EarVac: Negative Pressure Wound Therapy Device for Improved Microtia Reconstruction Surgery Recovery

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Abstract

Microtia is a congenital condition in which children are born with a malformed or absent ear. The standard remedy for this condition is reconstruction surgery, in which autologous rib cartilage is formed into the shape of a new auricle, then inserted underneath the skin flap of the affected ear. Complications following the operation are not uncommon, and include hematoma, skin necrosis, cartilage resorption, and scarring. Surgeons currently do not have a one-device method which conveniently reduces the risk of these complications and maintains a wound drain, which is routinely placed on the patient following microtia reconstruction. Negative pressure wound therapy (NPWT) is a gold-standard technique for augmenting healing on both open wounds and closed incisions. Devices (pre-assembled dressings and vacuum units) currently exist for this purpose, but are not specialized for the delicate nature of the ear. The use of NPWT in microtia surgery recovery is not well explored, and is predicted to have positive outcomes on reducing complication risk, increasing the speed of healing, and assisting in maintaining the shape of the new auricle. In addition, NPWT's use of a vacuum unit is enticing for compatibility with a wound drain, which can be automated when using the same vacuum apparatus as the NPWT dressing. The EarVac team proposes a novel NPWT device which will conform to the newly reconstructed auricle, consistently apply negative pressure to the closed incision, remove wound exudate, and allow automation of the standard wound drain. The EarVac will be tested according to FDA guidelines to ensure its safe and effective use. If proven viable, the EarVac could redefine microtia surgery recovery—accelerating healing while eliminating the burden of manual wound drainage.

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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 indicates 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]. This is also the technique used by the team's client, Dr. Cho. 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]. There is little in the literature regarding complication rates and risk factors for complications following microtia reconstruction surgery. A systematic review from 2013 on autologous cartilage microtia reconstruction found the complication incidence rate varying from 0% to 72.9%, meaning 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. There are several commercially available standard NPWT devices, such as the 3M™ Prevena™ Incision Management System used at the UW Hospital [8]. 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 [9]. 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 design challenge in postoperative microtia care. Specifically, 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 ear anatomy, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Background

Negative pressure wound therapy (NPWT) promotes wound healing through four main mechanisms of action [10]. The first mechanism, macrodeformation of tissue, allows the wound surface area to shrink depending on the deformability of the surrounding tissue. Therefore, wounds with more loose skin shrink faster than areas with tighter skin such as the scalp [11]. The second mechanism of action NPWT takes is through the drainage of extracellular fluid. The negative pressure removes fluid which decreases edema. Edema causes swelling that leads to cellular compression which diminishes proliferation and cellular response necessary for wound healing. Drainage of wound fluid also releases pressure and causes shear forces on the cells and movement of ions establishing electric fields which both promote cellular proliferation response [12]. Drainage of fluid also removes toxic materials that are known to disrupt the connective tissue matrix. The third mechanism in which NPWT promotes wound healing is through stabilization of the environment of the wound. The sponge used in NPWT is impermeable to proteins and microorganisms which prevents bacterial colonization in the wound. A study found bacterial count decreases from

10^8 to 10^3 organisms in 4 to 5 days when using NPWT, while the use of standard gauze dressings reported a significant increase in bacterial count in that same time frame [13]. The stabilization of the wound environment allows for less frequent dressing changes, while standard gauze dressings must be removed daily [14]. The final mechanism NPWT promotes healing is through microdeformation. Microdeformations are a key aspect of vac therapy as they promote cellular proliferation, angiogenesis, and granulation tissue formation. In pig models, granulation tissue formation increased by more than 60% when using NPWT compared to standard gauze dressings [13]. This enhanced tissue response is explained by mechanotransduction, a process in which mechanical forces modify cellular function. The application of negative pressure disrupts integrin bridges, triggering the release of intracellular messengers that alter gene transcription and stimulate cellular proliferation [15]. In contrast, standard gauze dressings have been shown to cause higher levels of cell death and lower fibroblast proliferation compared to NPWT [16].

The biological foundation of microtia reconstruction is the use of autologous costal cartilage, which provides a biocompatible, stable, and flexible framework capable of long-term integration with surrounding tissues [17]. Over time, chondrocytes within the graft maintain extracellular matrix production, while neovascularization of the overlying skin flap supports tissue survival and reduces necrosis risk [18]. Successful reconstruction depends on maintaining adequate vascular supply, minimizing infection and inflammation, and ensuring mechanical stability during healing.

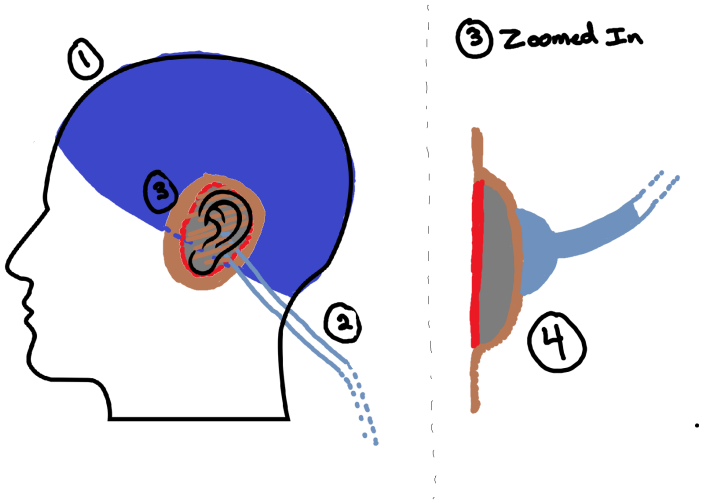
This project is conducted in collaboration with Dr. Daniel Cho, a pediatric plastic surgeon at UW Health who specializes in craniofacial reconstruction, and Ms. Nada Botros, a medical student and research collaborator on Dr. Cho's craniofacial surgery team [19] [20].

The EarVac is a negative-pressure wound therapy (NPWT) accessory designed to maintain a seal around microtia surgery incisions to remove fluid, reduce infection, and promote skin flap adherence. The device delivers a continuous pressure of −125 ± 5 mmHg and must remain stable during patient movement. It must be biocompatible, lightweight (250–350 g), and adjustable for comfort, especially in pediatric patients. All patient-contact materials will comply with FDA Class II medical device regulations and relevant ISO safety standards. The prototype will be developed under a $1,000 budget, using disposable dressings and reusable NPWT components. Further design, performance, and safety details are provided in the full Product Design Specification (Appendix A).

Preliminary Designs

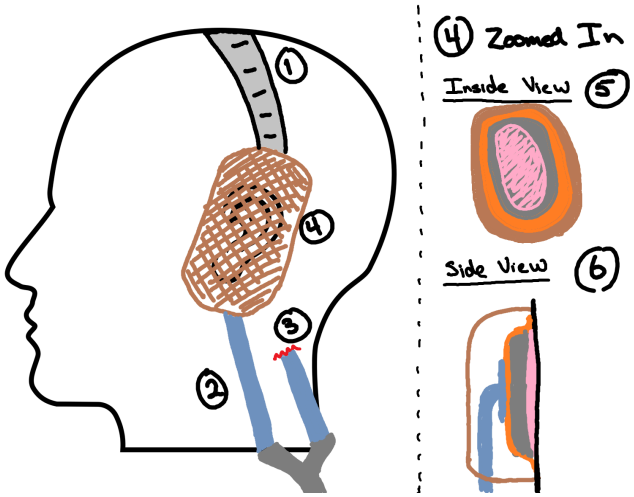
Note: In all designs, the wound drain tubing enters the body via the neck / jaw area. All proposed designs do not interfere with this area. Not pictured is the y-connector which connects the NPWT dressing vacuum tubing to the wound drain vacuum tubing.

Design #1: Hat



The first design, the Hat, takes the form of a soft, full-coverage cap. Around the ear, a concave surface maintains an airtight seal while conforming to the irregular surface of the reconstructed area. This design ensures a uniform suction environment and stable pressure but may compromise breathability and comfort during long wear due to its full-head coverage.

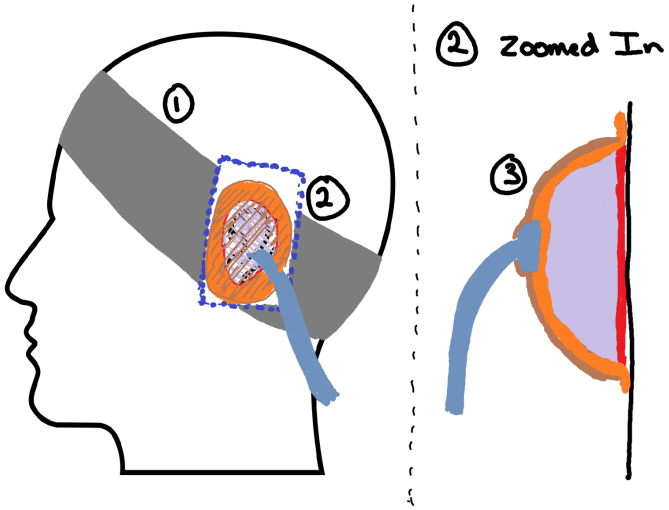
Design #2: Headphone



The second concept, the Headphone, focuses on targeted therapy by enclosing only the ear region within a rigid outer shell lined with a soft inner cushion. This over-ear “cup” structure mimics the shape of a headphone, allowing precise control of pressure and easy adjustment of fit through a single head strap. The design offers effective

localized suction directly over the wound area, minimizing interference with the rest of the head. However, because it relies heavily on edge sealing, maintaining airtightness can be challenging, and the asymmetrical weight may cause discomfort during extended use.

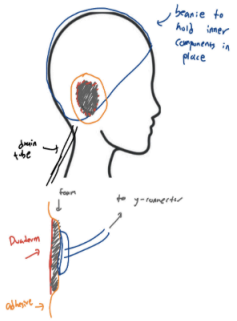
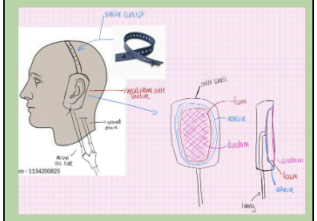
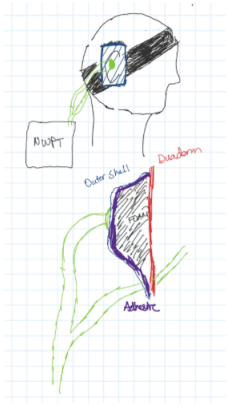
Design #3: Headband



The third design, the Headband, uses an adjustable elastic band that holds a detachable NPWT dressing in place over the ear. The transparent dressing beneath the band forms the airtight seal, while the external tubing connects to a suction source for drainage. This design is lightweight, easily adjustable, and provides good visibility for clinical monitoring. However, its smaller contact area results in less uniform pressure distribution, and the tension of the band may need periodic adjustment to maintain consistent sealing performance.

Preliminary Design Evaluation

Design Matrix

	Design 1: Hat	Design 2: Headphone	Design 3: Headband+Headphone
			
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

This design matrix compares the three proposed negative pressure wound therapy (NPWT) concepts — the Hat, Headphone, and Headband — across six weighted criteria: safety, comfort, ease of use, ease of application, durability, and cost.

The Headphone design achieved the highest overall score of 87/100, outperforming the other two options primarily due to its strong performance in safety, comfort, and ease of application. The rigid external frame combined with a soft internal seal provided both structural stability and localized negative pressure without compromising user comfort.

The Hat design followed with a total score of 80/100. It scored well in comfort and cost due to its simple, soft structure and even pressure distribution. However, its full-head coverage reduced ease of application and durability, making it less practical for frequent clinical use.

The Headband scored the lowest at 73/100. While it performed moderately in durability and cost, it lagged in comfort and safety due to the tension-based seal and smaller coverage area.

Overall, the matrix indicates that the Headphone concept provides the best balance between comfort, safety, and usability, making it the most promising candidate for further prototyping and testing.

Fabrication

Materials

The materials used to fabricate the EarVac are separated into two categories. The first category is the dressing sticker. The dressing sticker contains all necessary elements to successfully dress and apply negative pressure to the closed incision. The second category is the protective layer which will encase the sticker and secure it to the users' head. The protective layer includes 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 sticker will be fabricated for convenience, made possible by limited variation in the size of incisions. The segment of the sticker in contact with skin is often a hydrocolloid dressing due to their gentle nature when interacting with skin [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 management of exuding wounds [23]. DuoDERM will be utilized as the contact layer with the ear in the team's dressing. The next layer will contain a foam dressing. Polyurethane foam is most commonly used in negative pressure wound therapy dressings. Polyurethane foam ensures an even distributed negative pressure across the wound surface while absorbing exudates and reducing infection risks[22]. DuoDERM and polyurethane foam will be encapsulated in two separate layers of an acrylic adhesive. The acrylic adhesive layer is waterproof, skin-friendly, and creates a strong seal to encapsulate the wound[24]. The dressings are connected to the NPWT devices 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 will consist of two major components, the headband structure and ear muff protective layer. The headband structure will be 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 [26]. Nylon is durable and lightweight which ensures reliability in outpatient environments. The ear muff protective layer will be composed of thermoplastic polyurethane. Thermoplastic polyurethane (TPU) is a thermoplastic elastomer that combines the elasticity of rubber with the processability of plastic [27]. TPU can withstand bodily fluids, sterilization processes, and degradation. 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 [28]. Polyethylene foam will provide comfortability to the user during long-term wear.

To create an EarVac device, the dressing sticker will be connected to the ear muff protective layer via double-sided medical tape. Medical tape is fluid resistant which will allow the integration of the two pieces [29]. In addition to a single, modular device, adjustability was an important factor used to evaluate different designs. To allow adjustability, medical grade velcro will be utilized. Medical grade velcro is skin friendly, breathable, and durable [30].

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

Methods

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

The third procedure will be the fabrication of the dressing sticker. Due to the size and material constraints, the dressing sticker will be hand-assembled. The fourth procedure will be the attachment of all separate pieces. Utilizing the female and male structure of the two 3D printed components, assembly will involve snapping the two into place. Finally, to attach the dressing sticker to the ear muff protective layer, the team will utilize medical grade adhesive tape. All together, this assembly will produce a unified EarVac device.

Testing and Results

Test 1: Continuous Negative Pressure Transmission Test

The purpose of the continuous negative pressure transmission test is to assess the vacuum's ability to apply pressures of -60 to -120 mmHg for a continuous 8 hours whilst remaining accurate to the intended value. The tests will have the vacuum apply pressures of 60, 80, 100, and 120 mmHg below atmospheric pressure. Each pressure value will be tested for 8 hours. During each trial, the measured pressure values must not exceed +/- 5mmHg of the applied pressure values. Additionally, the intended pressure must be maintained for a minimum of 8 hours. Should the device meet both conditions, the test will be considered a pass. Any deviation will be noted.

Test 2: Consistent Vacuum Seal Test

The purpose of the consistent vacuum seal test is to assess the durability and viable duration of the seal following application of the NPWT dressing. The test setup will involve the entire seal (duoderm, foam, and adhesive) in addition to the vacuum tubing. The test will be run at our maximum potential pressure magnitude (-120 mmHg) and will run for 8 hours. To assess durability, the seal must not show any tears, rips, or openings during and after the test. Should any deviation occur, the length and characteristics of tear and time at which the tear occurred will be noted. The test will be run a minimum of 7 times, with an average number of tears, length of tears, time of tear, and location of tear being documented. Should the seal not show any tears, the test will be considered a pass.

Test 3: Strength of Seal Test

The purpose of the strength seal test is to assess the tensile strength of the adhesive, foam and duoderm seal. The test setup will consist of the adhesive, foam, and duoderm sample being applied to a “skin like material”. A 15mm by 70mm sample will be cut from the entire seal. The adhesive seal will then be gripped on the top claw of the MTS machine, while the skin material will be gripped to the bottom claw. The machine will pull the seal apart. The

applied force to break the seal must not be below 5N, as that is the strength required to rip off a bandaid. The test will be run on 4 sides of the seal, with each force being documented. The test will be run a minimum of 15 times. Should the average force be greater than 5N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

Test 4: Accelerated Aging Strength of Seal Test

The purpose of the strength seal test is to assess the tensile strength of the adhesive, foam and duoderm seal following simulated shelf life aging. As most devices will be used well after their creation date, the device must remain functional for up to 2.5 years on the shelf. As such, a 2 year accelerated aging pre-conditioning will be run on the device based on the Arrhenius equation via ASTM F1980 [31]. The most commonly used temperature is 55C for 92 days to simulate 2 years accelerated aging. Following the preconditioning, the seal will be attached to a "skin like material", which has yet to be determined. A 15mm by 70mm sample will be cut from the entire seal. The adhesive seal will then be gripped on the top claw of the MTS machine, while the skin material will be gripped to the bottom claw. The machine will pull the seal apart. The applied force to break the seal must not be below 5N, as that is the strength required to rip off a bandaid. The test will be run on 4 sides of the seal, with each force being documented. The test will be run a minimum of 15 times. Should the average force be greater than 5N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

Test 5: Strength of Tube/Seal Connection Test

The purpose of the strength of tube/seal connection test is to assess the tensile strength of the tubing to seal connection. The tubing seal connection will be created, and then the tube will be attached to the bottom grip of the MTS, while the seal will be attached to the top. The grips will pull apart the connection. The applied force to break the seal must not be below 5N. The test will be run a minimum of 15 times. Should the average force be greater than 5N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

Test 6: Accelerated Aging Strength of Tube/Seal Connection Test

As most devices will be used well after their creation date, the device must remain functional for up to 2.5 years on the shelf. As such, a 2 year accelerated aging pre-conditioning will be run on the device based on the Arrhenius equation via ASTM F1980 [31]. The most commonly used temperature is 55C for 92 days to simulate 2 years accelerated aging. The strength of the tube/seal connection test will then be performed.

Test 7: Anatomy of Ear Test

The purpose of the anatomy of ear test is to assess the wound surface following NPWT as well as the final cartilage frame atrophy. Using a replica model, the team will apply NPWT for a week. Following the test, the length of the wound will be measured and compared to the length prior to testing. The wound length should be at least 50% smaller than the original length. Additionally, degradation of the ear will be measured via frame atrophy [32]. A visual inspection will occur, where the shape of the ear prior to NPWT will be compared to after NPWT. The test will be run a minimum of 5 times. Should the wound length post-NPWT meet the aforementioned criteria, the test will pass.

Test 8: Fluid Removal Rate Test

The purpose of the fluid removal rate test is to assess the consistent drainage flow of fluids from the seal in addition to the amount of fluid draining. The test setup will consist of the foam component of the seal being doused with varying volume of fluid. Each run will have a different volume. The volumes will be 10mL, 20mL, 40 mL, 80mL,

and 100mL. The vacuum will be turned on and the fluid removal process will begin. The rate of fluid draining will be measured via a flow meter. The flow meter should indicate a constant flow rate from beginning to end. Any variation will be considered deviation; the standard deviation must not exceed +/- 1 mL/min. Additionally, a visual inspection of the foam will be conducted following the test, in which no fluid shall remain in the foam. Fluid remaining should be around 0mL, with any deviation being noted. Each individual volume run will be conducted a minimum of 5 times. Should the test pass all aforementioned criteria, the test will be considered a pass.

Test 9: Retrograde Fluid Prevention Test

The purpose of the retrograde fluid prevention test is to ensure no backflow of fluid will occur. Each run will consist of a different fluid volume being doused on the foam. The volumes will be 10mL, 20mL, 40 mL, 80mL, and 100mL. The vacuum will start and be shut off 2 minutes after start. Fluid re-entering the seal will then be collected via a new sponge. The expected amount of retrograde fluid is 0mL. Tolerance for backflow is 1 µLIf any deviation occurs, it will be noted and a design change will be conducted to ensure no backflow.

Discussion

The FDA mandates that all class II NPWT devices are performance tested prior to regulatory approval. This includes ensuring the device can maintain a set level of pressure over time, ensuring each compatible level of pressure is viable over time of suction, demonstrating compatibility of the device with accessory devices (fluid reservoir, the additional vacuum-applying drain in the case of the EarVac, dressings, and tubing), demonstrating efficacy of the device with varying levels of wound exudate, and demonstrating viability of the device in its ideal operating conditions [33]. If the EarVac can demonstrate all of these requirements, it will be in good standing to apply for regulatory approval. The aforementioned criteria will be demonstrated by tests 1, 2, 7, 8, and 9 above, with the additional tests ensuring the team's custom dressing is sufficiently strong for its application.

The team must consider the main demographic of usage for the device. Microtia reconstruction occurs almost exclusively in children aged 6-10 [1]. Pending regulatory approval, the device will still be a novel recovery apparatus for microtia recovery. To ensure its use remains ethical, consent from both the child and a parent / guardian must be granted for use of the device. Additionally, any concern regarding possible side effects from using the device must be disclosed to the patient and corresponding parent / guardian. Any anecdotal data gathered from patients that have undergone microtia reconstruction surgery must only be disclosed with explicit consent from the patient and corresponding parent / guardian, and any pictures obtained must only be disclosed under the same circumstances.

In the result of failure for test 1, a mode of failure analysis must be conducted to identify what section of the apparatus failed to maintain consistent pressure application. Once identified, the team must consider redesign of the apparatus, iterating the design accordingly before retesting. In a failure of test 2, an analysis of the tear profile must be conducted to determine what caused the tears. In the likely case of mechanical failure in the adhesive, the team must consider a stronger adhesive as a replacement in the design. In any other case of failure, the team must consider the adhesive's synergy with the rest of the design and redesign accordingly. A failure of test 3 indicates the seal will not have sufficient adherence to the skin. This indicates the team must increase the surface area of the adhesive on the skin or that a stronger adhesive must be selected. A failure of test 4 / test 6 indicates that the shelf life of the device is not up to standard. Depending on the mode of failure, material choice or design of the apparatus must be changed before retesting. A failure of test 5 indicates that the tubing does not connect with the dressing seal appropriately. To remedy this, the team could implement a luer-lock or other securing mechanism to ensure

increased strength. Failure of test 7 indicates that application of NPWT with the team's designed apparatus / dressing is not sufficiently emulating other NPWT setups in its healing properties and pressure on the ear. The team must do a mode of failure analysis to determine what aspect(s) of the design must be altered to allow for correct functionality. Failure of tests 8 and 9 indicate a significant flaw in the device's ability to handle fluid drainage. This would likely reflect a material problem with the foam or a design segment allowing fluid to collect. The exact mode of failure would be analyzed, the design reiterated, and each test reperformed to ensure correct functioning of the device.

Sources of error during testing can emerge from the devices used to collect data. This will be especially relevant with the usage of flow meters, as they must be properly calibrated and measurements can vary from meter to meter. The team must also ensure proper usage and calibration of the MTS machine, as improper usage will skew results. The team will attempt to perform each given test in a single event, such that day-to-day variation with device usage is limited, and other parties' usage of the machinery does not alter the team's results. For tests 8 and 9, the team must ensure that fluid collection reservoirs are of appropriate size such that measurements are of the correct magnitude for each application. For test 7, special consideration must be had for the ear replica the team decides to use. There must be several replicas which span the range of ear sizes / shapes the device will be used on, or the replica must represent a statistical average of the ear the device will be used on.

Conclusions

Clinicians currently do not have an optimized negative pressure wound therapy (NPWT) device for patients' recovery post-microtia reconstruction surgery. Application of NPWT on a newly formed auricle is especially beneficial for microtia reconstruction patients as an automated vacuum unit can also be used with the standard wound drain inserted in operation. The EarVac team has proposed a design for a NPWT apparatus resembling a headphone with an adjustable over-head strap. This design will be composed of four modular segments which fit together via male-female connections This design is compatible with the traditional wound drain which enters near the jaw. The design features a y-connector on the vacuum tubing to connect both the NPWT dressing and the drain. The team will work to iterate upon the proposed design via the discussed fabrication methods and testing protocols.

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] WoundSource, “3M Prevena Incision Management System,” accessed Oct. 8, 2025. [Online]. Available: https://www.woundsource.com/product/3m-prevena-incision-management-system

[9] 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.

[10] S. Normandin, T. Safran, S. Winocour, C. K. Chu, J. Vorstenbosch, A. M. Murphy, and P. G. Davison, “Negative pressure wound therapy: Mechanism of action and clinical applications,” *Seminars in Plastic Surgery*, vol. 35, no. 3, pp. 164–170, Sep. 2021, doi: 10.1055/s-0041-1731792.

[11] D. P. Orgill, E. K. Manders, B. E. Sumpio, R. C. Lee, C. E. Attinger, G. C. Gurtner, and H. P. Ehrlich, “The mechanisms of action of vacuum assisted closure: More to learn,” *Surgery*, vol. 146, no. 1, pp. 40–51, Jul. 2009, doi: 10.1016/j.surg.2009.02.002.

[12] J. K. Stechmiller, D. V. Kilpadi, B. Childress, and G. S. Schultz, “Effect of vacuum-assisted closure therapy on the expression of cytokines and proteases in wound fluid of adults with pressure ulcers,” *Wound Repair and Regeneration*, vol. 14, no. 3, pp. 371–373, Jun. 2006, doi: 10.1111/j.1743-6109.2006.00134.x.

[13]M. J. Morykwas, L. C. Argenta, E. I. Shelton-Brown, and W. McGuirt, “Vacuum-assisted closure: A new method for wound control and treatment: Animal studies and basic foundation,” *Annals of Plastic Surgery*, vol. 38, no. 6, pp. 553–562, Jun. 1997, doi: 10.1097/00000637-199706000-00001.

[14] P. Agarwal, R. Kukrele, and D. Sharma, “Vacuum assisted closure (VAC)/negative pressure wound therapy (NPWT) for difficult wounds: A review,” *Journal of Clinical Orthopaedics and Trauma*, vol. 10, no. 5, pp. 845–848, Sep.–Oct. 2019, doi: 10.1016/j.jcot.2019.06.015.

[15] V. Saxena, C. W. Hwang, S. Huang, Q. Eichbaum, D. Ingber, and D. P. Orgill, “Vacuum-assisted closure: microdeformations of wounds and cell proliferation,” Plastic and Reconstructive Surgery, vol. 114, no. 5, pp. 1086–1096, Oct. 2004, doi: 10.1097/01.prs.0000135330.51408.97

[16] A. K. McNulty, M. Schmidt, T. Feeley, and K. Kieswetter, “Effects of negative pressure wound therapy on fibroblast viability, chemotactic signaling, and proliferation in a provisional wound (fibrin) matrix,” Wound Repair and Regeneration, vol. 15, no. 6, pp. 838–846, Nov.–Dec. 2007, doi: 10.1111/j.1524-475X.2007.00287.x.

[17] 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

[18] K. M. Kawanabe and S. Nagata, “A comparison of auricular reconstruction using autologous rib cartilage and porous polyethylene implants,” Aesthetic Plastic Surgery, vol. 33, no. 4, pp. 508–513, Jul. 2009, doi: 10.1007/s00266-009-9327-y.

[19] “Daniel Cho, MD, PhD,” Department of Surgery, University of Wisconsin–Madison, 2025. [Online]. Available: https://www.surgery.wisc.edu/staff/daniel-cho/

[20] “Nada Botros,” Medical College of Wisconsin – Department of Neurosurgery, 2025. [Online]. Available: https://www.mcw.edu/departments/neurosurgery/people/nada-botros

[21]“Negative pressure wound therapy,” Solventum.com, Nov. 14, 2024. https://www.solventum.com/en-us/home/medical/advanced-wound-care/negative-pressure-wound-therapy/

[22]“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/

[23] “DuoDERM® Dressings & Patches for Wound Care - Convatec,” convatec.com. https://www.convatec.com/advanced-wound-care/duoderm-dressings/

[24]“Negative pressure wound therapy: Our adhesive solutions | Avery Dennison,” Averydennison.com, 2025. https://medical.averydennison.com/en/home/markets/negative-pressure-wound-therapy.html (accessed Oct. 08, 2025).

[25] “PVC PhthalateFree ® Medical Grade Tubing – Ormantine USA, Ltd. | Environmental Monitoring Division | Peristaltic Pump Tubing Division,” Ormantineusa.com, 2025. https://ormantineusa.com/tubing-products/pvc-medical-grade-tubing/ (accessed Oct. 08, 2025).

[26] Neway, “What is the role of Nylon in additive manufacturing for medical applications?,” Superalloy High temperature alloy Parts Manufacturer, 2025.

https://www.neway3dp.com/services/plastic-3d-printing/faq-what-is-the-role-of-nylon-in-additive-manufacturing-for-medical-applications (accessed Oct. 08, 2025).

[27] “TPU in Medical Devices: Properties and Applications,” cathetermelt.com, Jun. 05, 2025. https://cathetermelt.com/tpu-in-medical-devices/

[28] “Medical,” Zotefoams, Aug. 06, 2025. https://www.zotefoams.com/industries/medical/ (accessed Oct. 08, 2025).

[29] “3MTM Medical Tape, 9877,” Solventum.com, 2020. https://www.solventum.com/en-us/home/f/b10176353/ (accessed Oct. 08, 2025).

[30] Bernard, “Enhance Care: Custom Medical Fasteners | VELCRO® Brand Blog,” USA, May 31, 2025. https://www.velcro.com/news-and-blog/2025/05/dfl-medical-fasteners/ (accessed Oct. 08, 2025).

[31] “ASTM F1980 Is An Accelerated Aging Test Used For Medical Devices,” Micom Laboratories. https://www.micomlab.com/micom-testing/astm-f1980/

[32] 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, Nov. 2020, doi: https://doi.org/10.1016/j.bjps.2020.11.010.

[33] Center for Devices and Radiological Health, “Non-powered suction apparatus device intended for NPWT,” U.S. Food and Drug Administration, 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 (accessed Oct. 8, 2025).

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
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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#	Date	QTY	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										
									$0.00	
									$0.00	
								TOTAL:	**$0.00**	

No expenses have yet been needed. The budget for the team is $1000.

Appendix C: SolidWorks 3D Renderings