

## PROBLEM STATEMENT

Newly reconstructed ears after microtia reconstruction surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing. Current subdermal drains often lose suction and dressings fail to seal around the ear's contour which increases a burden on clinical staff. A device specifically shaped for postoperative ear anatomy would provide a more stable seal, more reliable pressure delivery, more reliable wound drainage, and greater protection during the critical early healing period.

## BACKGROUND

- Congenital condition where the ear is malformed/absent
  - Typically only affects 1 ear rather than both
- 1 in 5,000-7,000 births worldwide [1]
  - Andean, Native American, or Asian descent



Figure 1: Microtia Patients pre-surgery [3]

- Current Treatments: Autologous Cartilage Staged Reconstruction
  - 91.3% of plastic surgeons choose this method [2]

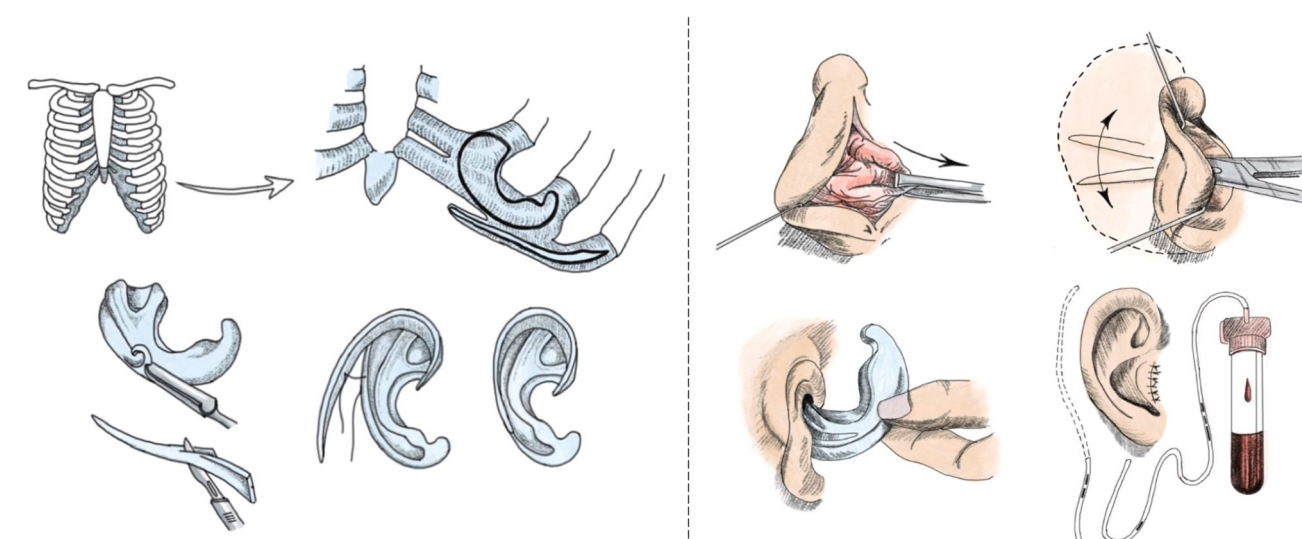


Figure 2: Reconstruction Surgery [4]

## MOTIVATION

- Complication rate - 16.2% [5]
- Constant pressure
  - Promote healing
- Automated wound drain
  - Mitigation of backflow
  - Reduces complication rate
  - Reduces need for drain maintenance



Figure 3: Manual JP Wound Drain [6]

- **Combine need for constant pressure & automated drainage - vacuum!**

## DESIGN SPECIFICATIONS

- -50 mmHg (conservative) to -125 mmHg (standard) [4]
- Design must be able to maintain seal for 7 days [7]
  - Must be child proof, tamper resistant
- Must maintain consistent, equal pressure to both wound drain and dressing
- \$1000 budget
- <1µL backflow
- Must not deform significantly under unexpected loading
- ISO 10993, 14971, IEC 62366 [8][9][10]

## FINAL DESIGN



Figure 4: SolidWorks model of final design, interior of earmuff included



Figure 5: The earmuff / headphone piece situated on a model while negative pressure is applied

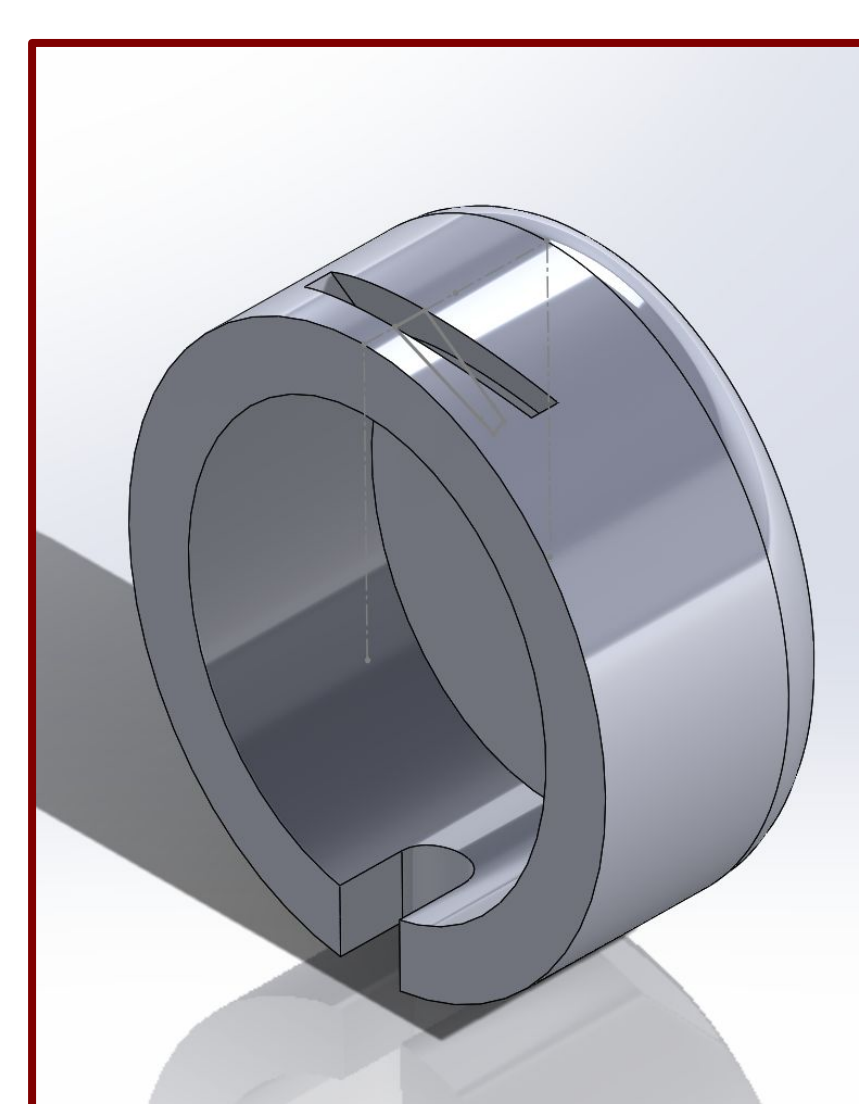


Figure 6: SolidWorks model of earmuff

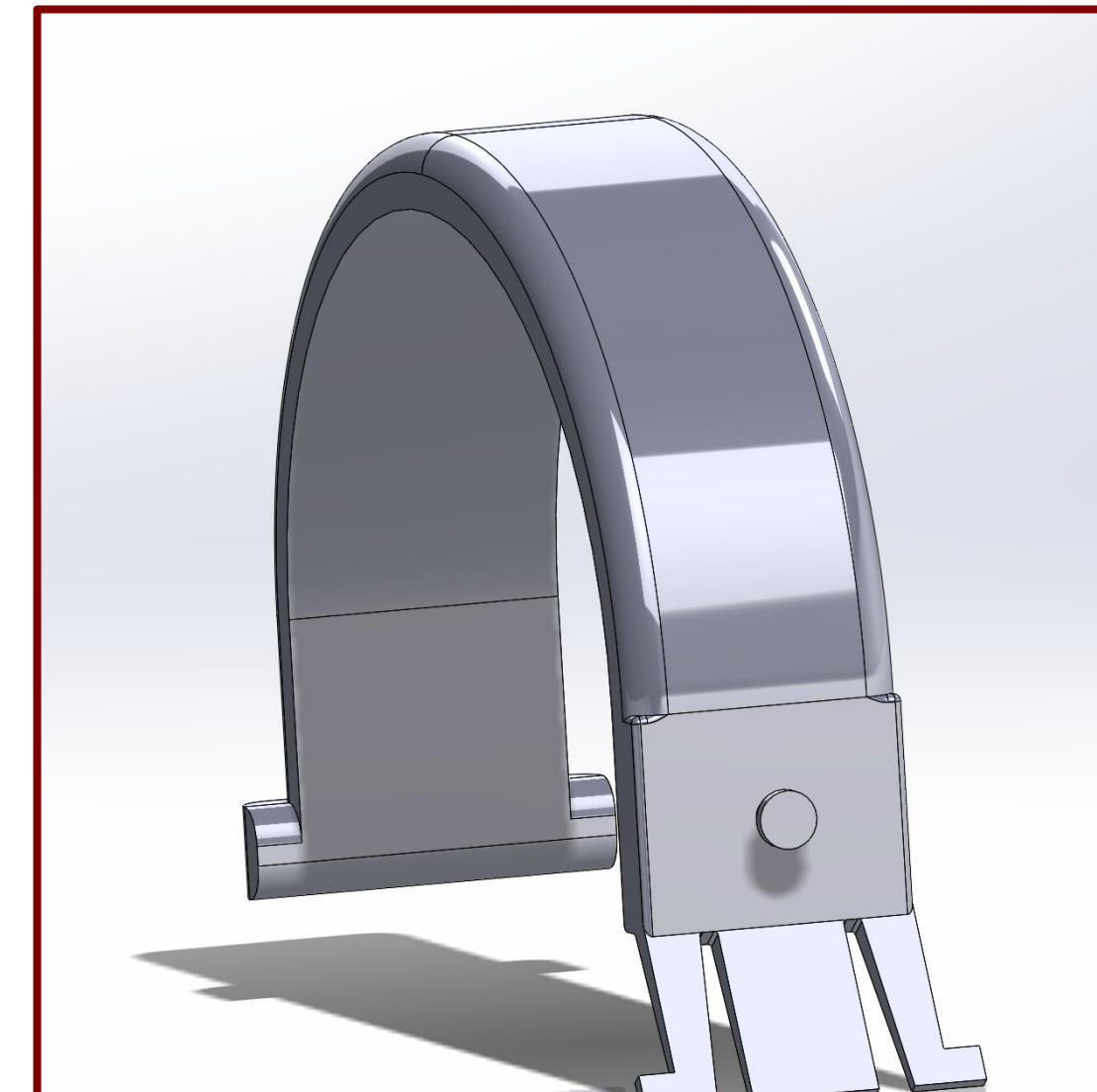
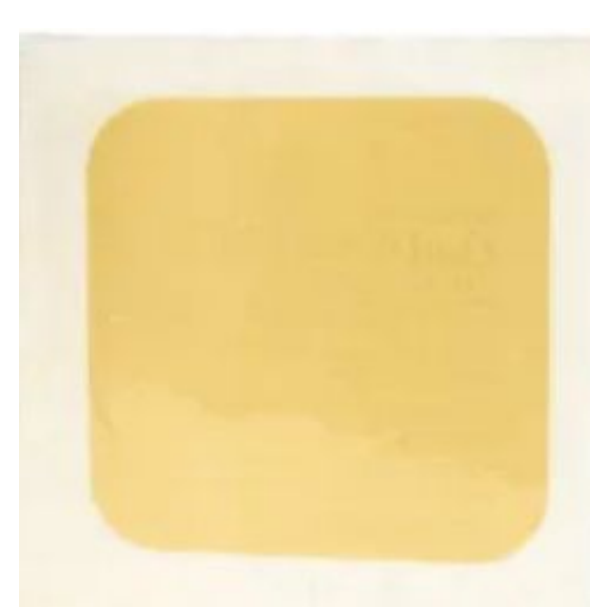


Figure 7: SolidWorks model of headband

- Headphone inspired design
  - Modular components
- 3D printed with Thermoplastic Polyurethane (TPU)
- 'Slide and Lock' mechanism used to connect the ear muff and headband
- Notches on the headband used for elastic material
  - Additional security around circumference of the head
- Cylindrical indent for NPWT tubing

### Skin-facing



- **Duoderm**
  - Skin-compatible
  - Microporous



- **Polyurethane Foam**
  - Distributes pressure evenly
  - Conformable per surgery stage (flat or crescent)



- **Adhesive Layer**
  - Allows pressure maintenance in a closed system



- **Silicone Stopper**
  - Vacuum feed-through for catheter

### Purpose

- Contours ear for both post stage 1 and stage 2 surgery
- Vacuum compatibility - efferent tube

### Application Steps

1. Apply duoderm-foam dressing around ear
2. Apply adhesive layer
3. Cut hole to allow tubing addition
4. Insert silicone stopper
5. Insert efferent tubing



Figure 8: Duoderm and Foam Dressing with Crescent Contour



Figure 9: Dressing with Applied Adhesive Layer for Vacuum Compatibility

## TESTING

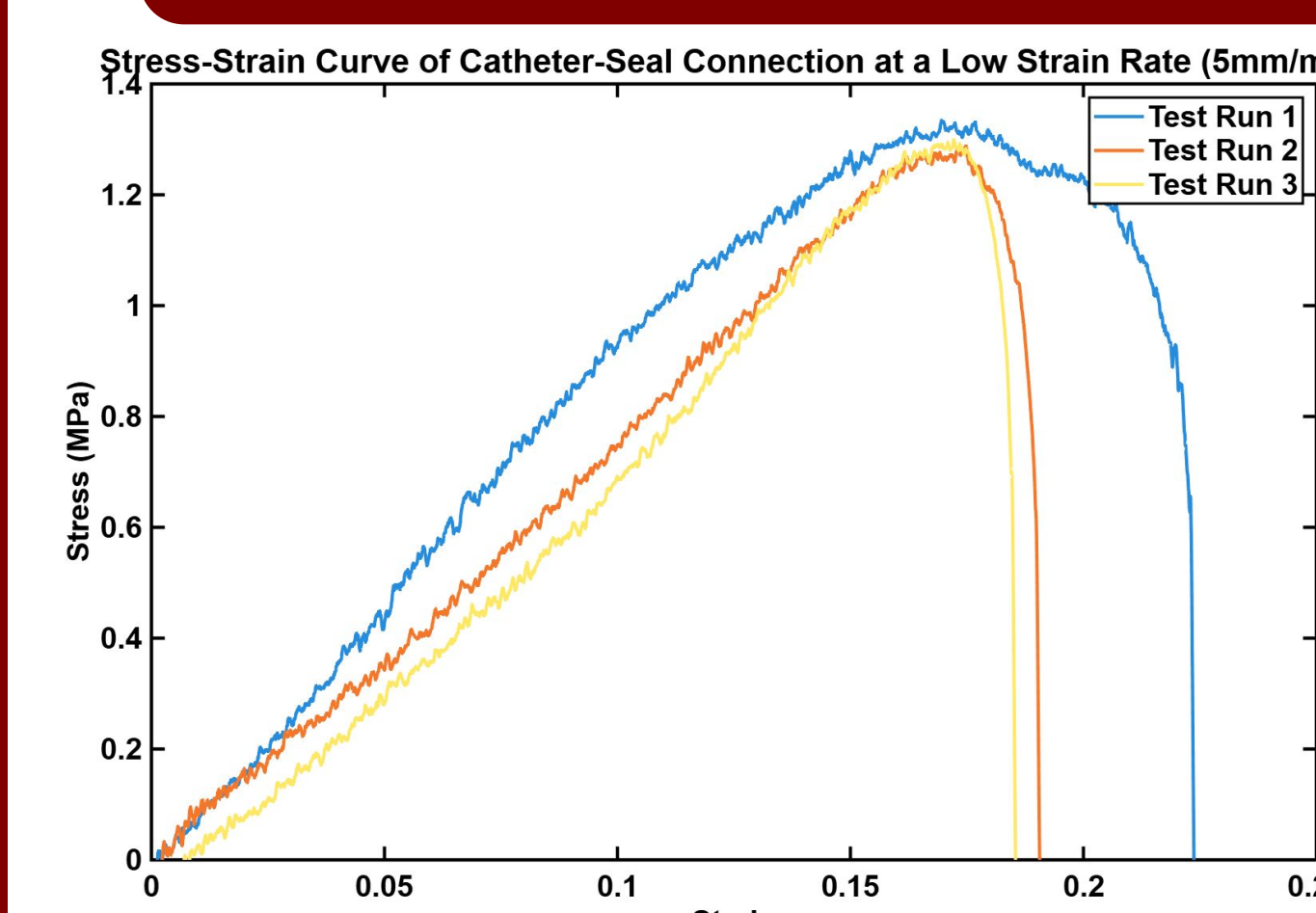


Figure 10: Stress-Strain Curve for Low Strain Rate

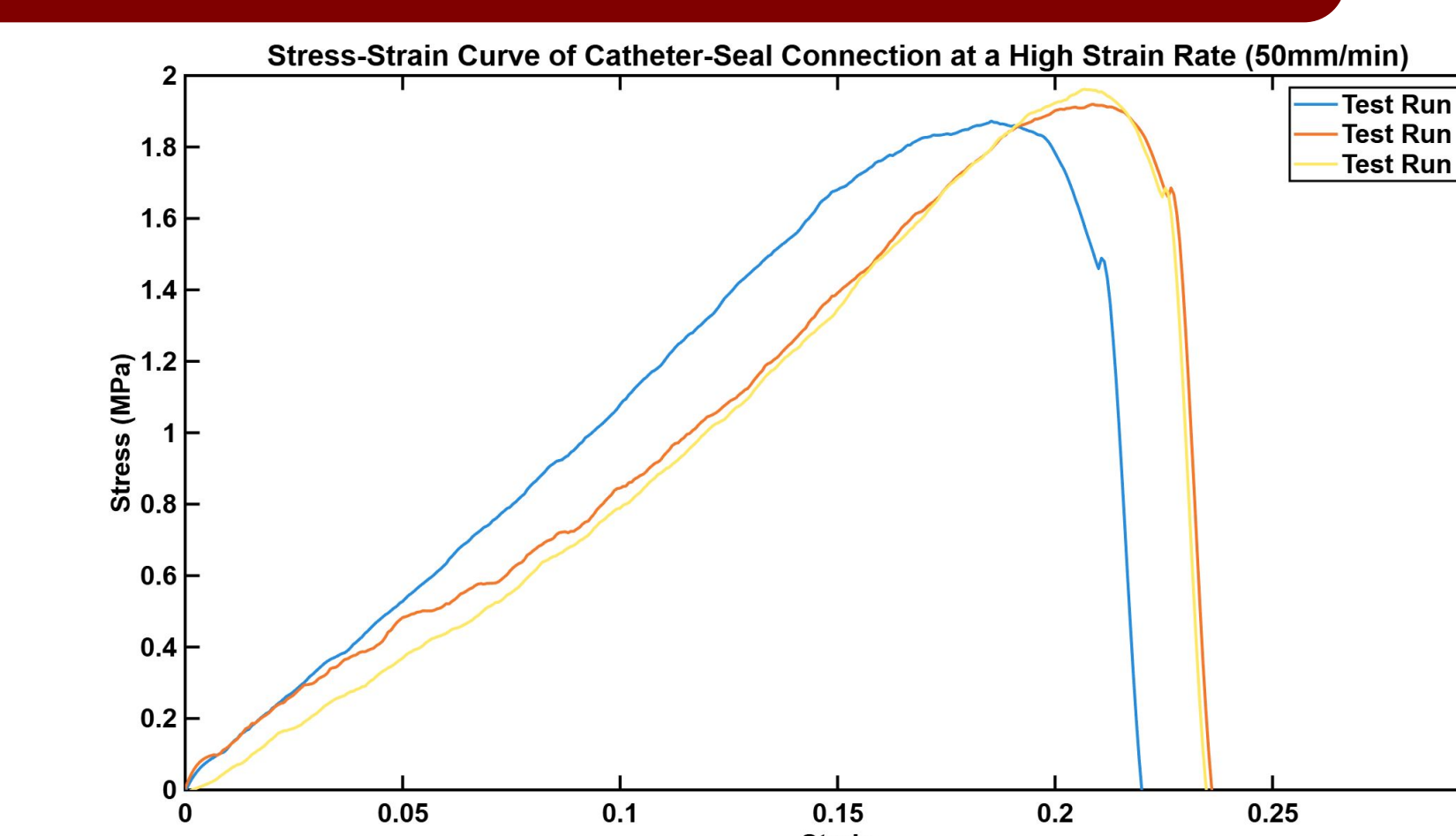


Figure 11: Stress-Strain Curve for High Strain Rate

- Stress-Strain Curve demonstrates high extensibility of prototype
- Validates fail-safe mechanism → tube disassociation instead of seal rip
- Youngs Modulus Graph 1: E1 = 10.2259 MPa
- Youngs Modulus for Graph 2: E2 = 10.0766 MPa

### Average Seal Stretch Before and During Suction at Varying Pressures

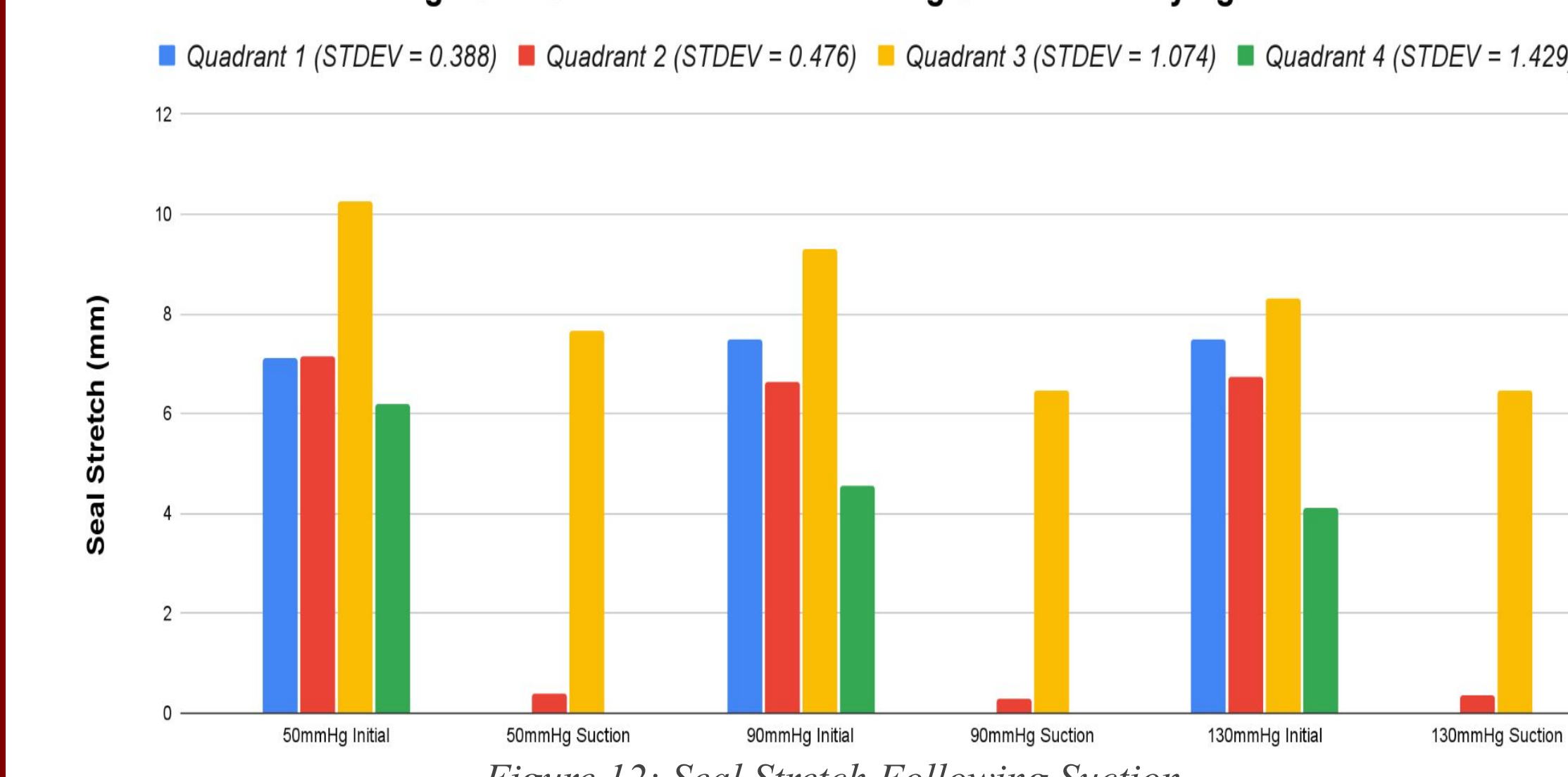


Figure 12: Seal Stretch Following Suction

- Suction test performed to ensure functionality, expecting 0 mm during suction
- STDEV for each quadrant is minimal → consistency across multiple iterations
- Quadrant 3 contains insertion hole → higher stretch during suction
- Quadrant 2 ear shape causes slight stretch during suction



Figure 13: Quadrant Locations

## FUTURE WORK

- Development of a scalable fabrication protocol suitable for commercial manufacturing
- Translation of the device into a portable kit for pediatric patients
- Testing in a clinical setting
- Development of a tube latch to provide additional mechanical strength and ensure one-way drainage

## REFERENCES

- [1] Stanford Medicine, Otolaryngology—Head & Neck Surgery, "Microtia," Accessed: Oct. 2, 2025. Supports prevalence (~1 in 5,000), unilateral >90%. [Online]. Available: <https://med.stanford.edu/ohns/ohns-healthcare/earinstitute/conditions-we-treat/microtia.html>
- [2] N. Baluch et al., "Auricular reconstruction for microtia: A review of available methods," *Plastic Surgery (Oakville)*, vol. 22, no. 1, pp. 39–43, 2014. Summarizes autologous vs. prosthetic options. [Online]. Available: <https://pmc.ncbi.nlm.nih.gov/articles/PMC412842/>
- [3] L. Camison, R. C. Lisk, and M. Soldanska, "Microtia," *Clinics in Plastic Surgery*, vol. 52, no. 2, pp. 227–244, Apr. 2025.
- [4] A. Panayi, "Evidence based review of negative pressure wound therapy," *World Journal of Dermatology*, vol. 6, no. 1, pp. 1–16, doi: <https://doi.org/10.5314/wjd.v6.i1.1>.
- [5] X. Long, N. Yu, J. Huang, and X. Wang, "Complication rate of autologous cartilage microtia reconstruction: A systematic review," *Plastic and reconstructive surgery*. Global open, <https://pmc.ncbi.nlm.nih.gov/articles/PMC4174059/> (accessed Dec. 4, 2025).
- [6] Cancer Resources from OncoLink | Treatment, Research, "Jackson-Pratt (JP) Surgical Drain," *OncoLink*, [www.oncolink.org/cancer-treatment/hospital-helpers/jackson-pratt-jp-surgical-drain](https://www.oncolink.org/cancer-treatment/hospital-helpers/jackson-pratt-jp-surgical-drain). Accessed 3 Dec. 2025.
- [7] R. Strlika, "CRITICAL CARE AIR TRANSPORT CLINICAL PRACTICE GUIDELINE - Negative Pressure Wound Therapy," Dec. 12, 2013. [https://jts.health.mil/assets/docs/cpgs/NPWT\\_CCATT\\_26\\_Feb\\_2025.pdf](https://jts.health.mil/assets/docs/cpgs/NPWT_CCATT_26_Feb_2025.pdf) (accessed Sep. 18, 2025).
- [8] O. for, "ISO 10993-1:2018," ISO, 2018. <https://www.iso.org/standard/68936.html#itcycle>
- [9] International Organization for Standardization, "ISO 14971:2019," ISO, Dec. 2019. <https://www.iso.org/standard/72704.html>
- [10] International Organization for Standardization, "IEC 62366-1:2015," ISO, 2015. <https://www.iso.org/standard/63179.html>
- [11] "Y-connectors," *shop.raumedic*, <https://shop.raumedic.com/products/y-connectors> (accessed Dec. 4, 2025).

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