



Negative Pressure Wound Therapy Device for Improved Microtia Surgery Recovery

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Clients

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Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid build up, 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.

Microtia Background

- Congenital condition where the external ear is malformed or absent
 - Most often unilateral rather than bilateral [1]
- 1 in 5,000-7,000 births worldwide [1]
 - Andean, Native American, or Asian descent
- Current treatments:
 - Surgical reconstruction - using rib cartilage [2]
 - Prosthetic ears - cosmetic replacement
- 91.3% of surgeons choose autologous cartilage staged reconstruction (National Survey of American Society of Plastic Surgeons) [3]



Figure 1: Microtia patients

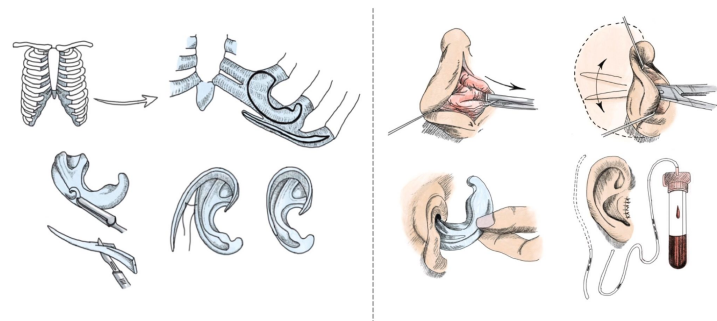


Figure 2: Reconstruction surgery

Motivation

- Clinical challenge:
 - Post-operative shaping and healing require both:[4]
 - Stable pressure
 - Controlled drainage
 - Complication rate:16.2% in average with a range of 0-72.9% [3]
 - During microtia reconstruction the exudate fluid is particularly apt to collect in the dead space of the concavo-convex shape of the frame [5]
 - Infection, skin necrosis, and cartilage exposure
 - NPWT therefore acts as a continuous external drainage system and promotes tissue adhesion



Product Design Specifications

- Device that maintains negative pressure for up to 7 days continuously
 - -125 mmHg (standard) to -50 mmHg (conservative) [6]
- Must allow for additional vacuum line for drainage / adherence
- Compatible with handheld vacuum units
- Must provide external protection of ear
- ISO 10993 [7], IEC 62366 [8]
- Must be comfortable for long periods of wear
 - ~250g - 350g weight [9]
 - Non-bulky, breathable
- Must mitigate fluid backflow / fluid buildup, tolerance 1 μ L
- Budget: \$1000



Figure 3: NPWT Devices

Existing Products

- 3M Prevena Incisional Vac
 - Ideal operating conditions / dressing components
 - Does not fit ear
 - Is not compatible with additional vacuum line
- Other negative pressure wound therapy (NPWT) devices
 - Often used in open wounds
 - Not specialized for delicate over-ear fit



Figure 4: 3M Prevena



Figure 5: Traditional NPWT Dressing Components

Design 1: Hat

- 1 → Beanie holds inner components in place
- 2 → Drain tubes for fluid via incisional VAC
- 3 & 4 → Location and design of inner components
- 4 → Duoderm, foam, and adhesive seal around incision

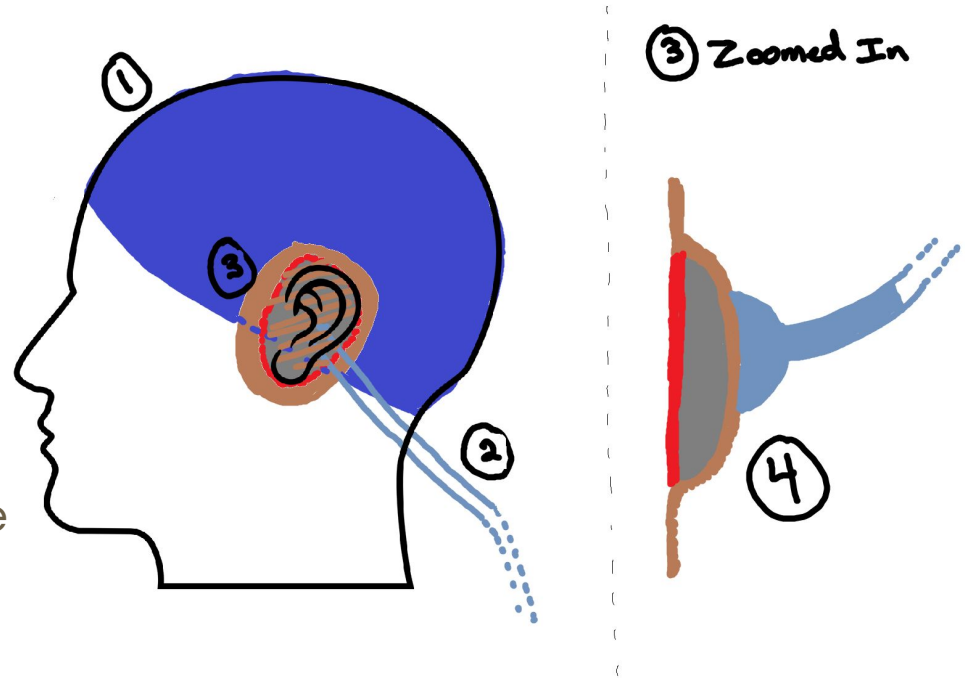


Figure 6: Preliminary Design of Hat

Design 2: Headphone

- 1 → Adjustable head strap
- 2 → Drain tube for fluid via incisional VAC
- 3 → Wound drain tube
- 4 → Headphone component
- 5 & 6 → Duoderm, foam, adhesive seal with hard covering

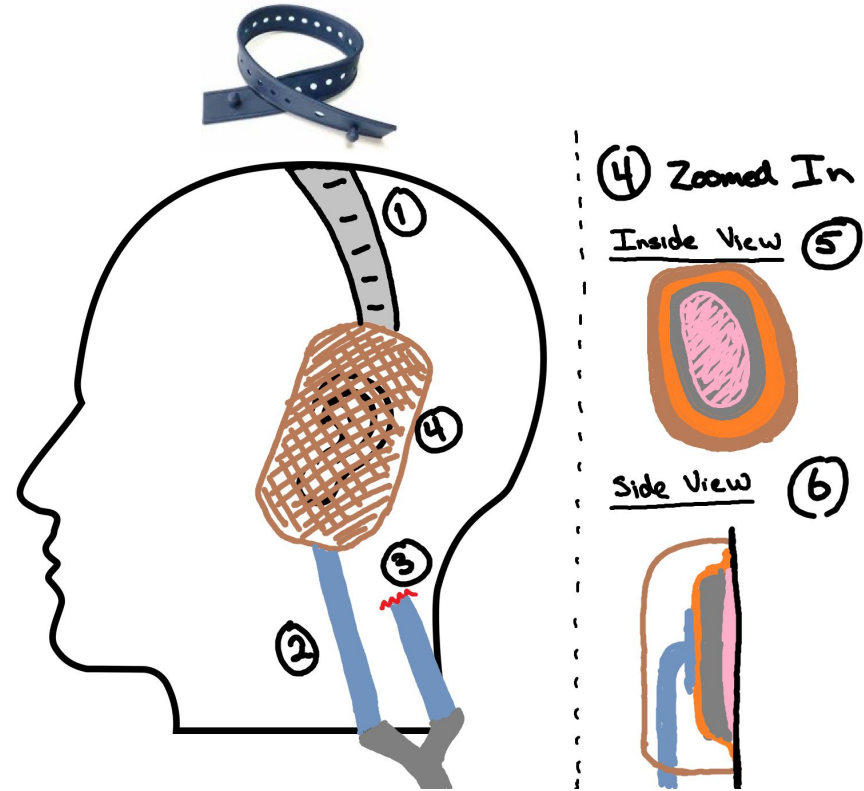


Figure 7: Preliminary Design of Headphone

Design 3: Headband

- 1 → Headband across forehead and back of head
- 2 → Inner components securely placed around incision site
- 3 → Duoderm, foam, adhesive, seal by ear
- 3 → Hard cover around the seal
- 3 → Drain tube for fluid via incisional VAC

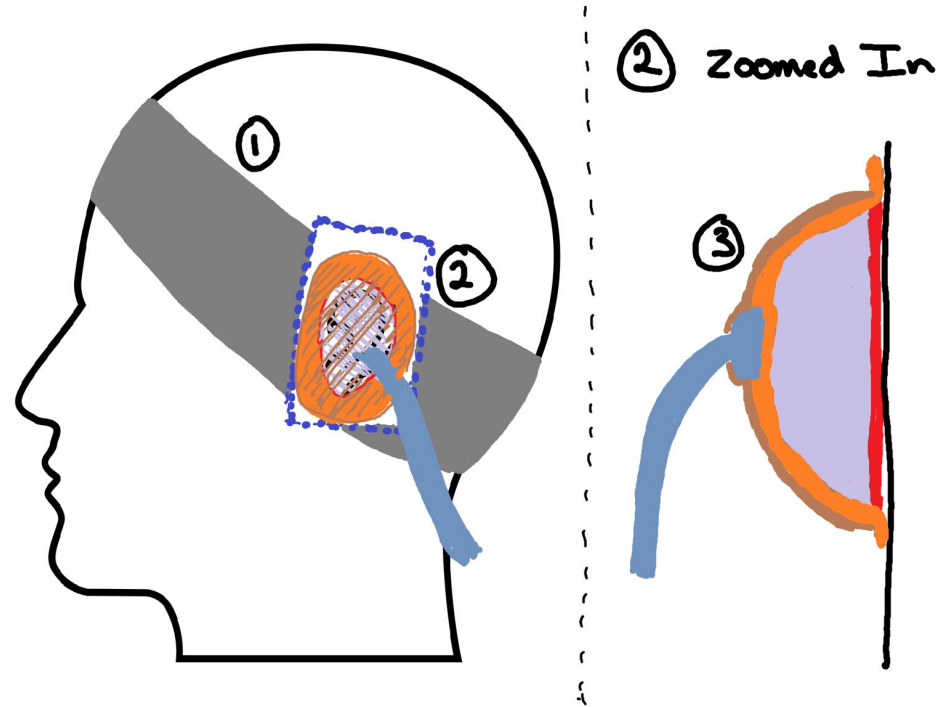
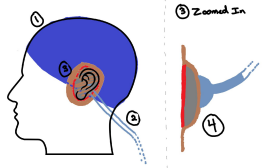
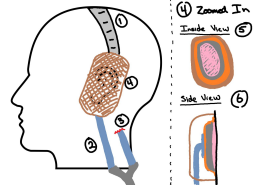
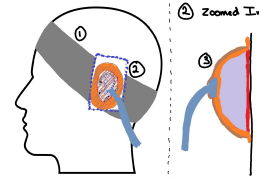


Figure 8: Preliminary Design of Headband

Design Matrix

	Design 1: Hat	Design 2: Headphones	Design 3: Headband
			
Safety (30)	18	27	20
Comfort (25)	25	25	15
Ease of Use (15)	15	15	15
Ease of Application (15)	9	12	9
Durability (10)	6	4	9
Cost (5)	5	4	5
Total (100)	80	87	73

Final Design

- Headphone inspired design
- Adjustable frame
- Flexible plastic material used as the base
- Tubing and dressings security ensured

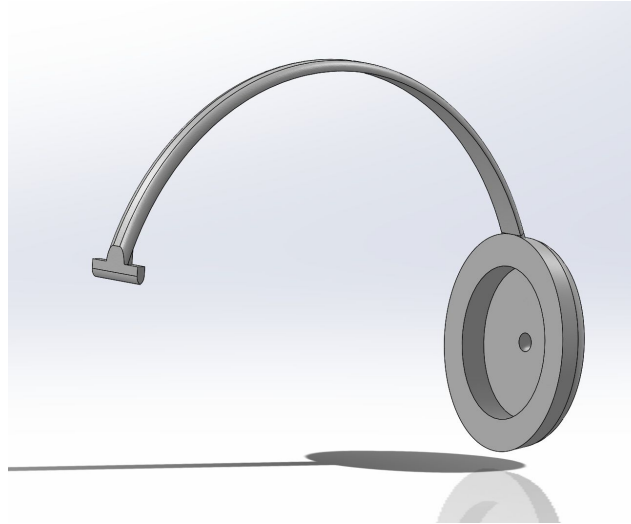


Figure 9. SolidWorks depiction of final design, interior included



Figure 10. SolidWorks depiction of final design, exterior included

Future Work

- Prototype Fabrication
 - Tailored for developing countries —> affordable materials
 - Headphone material and fabrication techniques
- Testing
 - Continuous negative pressure transmission
 - Both the wound vac and the drain
 - 25, 75, and 125 mmHg for 7 days
 - Consistent vacuum seal test
 - 7 days
 - Anatomy of ear test
- Potential Pitfalls
 - Even negative pressure → cushioning effect
 - No structural damage to the auricle of the reconstructed ear

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Questions?

