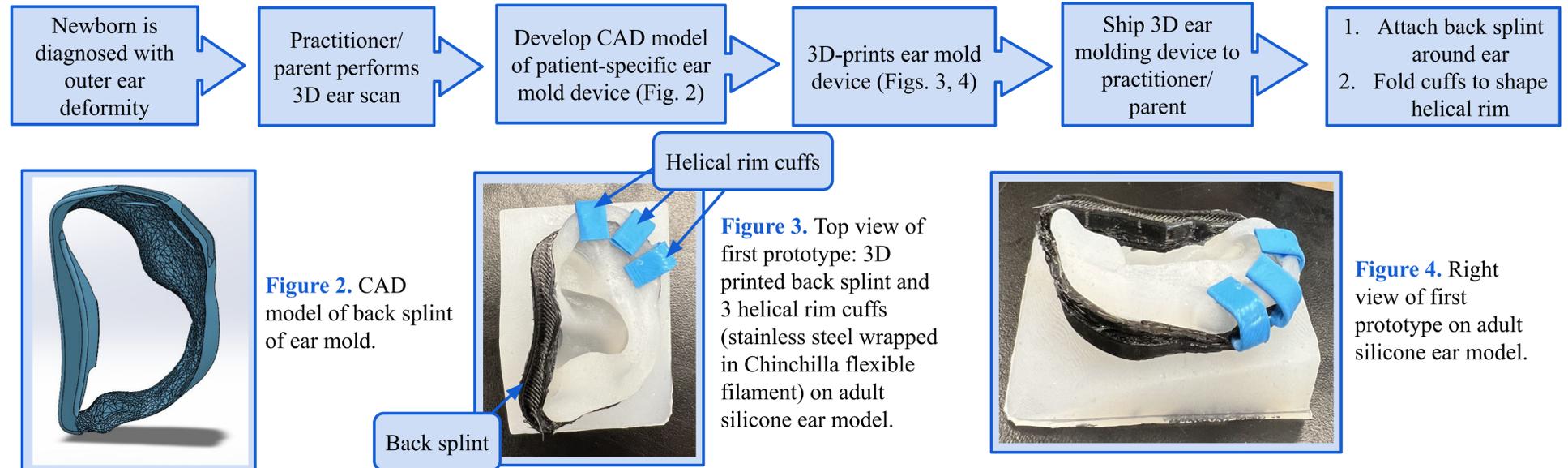
Goals

1. Create a customizable ear mold to non-surgically correct outer ear deformities in neonates within the first 2-6 weeks of life
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

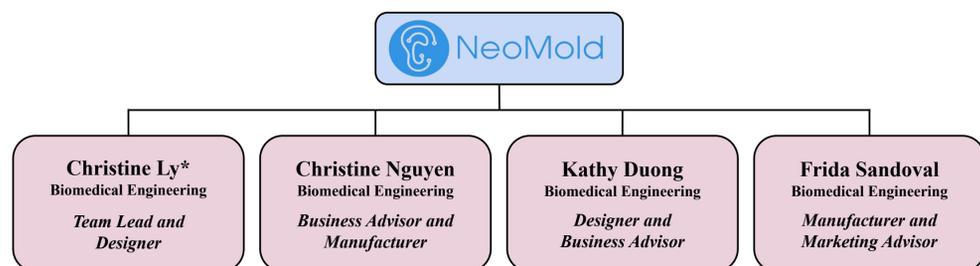


Device Verification and Validation

| 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 13485, IEC 62366, ISO 16142, ISO 13485 | Measure time to design and manufacture | Measure time to design, manufacture, and ship ear mold to physician |

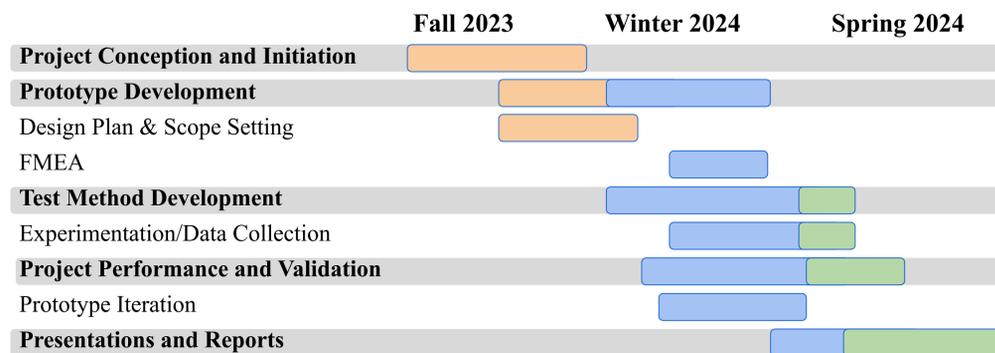
* Testing in progress

Team Organizational Chart



* Inquiries regarding this project should be directed to Christine Ly at cly13@uci.edu.

Timeline



References

- [1] Congenital deformities of the outer ear," Yale Medicine, <https://www.yalemedicine.org/conditions/congenital-deformities-of-the-outer-ear#:~:text=Options%20range%20from%20noninvasive%20ear,some%20cases%2C%20help%20restore%20hearing> (accessed Feb. 19, 2023).
- [2] C. H. Curtis, "Bright futures," Phoenix Children's Hospital, <https://phoenixchildrens.org/blog/2021/04/ear-deformities-newborns-and-ear-molding> (accessed Feb. 19, 2023).
- [3] J. E. Woo et al., "Effectiveness of ear splint therapy for ear deformities," *Annals of Rehabilitation Medicine*, vol. 41, no. 1, p. 138, 2017. doi:10.5535/arm.2017.41.1.138
- [4] "Earwell® - Becon medical," EarWell® Infant Ear Correction System, <https://www.earwells.com/> (accessed Feb. 19, 2023).
- [5] M. M. W. Feijen, C. van Cruchten, P. E. Payne, and R. R. van der Hulst, "Non-surgical correction of congenital ear anomalies: A review of the literature," *Plastic and Reconstructive Surgery - Global Open*, vol. 8, no. 11, 2020. doi:10.1097/gox.00000000000003250
- [6] EarBuddiesTM, "How does early ear correction work?," EarBuddies, <https://www.earbuddies.com/pages/how-it-works> (accessed Feb. 19, 2023).