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 afflicted (usually unilaterally) with a malformed or absent ear. The most common remedy for this condition is reconstruction surgery, in which autologous rib cartilage is formed into a new auricle and 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 and manually maintained 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 auricle reconstruction is not well explored, but is predicted to have positive outcomes on reducing complication risk. These benefits include increasing the speed of healing and assisting in maintenance of 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 unit as the NPWT dressing. The EarVac team has begun fabrication of 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 a wound drain. The EarVac will be tested according to FDA guidelines to ensure its safe and effective use. Current testing suggests the EarVac's protective covering should be made of a more industrial material. Testing must still be conducted to assess the viability of vacuum sealing of the auricle. 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.

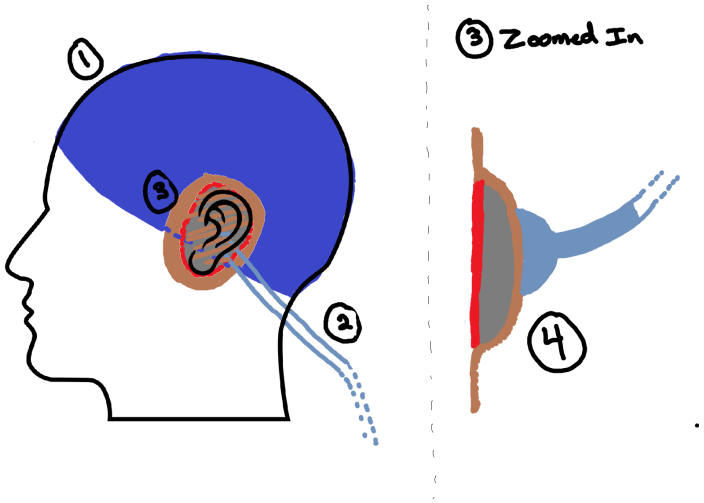
This project is conducted in collaboration with Dr. Daniel Cho, a pediatric plastic surgeon at UW Health who specializes in craniofacial reconstruction, and Ms. Nada Botros, a medical student and research collaborator on Dr. Cho's craniofacial surgery team [19] [20].

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

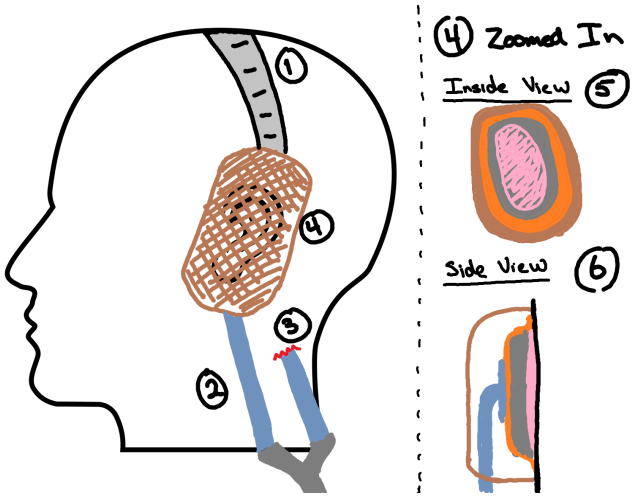
Note: In all designs, the wound drain tubing enters the body via the neck / jaw area. All proposed designs do not interfere with this area. Not pictured is the y-connector which connects the NPWT dressing vacuum tubing to the wound drain vacuum tubing.

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.

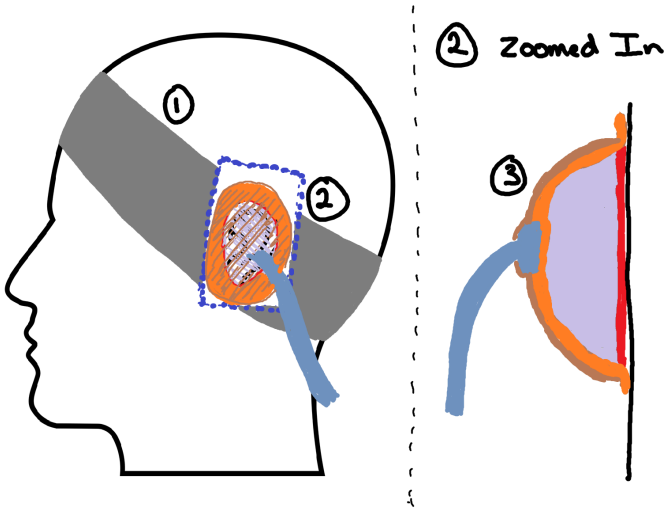
Design #2: Headphone



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.

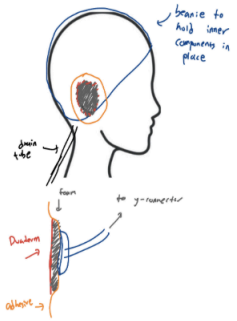
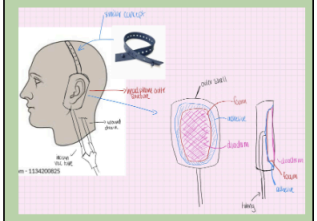
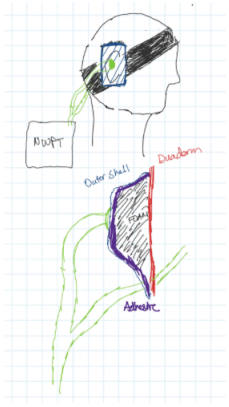
Design #3: Headband



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

The following categories were determined as important criteria for the EarVac to fulfill: safety, comfort, ease of use, ease of application, durability, and cost. Safety received a weight of 30 due to the device's use in children in a highly vulnerable post-surgical setting. Safety must therefore be a paramount priority of device design. Comfort received a weight of 25 due to the device's primary use in a young demographic. The device will be worn for extended periods of time, so if the device were to be uncomfortable it could harm patients' desire to use the device. Ease of use received a weight of 15 as the device will somewhat be operated independently of medical personnel. The device must be easy to maintain over the week-long wearing period, even after discharge from a medical facility. The device must also be easy to apply following surgery, hence the weight of 15. Surgeons must not have too much struggle applying the device, or its attractiveness as a medical device will be diminished. Durability is also an important criteria, receiving a weight of 10. The device must be able to withstand the wear-and-tear of a child's wear over a

week long period, and must be prepared for unexpected events of hits. Finally, cost received a weight of 5, as the team does not foresee any challenges with prototyping given the budget constraints.

This design matrix scored the three preliminary designs– the hat, the headphone, and the headband across these defined criteria.

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. The dressing 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 dressing 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 dressing will be fabricated for convenience, made possible by limited variation in the size of incisions. The segment of the dressing in contact with skin is often a hydrocolloid dressing, which are desirable due to their 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 management of exuding wounds [23]. DuoDERM will be utilized as the contact layer with the ear in the EarVac's dressing. The next layer will contain a 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 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 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 will consist of two major components, the headband structure and ear muff protective layer. Both components are 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 will provide comfortability to the user during long-term wear. In addition, the headband 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 [28]. Nylon is durable and lightweight which ensures reliability in outpatient environments.

To create an EarVac device, the dressing sticker is connected to the ear muff protective layer via 3M Super 77 Multipurpose Spray Adhesive. 3M Super 77 Multipurpose Spray Adhesive is utilized in industrial application 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 involves the integration of the NPWT device tubing and a wound drain, which is inserted in the lower neck. A single-use 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. The Ultimaker was utilized to 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 are attached along the inner radius of the headband structure. The second procedure, which includes the ear muff protective layer, will follow 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.

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 spray. All together, this assembly will produce a unified EarVac device.

Final Prototype

I. Headphone

Figure 1: 3D printed prototype of the headband and earmuff pieces assembled

Figure 2: SolidWorks model of final design, interior of earmuff included

Figure 3: SolidWorks model of final design, exterior of earmuff included

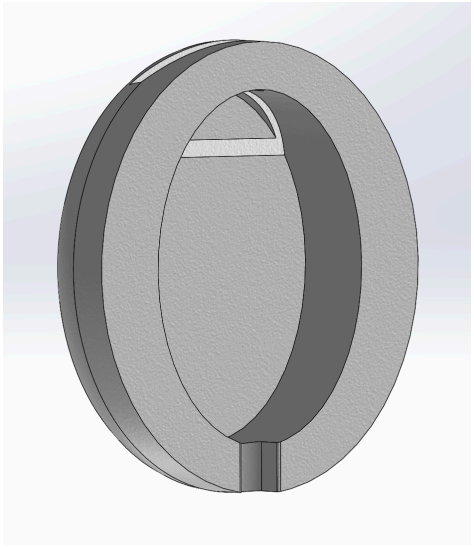


Figure 4: SolidWorks model of earmuff

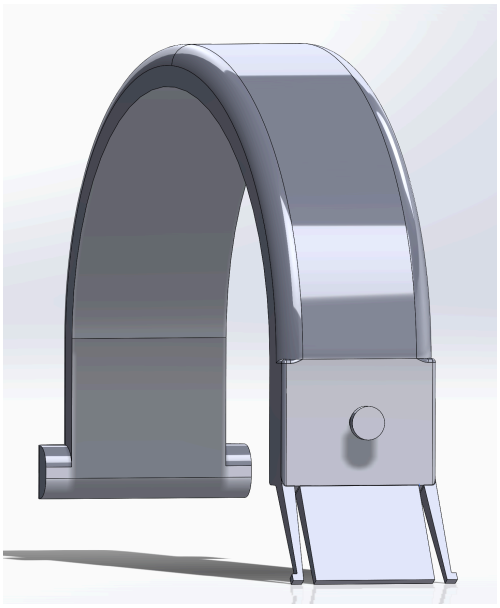


Figure 5: SolidWorks model of headband

II. Dressing

The final dressing design incorporates similar aspects to that of traditional NPWT dressings. Facing the skin is a layer of duoderm. Polyurethane foam is then placed around the duoderm. Several photographs of the dressing are shown below in Figure 6, Figure 7, and Figure 8.

Figure 6: The duoderm and polyurethane portion of the dressing

Figure 7: Demonstration of the adhesive layer being applied over the dressing with tubing applied

Figure 8: The dressing shows sufficient fit over the ear of our model, Harshad

The foam is cut such that a crescent shape is absent from half of the thickness of the foam. At the plane along the width and length directions at half the thickness, there is a more severe cut which allows fit of the helix and lobule into the dressing. As seen in Figure 6, a layer of duoderm is folded and inserted into the cut. The foam measures 110 mm in length (long axis), 72 mm in width (shorter axis), and 29 mm in width. The length along the width from which the foam is cut out (the crescent) is 38 mm. The cut into the foam for ear fit is as long as the foam permits before risk of perforation rises. These measurements are subject to change as creation of different dressing sizes to satisfy variation in patient anatomy is a possible direction for future work. Figure 8 shows sufficient fit and ear-conformation with the dressing.

Over both of these ear-conforming layers, an adhesive layer is applied over the dressing, adhering to the skin surrounding the ear on all sides. This can be seen in Figure 7. Once adhered, a slit is cut into the adhesive layer, and tubing is inserted. This tubing is connected to the vacuum unit and allows application of negative pressure.

III. Y-connector

According to standard fluid-mechanics theory, flow division in branched tubing depends heavily on the relative hydraulic resistances of each branch, which scale with tube length, fluid viscosity, and diameter to the fourth power (Hagen–Poiseuille) [31]. In practice, even small differences in inner diameter between two limbs of a Y-connector can lead to significantly unequal flow rates under a common pressure drop [32]. Experimental studies of laminar flow in rigid tube networks have also shown that mismatched branch resistances can produce non-intuitive flow distributions and instabilities, especially when fluid properties or boundary conditions vary [33].

Applying this model to the current NPWT configuration, the two branches of the Y-connector do not experience the same hydraulic resistance when different tubing diameters are used. Using Hagen–Poiseuille's relationship for hydraulic resistance:

$$R = \frac{128\mu L}{\pi d^4}$$

To evaluate the effect of a 125 mmHg suction setting, the hydraulic resistance and corresponding flow through each tubing branch were calculated. The two branches of the Y-connector were each modeled as a smooth circular pipe of length L = 1.0 m and pressure P = 125 mmHg. Air properties were taken as $\mu = 1.81 \times 10^{-5}$ Pa·s and $\rho = 1.2$ kg/m³ [34]. Although clinical NPWT flow is unsteady and may not remain strictly laminar, Hagen–Poiseuille scaling accurately captures the strong dependence of hydraulic resistance on tube diameter. Thus, the relative increase in resistance when decreasing from 3.5 mm to 3.3 mm is still valid for comparing branch behavior in the Y-connector. The flow rate under a pressure drop ΔP is:

$$Q = \frac{\Delta P}{R}$$

For the 3.5 mm NPWT dressing branch the resistance and flow were calculated:

$$R\_vac = 4.91 \times 10^6\ Pa{\cdot}s/m^3$$

$$Q\_vac = 3.39\ L/s$$

For the 3.3 mm wound drain branch the resistance and flow were calculated:

$$R\_drain = 6.22 \times 10^6\ Pa{\cdot}s/m^3$$

$$Q\_drain = 2.68\ L/s$$

A small change in inner diameter from 3.5 mm (Prevena™ NPWT dressing tube diameter) to 3.3 mm (standard 10 Fr wound drain tube) increases the resistance of the drain branch by roughly 25–30%. For the same applied negative pressure, this higher resistance translates into approximately 20% less flow in the drain branch compared to the NPWT dressing branch. As a result, suction is preferentially distributed to the dressing tube, so the pressure at the Y-junction becomes dominated by the low-resistance path. In practice, the wound drain may experience less effective negative pressure, and under certain conditions the pressure gradient across the junction may reverse locally, allowing air or fluid from the "easier" path to be pulled back into the higher-resistance line. This mismatch therefore not only makes pressure delivery uneven between the drain and dressing, but also introduces a plausible risk of backflow and cross-contamination between wound sites.

To combat this problem, two 10 French tubes (3.3 mm) will be integrated for both the drain and the wound dressing lines so that each branch of the Y-connector experiences equivalent hydraulic resistance. To simulate dual-line negative pressure delivery for the NPWT prototype, the team will integrate a VacuAide 7325 suction pump with a custom Y-connector assembly designed to interface with 10 Fr tubing. The vacuum output from the canister will be routed through the pump's standard ¼-inch suction tubing into a reducing Y-connector with one ¼-inch inlet and two 1/8-inch outlets. Each outlet will be fitted with a short segment of 1/8-inch inner-diameter silicone tubing, which will serve as a compliant adapter sleeve to create a secure, airtight connection to the 10 Fr lines. This configuration will allow the vacuum source to split evenly into two symmetric branches while maintaining compatibility between French-sized medical tubing and standard laboratory barbed fittings. An inline vacuum gauge may also be placed in the main ¼-inch line to verify pressure transmission prior to the split.

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.

See Appendix D for full protocol.

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.

See Appendix D for full protocol.

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 10N, 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 10N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

See Appendix D for full protocol.

Test 4: 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 10N. The test will be run a minimum of 15 times. Should the average force be greater than 10N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

See Appendix D for full protocol.

Test 5: 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.

See Appendix D for full protocol.

Test 6: 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.

See Appendix D for full protocol.

Test 7: SOLIDWORKS Deformation Test

The purpose of the SOLIDWORKS Deformation test is 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 will need to be analyzed, as the tubing diameter is 10Fr, equivalent to 3.33mm. If a force 100N or less demonstrates a deformation greater than 3.33mm, the team will have to re-evaluate the material used for the headphones.

See Appendix D for full protocol.

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 [35]. 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 indicates that the connection between the tubing and the seal is insufficient. Depending on the mode of failure, material choice or design of the apparatus must be changed before retesting. A failure of test 5 & 6 indicates 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. Failure of test 7 indicates that deformation of the device is unacceptably large, and may result in either plastic deformation of the protective headphone or deformation of the vacuum tubing. The consequences of this deformation should be extensively investigated, and either headphone material changed or stress concentrations reduced.

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 5 and 6, the team must ensure that fluid collection reservoirs are of appropriate size such that measurements are of the correct magnitude for each application. For tests involving fit to the ear, 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.

Future work for the team involves the testing detailed in this report as well as finishing fabrication of the device. Implementation of the dressing with the protective headphone still must be done. Fabrication of a custom y-connector for two 10 french tubes must also be done. The headband will also be altered to be adjustable via a velcro strap and a male-female segmentation of the current design.

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 fabricated a design for a NPWT apparatus resembling a headphone with an adjustable over-head strap. The future 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. Testing that has been conducted reveals a moderate hit to the device may result in deformation of the vacuum tubing, so there is an active proposal to make future designs out of a more industrial material. The team will work to iterate upon the fabricated design via the discussed fabrication methods and testing protocols.

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Appendix

Appendix A: Product Design Specifications

EarVac: Product Design Specification

Date: 09/18/2025

Project Title: EarVac

Group Members:
Leader: Bryan Heaton
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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.)

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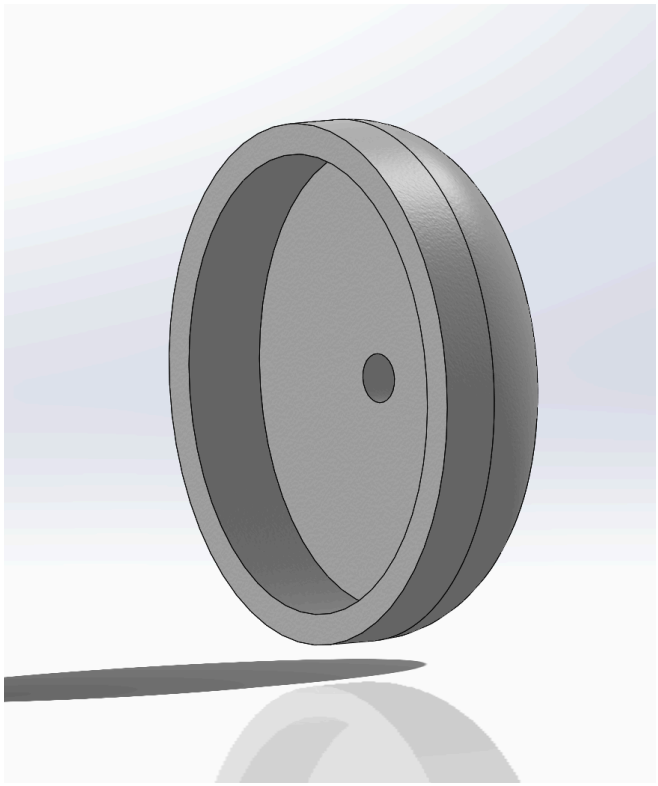
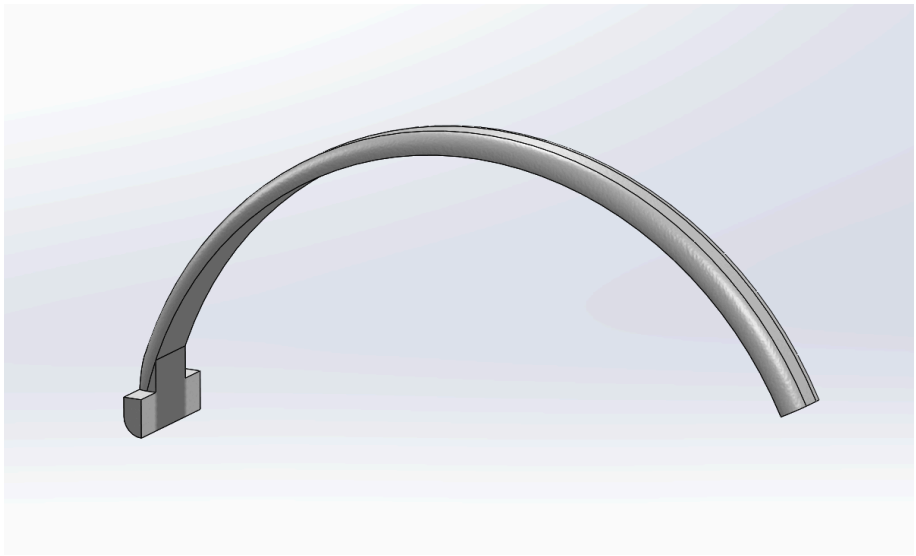
Appendix B: Expenses

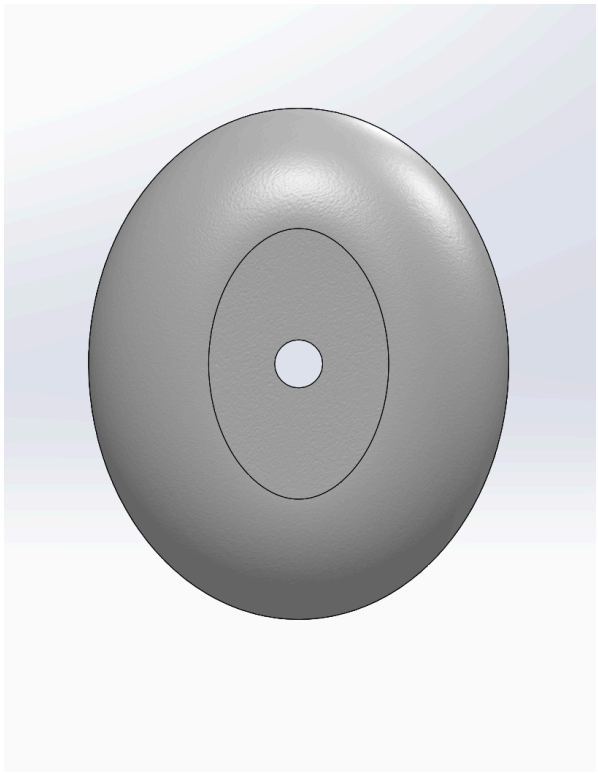
Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	QTY	Cost Each	Total	Link
Category 1 - Items ordered by client - Ms. Nada Botros									
Coloplast 4110 - Self-Cath Plus Soft Straight Hydrophilic Intermittent Catheter 10 Fr 16"	Sterile, single-use, hydrophilic-coated intermittent urinary catheter; 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

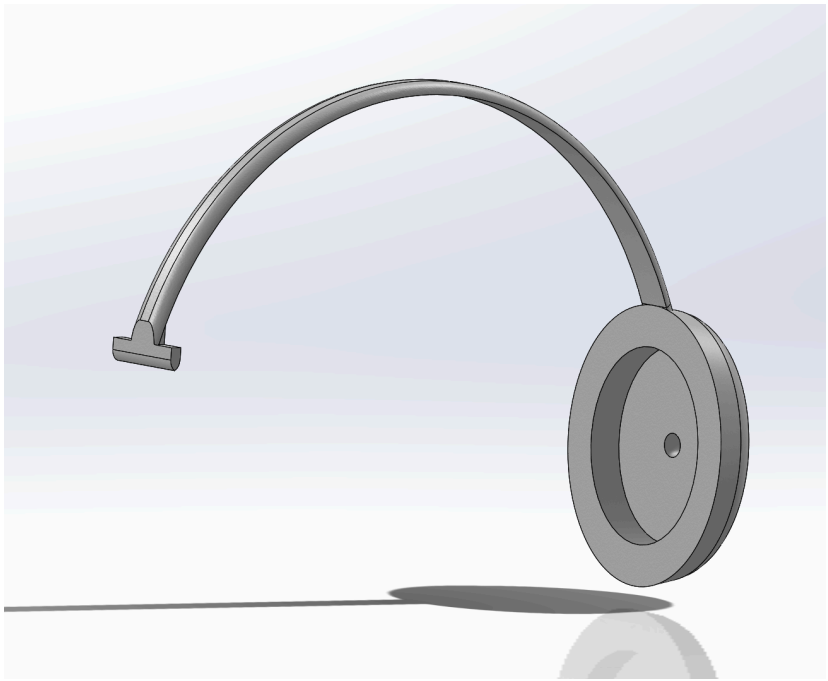
Coloplast 310 - Self-Cath Pediatric Straight Intermittent Catheter 10 Fr 10"	Sterile, uncoated pediatric straight-tip intermittent urinary catheter — 10 Fr (≈ 3.3 mm OD), 10″ length, luer end, latex-free,	Coloplast Inc	310	MedicalMega	SKU 310 -- CLP	10	$1.50	$15.00	https://medicalmega.com/10-fr-10-long-pediatric-intermittent-catheter
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 3D Renderings









Appendix D: Test Protocols

Negative Pressure Transmission Test Protocol

Overview: 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 1 hour 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 1 hour. During each trial, the measured pressure values must not exceed +/- 5mmHg of the applied pressure values. Additionally, the intended pressure must be maintained for the entire 1 hour. Should the device meet both conditions, the test will be considered a pass. Any deviation will be noted.

Procedure:

1) Turn the vacuum on and set the pressure applied to 60mmHg below atmospheric pressure.
2) Let the vacuum run for 1 hour. Monitor the pressure value via an external pressure meter. Also record the pressure displayed via the vacuum. Note down pressure readings every 10 minutes.
3) Should the displayed pressure and measured pressure exceed +/- 5mmHg of the intended pressure at any point, the test will be considered a fail. Additionally, if the vacuum does not continuously suction for 1 hour, the test will be considered a fail.
4) Repeat the test for 80, 100, and 120 mmHg below atmospheric pressure.

Consistent Vacuum Seal Protocol

Overview: 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 1 hour. 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.

Procedure:

1) Attach the seal to a skin like material. The seal order is as follows from closest to skin to furthest: duoderm, foam, and adhesive tape.

2) Connect one end of the fluid tubing to the vacuum and the other end to a hole in the seal.
3) Turn the vacuum on and set the pressure applied to 120 mmHg below atmospheric pressure.
4) Let the vacuum run for 1 hour. Assess to see if the seal shows any tears, rips, or openings during and after the test.
5) The test will be run a minimum of 7 times, with length of tears being the most documented.
6) If no tears show, the test will pass.

Test 3: Strength of Seal Test

Overview: 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 10N, 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 10N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

Procedure:

1) Build the seal: duoderm, foam, adhesive layer.
2) Cut a 15mm by 70mm sample from the seal.
3) Stick half of the seal (vertically) to a hard surface, with the other half being untouched.
4) Setup the MTS machine.
    a) Attach a 100N load cell into the machine.
    b) Setup a tensile pull method.
    c) Attach grips to both the bottom and top of the machine.
5) Attach the free half of the seal to the top grip.
6) Attach the sticky half of the seal to the bottom grip.
7) Have the machine pull the seal apart.
8) Run the test 10 times, if the average force is greater than 10N consider the test a pass.

Test 4: Strength of Tube/Seal Connection Test

Overview: 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

10N. The test will be run a minimum of 15 times. Should the average force be greater than 10N, the test will be considered a pass. Additionally, the standard deviation must not exceed +/- 0.5N.

Procedure:

1) Attach the tube to a preformed seal.
2) Setup the MTS machine.
    a) Attach a 100N load cell into the machine .
    b) Setup a tensile pull method.
    c) Attach grips to both the bottom and top of the machine.
3) Attach the tube end of the seal to the top grip.
4) Attach the seal to the bottom grip.
5) Have the machine pull the seal apart.
6) Run the test 10 times, if the average force is greater than 10N consider the test a pass.

Test 5: Fluid Removal Rate Test

Overview: 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. Should the test pass all aforementioned criteria, the test will be considered a pass.

Procedure:

1) Create a fully fledged vacuum seal.
2) Dip the seal into a bucket filled with certain volumes of water.
    a) 10ml
    b) 20ml
    c) 40ml
    d) 80ml
    e) 100ml
3) Have a bucket to catch fluid on the side.
4) Connect a flow meter to the end of the tube and beginning of the bucket.
5) Turn on the vacuum.
6) Monitor the flow rate for each volume of water.

7) If the deviation between each buck does not exceed 1mL/min, the test shall be considered a pass.

Test 6: Retrograde Fluid Prevention Test

Overview: 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 μL. If any deviation occurs, it will be noted and a design change will be conducted to ensure no backflow.

Procedure:

1) Create a fully fledged vacuum seal.
2) Dip the seal into a bucket filled with certain volumes of water.
    a) 10ml
    b) 20ml
    c) 40ml
    d) 80ml
    e) 100ml
3) Have a bucket to catch fluid on the side.
4) Run the vacuum until the bucket is empty.
5) Transfer the seal to an empty bucket and turn off the vacuum.
6) Record the amount of water that is removed from the seal. If it is greater than 1μL, consider the test a failure.

Test 7: SOLIDWORKS Deformation Test

Overview: The purpose of the SOLIDWORKS Deformation test is 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 will need to be analyzed, as the tubing diameter is 10Fr, equivalent to 3.33mm. If a force 100N or less demonstrates a deformation greater than 3.33mm, the team will have to re-evaluate the material used for the headphones.

Procedure:

1) Set the fixed counter–forced on the inside of the headband portion.
2) Apply a compression force onto the clip connection point and the entire outer surface of the earmuff.
3) Run the FEA simulation with the determined material.
    a) 5N

b) 20N
c) 100N

4) If the deformation is greater than 3.33mm around the tubing hole of the design, consider the test a failure and re-evaluate with a stronger material.