Annals of Biomedical Engineering

The Journal of the Biomedical Engineering Society

EarVac: A Novel Implementation of Negative Pressure Wound Therapy for Microtia Reconstruction Recovery

Serena Evers (skevers@wisc.edu), Harshad Gunasekar (@hgunasekar@wisc.edu), Bryan Heaton (bmheaton@wisc.edu), Meghan Kaminski (mfkaminski@wisc.edu) & Dhruv Nadkarni (@dnadkarni@wisc.edu)

University of Wisconsin-Madison, Department of Biomedical Engineering, Madison, WI, USA

Acknowledgements:

Dr. Daniel Cho, University of Wisconsin School of Medicine and Public Health Department of Surgery, Division of Plastic Surgery

Nada Botros & Jasmine Craig, University of Wisconsin School of Medicine and Public Health

Dr. Russ Johnson, University of Wisconsin-Madison, Office of Corporate Relations

Statements and Declarations:

The authors declare no conflicts of interest.

Keywords:

Negative Pressure Wound Therapy (NPWT), Microtia Reconstruction, Auricle anatomy, Retrograde Fluid Flow

Abstract

This study aimed to design and evaluate a novel, anatomy-specific negative pressure wound therapy (NPWT) device for use following microtia reconstruction. The study investigated the feasibility of a wearable, auricle-conforming NPWT system that met several success criteria: maintaining controlled negative pressure, maintaining mechanical stability under varying conditions, and preserving dressing seal integrity. To protect the NPWT dressing, the device integrated an over-ear hard shell covering. Testing involved mechanical deformation and seal functionality testing. Solidworks simulations illustrated material capability to withstand excessive force on the headphones. Catheter-seal tensile testing validated the failsafe design by ensuring the recorded force was no greater than 10N for varying strain rates. Functionality testing demonstrated the ability of the seal to completely compress under vacuum conditions, ensuring no seal stretch was present. Test data indicated that the selected materials, connector geometry, and vacuum interface configuration were appropriately specified during the design phase. EarVac's standardization of pressure and drainage aimed to reduce post-operational complication rates and improve patient outcomes.

Introduction

Microtia is a congenital condition characterized by ear malformations ranging from minor structural abnormalities to complete absence of the ear (anotia) [1]. In most cases, microtia manifests unilaterally rather than bilaterally [2]. Microtia is a rare condition. Epidemiological data indicate that prevalence varies between 1 in 5,000-7,000 births worldwide, with higher incidence among individuals of Andean, Native American, and Asian descent [2] [3]. Due to the intricate anatomy of the ear, auricular defects are difficult to reconstruct [4].

Among the various surgical techniques for microtia reconstruction, autologous reconstruction is the most widely practiced. In a 2013 survey, 91.3% of American plastic surgeons identified it as their preferred method [5]. Autologous reconstruction usually involves two to four stages and is performed on children starting around the age of seven to ten years, as the human ear reaches maturity around age seven [1]. The complication incidence rate varies from 0% to 72.9%, meaning the complication rate of microtia reconstruction is hugely variable [5]. Possible complications include skin necrosis, cartilage exposure and resorption, hypertrophic scarring, wire extrusion, infection, pneumothorax, and hematoma formation. Current clinical techniques to promote healing post-op vary, but generally include the use of standard gauze headwrap and a wound drain that is removed before discharge. Patients' wound healing are monitored weekly [1].

The use of negative pressure wound therapy (NPWT) is considered the gold standard for treatment of open wounds and is well-established in the treatment of surgical incisions, but reports on methods using NPWT for microtia reconstruction are scarce [6] [7]. There are no existing NPWT devices targeted for microtia reconstruction currently on the market. Few studies

have attempted to quantify and record the use of negative pressure for microtia reconstruction. In one such study, Kim et al. published a customized negative pressure system in 2014, integrating negative pressure via a feeding tube connected to a syringe and the use of alginate dressing [8]. This custom-built system was used because the contour of the ear made the use of commercially available NPWT polyurethane foam difficult to apply.

These limitations highlight a critical gap in postoperative microtia care. Specifically, newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely [9]. Clinicians needed a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure, and safely collects drainage to reduce complications and support consistent healing. To address these limitations, we developed a novel wearable headband device designed specifically for patients following microtia reconstruction. This device integrated controlled application of NPWT in a form tailored to the auricular anatomy. By providing uniform, sustained negative pressure while maintaining patient comfort and mobility, the system aimed to reduce postoperative complications such as framework extrusion or exposure, graft loss, framework resorption, wire exposure, and scalp/auricular scar complications [9]. Importantly, the headband device was engineered to standardize pressure delivery across patients, thereby minimizing variability in postoperative management. Through this design, we sought to translate the established benefits of NPWT to microtia reconstruction in a manner that is anatomically appropriate, clinically feasible, and scalable for routine postoperative care.

Materials

The materials used to fabricate the EarVac are separated into two categories. The first category is the dressing. The dressing contained all necessary elements to successfully dress and apply negative pressure to the closed incision. The second category was the protective layer, which encased the dressing and secured it to the user's head. The protective layer included the headband and protective ear muff.

The dressing utilized in negative pressure wound therapy devices can be assembled layer by layer, which allows flexibility in size range applications. Companies, such as Solventum, have created preassembled dressings for negative pressure wound therapy devices [21]. For the application of the EarVac, a preassembled dressing was fabricated for convenience, made possible by the limited variation in the size of incisions. The segment of the dressing in contact with skin is often a hydrocolloid dressing, which is desirable due to its gentle texture [22]. Hydrocolloid dressings induce a moist wound-healing environment, which improves healing rate, reduces infection, and enhances collagen synthesis [22]. DuoDERM dressings utilize modern hydrocolloid dressings for the management of exuding wounds [23]. DuoDERM is utilized as the contact layer with the ear in the EarVac's dressing. The next layer contains polyurethane foam. Polyurethane foam ensures an evenly distributed negative pressure across the wound surface while absorbing exudate, reducing infection risks [22]. DuoDERM and

polyurethane foam are encapsulated in a layer of acrylic adhesive. The acrylic adhesive layer is waterproof, skin-friendly, and creates a strong seal to encapsulate the wound [24]. The dressing is connected to an automated vacuum unit via medical-grade tubing. Medical-grade tubing utilized in NPWT devices is typically made from phthalate-free PVC [25]. These elements constitute the dressing sticker.

The protective layer consisted of two major components: the headband structure and ear muff protective layer. Both components were fabricated out of thermoplastic polyurethane. Thermoplastic polyurethane (TPU) is a thermoplastic elastomer that combines the elasticity of rubber with the processability of plastic [26]. TPU can withstand bodily fluids, sterilization processes, and degradation. In future iterations, both the headband structure and ear muff protective layer will be lined with a layer of closed-cell polyethylene foam. Polyethylene foam is commonly used in wearable medical devices [27]. Polyethylene foam provided comfort to the user during long-term wear. In addition, the headband was constructed of Nylon PA12. Nylon PA12 has high tensile strength and fatigue resistance, making it commonly used in devices such as prosthetics, orthotic braces, and wearable medical supports [28]. Nylon is durable and lightweight, which ensures reliability in outpatient environments.

To create the EarVac device entirely, the dressing sticker was connected to the ear muff protective layer via 3M Super 77 Multipurpose Spray Adhesive. 3M Super 77 Multipurpose Spray Adhesive is utilized in industrial applications with a variety of suitable materials, such as plastic, paper, and foam [29]. In addition to a single, modular device, adjustability was an important factor used to evaluate different designs. In the future, to incorporate an adjustable aspect of the headband, medical-grade Velcro will be utilized. Medical-grade velcro is skin-friendly, breathable, and durable [30].

The final portion of the design involved the integration of the NPWT device tubing and a wound drain, which is inserted in the lower neck. A single-use Y-Connector was used to integrate the two tubes. This will supply constant negative pressure to both pathways, allowing efficient healing.

Methods

I. Fabrication

The EarVac fabrication was separated into four procedures. The first included the headband structure of the protective layer. The Ultimaker was utilized to 3D print the structure in TPU 95A. To initiate 3D printing, a 3D rendering created in SolidWorks was used to represent the headband. Once 3D printed, hand-assembled pieces of polyethylene foam were attached along the inner radius of the headband structure. The second procedure, which included the ear muff protective layer, followed a similar approach. In the future, the Stratasys F370 in the UW-Madison Makerspace will be used to print in nylon to provide a stronger structure.

Figure 1. 3D printed EarVac device on foam head for testing

The third procedure was the fabrication of the dressing sticker. Due to size and material constraints, the dressing sticker was hand-assembled. DuoDERM was cut into an oval and placed on the subject's skin, ensuring protection from the polyurethane foam. The polyurethane foam was cut in an oval shape to conform to the ear. The polyurethane foam measured 110 mm in length (long axis), 72 mm in width (shorter axis), and 29 mm in height. These measurements are subject to change as the creation of different dressing sizes to satisfy variations in patient anatomy. The adhesive layer was cut with a small hole on one end to allow addition of a silicone stopper. The stopper was inserted into the cut, with the smaller end inserted first.

Figure 2. Dressing sticker on foam head for testing

Over both ear-conforming layers, the adhesive layer with the silicone stopper was applied over the dressing, adhering to the skin surrounding the ear. To ensure a proper seal, a hydrocolloid dressing was applied along the circumference of the contact point between the silicone stopper and the adhesive layer. Tubing was inserted into the open end of the silicone stopper to supply vacuum pressure (-50mmHg) and create a sealed environment. The tubing was connected to the vacuum unit, allowing the application of negative pressure.

The fourth procedure was the attachment of all separate pieces. Utilizing the female and male structures of the two 3D printed components, assembly involved snapping the two into place. Finally, to attach the dressing sticker to the ear muff protective layer, the team used medical-grade tape. All together, this assembly produced a unified EarVac device.

II. Testing Methods

Testing of the device included methods to ensure functional and mechanical properties are maintained.

Prior to any physical prototype, the team ran deformation simulations on SOLIDWORKS. The purpose of the SOLIDWORKS Deformation test was to simulate deformation around the tubing insert of the headphones. A fixed counter-force was placed on the interior of the headband portion of the headphones, whilst forces of varying values were placed on the clip and external shell of the earmuff. Deformation greater than 3.33mm needed to be analyzed, as the tubing diameter is 10Fr, equivalent to 3.33mm. If a force of 100N or less demonstrated a deformation greater than 3.33mm, the team had to re-evaluate the material used for the headphones.

Once the prototype was made, the team tested the durability of the adhesive seal before, during, and after vacuum suctioning. The purpose of the continuous negative pressure transmission test was to assess the vacuum's ability to apply varying pressures for 10-minutes whilst remaining consistent. Additionally, the mm deviation of the adhesive seal from the original value (pre-vacuum) was noted on each run to determine the efficacy of the adhesive and seal stickiness. The tests had the vacuum apply pressures of 50, 90, and 130 mmHg below atmospheric pressure. Each pressure value was tested for 10 minutes, 2 times. During each trial, the team noted the deviations of adhesive seal quadrants. Additionally, the pressure values were limited to +/- 5mmHg deviation from the applied pressure values.

With regards to mechanical strength testing, the team performed a tensile test on the seal-to-tube connection point. The purpose of the test was to validate the failsafe design of the connection. The failsafe design ensured that if tension is applied to the tubing, then the tube pulls out of the connection sight rather than ripping the seal. A 15mm by 70mm sample was cut from the entire seal. The tubing was gripped on the top claw of the MTS machine, while the skin material was gripped by the bottom claw. The machine pulled the tube seal connection apart. To pass the test, the force required to break the seal must have exceeded 10N, as that is the strength required to rip off a Band-Aid. The test was run a minimum of 3 times at 2 strain rates (5mm/min and 50 mm/min). Should the average force have been greater than 10N, the test was considered a fail.

Results

I. SOLIDWORKS Deformation Testing

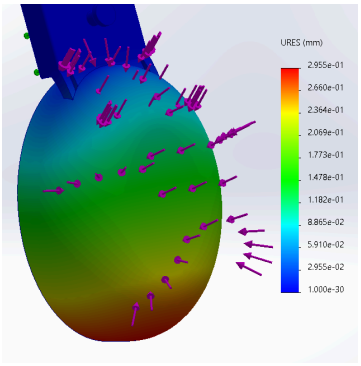

Figure 3: 5N Applied Force

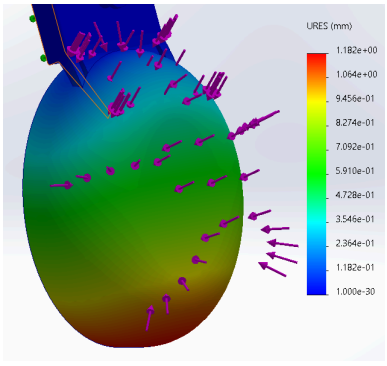

Figure 4: 20N Applied Force

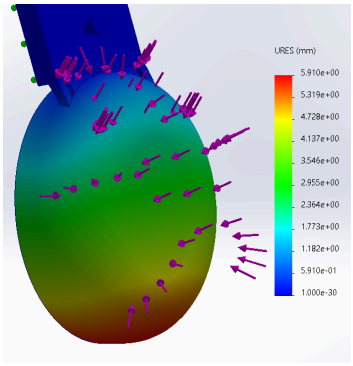

Figure 5: 100N Applied Force

Preliminary SOLIDWORKS testing of the model was completed and significant deformation was defined as any deformation at or exceeding 3.3mm. Significant deformation of the headphone part was observed in the 100N test, and thus the team is to conduct a reassessment of the headphone's constituent material.

II. Seal Tear Monitoring & Adhesive Cover Measurement

	Deviation (mm)			
Pressure Applied	Quadrant 1 (Top)	Quadrant 2 (Left)	Quadrant 3 (Bottom)	Quadrant 4 (Right)
50 mmHg (pre)	7.55	3.94	7.40	3.87
50 mmHg (2 - 5 min)	4.09	2.36	3.72	0
50 mmHg (post 10min)	7.08	3.66	7.47	3.88
90 mmHg (pre)	7.29	3.66	7.88	3.97
90 mmHg (2 - 5 min)	3.04	2.16	4.01	0
90 mmHg (post 10min)	6.58	2.90	7.21	3.90
130 mmHg (pre)	6.02	2.59	6.08	4.21
130 mmHg (2 - 5 min)	2.95	1.63	3.07	0
130 mmHg (post 10min)	4.58	3.21	5.88	4.27

Table 1: Test on 02/20/2026 of Original Design. No tears, no suction deviation visible.

	Deviation (mm)			
Pressure Applied	Quadrant 1 (Top)	Quadrant 2 (Left)	Quadrant 3 (Bottom)	Quadrant 4 (Right)
50 mmHg (pre)	5.6	2.3	4.5	2.8
50 mmHg (2 - 5 min)	0	0	0	0
50 mmHg (post 10min)	5.3	1.4	4.2	1.8
90 mmHg (pre)	5.3	2.6	4.8	2.4
90 mmHg (2 - 5 min)	0	0	0	0
90 mmHg (post 10min)	3.7	1.3	3.8	1.6
130 mmHg (pre)	4.5	2.3	4.0	2.2
130 mmHg (2 - 5 min)	0	0	0	0
130 mmHg (post 10min)	3.8	2.6	4.5	1.8

Table 2: Test on 04/11/2026 of Original Design. No tears, no suction deviation visible.

	Deviation (mm)			
Pressure Applied	Quadrant 1 (Top)	Quadrant 2 (Left)	Quadrant 3 (Bottom)	Quadrant 4 (Right)
50 mmHg (pre)	6.8	7.7	9.4	7.8
50 mmHg (2 - 5 min)	0	0.4	7.1	0
50 mmHg (post 10min)	6.2	6.8	7.8	3.3
90 mmHg (pre)	7.2	6.9	8.8	4.8
90 mmHg (2 - 5 min)	0	0.3	5.1	0
90 mmHg (post 10min)	5.6	6.6	6.8	3.3
130 mmHg (pre)	7.2	7.0	8.4	3.9
130 mmHg (2 - 5 min)	0	0.4	5.2	0
130 mmHg (post 10min)	5.9	6.6	8.4	4.5

Table 3: Test on 04/11/2026 of New Design. No tears, no suction deviation visible.

	Deviation (mm)			
Pressure Applied	Quadrant 1 (Top)	Quadrant 2 (Left)	Quadrant 3 (Bottom)	Quadrant 4 (Right)
50 mmHg (pre)	7.4	6.6	11.1	4.6
50 mmHg (2 - 5 min)	0	0.4	8.2	0
50 mmHg (post 10min)	4.2	6.2	7.2	2.0
90 mmHg (pre)	7.8	6.4	9.8	4.3
90 mmHg (2 - 5 min)	0	0.3	7.8	0
90 mmHg (post 10min)	4.5	6.0	7.2	1.8
130 mmHg (pre)	7.8	6.5	8.2	4.3
130 mmHg (2 - 5 min)	0	0.3	7.7	0
130 mmHg (post 10min)	4.7	6.0	8.2	2.0

Table 4: Test on 04/11/2026 of New Design. No tears, no suction deviation visible.

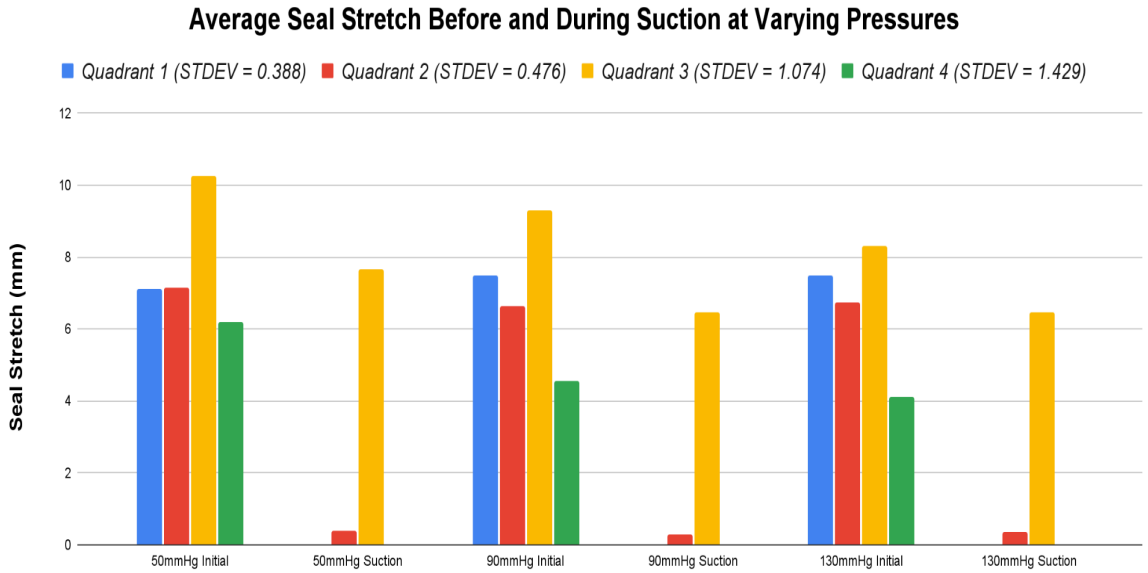

Figure 6: Average measured seal stretch prior to suction and during suction at all quadrants

Each negative pressure magnitude tested measured no significant decrease in adherence to the skin (in each quadrant) before and after suction. The post-suction deviation decreases post-suction were favorable, and when observed, indicate that the spurt of suction increased the adhesive layer's adherence to the surface. While an increased stretch is noticed at Quadrant 3, a minimal change to the location of the insertion plug counteracted any stretch via a visual observation.

III. Tensile Testing of the Seal-Tube Connection

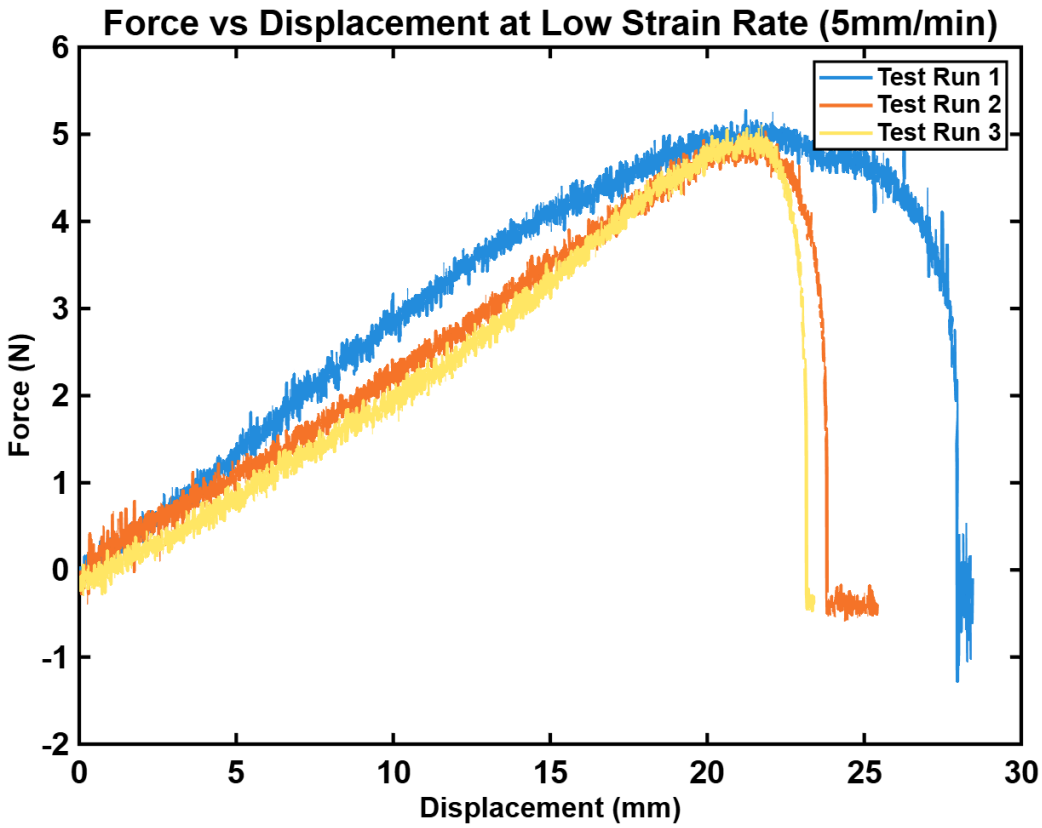

Figure 7: Force vs Displacement at a low strain rate (5mm/min)

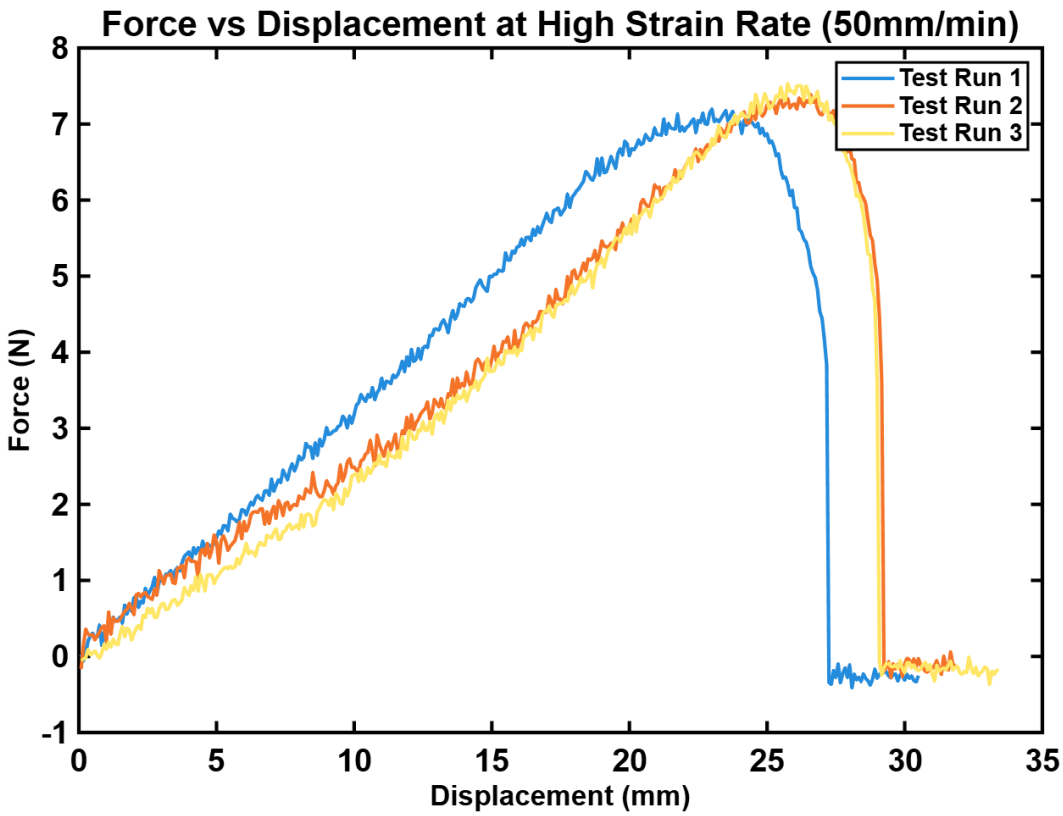

Figure 8: Force vs Displacement at a high strain rate (50mm/min)

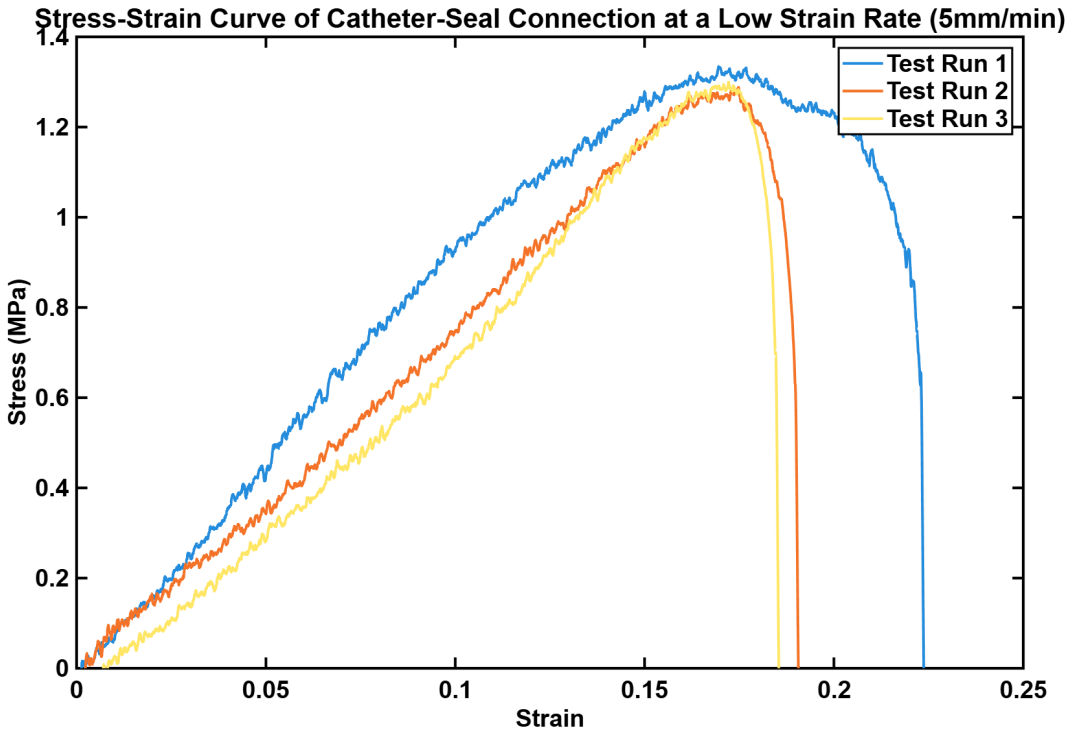

Figure 9: Stress-strain curve of catheter tube to seal connection at low strain rate

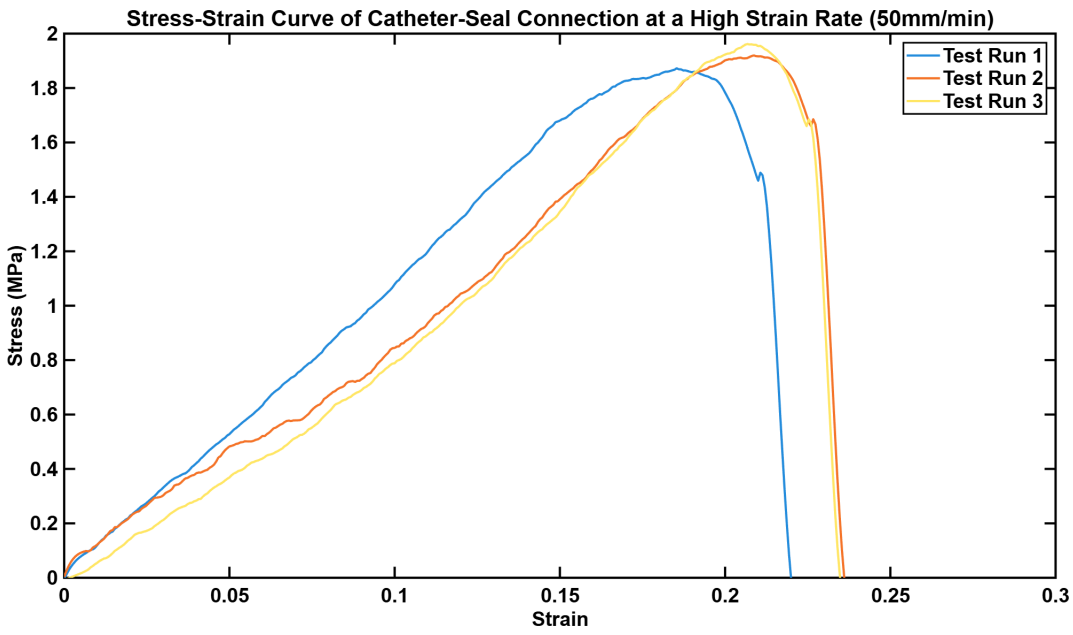

Figure 10: Stress-strain curve of catheter tube to seal connection at high strain rate

Results indicated that the force required to remove tubing from the seal was sub 10N, hence the failsafe worked as intended. A majority of the seal protection came from the headphone covering, hence the softer seal.

Discussion

This study evaluated the functional and mechanical performance of EarVac, a novel auricle-specific negative pressure wound therapy (NPWT) interface, under controlled benchtop conditions. The primary objective was to determine whether the device could (1) maintain stable subatmospheric pressures within clinically relevant ranges (−50 to −130 mmHg), (2) preserve adhesive seal integrity under sustained suction, and (3) maintain structural conformity without clinically significant deformation. The results demonstrated that the system met all predefined performance criteria without requiring iterative redesign.

Pressure Stability and Leak Resistance

Across all tested pressure magnitudes (−50, −90, and −130 mmHg), the system maintained the target negative pressure for the full 10-minute duration without deviation exceeding ±5 mmHg. No measurable suction decay or oscillatory instability was observed. These findings indicate that the integrated tubing system, Y-connector configuration, and adhesive interface achieved effective airtight coupling under static conditions.

In NPWT systems, pressure instability is commonly associated with microleaks at adhesive margins, connector interfaces, or tubing junctions. The absence of pressure decay suggests that the selected acrylic adhesive layer and dressing encapsulation strategy were mechanically sufficient to prevent leak formation. Importantly, quadrant-based adhesive measurements demonstrated no clinically significant separation before and after suction application at any tested pressure level (Tables 1–3). In several quadrants, post-suction deviation decreased relative to pre-suction measurements, indicating improved adhesive conformity under negative pressure loading.

This phenomenon likely reflects enhanced mechanical coupling between the hydrocolloid interface and the surrounding substrate as compressive forces redistributed surface tension. From an engineering perspective, this suggests that the dressing design not only resists leak formation but may mechanically stabilize under therapeutic suction levels.

Structural Stability and Deformation Analysis

Finite element analysis performed in SOLIDWORKS demonstrated that deformation remained below the predefined clinical threshold of 3.33 mm under forces up to 20 N. At 100 N, deformation exceeded the threshold, indicating that extreme loading conditions could compromise tubing integrity. However, forces approaching 100 N exceed expected physiologic loads during routine postoperative recovery, suggesting that the structure was mechanically appropriate for intended use scenarios.

Importantly, physical prototype testing demonstrated no observable collapse, buckling, or structural instability of the foam–adhesive dressing during suction application. Controlled macrodeformation is a therapeutic mechanism in NPWT, promoting microstrain and cellular proliferation; however, excessive collapse can impair uniform pressure distribution. The absence of undesirable deformation suggests that the polyurethane foam stiffness and encapsulating adhesive layer achieved an appropriate balance between flexibility and structural resistance.

This is particularly relevant in microtia reconstruction, where the reconstructed auricular framework is fragile and susceptible to compression-related compromise. Even pressure distribution without focal collapse reduces the risk of perfusion impairment or framework distortion.

System Reliability and Design Validation

Notably, the prototype achieved all predefined functional criteria without requiring iterative structural modification following benchtop testing. Early-stage medical device prototypes commonly reveal pressure drift, connector loosening, seal tearing, or tubing collapse under sustained loading. The absence of these failure modes suggests that material selection—including thermoplastic polyurethane (TPU), hydrocolloid dressing, polyurethane foam, and acrylic adhesive—was appropriately specified during the design phase.

The modular architecture of EarVac enabled standardized pressure delivery across patients while accommodating minor anatomical variation. Unlike generalized NPWT dressings, this system was geometrically tailored to the auricle, addressing a key limitation in current postoperative microtia management.

Clinical Implications

Microtia reconstruction presents unique postoperative challenges due to the complex three-dimensional auricular contour, risk of hematoma formation, and vulnerability of the cartilage framework to exposure or extrusion. Conventional headwrap techniques provide inconsistent compression and lack controlled pressure regulation.

By demonstrating reliable pressure maintenance and seal integrity in an auricle-specific geometry, EarVac supported translation of established NPWT mechanisms—microstrain stimulation, enhanced perfusion, and controlled exudate removal—into microtia-specific postoperative care.

Standardizing pressure application may reduce variability in postoperative management and potentially decrease complication rates such as graft loss, cartilage resorption, and framework exposure. Although biological endpoints were not evaluated in this study, the engineering validation presented here establishes foundational mechanical feasibility for future clinical investigation.

Limitations

Despite favorable performance outcomes, several limitations warrant consideration. Testing was conducted under static benchtop conditions rather than dynamic physiologic environments. Long-term durability beyond the 10-minute testing interval was not evaluated. Biological healing responses, perfusion changes, and tissue-level effects were not assessed. Comparative performance testing against commercial NPWT systems was not performed. Pediatric anthropometric variability was not modeled beyond the standardized test substrate.

Future work should include cyclic mechanical loading, simulated head movement testing, extended-duration suction studies, fluid backflow testing, and in vivo evaluation to assess biological efficacy and long-term performance. Once clinically validated, the device holds strong potential for intellectual property development and scalable commercial manufacturing.

References

[1] L. Camison, R. C. Lisk, and M. Soldanska, “Microtia: A Review,” Seminars in Plastic Surgery, vol. 38, no. 5, pp. 261–268, Oct. 2024, doi: 10.1055/s-0044-1788327

[2] Stanford Medicine, “Microtia,” Otolaryngology — Head & Neck Surgery, Stanford Medicine, accessed Oct. 8, 2025. [Online]. Available: https://med.stanford.edu/ohns/OHNS-healthcare/earinstitute/conditions-we-treat/microtia.html

[3] D. V. Luquetti, C. L. Heike, A. V. Hing, M. L. Cunningham, and T. C. Cox, “Microtia: Epidemiology and genetics,” *American Journal of Medical Genetics Part A*, vol. 158A, no. 1, pp. 124–139, 2012, doi: 10.1002/ajmg.a.34352

[4] S. S. Park and R. J. Hood, “Auricular reconstruction,” *Otolaryngologic Clinics of North America*, vol. 34, no. 4, pp. 713–738, Aug. 2001, doi: 10.1016/S0030-6665(05)70015-3

[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*, vol. 1, no. 7, p. e57, Nov. 2013, doi: 10.1097/GOX.0b013e3182aa8784

[6] Smith + Nephew, *NPWT Clinical Guidelines – FINAL APPROVED*, 2025. [Online]. Available: https://sn-npwtportal.com/sites/default/files/npwtPortal/EDGE/gettingStarted/NPCE9-42082-0125-NPWT%20Clinical%20Guidelines-FINAL%20APPROVED.pdf

[7] K. Sasaki, M. Sasaki, J. Oshima, A. Nishijima, Y. Aihara, and M. Sekido, “Salvaging exposed microtia cartilage framework with negative pressure wound therapy,” *Journal of Plastic, Reconstructive & Aesthetic Surgery*, vol. 74, no. 6, pp. 1355–1401, Jun. 2021, doi: 10.1016/j.bjps.2021.02.013.

[8] J. T. Kim, Y. H. Kim, and S. W. Kim, “Customized negative pressure wound therapy for intractable auricular defects using alginate dressings and feeding tubes,” *Journal of Plastic, Reconstructive & Aesthetic Surgery*, vol. 67, no. 11, pp. e284–e286, Nov. 2014, doi: 10.1016/j.bjps.2014.07.029.

[9]E. M. Ronde, M. Esposito, Y. Lin, F. S. van Etten-Jamaludin, N. W. Bulstrode, and C. C. Breugem, “Long-term complications of microtia reconstruction: A systematic review,” Journal of Plastic, Reconstructive & Aesthetic Surgery, vol. 74, no. 12, pp. 3235–3250, Dec. 2021, doi: https://doi.org/10.1016/j.bjps.2021.08.001.

Appendix

Appendix A: Product Design Specifications

EarVac: Product Design Specification

Date: 09/18/2025

Project Title: EarVac

Group Members:
Leader: Bryan Heaton
Communicator: Meghan Kaminski
BSAC: Serena Evers
BWIG: Dhruv Nadkarni
BPAG: Harshad Gunasekar

Client: Ms. Nada Botros & Dr. Daniel Cho
Advisor: Russ Johnson

Function

Design a negative-pressure wound therapy (NPWT) accessory ("EarVac") that reliably forms and maintains a seal around incisions formed from microtia surgery to evacuate fluid, reduce hematoma and infection formation, and promote adherence of the skin flap to the sculpted ear. The system should deliver constant negative pressure within safe limits, be compatible with a y-connector for a second vacuum tube, and be simple for medical personnel to apply, remove, and replace in the clinic and at home.

Client requirements

The client specified that an incision on the ear skin-flap is generated during microtia surgery. The device should provide constant negative pressure therapy at around -125 mmHg over the entire newly formed ear structure, though the acceptable operating range of applied pressure must be verified with the surgical team. The device must also be compatible with a y-connector, allowing negative pressure to be applied in a routine location behind the ear's skin flap to ensure adherence of the skin to the ear structure.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**: The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.
        i. Negative Pressure Wound Therapy (NPWT) dressings can be left in place for 24 to 72 hours, depending on wound characteristics [1] with potential use extending up to 7 days per patient episode.
        ii. The system must withstand both static loading from the device's securing mechanism and dynamic loading resulting from patient movement. Common disturbances include jaw

movement during speech or mastication, neck rotation, or coughing, each of which may disrupt the seal or induce pressure fluctuations [2].

1. The device must withstand or detect and correct such disturbances without compromising pressure stability or therapeutic effectiveness.

iii. The system must maintain a consistent therapeutic range suitable for delicate tissues. General clinical practice indicates that “a continuous pressure of −80 mmHg to −125 mmHg is most commonly used in traumatic orthopaedic wounds” [3], though ranges between −50 mmHg and −150 mmHg are documented depending on wound type and sensitivity [4]. For cranial applications, the device will be required to deliver a continuous −125 mmHg ± 5 mmHgto ensure both safety and efficacy.

b. **Safety**: Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.

i. NPWT devices are classified as Class II medical devices, requiring adherence to FDA design controls (21 CFR 878)[5] and special controls that address risks such as infection, bleeding, and electrical hazards. Compliance with ISO 14971 (risk management) and IEC 60601-1 (basic safety and performance) is required for commercialization.

ii. Device labeling must follow the FDA’s *Guidance on Medical Device Patient Labeling*. Warnings about bleeding risks, infection control, and patient monitoring requirements are mandated, and labeling should include standardized symbols from ISO 15223-1 [6].

1. The patient labeling should contain information regarding the indications for use, directions for use, and possible adverse reactions written in lay terms for comprehension by the general public [7].

iii. All patient-contact components must be biocompatible per ISO 10993-1. Specific hazards require warnings on labeling per 21 CFR 801.437. The FDA also requires evidence of sterilization validation and microbial barrier performance for disposable dressings [8].

c. **Accuracy and Reliability**: Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.

i. Although the FDA does not provide a specific allowed deviation from the “true” value in order for a product to be commercialized, it issues a guideline for design controls. Each manufacturer shall establish and maintain procedures to control the design of the device to ensure that specified design requirements are met during all steps of the design process [9]. Some major design considerations the team needs to consider under the pretense of precision include the negative pressure system and fluid drainage system.

ii. With regards to the negative pressure system, general clinical practices indicate “a continuous pressure of -80 mmHg to -125 mmHg is most commonly used in traumatic orthopaedic wounds” [10]. However, the normal levels can vary between -50 and -150 mmHg depending on wound type and sensitivity [11]. Currently, the FDA consensus standard is within the aforementioned range, but more focused around -125 mmHg to ensure both patient safety and product effectiveness for dense orthopedic wounds. The team's product aims to deliver a continuous pressure to the ear, an area more delicate than normal orthopedic wounds; hence, a continuous -125 mmHg ± 5 mmHg pressure will be outputted by the pressure system to ensure patient safety and product effectiveness in the cranial area. Negative pressure validation on a flesh-like material must be performed before each use to ensure the suction pressure is within the defined range.

iii. With regard to the fluid drainage system, the team must ensure that fluid reflux is at a minimum. Fluid reflux is very dangerous and could severely harm the patient if the blood

is contaminated within the drainage system, thus extensive testing and design validation must be performed. The team aims for a ***0 µL backflow of fluid, with a tolerance of 1µL.***

d. **Life in Service**: Establish service requirements, including how short, how long, and against what criteria? (i.e., hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)
    i. The product will be used post-autograft of a portion of a rib to become an ear structure. The securing mechanism and tubing will be one-time use, and will be replaced daily. The negative pressure system and fluid collection container are reusable with a 10-year lifespan. The team is not required to develop a new NPWT unit, so they intend to purchase and/or utilize a unit with the aforementioned lifespan. Every 6 months, maintenance and qualification will be conducted on the entire negative pressure device to ensure it is up to standard.
    ii. With regards to patient usage, the device will be used for up to a week post-surgery.

e. **Shelf Life**:
    i. The device will need to last from the time it is shipped to the hospital until after the patient is done with its use. Plastics used for traditional securing mechanisms do not normally degrade over time under moderate conditions such as the conditions present in a hospital, so shelf life is not a major concern until years or decades have passed.
    ii. Patients will wear the headband for up to 7 days, beginning immediately after surgery in the operating room [12]. The device must not degrade or otherwise age in this time beyond acceptable use conditions.

f. **Operating Environmen**t: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.
    i. The device will be used and handled in a well-controlled operating room environment, which will be controlled for temperature, pressure, humidity, and air particulate concentration.
        1. Standard 15.01.02 of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers states that temperature must be maintained for “patient comfort” and “safe equipment operation”, humidity must be between 20%-60%, and that air pressure must remain positive to disallow “contaminants from entering sterile fields” [13]. The device must withstand these conditions.
    ii. The device must also withstand a large variety of weather conditions, as the device will be worn by the patient outside of the hospital.
    iii. The device will only be operated by nurses, surgeons, or other medical personnel trained specifically in NPWT.
    iv. The device, particularly the segments exposed to its generated negative pressure conditions, will be exposed to -125 mmHg pressure for many hours at a time, up to 7 days [14].

g. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc.
    i. Microtia surgery is most commonly done to children. To better fit this demographic, the device must be especially comfortable. To achieve this comfort, some level of adjustability must be possible in the device.

ii. Due to the device's usage in a delicate area immediately post-surgery, the negative pressure applied must be high enough to be in the therapeutic range, but low enough to ensure mitigation of injury and other complications.

h. **Size**:
   i. The EarVac device will cover the incision on the ear produced from microtia surgery and the surrounding ear area.
      1. The device must be lightweight and non-bulky so that it fits comfortably on a patient's head post-surgery.
      2. The headband must not be tight on the skin to the point of irritation / other surface irritation complications.
   ii. The EarVac device will be designated as single-patient use NPWT (sNPWT) [15].
      1. The securing device will be adjustable and disposable.
      2. The vacuum tubing will be disposable.
   iii. Tubes must not be placed on skeletal pressure points to prevent the formation of pressure ulcers [16].

i. **Weight**:
   i. The EarVac device must be lightweight and non-restrictive.
      1. The device must not be burdensome to wear for days at a time
      2. According to standard over-ear headphone weights on the market, a safe range for the weight of the device could be 250g - 350g [X].

j. **Materials**: Establish restrictions on certain materials that should be used and if certain materials should NOT be used (for example, ferrous materials in an MRI machine).
   i. The device will be secured within a headband spanning the circumference of the head.
      1. The outer shell of the headband should be made of a comfortable and flexible material. Thermoplastic polyurethane is flexible, biocompatible, and often used in medical devices [17].
      2. Alternatively, the device can be disposable with a more comfortable material choice for the patient. Nylon and polyester textiles are commonly used as prosthetic straps and compression garments [18].
   ii. The HeadVac device will utilize negative pressure wound therapy. To secure the incision sites, dressings used in post-operative care and negative pressure wound therapy application will be utilized.
      1. Non-adherent dressings are applied to the wound to create a barrier [19]. Some materials to take in consideration are Adaptic [20], Mepitel [21], and petroleum gauze [22].
      2. Polyurethane foam is utilized to fill the wound cavity, ensuring vacuum pressure is evenly distributed [23].
      3. A thermoplastic polyurethane film can be applied to secure the foam, creating a sealed environment [24].
      4. Alternatively, hydrocolloid dressings can be utilized in conjunction with NPWT devices. Hydrocolloid dressings contain a gel-forming agent and tend to be more flexible than foam [23].

k. **Aesthetics, Appearance, and Finish**: Color, shape, form, and texture of finish should be specified where possible (get opinions from as many sources as possible).

i. Due to the novel nature of the device, the shape, color, form, and texture of the finished device will be up to the client's discretion.
    1. In microtia surgery, incision cuts are located on the ear. To ensure variability, the EarVac will extend around the circumference of the ear. The device will be unilateral, and will have some method of securing the device to the head, likely extending from the ear to the top of the head.
    2. Dressings and device application will occur at the end of the surgical procedure. The color of the device will be a neutral tone. Due to the Code of Federal Regulation, Title 21 [26], neutral tones are required in operating rooms [27].
    3. The client has requested a comfortable material and texture for patients. The texture of the device must be soft, adaptive, and supportive.

2. **Production Characteristics**
    a. **Quantity**: number of units needed
        i. The target prototype accounts for all head sizes with the integrated negative pressure system attached to it, in addition to the dressing. This would enable the user, no matter the demographic, to be able to purchase and use one singular product

    b. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products
        i. The client has given the team a budget of $1000 to develop a prototype. The entire device can be split into 3 major components: the gauze/dressing, the fluid container, and the negative pressure system.
        ii. The Gauze/dressing and the fluid container retail for as low as $5.00. The headband containing the gauze and tubing is what the team is developing, for which $400 will be allocated for the development. Cost includes purchasing materials, sensors, and manufacturing costs of the headband.
        iii. The team is not required to build a new NPWT unit. On the market, full-fledged units retail from $300 to $2500. The team plans on allocating upwards of $500 to purchase a unit.
        iv. The most common sales model for an NPWT system is a rental model, with prices upwards of $25.00 per day [28].

3. **Miscellaneous**
    a. **Standards and Specifications**
        i. This medical device will likely be listed as a class II medical device. This is due to the device's direct interaction with the body, but its lack of use in life-sustaining applications. The device will likely require a 501(k) premarket notification [29].
        ii. ISO 10993: The device must comply with this standard to meet general safety requirements for medical devices. The device will be analyzed according to this standard to ensure general safety and fitness for use in its applications [30].
        iii. ISO 11135/11137: The device must comply with standards relating to ethylene oxide (EO) sterilization or radiation sterilization, depending on the optimal sterilization technique used by target hospitals. If the device is disposable, this standard is not a concern [31].
        iv. ISO 13485: If the device is eventually manufactured in mass, it must comply with relevant standards for quality and safety during use as it relates to its manufacturing processes [32].

v. ISO 14971: This standard helps identify risks and hazards associated with medical devices. This standard specifies that the medical device's manufacturer must establish objective criteria for risk acceptability as it pertains to the medical device [33].
vi. IEC 62366: Because of the particular, nuanced, and skill-requiring procedure required to successfully apply NPWT, the device should be analyzed according to IEC 62366 to determine its usability in relation to safety. This standard will assist in identifying risks in correct use and in erroneous use of the device [34].

b. **Customer**: Specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
    i. The client does not have any specific likes, dislikes, preferences, or prejudices restricting the design of the device. The device should be adjustable, disposable, and be applicable to multiple rhytidectomy incision locations.

c. **Patient-related concerns**:
    i. Patient-related concerns are up to the surgeon's discretion, as microtia surgery results are highly individualized [35].
d. **Competition**: Are there similar items that exist (perform a comprehensive literature search and patents search)?
    i. <u>NPWT in Head & Neck</u>
        1. There are medical reports and studies using NPWT for wounds in the head/neck region. For example, *"Negative Pressure Wound Therapy in the Head and Neck"* (PMC) discusses use of standard NPWT with adjustable negative pressure, dressings, etc., in this region. [36]
        2. Also, Negative Pressure Wound Therapy in Head and Neck … shows use of foam sponges, occlusive dressings etc., for facial wounds.
    ii. <u>Patents / Devices for NPWT</u>
        1. **US8663198B2**: A flexible housing with a gasket, port, non-woven absorption material, wound interface layer; foldable housing for appendages, with improved sealing mechanisms. [37]
        2. **US-11471585-B2**: A negative pressure wound therapy device / system / method. The details differ depending on embodiment. [38]
        3. **US-7534240B1**: NPWT system combining the foam pad with introduction of wound-healing agents (e.g. growth factors). [39]
        4. **US-9962295-B2**: A wound closure device via negative pressure.[40]
        5. **US-11896465-B2**: Smith & Nephew patent for device activation/control in NPWT (likely includes safety features, sensing, etc.)

References

[1]R. Strilka, "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 (accessed Sep. 18, 2025).

[2]A. Mellott, D. Zamierowski, and B. Andrews, "Negative Pressure Wound Therapy in Maxillofacial Applications," Dentistry Journal, vol. 4, no. 3, p. 30, Sep. 2016, doi: https://doi.org/10.3390/dj4030030.

[3]O. Borgquist, R. Ingemansson, and M. Malmsjö, “The influence of low and high pressure levels during negative-pressure wound therapy on wound contraction and fluid evacuation,” Plastic and Reconstructive Surgery, vol. 127, no. 2, pp. 551–559, Feb. 2011, doi: https://doi.org/10.1097/PRS.0b013e3181fed52a.

[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]“Medical Devices; General and Plastic Surgery Devices; Classification of Non-Powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy,” Federal Register, Nov. 17, 2010. https://www.federalregister.gov/documents/2010/11/17/2010-28873/medical-devices-general-and-plastic-surgery-devices-classification-of-non-powered-suction-apparatus (accessed Sep. 18, 2025).

[6]“Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers,” 2001. Available: https://www.fda.gov/media/71030/download

[7]C. for D. and R. Health, “Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT) - Class II Special Controls Guidance for Industry and FDA Staff,” FDA, Feb. 2020, Available: https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/non-powered-suction-apparatus-device-intended-negative-pressure-wound-therapy-npwt-class-ii-special

[8]C. for D. and R. Health, “Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT) - Class II Special Controls Guidance for Industry and FDA Staff,” FDA, Feb. 2020, Available: https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/non-powered-suction-apparatus-device-intended-negative-pressure-wound-therapy-npwt-class-ii-special

[9]“Federal Register :: Request Access,” unblock.federalregister.gov. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/subpart-C/section-820.30

[10]S. Putnis, W. S. Khan, and J. M.-L. Wong, “Negative Pressure Wound Therapy – A Review of its Uses in Orthopaedic Trauma,” The Open Orthopaedics Journal, vol. 8, pp. 142–147, Jun. 2014, doi: https://doi.org/10.2174/1874325001408010142.

[11]M. Y. Hasan, R. Teo, and A. Nather, “Negative-pressure wound therapy for management of diabetic foot wounds: a review of the mechanism of action, clinical applications, and recent developments,” Diabetic Foot & Ankle, vol. 6, no. 1, p. 27618, Jan. 2015, doi: https://doi.org/10.3402/dfa.v6.27618.

[12]“Therapy Clinical Guidelines A reference for clinicians Rx Only.” Available: https://www.solventum.com/content/dam/public/language-masters/en/msb/document/2025/vac-therapy-clinical-guidelines-ms-npwt-en-us.pdf

[13]R. Johnson, “Temperature, Humidity, and Airflow in Your ASC Operating Rooms,” ACHC.ORG - National accrediting organization, May 20, 2025. https://achc.org/temperature-humidity-and-airflow-in-your-asc-operating-rooms/

[14]M. Andrés, “prevena-bandage-patient-guide,” Scribd, 2025. https://www.scribd.com/document/865175809/prevena-bandage-patient-guide (accessed Sep. 18, 2025).

[15]“RENASYS and PICO Negative Pressure Wound Therapy Systems Clinical guidelines.” Accessed: Sep. 18, 2025. [Online]. Available: https://sn-npwtportal.com/sites/default/files/npwtPortal/EDGE/gettingStarted/NPCE9-42082-0125-NPWT%20Clinical%20Guidelines-FINAL%20APPROVED.pdf

[16]S. Normandin et al., “Negative Pressure Wound Therapy: Mechanism of Action and Clinical Applications,” Seminars in Plastic Surgery, vol. 35, no. 03, pp. 164–170, Aug. 2021, doi: https://doi.org/10.1055/s-0041-1731792.

[17]“Negative Pressure Wound Therapy (NPWT) - Medical Solutions by UFP MedTech,” Medical Solutions by UFP MedTech, Aug. 26, 2025. https://ufpmedtech.com/markets/negative-pressure-wound-therapy/ (accessed Sep. 18, 2025).

[18]“Compression Wear 101: Materials, Technologies, and What They Mean for You,” Compressionsale.com, 2025. https://www.compressionsale.com/blogs/compressionsale-com-blog-2/compression-wear-101-materials-technologies-and-what-they-mean-for-you

[19]V. Zaver and Pradeep Kankanalu, “Negative Pressure Wound Therapy,” Nih.gov, Sep. 04, 2023. https://www.ncbi.nlm.nih.gov/sites/books/NBK576388/ (accessed Sep. 18, 2025).

[20]“3MTM AdapticTM Non-Adhering Dressing | Solventum,” Solventum.com, 2014. https://www.solventum.com/en-us/home/f/b5005265095/

[21]“Mepitel transparent wound contact layer with Safetac | Mölnlycke,” Molnlycke.us, 2024. https://www.molnlycke.us/products-solutions/mepitel/

[22]“Overview: Petrolatum Impregnated Gauze Wound Dressings,” WoundSource, Nov. 20, 2014. https://www.woundsource.com/blog/overview-petrolatum-impregnated-gauze-wound-dressings

[23]“What Dressing is Used with Negative Pressure Wound Therapy?(NPWT) - Bluemed Medical,” What Dressing is Used with Negative Pressure Wound Therapy?, 2025. https://www.bluemedmedical.com/blogs/what-dressing-is-used-with-negative-pressure-wound-therapy-npwt/ (accessed Sep. 18, 2025).

[24]“Negative Pressure Wound Therapy (NPWT) - Medical Solutions by UFP MedTech,” Medical Solutions by UFP MedTech, Aug. 26, 2025. https://ufpmedtech.com/markets/negative-pressure-wound-therapy/ (accessed Sep. 18, 2025).

[25]“Facelift Procedure Steps,” American Society of Plastic Surgeons. https://www.plasticsurgery.org/cosmetic-procedures/facelift/procedure

[26]“Federal Register :: Request Access,” unblock.federalregister.gov. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-73

[27]“Color Additives for Medical Device Plastics.” Accessed: Sep. 18, 2025. [Online]. Available: https://www.fostercomp.com/wp-content/uploads/2018/12/Presentation-Content-Color-Additives-for-Medical-Device-Plastics_0.pdf

[28]M. Deigan, “Changes in Coverage for Negative Pressure Wound Therapy Pumps in Medicaid Nursing Home Daily Rate. https://www.dhs.wisconsin.gov/familycare/mcos/communication/wound-therapy-coverage.pdf,” Jan. 10, 2011.

[29]“FDA Medical Device Classes,” Arterex Medical, Mar. 26, 2025. https://arterexmedical.com/what-to-know-about-fda-medical-device-classes/ (accessed Sep. 18, 2025).

[30]O. for, “ISO 10993-1:2018,” ISO, 2018. https://www.iso.org/standard/68936.html#lifecycle

[31]ISO, “ISO 11135:2014,” ISO, 2014. https://www.iso.org/standard/56137.html

[32]O. for, “ISO 11137-1:2025,” ISO, 2025. https://www.iso.org/standard/81721.html

[33]International Organization for Standardization, “ISO 14971:2019,” ISO, Dec. 2019. https://www.iso.org/standard/72704.html

[34]International Organization for Standardization, “IEC 62366-1:2015,” ISO, 2015. https://www.iso.org/standard/63179.html

[35]“Facelift (Rhytidectomy): What Is It, Recovery & What to Expect,” Cleveland Clinic, Aug. 24, 2021. https://my.clevelandclinic.org/health/treatments/11023-facelift

[36]Robert Michael Liebman, K. S. Hanubal, and P. T. Dziegielewski, “Negative Pressure Wound Therapy in the Head and Neck: A Summary of Uses and Application Techniques,” Seminars in Plastic Surgery, vol. 37, no. 01, pp. 009-018, Dec. 2022, doi: https://doi.org/10.1055/s-0042-1759562.

[37]“US8663198B2 - Negative pressure wound therapy device - Google Patents,” Google.com, Apr. 16, 2010. https://patents.google.com/patent/US8663198B2/en (accessed Sep. 18, 2025).

[38]PubChem, “Negative pressure wound therapy device, system and method - Patent US-11471585-B2 - PubChem,” Nih.gov, 2025. https://pubchem.ncbi.nlm.nih.gov/patent/US-11471585-B2 (accessed Sep. 18, 2025).

[39]“US7534240B1 - Negative pressure wound therapy system with provision for introduction of an agent - Google Patents,” Google.com, Mar. 31, 2000. https://patents.google.com/patent/US7534240B1/en (accessed Sep. 18, 2025).

[40]“Unified Patents - Analytics Portal,” Unifiedpatents.com, 2025. https://portal.unifiedpatents.com/patents/patent/US-9962295-B2 (accessed Sep. 18, 2025).

Appendix B: Expenses

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	QTY	Cost Each	Total	Link
Category 1 - Items ordered by client - Ms. Nada Botros									
Coloplast 4110 - Self-Cath Plus Soft Straight Hydrophilic Intermittent Catheter 10 Fr 16"	Sterile, single-use, hydrophilic-coated intermittent urinary catheter; 10 Fr outer diameter (≈ 3.33 mm), 16″ length, with soft flexible medical-grade PVC shaft, fire-polished eyelets for smooth insertion, uncoated GripZone for handling, latex-free	Coloplast Inc	4110	MedicalMega	N/A	1	$3.00	$3.00	https://medicalmega.com/self-cath-plus-soft-straight-hydrophilic-intermittent-catheter-10-fr-16
Medela 876227 - Invia Foam Dressing Kit with FitPad, Large	Sterile, single-use negative-pressure wound therapy (NPWT) foam dressing kit: includes a hydrophobic, reticulated polyurethane/ polyether charcoal foam pad (~ 10 cm × 8 cm × 3 cm), a transparent film cover (approx. 26 cm × 32 cm for “Large” size), and a dual-lumen suction interface (FitPad) with quick-connector — for use with Invia NPWT systems to manage chronic/acute wounds or post-surgical incisions (exudate removal, promote granulation, reduce edema)	Invia/Medela	876227	MedicalMega	0876227-MDLA	1	$69.00	$69.00	https://medicalmega.com/Invia-Foam-Dressing-Kit-with-FitPad-Large
ConvaTec 187658 - DuoDerm CGF Hydrocolloid Dressing 4" x 4"	Sterile, square 4″ × 4″ hydrocolloid wound dressing — moisture-retentive, adhesive gel polymers create a protective gel on contact with exudate; self-adherent, waterproof barrier that helps maintain a moist wound healing environment while protecting against bacteria/viruses;	Convatec	187658	MedicalMega	187658-CON	2	$8.00	$16.00	https://medicalmega.com/duoderm-cgf-sterile-dressing-square-4-x-4

Coloplast 310 - Self-Cath Pediatric Straight Intermittent Catheter 10 Fr 10"	Sterile, uncoated pediatric straight-tip intermittent urinary catheter — 10 Fr (≈ 3.3 mm OD), 10″ length, luer end, latex-free,	Coloplast Inc	310	MedicalMega	SKU 310 -- CLP	10	$1.50	$15.00	https://medicalmega.com/10-fr-10-long-pediatric-intermittent-catheter
Silicone Gripper Elastic for Clothing, 30mm Wide 5 Yards, Black Elastic Band Non-Slip Sewing Elasticity Band for Wig Sewing (30mm(FBA))	Stretchy, silicone-backed, non-slip elastic webbing tape — about 30 mm (≈1.2 in) wide, poly-/rubber blend elastic band with silicone gripper surface to prevent slipping on skin or fabric; u	N/A	ASIN B07MKQRZDP	Amazon	B07MKQRZDP	1	$14.76	$14.76	https://www.amazon.com/Elastic-Silicone-Gripper-Webbing-Non-Slip/dp/B07MKQRZDP
SimCoach Piercing Practice Body Parts, Silicone Ear Models for Piercing Practice, Fake Ear Mold for Earring Jewelry Display, Acupuncture Teaching Tool (2PCS)	Soft silicone ear model — a practice “body part” for ear-piercing training / practice; designed to mimic human ear skin/contours	SimCoach	B0CMWZT215	Amazon	B0CMWZT215	1	$14.76	$14.76	https://www.amazon.com/dp/B0CMWZT215?ref=ppx_yo2ov_dt_b_fed_asin_title

Appendix C: SolidWorks Images

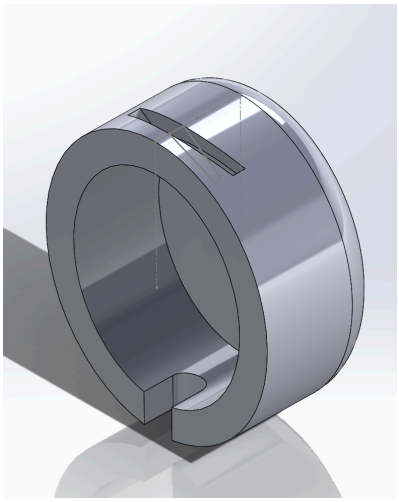

Figure 11. SolidWorks model of earmuff

Figure 12. SolidWorks model of final design, interior of earmuff included

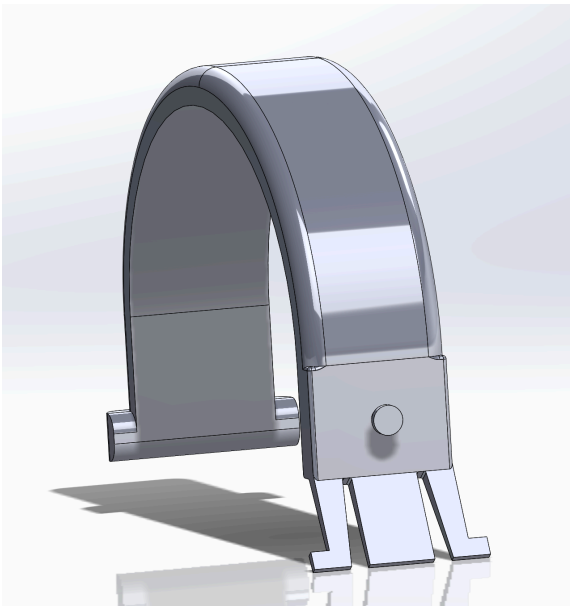

Figure 13. SolidWorks model of headband