EarVac: Negative Pressure Wound Therapy Device

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BME Design Practicum 400, Fall 2025

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 temporary drains often lose suction and dressings fail to seal around the ear's contours 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

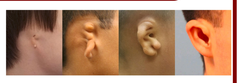


Figure 1: Microtia Patients pre-surgery [3]

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

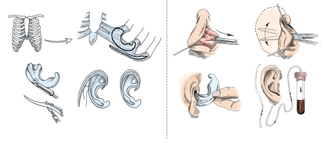


Figure 2: Reconstruction Surgery [4]

Motivation

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

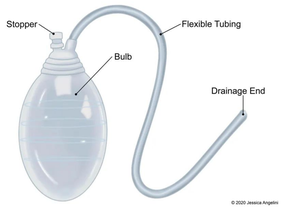


Figure 3: Manual JP Wound Drain [6]

- **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: SolidWorks model of final design, exterior of earmuff included

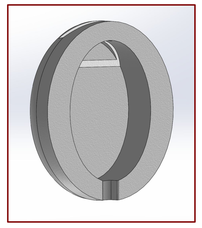


Figure 6: SolidWorks model of earmuff

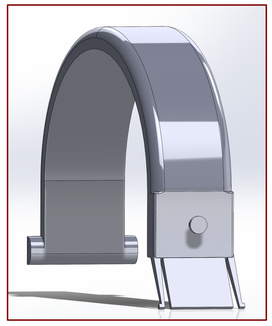
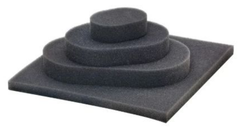


Figure 7: SolidWorks model of headband

- 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 → **Top**

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



- **Polyurethane Foam**
  - Distributes pressure evenly
  - Slit within to accommodate ear flap

- **Adhesive Layer**
  - Creates seal
  - Allows pressure maintenance in system

Figure 8: Duoderm and Foam Dressing with Crescent Contour

Figure 9: Dressing with Applied Adhesive Layer for Vacuum Compatibility

Purpose

- Crescent-back for fit around ear
- Foam surrounds to avoid crushing of auricle
- 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. Implement efferent tubing

Testing

SOLIDWORKS Deformation Simulation

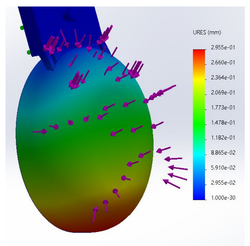


Figure 10: 5N Applied Force

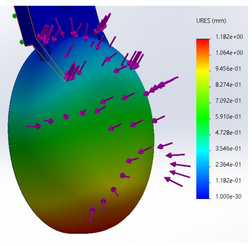


Figure 11: 20N Applied Force

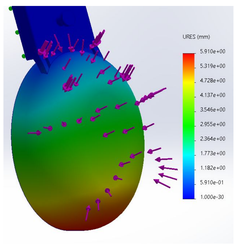


Figure 12: 100N Applied Force

- Illustrates deformation by tube hole
  - 5N Force: Deformation = ~0.2955mm
  - 20N Force: Deformation = ~1.182mm
  - 100N Force: Deformation = ~5.910mm
- High deformation with TPU → Switch to more industrial material

- Future testing planned for comfort, durability, and function
  - Strength of seal
  - Connection points
  - Fluid removal rate

Future Work

- Finish Fabrication
  - Implement y-connector
    - Evaluate equal size tubing
  - Adjustable headband
- Prototype testing
  - Continuous negative pressure transmission test
  - Consistent vacuum seal test
  - Strength of tube/seal connection test

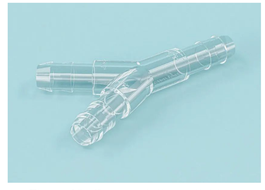


Figure 10: Commercially available y-connector [11]

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Acknowledgements

The team would like to thank our clients, Dr. Daniel Cho & Ms. Nada Botros, as well as our advisor, Dr. Russ Johnson for their continued support and involvement throughout this process. Additionally, the team would like to thank Ms. Jasmine Craig, Mr. Muhaison Ibrahim, and Dr. John Puccinelli for their support.