BME Design-Fall 2025 - BRYAN HEATON
Complete Notebook

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BRYAN HEATON

on

Dec 10, 2025 @09:14 PM CST

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Dhruv Nadkarni - Sep 05, 2025, 6:17 PM CDT

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Project description

SERENA EVERS - Dec 09, 2025, 10:31 PM CST

Course Number: B M E 400

Project Name: HeadVac: Negative pressure incisional dressing for rhytidectomy

Short Name: HeadVac

Project description/problem statement:

Newly reconstructed ears after microtia reconstruction surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing. Current temporary drains often lose suction and dressings fail to seal around the ear’s contours which increases a burden on clinical staff. A device specifically shaped for postoperative ear anatomy would provide a more stable seal, more reliable pressure delivery, more reliable wound drainage, and greater protection during the critical early healing period.

About the client:

Dr. Daniel Cho is a pediatric plastic surgeon at UW Health. He specializes in the treatment of infants and children with craniofacial differences. Ms.Nada Botros is a medical student at the Medical College of Wisconsin doing a dedicated research year with Dr. Cho in the CRANILab.

9/11/2025 - First Client Meeting

BRYAN HEATON - Sep 11, 2025, 9:47 AM CDT

Title: First Client Meeting Notes

Date: 9/11/2025

Content by: All

Present: Team + Ms. Botros

Goals:

1. Gain initial understanding of the problem
2. Gain understanding of clinical usage of NPWT
3. Gain understanding of challenges with using NPWT in craniofacial applications

Content:

A list of questions was generated by the team prior to the client meeting. Questions that were asked are underlined, with their answers in bullet points below. Questions to be asked / reconsider asking are not underlined. Additional notes from the meeting are found below the questions.

- Are there specific patient populations or risk factors that make this device especially important?
- What is the priority for outcomes they are hoping to improve — cosmetic sustainability, healing time, complication rates, etc.?
- Images?
    - Rhytidectomy, pre-auricular, post-auricular, and temporal are all varieties
    - Not accounting for all facelifts, should cover EAR AS PRIMARY FOCUS on both sides
    - PRE-AURICULAR IS PRIMARY INTEREST
- Maximum and minimum dimensions/size?
- What are the main limitations or frustrations with current post-rhytidectomy dressing techniques?
    - Wound dressing changed frequently, hair another big difficulty for applying a seal
- Who is the target patient, or does it range? Should the headband be adjustable?
- Are there specific incision patterns or variations we need to accommodate?
    - Usually hidden
    - In front of the ear or behind the ear
    - Depends on surgery
- Should pressure be constant or intermittent? **RE-ASK Dr. Cho**
    - Constant
- Optimal pressure level?
        - Look up Pressure levels on the incisional wound vac
- Material constraints?
- Power supply?
- Restraints on the location of the headband?
- It was stated in the problem statement that negative pressure wound therapy has not yet been explored for rhytidectomy and other facial aesthetic surgery healing processes, partly because of challenges in adapting devices to the unique and curved anatomy of the head and face. Are there any other challenges you are worried about for this project, specifically related to the rhytidectomy surgery or healing process?
    - Other challenge: Getting tape to stick on hairy surface
- Do you have an NPWT machine that we could look at?
    - Yes!

- Is heat buildup from electronics a safety concern?
- Does the system need active/passive cooling to avoid harming the healing tissue?
- Which type of rhytidectomy procedure should the headband work with? (Traditional Facelift: Targets the full face and neck. Involves extensive incisions (ears, hairline, chin). SMAS Facelift: Tightens the muscle layer (superficial musculoaponeurotic system) – relevant for deep tissue healing. Mini-Facelift: Less invasive, used for early signs of aging.)
    - Where the incision is placed is what's important
        - Different types usually use same incision
- What is the typical drainage volume after rhytidectomy, and what range should the device be designed to handle?
- How should the device handle blockages, leaks, or pump failures (e.g., alarms, auto shut-off)?
    - Should the device include fail-safes to prevent over-suction or prolonged use?
- Do you see this as a device primarily for high-risk patients or as a standard of care for all rhytidectomy patients?
    - Face lift - Standard of care t
    - Neurosurgical - High-risk
    - Does the surgical team collect risk factor data prior to surgery? Could be helpful if we want to make a personalized solution.
        - Epic has all medical history
        - Theoretically way down the line we could have an aspect of personalization, but we should stay focused on one aspect when developing the prototype.
- How would success be measured from the clinician's point of view (complication reduction %, cosmetic satisfaction surveys, reduced clinic revisits)?
    - Testing in animal models & humans
    - Stick to different contours
    - Hair shouldn't be a problem
    - FORMS A SEAL - most important
- Do you see broader applications (scalp, craniofacial, neurosurgery) as important future directions?
    - Facelift
    - Scalp surgery,
- What infection control standards must be considered?

-Blood vessels feed structures in face
-facelift relies on little blood vessels of face, fluid build up occludes blood vessels and causes complications (necrosis,
-if you cant close wound in surgery (skin too tight, infection) invented at wake forest "wound vac" sponge over an area with clear plastic adhesive strip in middle and vacuum thru hole
-problem with wound vac for facelift and scalp incisions: contour of face is difficult
Solutions: Headbandvac (hole for ear) , Hatvac w/ strap?
-different surgeons have different techniques for incisions
-facelift is cosmetic and scalp incisions usually for tumor removal
-$1000 funding
- 414-687-9117
-Nurses need to be able to change the headband
-first step: proof of concept
-cadaver testing to ensure a seal can be formed around an incision
-main target area is on cheek and ear area
-watch video of rhytidectomy
-look at images of post op
- look up pressure levels on an incisional wound vac

Conclusions/action items:

- Continue contact with client as PDS is drafted
- Consider constraints / guidance from clients as PDS is drafted

9/18/2025 - Pre-PDS Completion Client Meeting

BRYAN HEATON - Sep 18, 2025, 1:54 PM CDT

Title: Client Meeting

Date: 9/18/25

Content by: Meghan, Bryan

Present: Team + Clients

Goals:

1. Finalize understanding of preliminary research
2. Continue to dial in the scope of the project, optimizing for maximal impact in ORs

Content:

- A more specific vision for the final product would be really helpful
    - Should we focus on the around the ears incisions?
        - Wearable version of NPWT device
        - Facelift and ear incisions are most important (focus)
- Adjustable headband or different sizes?
    - Adjustable, elastic, velcro maybe?
- Do we want the headband to be reusable / sterilizable between patients?
    - **Disposable**
    - JP drain?
    - For shelf-life section of PDS
        - And patient-related concerns section
    - PDS size specification: Clinicians must be able to easily inspect and replace dressings without dismantling the headband OR the device must allow for simple removal and reapplication ???
        - Will be single use
        - Headband disposable. Tubing also disposable. Vacuum already exists and will be reusable.
- ~~Shelf life of headband expectations? Or would you think this is dependent on material we end up choosing?~~
    - Probably dependent on the material/ npwt device we use.
    - put down the most basic FDA standard for a device sitting on a shelf.
- Do you envision this to be used one time the day after the patient's facelift surgery or would it be a "recurring" service where the patients comes back multiple times?
    - For facelift, only one application
- Likes/dislikes/preferences with surgical techniques, NPWT devices, etc.
    - No preferences, as long as it works
    - Hair bearing region
    - Can be adjustable
    - No specific constraints
    - Can we cover our ears
        - Muffs would be so cool
        - Follow up with doctor Cho
    - Overall specific opinions on the project concept/usage of the product
    - Preferred shape of the headband/npwt device
- Are we making our own NPWT device?
    - No incisional wound vac
    - Bulser(ball of guaze) and head wrap for dressings
- Any weight specifications?
    - Lightweight and ambulatory
    - Not restrictive
- What is the **typical drainage volume** after rhytidectomy, and what range should the device be designed to handle?

        - **Shouldn’t be much, ~20 mls a day**
    - What variable are we going to test our products success on?
        - Just make something that seals and works for now, variables for success can come later.
    - Should the device include fail-safes to prevent over-suction or prolonged use?
        - Bar on vacuum that indicates if seal is present or if over-suction is occuring
        - Bar usually at 100% during usage

Questions STILL TO ASK for Dr. Cho:

- Are there specific patient populations or risk factors that make this device especially important?
- What is the priority for outcomes they are hoping to improve — cosmetic sustainability, healing time, complication rates, etc.?
    -
- Maximum and minimum dimensions/size?
- Who is the target patient, or does it range? Should the headband be adjustable?
- Restraints on the location of the headband?
- It was stated in the problem statement that negative pressure wound therapy has not yet been explored for rhytidectomy and other facial aesthetic surgery healing processes, partly because of challenges in adapting devices to the unique and curved anatomy of the head and face. Are there any other challenges you are worried about for this project, specifically related to the rhytidectomy surgery or healing process?
    - Other challenge: Getting tape to stick on a hairy surface
- Is heat buildup from electronics a safety concern?

Notes:

- New possible avenue:
    - Microtia, harvesting cartilage
    - Have to suction out the extra air in the “skin pocket”
    - SOMETHING THAT IS VARIABLE
- Sports/Elastic Headband, Velcro Adjustable or comes in different sizes
    - Can't be super tight on the face
    - Disposable Headband, 1 per patient
- JP Drain
    - Bulb/Plastic Balloon, squeezes everything out of a fluid-filled cavity
- Do not make any technology that has already been made, like the vacuum unit itself

Conclusions/action items:

- **Schedule in-person meeting to see NPWT setup**

9/25/2025 - Client Meeting at Hospital - Project Shift

BRYAN HEATON - Sep 30, 2025, 12:48 PM CDT

Title: Client Meeting at Hospital - Project Shift

Date: 9/25/2025

Content by: All

Present: All

Goals:

- Explore possible engineering solutions for concerns with rhytidectomy device
- See what avenue would have most impact

Content:

Summary: The project focus has shifted to a microtia surgery recovery device. This simplifies the team's objective as they no longer have to consider hair at the site of adhesion, applying negative pressure to the delicate inner ear structures, and complex incisions. The team will likely go towards a design which resembles an ear muff, applying negative pressure to the entire external ear. The design must also feature a y-connector on the vacuum tube which will function to both drain fluid from inside the ear and pull the new skin flap over the newly structured ear.

- Microtia TOTAL SHIFT YAAAAAYYY!!!!!!!
- Widely applicable besides microtia
- Prevena incisional vac
- Compatible for kids

    Suction drain and something under the skin

    Grade 3

    No ear and lumps of cartilage

        Associated with oral atresia (no ear hole)

    1-2 inches shaven around the ears in every case

        Don’t need to worry about adhesive on hair

    Ribs carved for ear attachment

    One device that connects two tubes to one vac

    An earmuff that is flexible

        Incisional vac sponge

    Suction on top and underneath the skin

    Two tubes connected to the same vacuum

    Incisional vac sponge designed to go directly onto the skin

    Duaderm tape

    The uncommonness of microtia main reason why this hasn't been done yet

    Incisional vac compatibility for this device

    Problems with using the drains currently:

- Drain put in below the ear

    - Cheaper, disposable vac IS ANOTHER GOAL in the future?
- Suction getting blocked was a big problem
- The phlebotomy tube is not having enough pressure another problem
- Adjustable pressure in y-connecter would be cool, but not necessary
- Not bulky ideally
- Masticol: tree sap derived liquid to help the sponge stick for longer
- Layers of vac application (dressing):
    - Duaderm tape protects the skin
    - Sponge on top
    - Adhesive on top top

- DISPOSABLE AND COST EFFECTIVE PART
- 125mmHG Sustained

New demographic - kids

- No ear hole opening
- Dont have to worry about suction on a ear drum
- Complex geometry with Incsisional vac component
    - Dressings needs to run along decision
- Subcutaneous drain that sucks fluid down
- DRessings + Wound Drain + Wound Drain
- Combined all into one
- Earmuff, That when sucks puts pressure thats ½
- Drain, that sucks underneath the skin ½
- Wraps around head
- Vaccupressure tubes - needles
- Constant Pressure - Replace containers

Conclusions/action items:

- Update the PDS accordingly
- Prepare for advisor meeting to discuss this shift

10/24/2025 - Client Meeting

BRYAN HEATON - Oct 24, 2025, 12:44 PM CDT

Title: Client Meeting Notes

Date: 10/24/2025

Content by: Bryan, Meghan, Harshad, Dhruv

Present: All

Goals:

1. Ask more technical questions regarding crushing the ear
2. Gain insight on client vision for design

Content:

Technical questions:

- How do you currently dress the ear to accommodate pressure being put on the flap
    - Would a sponge around the ear and behind provide enough support
- Do you foresee NPWT doing damage to the cartilage of the ear
- How much pressure would be ideal for the wound drain, could you foresee there being contradictions between the pressure
    - Our research indicates varying pressures with the average being about 80mmHg sub atmospheric, but the worry stems from crushing the newly built ear. Would they happen to know if 50 or 60 mmHg sub atmospheric would be enough?
- Wallvac/do they have anything we can use to create a negative pressure environment

Resource requests:

- Do they have the Prevena wound vac specifications sheet at the hospital?? (otherwise email solventum guy)
- CAN WE GET PREVENA TUBING CAD FILES?
- Can we get a human model?
- Structure/parameters of wound drain/ example of typical wound drain
- Any skin-like materials we can use for testing?
    - Silicone

Notes:

- Solventum meeting:
    - Bolster (Ball of gauze) typically
        - Cotton with oil to get into crevices, bolster is applied on top of that
        - Some foam behind the ear, so
        - HOT DOG BUN
            - Ear is the hot dog

        - KELOID EARING (inspiration)

- Design:
    - Beats headphones, outside
    - Replaceable adhesive on the outside of the headphone circumference to prevent buildup of Natural oils
    - Nada likes the foam on the outside of to headphones
        - Foam + Adhesive = Difficult to seal
    - Imagining the sticker on the headphone like a goggle-like material
    - Mastazol
    - Avoid skin touching to skin
- **In current bolsters, they use a “hot dog bun” type of design for the foam**
    - Good! This aligns our current thoughts
- Foam behind ear should be good to prevent damage to the ear, necrosis, breakdown of skin
    - Score the inside part of the “hot dog”, allowing flexible adhesion to the intricate outer ear
- Wall Vac:
    - Similar to vacuum tubes in chem labs, only know of manual ones though
    - UW OR - Gauge for pressure desired
        - Could just use manual wall vac with pressure sensor for testing
    - Proof of concept: Use wall vac to prove it works
    - ECB Lab, Portable Suction generator(Expensive), Giant syringes to create some suction as well
        - For testing
        - Controlling how the VAC sucks would be great for the demo
    - NADA WILL FIND MANNEQUIN WOOOOOHOOOOOOOOOOOOOOOOO
        - Silicone very close substrate to ear cartilage
        - Styrofoam head (Silicone Ear)
            - Similar to human skin → *FOR DHRUV TO REMEMBER: Make the test methods that require skin like material based on silicone.*
- WOUND DRAIN
    - Surgeon preference in tubing size
    - Universal tubing size?
    - 8 or 10 french (Fr) size tube (10 is largest)
        - Proceed with 10 french
    - Can build in one way valve into the drain
        - Check with my blood lab at JnJ
        - We might have a way to prevent backflow. It’s an addition to the Y connector that will help with the backflow issue.
    - 100 mmHG instead of 125,
- Could add stopcock to the tubes

- 2 wound drains - both under skin pocket
    - 1 in front of cartilage
    - 1 behind cartilage
- Interference with headphones
    - NON-EXISTENT DESIGN IS GOOD

- TESTING
    - 4 hours a day
    - After testing - Should
    - Week-long vs day-long test, no difference according to nada
        - For the long durability tests, we can have a tension and compression movement form the MTS machine to simulate a child jumping, running, etc…
    -
    - Dr. Cho is okay with a week long, I think we should still include the MTS compression and tension movements to add some variability.
    - SHOP VAC with adjustable Pressure for testing
    - SILICON EAR MODEL

- ADHESIVE
    - Skin glue, Dermabond
        - Might be our answer
    - Research alternative gluing methods
        - Dermabond is heat-activating **, NO DERMABOND**
        - Mastacol would be used by surgeon if needed for extra adhesion of headphone to adhesive layer
- Consider NOT RIGID headband, safari drawstring hat
    - Combats kids being kids
- Mastisol

EAR MOLDING Technology - EAR WELL

Infant ear - use as inspiration

- Ear Well vs InfantEar Device

- Theoretically could make both tubes same diameter
    - 10 French for both?

    - Def look into this

- Flow rate doesn't matter
    - 10 ccs of fluid at most
    - WoundVac tube inner diameter ~ 3.5mm, wound drain = 10 french = 3.3mm □ □ □□□□ □ □□□ □ □ □□□□

Conclusions/action items:

- Research any relevant pressure sensor compatible with wall vacuum (as found in chem lab, BME design lab)
- Begin design of foam in “hot dog” design
- Look into models for ear, silicone is ideal
- Look into Earwell - could be huge inspo for inner headphone design, could create sticker via this design
    - Inspo for adhesion to skin, allowing device to stick to ear
    - InfantEar more modular

11/24/25: Client Meeting before break

MEGHAN KAMINSKI - Dec 07, 2025, 8:28 PM CST

Title: Client Meeting before break

Date: 11/24/25

Content by: Meghan

Present: Meghan, Serena, Nada

Goals: Update clients on all deliverables

Content:

Brief meeting with Nada

- General checkup on design changes
- No concerns from Nada regarding design
- Confirmed all materials were being ordered
    - Excel sheet with material information sent from Nada
- Updated Nada on all upcoming dates

Conclusions/action items: Continue working on final deliverables. Keep in contact with Nada for upcoming orders.

9/26/2025 - Meeting Post-Microtia Shift

BRYAN HEATON - Sep 30, 2025, 12:51 PM CDT

Title: Meeting Post-Microtia Shift

Date: 9/26/2025

Content by: All

Present: All

Goals:

1. Present new project focus and discuss implications of shift
2. Gain insight into potential new engineering challenges with design

Content:

Notes from Russ:

- Think about pressure differences of the drain and the vac and how that might affect the drainage and the possibility of infection
- Devices to look at
    - The House institute dressing
- Infection is an issue
    - Try to combat fluid flowing back into the wound
- Pressure level differential in front and behind ear could increase infection risk

Conclusions/action items:

- Consider new challenges with design
- Delegate new research to teammates

10/10/2025 - Advisor Meeting

BRYAN HEATON - Oct 12, 2025, 4:06 PM CDT

Title: Advisor Meeting

Date: 10/10/2025

Content by: Bryan Heaton

Present: Bryan Heaton + Meghan Kaminski

Goals:

1. Update advisor with information from Solventum meeting
2. Collect insight on design ideas
3. Identify priorities moving forward

Content:

- Drawings were a little difficult to comprehend, CAD was good
- GET PROTOTYPING!
    - Even without final materials
- Don’t wait too long to do outreach, do this semester if possible
- Continue to prioritize labarchives entires
- From Solventum meeting:
    - Oval sponge over whole ear would crush the ear
    - What magnitudes of pressure would do this?
- FInd a way to stabilize ear with the use of NPWT

Action Items:

- Look at ENT dressings for ears
    - Medtronic
    - Olympus
- Ask for a head model
- Research magnitudes of NPWT used

Questions for clients:

- Clarify main use for NPWT: is it to drain the fluid from the wound or to apply physical pressure to the external ear, or are both equally important?
- What is the main problem seen from the Vietnam trip that prompted the NPWT idea?
- What is the optimal negative pressure magnitude for the oval to still work?

Conclusions/action items:

- Action items listed above

10/17/2025 - Advisor Meeting

BRYAN HEATON - Dec 10, 2025, 1:28 PM CST

Title: Advisor Meeting

Date: 10/17/2025

Content by: All

Present: All

Content:

Questions for clients:

- What is the tube size of the wound drain? How does it differ from the main NPWT

Notes:

- Jackson Pratt vs Cathater for wound drain
    - Tube Diameter Discrepancies -
- Tegaderm?
- Pressure Synchronization:
    - Diameter of tubes
    - Flow
    - Pressure
        - Ensure Fluid Trap at the bottom of the vacuum is the lowest pressure
    - Serena can work on this Fluid Dynamics □😀

Conclusions/action items:

- Start making sponge varieties to investigate crushing problem
- Look into wallvac (from Nada)
- Look into woundvac specs
    - Leakage alarms
- 3D print custom y-connector?

11/14/2025 - Advisor Meeting

BRYAN HEATON - Dec 10, 2025, 1:29 PM CST

Title: Advisor Meeting

Date: 11/14/2025

Content by: All

Present: All

Content:

- Piece-by-piece connection of tubing to dressing should work for different diameter tubing
- Use 1002 vacuum for now
- Use a regulator for wall vacuum
    - Eliminates need for in-line pressure sensor
- Time for testing next semester

Conclusions/action items:

- CAD sealing ring for 10-french tubes?
- Purchase vacuum
    - Find one that specs down to -50 mmHg
- Touch base with “healing in alignment” team
    - Serena reach out to Jacob
- Find regulator - could not even need the in-line sensor with this
    - Reach out to Dr. P
        - Meghan did this
    - Check with rockwell lab
        - Bryan to do

11/21/2025 - Advisor Meeting

BRYAN HEATON - Dec 10, 2025, 1:30 PM CST

Title: Advisor Meeting

Date: 11/21/2025

Content by: All

Present: All

Content:

- No necessary data for poster
- Less words!!

Conclusions/action items:

- Use head / body model from teaching lab
- Cut to the chase on the poster, use pics
    - High-level explanation
- Lots of images little text
- Keep it very straight to the point for the speaking
- Comfort test
    - Pad for the other side of the headphone so it doesn’t create a pressure wound
- Qualitative test of how to ear looks after removing the device

11/20/2025 - Initial Dressing Prototyping

BRYAN HEATON - Nov 21, 2025, 1:19 PM CST

Title: Initial Dressing Prototyping

Date: 11/20/2025

Content by: Bryan Heaton

Present: Bryan, Harshad, Meghan, Serena

Goals:

1. Being cutting foam and securing duoderm inside
2. Confirm proof of concept for slit in foam idea

Content:

- The team met and cut into the given foam and duoderm samples
- Determined that this should work, especially when negative pressure is applied

Conclusions/action items:

- Need to make headphone interior deeper / wider to accommodate dressing
- Make document outlining how we think dressing will be applied after surgery, steps to do so

BRYAN HEATON - Nov 20, 2025, 3:27 PM CST

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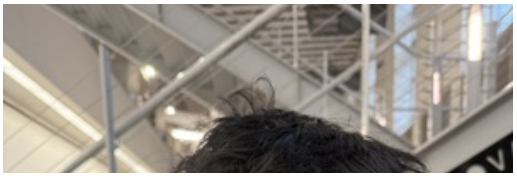
BRYAN HEATON - Nov 20, 2025, 3:27 PM CST



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BRYAN HEATON - Nov 20, 2025, 3:27 PM CST

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BRYAN HEATON - Nov 20, 2025, 3:27 PM CST

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BRYAN HEATON - Nov 20, 2025, 3:28 PM CST

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12/4/2025 - Dressing Prototyping for Poster Presentation

BRYAN HEATON - Dec 04, 2025, 1:27 PM CST

Title: Dressing Prototyping for Poster Presentation

Date: 12/4/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Recreate the dressing from our initial prototypes, with cleaner more measured cuts

Content:

- The dressing is shown below.
- All head models in the BME fab lab did not have protruding ears, therefore the model did not fit on them
    - The model heavily relies on the protruding structure of the ear to be stable when applied
- The dressing (foam, duoderm) measures 110mm (l) x 72 mm (w) x 29 mM (t)
    - 38mm max depth of cut out (crescent shape)
    - Cut into foam for ear fit goes until risk of perforating other side

Notes post-fabrication

- The adhesive is extremely sticky and tedious to work with.
- We will have to see how much of the adhesive layer is minimal to ensure stickage to desired surface, hopefully area around ear is enough.

Conclusions/action items:

- N/A

2025/11/03 - Budget Spreadsheet

HARSHAD GUNASEKAR - Dec 10, 2025, 7:37 PM CST

Title: Budget Spreadsheet

Date: 11/3/2025

Content by: Harshad Gunasekar (BPAG)

Present: Team and Client

Goals: Keep track of materials and expenses throughout the project life-cycle

Content:

c

Conclusions/action items:

- Keep track of items next semester as well

- Gather more materials if needed and keep recording materials

Ensure we are remaining on track for being under our budget of $1000

HARSHAD GUNASEKAR - Dec 10, 2025, 1:57 PM CST

Download

BPAG_Expense_Spreadsheet_-_Sheet1.pdf (110 kB)

10/22/25-Initial SolidWorks Design

MEGHAN KAMINSKI - Dec 08, 2025, 1:04 PM CST

Title: Initial SolidWorks Design

Date: 10/22/25

Content by: Meghan, Dhruv

Present: N/A

Goals: Create initial design for headband and earmuff

Content:

See attachment

Conclusions/action items: 3D print in PLA for show and tell

MEGHAN KAMINSKI - Dec 08, 2025, 12:52 PM CST

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Headband_preliminary_3DPrint_1.SLDPRT (242 kB)

10/27/25-Initial earmuff update

MEGHAN KAMINSKI - Dec 08, 2025, 1:03 PM CST

Title: Initial earmuff update

Date: 10/27/25

Content by: Meghan

Present: N/A

Goals: Update the earmuff according to new dimensions

Content:

See attachment

Conclusions/action items: 3D print in PLA to test dimensions

MEGHAN KAMINSKI - Dec 08, 2025, 12:52 PM CST

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ear_muff_update_1.SLDPRT (236 kB)

2025/10/28 - Male Connection SolidWorks Model

Dhruv Nadkarni - Oct 28, 2025, 6:09 PM CDT

Title: 1/2 SolidWorks Model

Date: 2025-10-28

Content by: Dhruv Nadkarni

Present: Meghan Kaminski

Goals: Create the connection points for the headphones

Content:

Attached is solidworks model.

Conclusions/action items:

Create an assembly once both sides are created.

Dhruv Nadkarni - Oct 28, 2025, 6:09 PM CDT

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DhruvSolidWorksMaleComponent.SLDPRT (486 kB)

11/13/25-Headband with updated connection site

MEGHAN KAMINSKI - Dec 08, 2025, 1:02 PM CST

Title: Headband with updated connection site

Date: 11/13/25

Content by: Meghan

Present: N/A

Goals: Update SolidWorks with new connection site

Content:

See attachment

Conclusions/action items: 3D print in PLA to test connection site

MEGHAN KAMINSKI - Dec 08, 2025, 12:50 PM CST

Download

2024headband.newconnectionsite.SLDPRT (306 kB)

11/13/25- Earmuff with updated connection site

MEGHAN KAMINSKI - Dec 08, 2025, 1:02 PM CST

Title: Earmuff with updated connection site

Date: 11/13/25

Content by: Meghan

Present: N/A

Goals: Update SolidWorks with new connection site

Content:

See attachment

Conclusions/action items: 3D print in PLA to test connection site

MEGHAN KAMINSKI - Dec 08, 2025, 12:50 PM CST

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2024earmuff.newconnectionsite.SLDPRT (293 kB)

11/24/25-Scaled earmuff piece

MEGHAN KAMINSKI - Dec 08, 2025, 1:05 PM CST

Title: Scaled earmuff piece

Date: 11/24/25

Content by: Meghan

Present: N/A

Goals: Resize pieces to create space for dressing

Content:

See attachment

Conclusions/action items: 3D print in PLA to test dimensions

MEGHAN KAMINSKI - Dec 08, 2025, 12:52 PM CST

Download

scaled.earmuff.newconnectionsite.SLDPRT (343 kB)

11/24/25-Scaled headband piece

MEGHAN KAMINSKI - Dec 08, 2025, 1:05 PM CST

Title: Scaled headband piece

Date: 11/24/25

Content by: Meghan

Present: N/A

Goals: Resize pieces to create space for dressing

Content:

See attachment

Conclusions/action items: 3D print in PLA to test dimensions

MEGHAN KAMINSKI - Dec 08, 2025, 12:52 PM CST

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scaled.headband.newconnectionsite.SLDPRT (379 kB)

12/3/25-Final Headband SolidWorks Model

MEGHAN KAMINSKI - Dec 08, 2025, 1:00 PM CST

Title: Final Headband SolidWorks Model

Date: 12/3/25

Content by: Meghan

Present: N/A

Goals: Create SolidWorks model to be 3D printed

Content:

See attachment

Conclusions/action items: 3D print in thermoplastic polyurethane

MEGHAN KAMINSKI - Dec 08, 2025, 12:49 PM CST

Download

finalheadband.newconnectionsite.SLDPRT (359 kB)

12/3/25- Final earmuff SolidWorks model

MEGHAN KAMINSKI - Dec 08, 2025, 1:01 PM CST

Title: Final Earmuff SolidWorks Model

Date: 12/3/25

Content by: Meghan

Present: N/A

Goals: Create SolidWorks model to be 3D printed

Content:

See attachment

Conclusions/action items: 3D print in thermoplastic polyurethane

MEGHAN KAMINSKI - Dec 08, 2025, 12:49 PM CST

Download

finalearmuff.newconnectionsite.SLDPRT (265 kB)

2025/10/23 - Negative Pressure Transmission Protocol

Dhruv Nadkarni - Dec 09, 2025, 9:04 PM CST

Title:

Negative Pressure Transmission Test Protocol

Date: 2025-10-23

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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 a minimum of 8 hours. 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.
3. Should the displayed pressure and measured pressure exceed +/- 5mmHg of the intended pressure, the test would fail. Additionally, if the vacuum does not continuously suction for 1 hour, the test will fail.
4. Repeat the test for 80, 100, and 120 mmHg below atmospheric pressure.

Conclusions/action items:

Continue writing other test procedures.

2025/10/23 - Consistent Vacuum Seal Protocol

Dhruv Nadkarni - Dec 09, 2025, 9:04 PM CST

Title:

Consistent Vacuum Seal Protoco

Date: 2025-10-23

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Strength of Seal Test

Dhruv Nadkarni - Dec 09, 2025, 9:04 PM CST

Title: Strength of Seal Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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 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 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.
    1. Attach a 100N load cell into the machine.
    2. Setup a tensile pull method.
    3. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Strength of Tube/Seal Connection Test

Dhruv Nadkarni - Dec 09, 2025, 9:05 PM CST

Title: Strength of Tube/Seal Connection Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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 5N. 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.
    1. Attach a 100N load cell into the machine .
    2. Setup a tensile pull method.
    3. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Fluid Removal Rate Test

Dhruv Nadkarni - Dec 09, 2025, 9:05 PM CST

Title: Fluid Removal Rate Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.
    1. 10ml
    2. 20ml
    3. 40ml
    4. 80ml
    5. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Retrograde Fluid Prevention Test

Dhruv Nadkarni - Dec 09, 2025, 9:05 PM CST

Title: Retrograde Fluid Prevention Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.
    1. 10ml
    2. 20ml
    3. 40ml
    4. 80ml
    5. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - SOLIDWORKS Deformation Test

Dhruv Nadkarni - Dec 09, 2025, 9:06 PM CST

Title: SOLIDWORKS Deformation Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.
    1. 5N
    2. 20N
    3. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12/04 - SOLIDWORKS Deformation Test

Dhruv Nadkarni - Dec 09, 2025, 9:07 PM CST

Title: SOLIDWORKS Deformation Test Results

Date: 2025-12-04

Content by: Dhruv Nadkarni

Present: N/A

Goals: Perform the SOLIDWORKS Deformation Test

Content:

Attached are results.

Conclusions/action items:

Perform the other tests.

Dhruv Nadkarni - Dec 09, 2025, 9:08 PM CST

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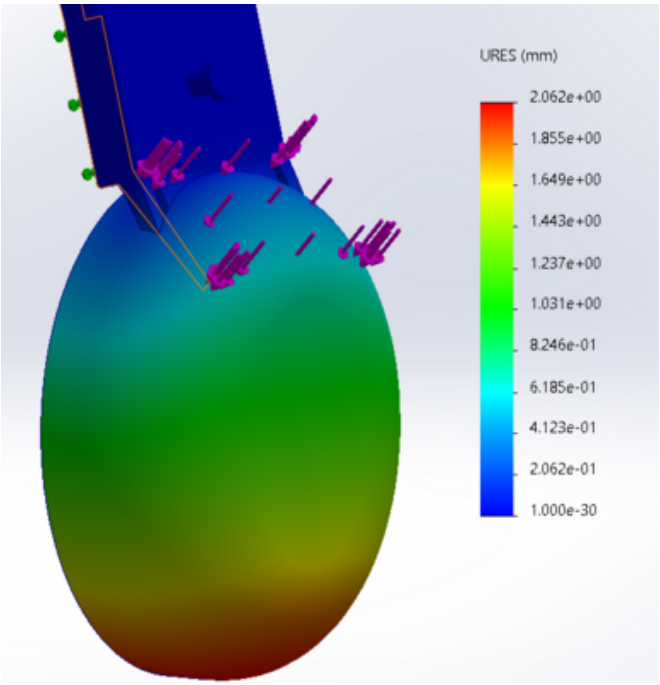
Assem1.SLDASM (254 kB)

Dhruv Nadkarni - Dec 09, 2025, 9:08 PM CST



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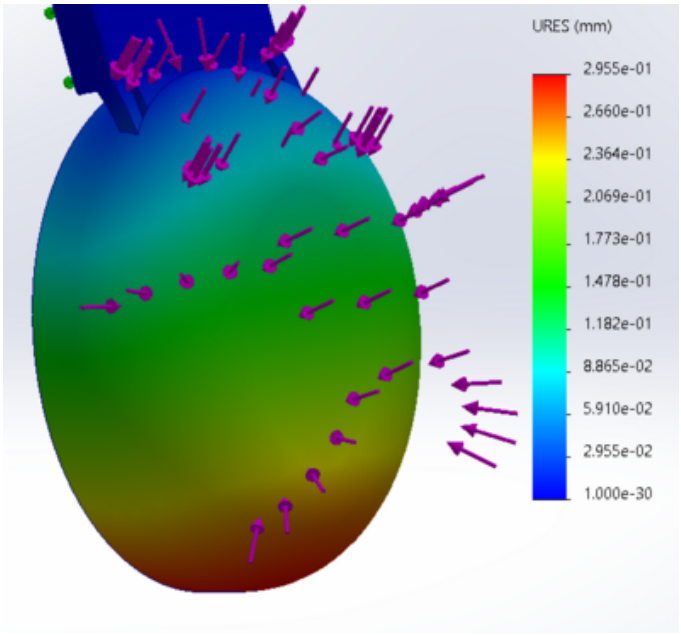
Dhruv Nadkarni - Dec 09, 2025, 9:08 PM CST



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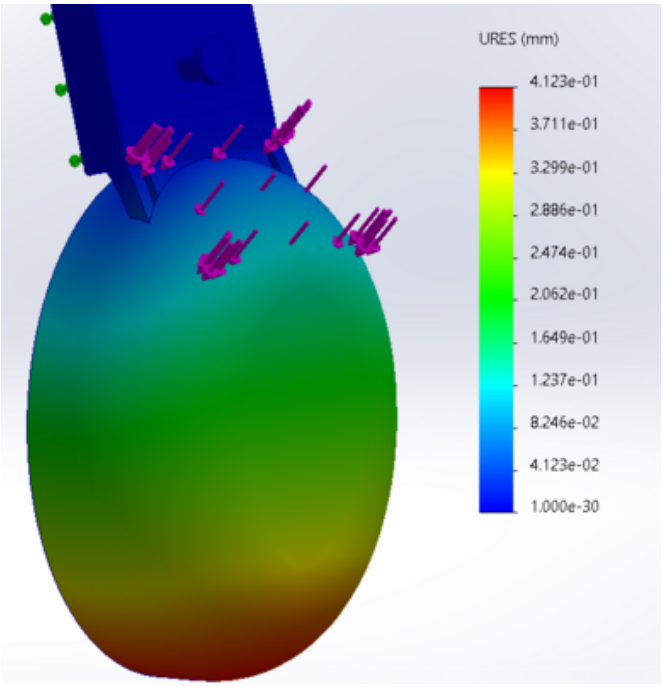
Dhruv Nadkarni - Dec 09, 2025, 9:08 PM CST



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10/3/25-Preliminary Presentation

MEGHAN KAMINSKI - Dec 07, 2025, 8:41 PM CST

Title: Preliminary Presentation

Date: 10/3/25

Content by: All

Present: All

Goals: Deliver preliminary presentation to advisors and fellow students

Content:

See attachment

Conclusions/action items: Begin fabrication and testing of the initial prototypes. Continue general research on NPWT.

MEGHAN KAMINSKI - Dec 07, 2025, 8:41 PM CST

Download

Preliminary_Presentation.pptx (8.34 MB)

10/8/2025 - Product Design Specifications

BRYAN HEATON - Oct 08, 2025, 10:10 PM CDT

Title: Product Design Specifications

Date: 10/8/2025

Content by: Bryan Heaton (v2), All (v1)

Present: N/A

Goals:

1. Establish quantitative criteria for the device's fabrication, testing, and design criteria.

Content:

HeadVac: Product Design Specification

Date: 09/18/2025

Project Title: HeadVac

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

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

Function

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

Client requirements

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

Design requirements

1. **Physical and Operational Characteristics**
    1. **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.
        1. 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.
        2. 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.

3. 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.

2. **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.

    1. 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.

    2. 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].

    3. 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].

3. **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.

    1. 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.

    2. 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.

    3. 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.*

4. **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.)

    1. 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.

2. With regards to patient usage, the device will be used for up to a week post-surgery.

5. **Shelf Life**:
    1. 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.
    2. 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.

6. **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.
    1. 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.
    2. The device must also withstand a large variety of weather conditions, as the device will be worn by the patient outside of the hospital.
    3. The device will only be operated by nurses, surgeons, or other medical personnel trained specifically in NPWT.
    4. 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].
7. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc.
    1. 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.
    2. 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.
8. **Size**:
    1. 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.
    2. 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.
    3. Tubes must not be placed on skeletal pressure points to prevent the formation of pressure ulcers [16].

9. **Weight**:

1. 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].

10. **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).
    1. 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].
    2. 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].

11. **Aesthetics, Appearance, and Finish**: Color, shape, form, and texture of finish should be specified where possible (get opinions from as many sources as possible).
    1. 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**
    1. **Quantity**: number of units needed
        1. 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

2. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products

1. 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.
2. 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.
3. 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.
4. The most common sales model for an NPWT system is a rental model, with prices upwards of $25.00 per day [28].

3. **Miscellaneous**
    1. **Standards and Specifications**
        1. 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].
        2. 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].
        3. 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].
        4. 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].
        5. 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].
        6. 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].
    2. **Customer**: Specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
        1. 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.
    3. **Patient-related concerns**:
        1. Patient-related concerns are up to the surgeon's discretion, as microtia surgery results are highly individualized [35].
    4. **Competition**: Are there similar items that exist (perform a comprehensive literature search and patents search)?
        1. NPWT in Head & Neck
            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.
        2. Patents / Devices for NPWT

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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Conclusions/action items:

Update accordingly as the project continues to evolve

10/8/25- Preliminary Report

MEGHAN KAMINSKI - Dec 07, 2025, 8:34 PM CST

Title: Preliminary Report

Date: 10/8/25

Content by: All

Present: N/A

Goals: Create preliminary report which follows all guidelines in the rubric

Content:

See attachment

Conclusions/action items: Use the preliminary report as a guide for fabrication and testing. Continue to update and edit a copy of the report for the final report.

MEGHAN KAMINSKI - Dec 07, 2025, 8:36 PM CST

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

BME 400: Preliminary Report

October 1, 2025

Client:
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Ms. Nada Botros

Adviser:
Dr. Russ Johnson

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Download

Team_EarVac_-_Preliminary_Report_1_.pdf (2.15 MB)

12/5/25- Final Poster

MEGHAN KAMINSKI - Dec 07, 2025, 8:31 PM CST

Title: Final Poster

Date: 12/5/25

Content by: All

Present: All

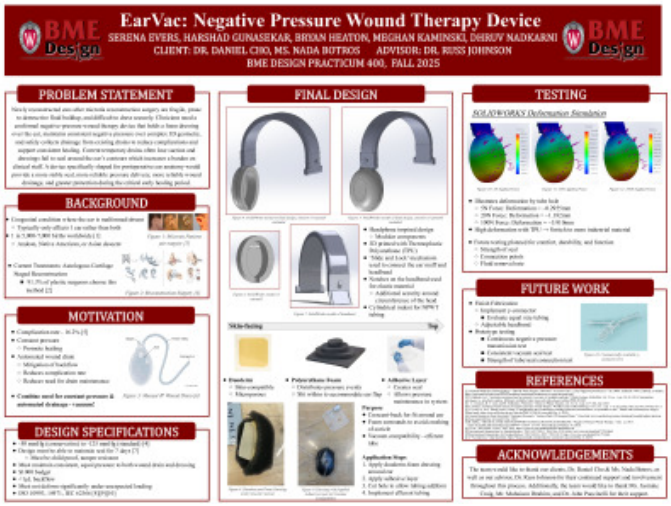
Goals: Create a final poster which effectively showcases the design and progress through the semester.

Content:

See attachment

Conclusions/action items: Continue working on ideas in the future work section of the poster and finish the final report

MEGHAN KAMINSKI - Dec 07, 2025, 8:32 PM CST



Download

Final_Poster.pptx (7 MB)

12/10/25- Final Report

MEGHAN KAMINSKI - Dec 07, 2025, 8:37 PM CST

Title: Final Report

Date: 12/10/25

Content by: All

Present: All

Goals: Create a final report with all important information according to the rubric.

Content:

See attachment

Conclusions/action items: Continue prototyping, testing, and future work next semester.

9/12/25-Progress Report 1

MEGHAN KAMINSKI - Dec 08, 2025, 11:38 AM CST

Title: Progress Report 1

Date: 9/12/25

Content by: All

Present: N/A

Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 11:39 AM CST

Novel Negative Pressure Wound Therapy Device for Rhytidectomy Recovery

Client: Ms. Nada Ikotos
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Sreem Even (BSAC)
Harshul Gunnelur (BPAG)

Date: September 5, 2025 - September 12, 2025

Problem Statement

Hematoma remains the most common and severe complication after rhytidectomy due to the facial flap's limited blood supply, and current prevention methods are inconsistently effective. There is a need for a specialized, anatomically compatible negative pressure wound therapy solution to reduce fluid build-up and improve surgical outcomes in facelift procedures.

Brief Status Update

The team held their first client meeting with Ms. Ikotos on Thursday morning and asked all preliminary questions. Next steps for the team are beginning the PDS, continuing preliminary research, and beginning to formulate design ideas.

Download

Progress_Report_1__Team_Facelift_Week_of_9_8_.pdf (145 kB)

9/19/25-Progress Report 2

MEGHAN KAMINSKI - Dec 08, 2025, 12:43 PM CST

Title: Progress Report 2

Date: 9/19/25

Content by: All

Present: N/A

Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 11:40 AM CST

Novel Negative Pressure Wound Therapy Device for Rhytidectomy Recovery

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Harshul Gunnelur (BPAG)

Date: September 12, 2025 - September 19, 2025

Problem Statement

Hematoma remains the most common and severe complication after rhytidectomy due to the facial flap's limited blood supply, and current prevention methods are inconsistently effective. There is a need for a specialized, anatomically compatible negative pressure wound therapy solution to reduce fluid build-up and improve surgical outcomes in facelift procedures.

Brief Status Update

The team held their second client meeting with Ms. Botros and Dr. Cho on Thursday morning and asked all remaining preliminary questions. They also completed an initial draft of the PDS. Next steps for the team are to continue with research and creating preliminary designs.

Download

Progress_Report_2__Team_Facelift_Week_of_9_15_.pdf (148 kB)

9/25/25-Progress Report 3

MEGHAN KAMINSKI - Dec 08, 2025, 12:43 PM CST

Title: Progress Report 3

Date: 9/25/25

Content by: All

Present: N/A

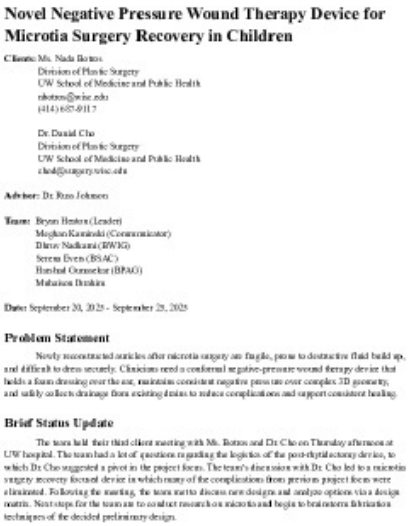
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 11:40 AM CST



Novel Negative Pressure Wound Therapy Device for Microtia Surgery Recovery in Children

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Sriram Iyers (BSAC)
Harshul Gunnekar (BPAG)
Mahaison Benkira

Date: September 20, 2025 - September 26, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid build up, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team held their third client meeting with Ms. Ikotos and Dr. Cho on Thursday afternoon at UW hospital. The team had a lot of questions regarding the logistics of the post-thyridectomy device, to which Dr. Cho suggested a pivot in the project focus. The team's discussion with Dr. Cho led to a microtia surgery recovery focused device in which many of the complications from previous project focus were eliminated. Following the meeting, the team met to discuss new designs and analyze options via a design matrix. Next steps for the team are to conduct research on microtia and begin to brainstorm fabrication techniques of the decided preliminary design.

Download

Progress_Report_3__Team_Facelift_Week_of_9_22_.pdf (157 kB)

10/2/25-Progress Report 4

MEGHAN KAMINSKI - Dec 08, 2025, 12:43 PM CST

Title: Progress Report 4

Date: 10/2/25

Content by: All

Present: N/A

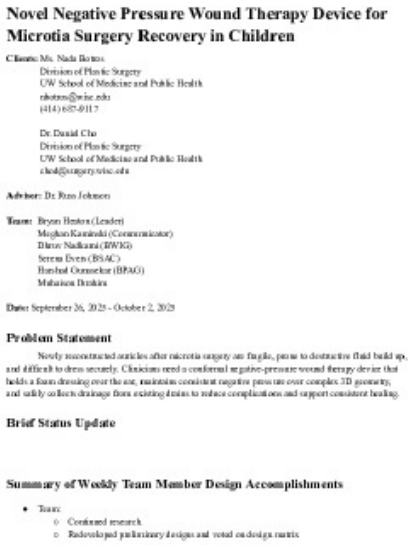
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 11:41 AM CST



Novel Negative Pressure Wound Therapy Device for Microtia Surgery Recovery in Children

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Sreem Even (BSAC)
Harshul Ommeshar (BPAG)
Mahaison Benkira

Date: September 26, 2025 - October 2, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid build up, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Continued research
  - Redeveloped preliminary designs and voted on design matrix

Download

Progress_Report_4__Team_Facelift_Week_of_9_29_.pdf (147 kB)

10/9/25-Progress Report 5

MEGHAN KAMINSKI - Dec 08, 2025, 12:42 PM CST

Title: Progress Report 5

Date: 10/9/25

Content by: All

Present: N/A

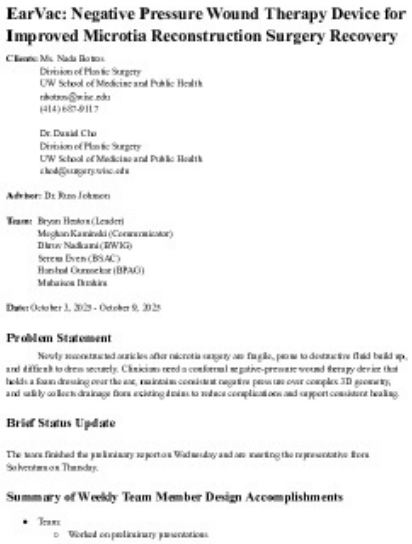
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:42 PM CST



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

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Harshul Gunnolkar (BPAG)
Mahaison Benkira

Date: October 3, 2025 - October 9, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid build up, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team finished the preliminary report on Wednesday and are meeting the representative from Solventum on Thursday.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Worked on preliminary presentation

Download

Progress_Report_5__Team_EarVac_Week_of_10_06_.pdf (149 kB)

10/16/25-Progress Report 6

MEGHAN KAMINSKI - Dec 08, 2025, 12:43 PM CST

Title: Progress Report 6

Date: 10/16/25

Content by: All

Present: N/A

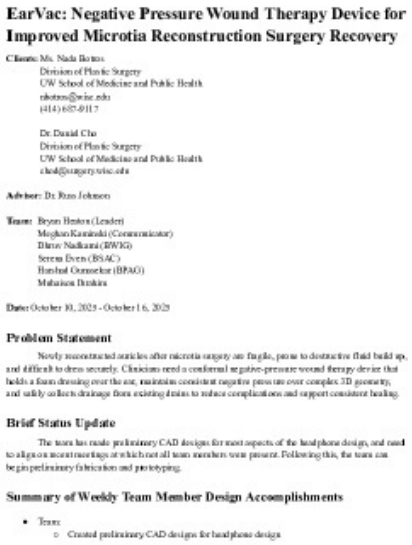
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:44 PM CST



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

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Sereen Even (BSAC)
Harshul Ommeelur (BPAG)
Mahaison Benkira

Date: October 10, 2025 - October 16, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid build up, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team has made preliminary CAD designs for most aspects of the headphone design, and need to align on next meetings at which not all team members were present. Following this, the team can begin preliminary fabrication and prototyping.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Created preliminary CAD designs for headphone design

Download

Progress_Report_6__Team_EarVac_Week_of_10_13_.pdf (144 kB)

10/26/25-Progress Report 7

MEGHAN KAMINSKI - Dec 08, 2025, 12:44 PM CST

Title: Progress Report 7

Date: 10/26/25

Content by: All

Present: N/A

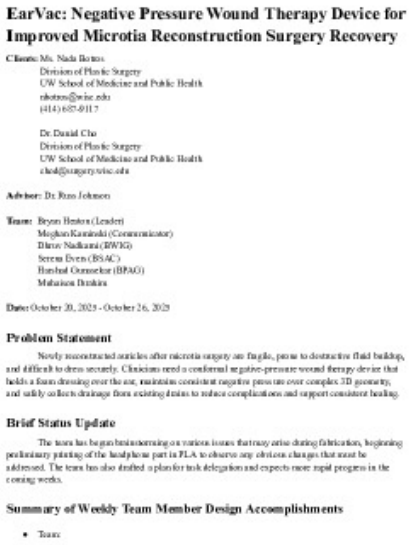
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:44 PM CST



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

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Mahaison Benkira

Date: October 20, 2025 - October 26, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team has begun brainstorming on various issues that may arise during fabrication, beginning preliminary printing of the headphone part in PLA to observe any obvious changes that must be addressed. The team has also drafted a plan for task delegation and expects more rapid progress in the coming weeks.

Summary of Weekly Team Member Design Accomplishments

- Team:

Download

Progress_Report_7__Team_EarVac_Week_of_10_20_.pdf (148 kB)

10/30/25-Progress Report 8

MEGHAN KAMINSKI - Dec 08, 2025, 12:44 PM CST

Title: Progress Report 8

Date: 10/30/25

Content by: All

Present: N/A

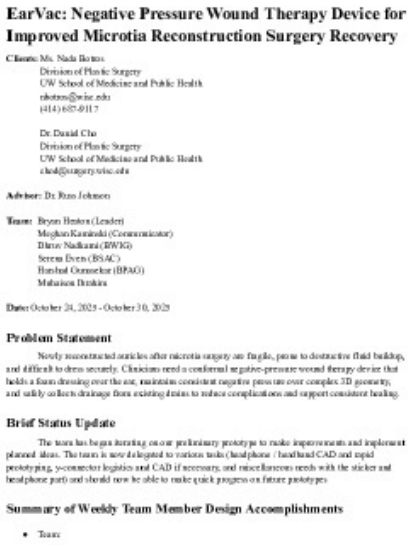
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:45 PM CST



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

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Date: October 24, 2025 - October 30, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team has begun iterating on our preliminary prototype to make improvements and implement planned ideas. The team is now delegated to various tasks (headphone / headband CAD and rapid prototyping, y-connector logistics and CAD if necessary, and miscellaneous needs with the sticker and headphone port) and should now be able to make quick progress on future prototypes

Summary of Weekly Team Member Design Accomplishments

- Team:

Download

Progress_Report_8__Team_EarVac_Week_of_10_27_.pdf (149 kB)

11/6/25-Progress Report 9

MEGHAN KAMINSKI - Dec 08, 2025, 12:46 PM CST

Title: Progress Report 9

Date: 11/6/25

Content by: All

Present: N/A

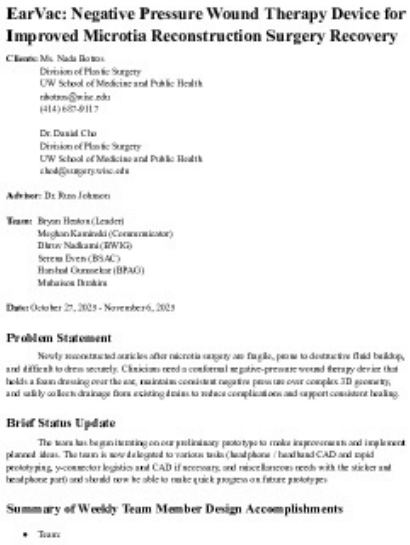
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:45 PM CST



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

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Date: October 27, 2025 - November 6, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team has begun iterating on our preliminary prototype to make improvements and implement planned ideas. The team is now delegated to various tasks (headphone / headband CAD and rapid prototyping, y-connector logistics and CAD if necessary, and miscellaneous needs with the sticker and headphone port) and should now be able to make quick progress on future prototypes

Summary of Weekly Team Member Design Accomplishments

- Team:

Download

Progress_Report_9__Team_EarVac_Week_of_11_4_.pdf (147 kB)

11/13/25-Progress Report 10

MEGHAN KAMINSKI - Dec 08, 2025, 12:47 PM CST

Title: Progress Report 10

Date: 11/13/25

Content by: All

Present: N/A

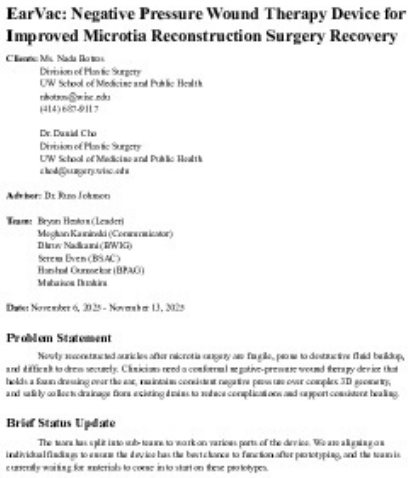
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:46 PM CST



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

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Mahaison Benkira

Date: November 6, 2025 - November 13, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team has split into sub-teams to work on various parts of the device. We are aligning on individual findings to ensure the device has the best chance to function after prototyping, and the team is currently waiting for materials to come in to start on these prototypes.

Download

Progress_Report_10__Team_EarVac_Week_of_11_9_.pdf (148 kB)

11/20/25-Progress Report 11

MEGHAN KAMINSKI - Dec 08, 2025, 12:47 PM CST

Title: Progress Report 11

Date: 11/20/25

Content by: All

Present: N/A

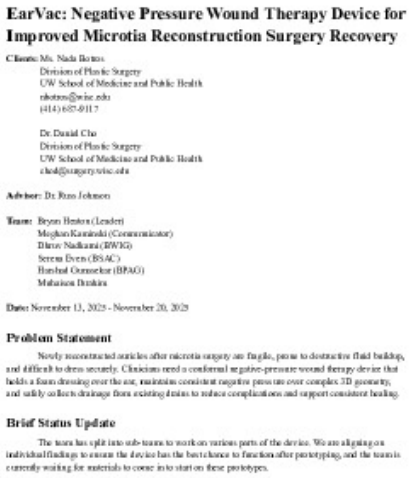
Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:47 PM CST



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

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Mahaison Benkira

Date: November 13, 2025 - November 20, 2025

Problem Statement

Newly reconstructed auricles after microtia surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing.

Brief Status Update

The team has split into sub-teams to work on various parts of the device. We are aligning on individual findings to ensure the device has the best chance to function after prototyping, and the team is currently waiting for materials to come in to start on these prototypes.

Download

Progress_Report_11__Team_EarVac_Week_of_11_9_.pdf (146 kB)

12/4/25-Progress Report 12

MEGHAN KAMINSKI - Dec 08, 2025, 12:47 PM CST

Title: Progress Report 12

Date: 12/4/25

Content by: All

Present: N/A

Goals: Update the clients on progress made in the past week.

Content:

See attachment

Conclusions/action items: As a team, delegate and attempt to complete the goals listed in the progress report

MEGHAN KAMINSKI - Dec 08, 2025, 12:48 PM CST

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

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Date: November 21, 2025 - December 4, 2025

Problem Statement

Newly reconstructed ears after microtia reconstruction surgery are fragile, prone to destructive fluid buildup, and difficult to dress securely. Clinicians need a conformal negative-pressure wound therapy device that holds a foam dressing over the ear, maintains consistent negative pressure over a complex 3D geometry, and safely collects drainage from existing drains to reduce complications and support consistent healing. Current temporary drains often lose suction and dressings fail to seal around the ear's contours which increases a burden on clinical staff. A device specifically shaped for postoperative auriculotomy would provide a more stable seal, more reliable pressure delivery, more reliable wound drainage, and greater protection during the critical early healing period.

Brief Status Update

The team is preparing for the first semester poster presentation! The team has established a solid CAD / 3D print design for the headphone / headband, completed a first prototype of the dressing, and are beginning to utilize y-connectors.

Download

Progress_Report_12__Team_EarVac_Week_of_12_1_1_.pdf (113 kB)

10/16/2025 - Team Alignment Meeting

BRYAN HEATON - Oct 16, 2025, 6:28 PM CDT

Title: Team Alignment Meeting

Date: 10/16/2025

Content by: Bryan Heaton

Present: All

Goals:

1. Align on current SOLIDWORKS designs
2. Determine next steps for CAD modeling / fabrication
3. Align on notes from Solventum meeting, Bryan / Meghan's conversation about implications
4. Align on advisor meeting from last Friday

Content:

Solventum

- We now have a 3M Prevena sticker
- Foam over entire ear may crush the ear
    - How much negative pressure would allow for optimal compression without crushing the ear to the head?
    - How do you currently dress the ear to accommodate pressure being put on the ear so not to crush the new auricle?
- Proposal to fix issue: sponge going over the whole ear still with slit to allow holding the ear up
- Layer on the skin: Soft wicking layer with silver
- Sticky layer: acrylic and silicone
- If we don't have the wound drain completely sealed, could set off alarms
    - Need to find a way to seal the wound drain in
- Prevena sponge is finer, a lot less rough on the skin
    - Need soft polyurethane for sponge

Advisor Meeting

- Research magnitudes of NPWT used
    - What's the lowest therapeutic pressure we can use?
- Is it to drain the fluid from the wound or to apply physical pressure to the external ear, or are both equally important?
- What is the main problem seen from the Vietnam trip that prompted the NPWT idea?
- What is the optimal negative pressure magnitude for the oval to still work?

Fabrication

- Headphone and sticker packaged together ideally
- Print just headphone part soon to get ideas of what we'll need to change

Conclusions/action items:

- Ask Dr. Cho about budget
- Print preliminary headphone design after Harshad re-designs hole in design
- Collect client question list for next Friday
- Make plan for client meeting

10/29/2025 - Adhesive Options to Research

BRYAN HEATON - Oct 29, 2025, 10:09 PM CDT

Title: Adhesive Options to Research

Date: 10/29/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Collect adhesive options mentioned from meetings for research
    1. Adhesive will be to adhere the headphone part to the outer part of the adhesive sticker

Content:

From meeting notes

- **3M adhesive spray**
    - Solid option
    - Mentioned that our adhesive now does not have to be the final one, we just need one for prototyping
- **Adhesive should be replaceable** to counteract natural oil buildup on ears
- **Mastacol** would be **used by surgeon** to have extra adhesion if needed
- **DO NOT USE DERMABOND!**

- 3M adhesive spray comes in many forms, strengths, etc.
    - Super 77 multipurpose spray solid for light-duty materials (cleared for both fabric and plastic, what we'll likely have for headphone)
    - Link is here
    - Can buy at home depot around Madison
    - Be careful with application technique if used
    - 3M Adhesive 24 is also a good option, more specialized for fabric to other substrates
    - Link is here

Conclusions/action items:

- Could buy both adhesives and see which works better, leaning towards 24

9/22/2025 - Hematoma and Their Presence in Facelifts

BRYAN HEATON - Sep 22, 2025, 11:35 PM CDT

Title: Hematoma and Their Presence in Facelifts

Date: 9/22/2025

Content by: Bryan Heaton

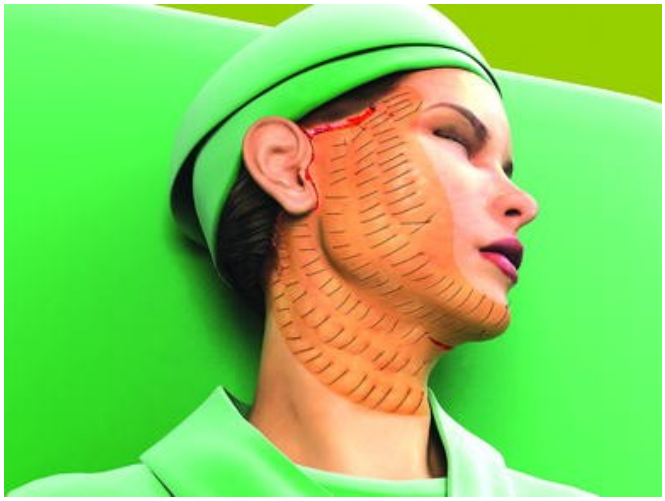
Present: Bryan Heaton

Goals:

1. Better understand how hematomas form post-rhytidectomy
2. Gain understanding of hematoma to better analyze the client situation

Content:

- Certain factors predispose certain patients to more hematoma risk
    - Being male [1]
    - prior hypertension [1]
- Postoperative blood pressure elevation is most common cause of increasing risk of hematoma [1]
    - Therapies to help with post-operation hypetension exist [1]:
        - anti-hypersensitive agents
        - calcium channel blockers
    - Post-operative anxiety, full bladder, and nausea and vomiting increase BP [1]
- Hemostatic net decreased rate of hematoma from 14.2% to 0% [2]
    - This article also discusses the difficulty with drains, tissue glues, and other attempted therapies for hematomas
- Hemostatic net appears work intensive for surgeons, occurs while patient is anesthetized [2]
- No necrosis or other scarring of the skin occurred for any patient post net [2]
- Photograph of full hemostatic net below:



- Decision to use nets dependent on surgeon-specific rates of hematoma, varying in cost-efficiency [1].
- Maintaining patient systolic BP below 120 mmHg reduced risk of hematoma to 0.5% [1].

Conclusions/action items:

- Research the ability of NPWT to be used around the ear

References:

[1] F. Nahai, B. Bassiri-Tehrani, and K. B. Santosa, “Hematomas and the facelift surgeon: It’s time for us to break up for good,” Aesthetic surgery journal, https://pmc.ncbi.nlm.nih.gov/articles/PMC10501745/ (accessed Sep. 22, 2025).

[2] A. A. LA;, “Hemostatic net in rhytidoplasty: An efficient and safe method for preventing hematoma in 405 consecutive patients,” Aesthetic plastic surgery, https://pubmed.ncbi.nlm.nih.gov/23949130/ (accessed Sep. 22, 2025).

10/5/2025 - Understanding Microtia

BRYAN HEATON - Oct 05, 2025, 4:29 PM CDT

Title: Understanding Microtia

Date: 10/5/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Identify primary demographic and higher impacted populations with microtia
2. Understand the extent to which microtia impacts the ears

Content:

- Microtia can vary in severity from minimal to the ear fully missing (anotia) [1]
- Microtia likely not caused by lack of vascularity in the embryo
- Microtia tied to many conditions in the mother, including type I diabetes, anemia, or exposure to certain chemicals
- Multiple genetic factors involved with microtia development
- 15%-60% of microtia cases born with comorbid conditions
    - cleft palate most common
    - mostly facial deformities

Conclusions/action items:

- Continue to research background of microtia

References:

[1] C. Gendron, A. Schwentker, and J. A. van Aalst, “Genetic advances in the understanding of Microtia,” Journal of pediatric genetics, https://pmc.ncbi.nlm.nih.gov/articles/PMC5123892/#sec20 (accessed Oct. 5, 2025).

10/5/2025 - Microtia Reconstruction Process

BRYAN HEATON - Oct 05, 2025, 4:51 PM CDT

Title: Microtia Reconstruction Process Research

Date: 10/5/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Identify and understand how the microtia reconstruction process works
    1. Ideally understand main variances between patients

Content:

- Wait until the patient is ~6 yrs. old for
    - full size alternate ear for better shaping of new ear
    - cartilage is of correct size
    - patient can understand implications of surgery
- Post-insertion of new ear, drain in place to suction skin to new structure
    - drain remains in place for 2 days
- Seems like most variance in the operation is due to presence of ear canal and other factors that influence the yes/no of the surgery, not impacting the specifics of the surgery itself

Conclusions/action items:

- Research the specific dimensions of auricle area before and after surgery to begin fabrication

References:

[1] R. A. Bly, A. D. Bhrany, C. S. Murakami, and K. C. Y. Sie, “Microtia reconstruction,” Facial plastic surgery clinics of North America, https://pmc.ncbi.nlm.nih.gov/articles/PMC5950715/ (accessed Oct. 5, 2025).

12/10/2025 - Competing Designs' Vacuum Magnitude

BRYAN HEATON - Dec 10, 2025, 5:13 PM CST

Title: Competing Designs' Vacuum Magnitude

Date: 12/10/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Investigate the magnitude of negative pressure used in competing designs
2. Identify a lower bound value that may be suitable for auricular iNPWT
3. Identify differences in lower bound values for negative pressure magnitude between normal NPWT and incisional NPWT

Content:

- Several studies have used the PICO system for iNPWT at -80 mmHg [1]
- Prevena operated at -125 mmHg usually [1]
- This meta-analysis suggests little difference in healing between NPWT operated at -75 mmHg and -125 mmHg incisionally

Conclusions/action items:

- Investigate cases of lower magnitude negative pressure application

References:

[1] https://jamanetwork.com/journals/jamasurgery/fullarticle/2702088

12/10/2025 - Deeper Dive into iNPWT Pressure Magnitudes

BRYAN HEATON - Dec 10, 2025, 5:26 PM CST

Title: Deeper Dive into iNPWT Pressure Magnitudes

Date: 12/10/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Investigate the magnitude of negative pressure used in competing designs
2. Identify a lower bound value that may be suitable for auricular iNPWT

Content:

- This study suggests a drop-off in applied wound pressure of ~50% in the first 20 minutes of NPWT operation even with constant vacuum unit pressure [1].
    - Operation at -50mmHg would correspond to a longer term (over the 7 days) of just -25 mmHg
- However, this same study indicates "Even low external negative pressure (about 50 mmHg) led to relevant negative pressure within the wound" [1].
    - Infers -50 mmHg still applies negative pressure to the wound

Conclusions/action items:

- More thorough studies indicating therapeutic range of NPWT might be required
- The lowest magnitude iNPWT device on the market seems to go to -80 mmHg, so that could be an alternative target if -50 mmHg doesn't work.

References:

[1] https://onlinelibrary.wiley.com/doi/10.1155/2018/7058461

9/10/2025 - Negative Pressure Wound Therapy

BRYAN HEATON - Sep 10, 2025, 4:29 PM CDT

Title: Negative Pressure Wound Therapy (NPWT) Overview

Date: 9/10/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Gain a preliminary understanding of NPWT and the specifications for its usage

Content:

- NPWT in it's current state (as of 9/23) is composed of a porous dressing through which **persistent OR intermittent** suction is applied, down to **125 mmHg below ambient**[1].
    - More modern systems offer a range of pressures from **-40mmHg to -200mmHg** [1].
- Also called Vacuum-Assisted Closure (VAC) [1].
- Only usable by trained professionals, usually in the operating room [1].
- The porous foam is usually made of "polyurethane (PU) (black) or polyvinyl alcohol (PVA) (white)" [1].
- Disposable VACs exist for smaller wounds
    - Do we want ours to be disposable?
- NPWT heals in a few different ways [1]:
    - macro deformation: Wound shrinkage simply via the vacumming, can reduce wound size by up to 80%
    - micro deformation: Stress on the wound wall --> hypoxia of wound wall cells --> growth factor release --> faster wound healing
    - Direct transport of exudate away from the wound, alleviating fluid pressure in the wound
- NPWT technique [1]:
    - Closed wounds require a sealed area (duh) to apply the negative pressure
    - The dressing should be entirely covered by the sealant tape
- Hypersensitivity to the foam materials has been reported
    - What kinds of groups have this hypersensitivity? Something to consider?

Conclusions/action items:

NPWT is a very versatile therapeutic method, so will likely have good benefit for rhytidectomy recovery.

Are there specific groups of people that are extra sensitive to the risks of NPWT? How should we account for this?

Is disposable VACs something we want to consider? With the custom-tailored dressings, will they be disposable or moldable?

References:

[1] V. Zaver, “Negative pressure wound therapy,” StatPearls [Internet]., https://www.ncbi.nlm.nih.gov/books/NBK576388/ (accessed Sep. 10, 2025).

9/17/2025 - Operating Conditions for Rhytidectomy Treatment via NPWT

BRYAN HEATON - Sep 17, 2025, 9:26 PM CDT

Title: Operating Conditions for Rhytidectomy Treatment via NPWT

Date: 9/17/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Identify specific operating conditions for NPWT as pertaining to NPWT
    1. Identify conditions the device may be exposed to during usage, storage, or at any other time

Content:

- The device will be operated in a surgical operating room, which are standardized in their temperature, humidity, and air quality
    - According to ASHRAE standard 15.01.02 [X]
    - Humidity remains between 20%-60% in ORs
    - Temperature must be maintained for optimal patient comfort, likely around room temp (~25C)
    - Air pressure must remain positive to not allow particulate entry into OR space
        - NPWT operation must be strictly regulated and only turned on if a seal is tight so as to not violate this standard
- The device will be operated by highly trained nurses, surgeons, or other personnel with sufficient knowledge and experience with NPWT.
- Segments of the device in proximity to the vacuum entry will be exposed to negative pressure conditions (125 +- 5 mmHg) for many hours at a time up to 7 days before a dressing change [X].

Conclusions/action items:

- Relay this information to the PDS

References:

[1] ACHC, “Temperature, Humidity, and Airflow in Your ASC Operating Rooms,” *ACHC*. [Online]. Available: https://achc.org/temperature-humidity-and-airflow-in-your-asc-operating-rooms/

[2] “Prevena Bandage Patient Guide,” *Scribd*. [Online]. Available: https://www.scribd.com/document/865175809/prevena-bandage-patient-guide

9/17/2025 - Standards and Specifications relating to NPWT

BRYAN HEATON - Sep 17, 2025, 9:32 PM CDT

Title: Standards and Specifications relating to NPWT

Date: 9/17/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Identify and research standards and specifications related to NPWT and
    1. The design of the HeadVac
    2. The manufacturing of the HeadVac
    3. The safe and effective use of the HeadVac
    4. The sterilization of the HeadVac (if reusable)

Content:

- 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 [1].
- 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 [2.
- ISO 11135/11137: The device must comply with standards relating to ethylene oxide (EO) sterilization or radiation sterilization depending on optimal sterilization technique used by target hospitals. If the device is disposable, this standard is not a concern [3, 4].
- 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 [5].
- 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 [6].
- IEC 62366: Because of the particular, nuanced, and skillful nature 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 [7].

Conclusions/action items:

- Relay this information to the PDS

References:

[1] Arterex, "What to Know About FDA Medical Device Classes," *Arterex Medical*, Feb. 7, 2024. [Online]. Available: https://arterexmedical.com/what-to-know-about-fda-medical-device-classes/

[2] ISO, *ISO 10993-1:2018 – Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*, International Organization for Standardization, 2018. [Online]. Available: https://www.iso.org/standard/68936.html

[3] ISO, *ISO 11135:2014 – Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*, International Organization for Standardization, 2014. [Online]. Available: https://www.iso.org/standard/56137.html

[4] ISO, *ISO 11137-1:2025 – Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*, International Organization for Standardization, 2025. [Online]. Available: https://www.iso.org/standard/81721.html

[5] ISO, *ISO 13485:2016 – Medical devices — Quality management systems — Requirements for regulatory purposes*, International Organization for Standardization, 2016. [Online]. Available: https://www.iso.org/standard/59752.html

[6] ISO, *ISO 14971:2019 – Medical devices — Application of risk management to medical devices*, International Organization for Standardization, 2019. [Online]. Available: https://www.iso.org/standard/72704.html

[7] IEC, *IEC 62366-1:2015 – Medical devices — Part 1: Application of usability engineering to medical devices*, International Electrotechnical Commission, 2015. [Online]. Available: https://www.iso.org/standard/63179.html

9/23/2025 - Suction Cup Integrating Headband

BRYAN HEATON - Nov 14, 2025, 1:13 PM CST

Title: Suction Cup Integrated Headband

Date: 9/23/2025

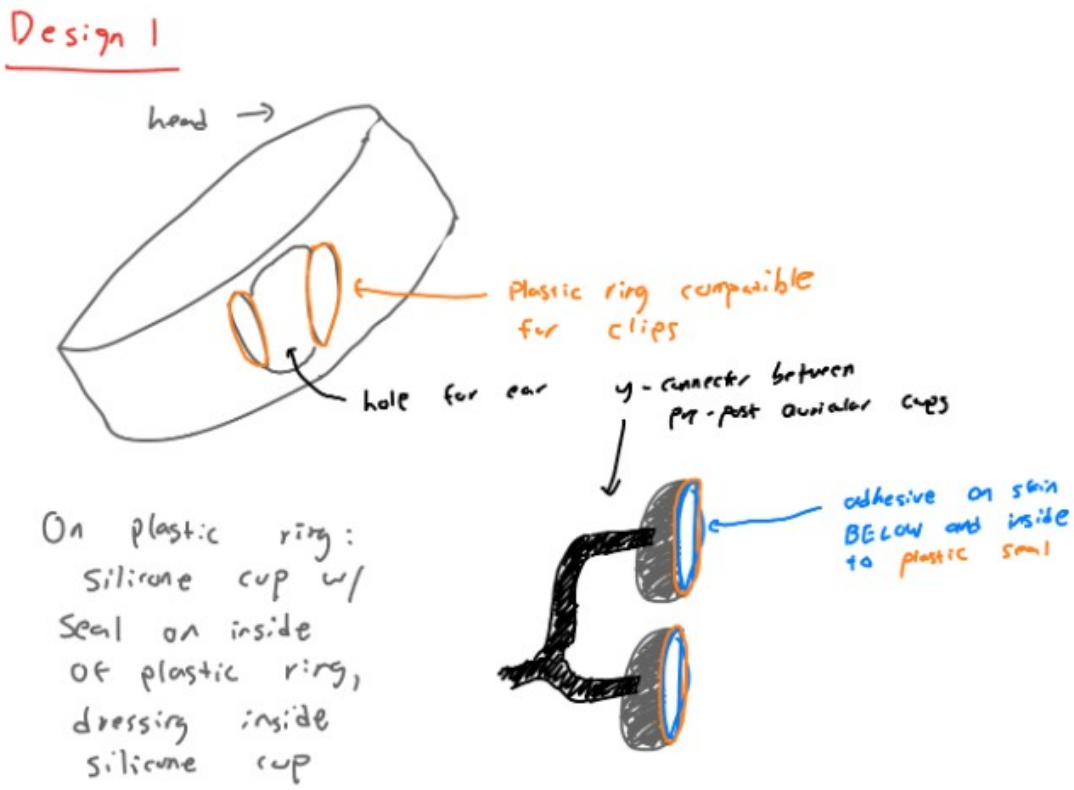
Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Illustrate an idea for the NPWT headband

Content:



Conclusions/action items:

- Bring to team discussion for design deliberation

11/14/2025 - Plan for device application

BRYAN HEATON - Nov 14, 2025, 1:15 PM CST

Title: Plan for device application

Date: 11/14/2025

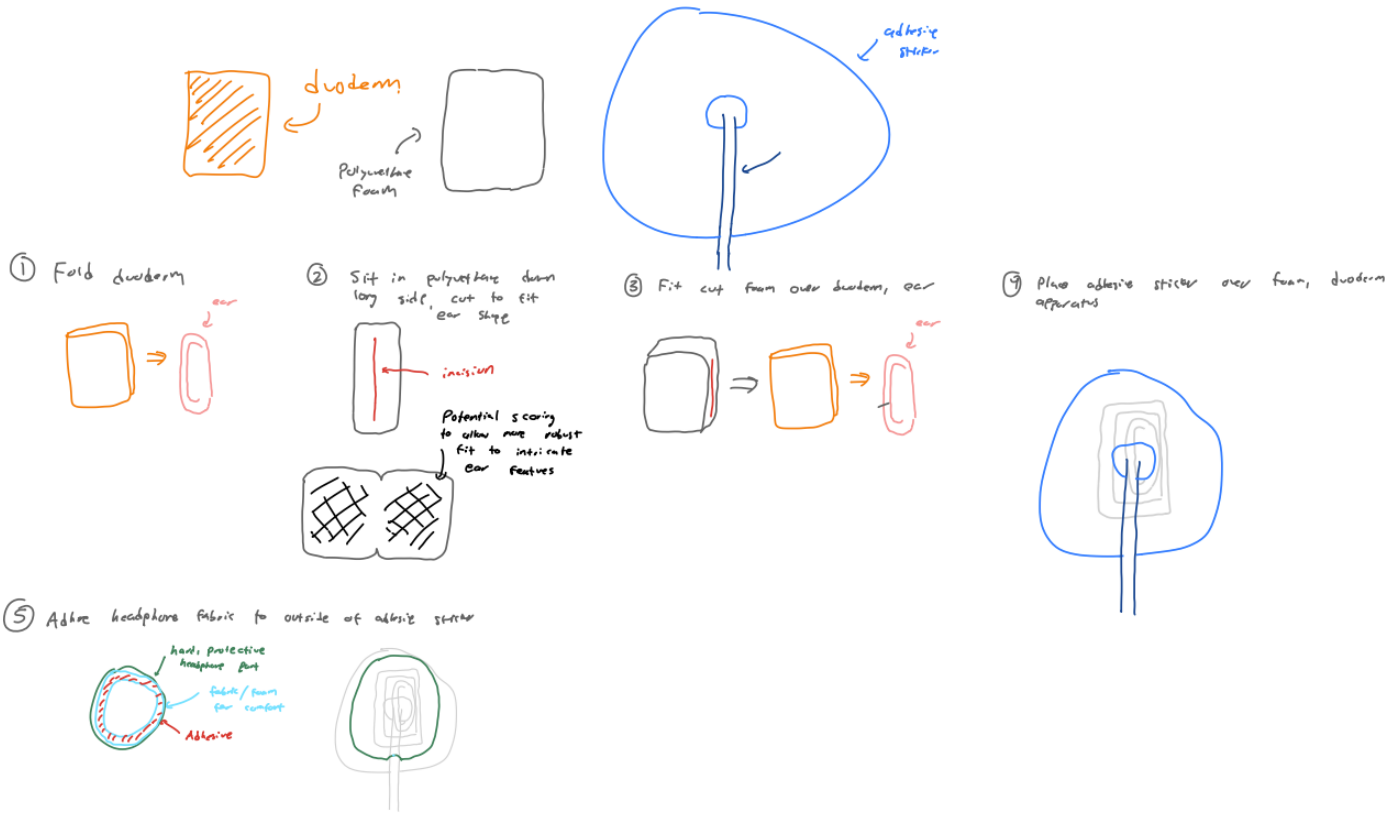
Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Draw out plan for dressing application and it's fit with the headphone.

Content:



Conclusions/action items:

START MAKING IT

2024/3/5 - Machining Permit

BRYAN HEATON - Mar 12, 2024, 11:16 PM CDT

Title: Machining Permit

Date: 3/5/2024

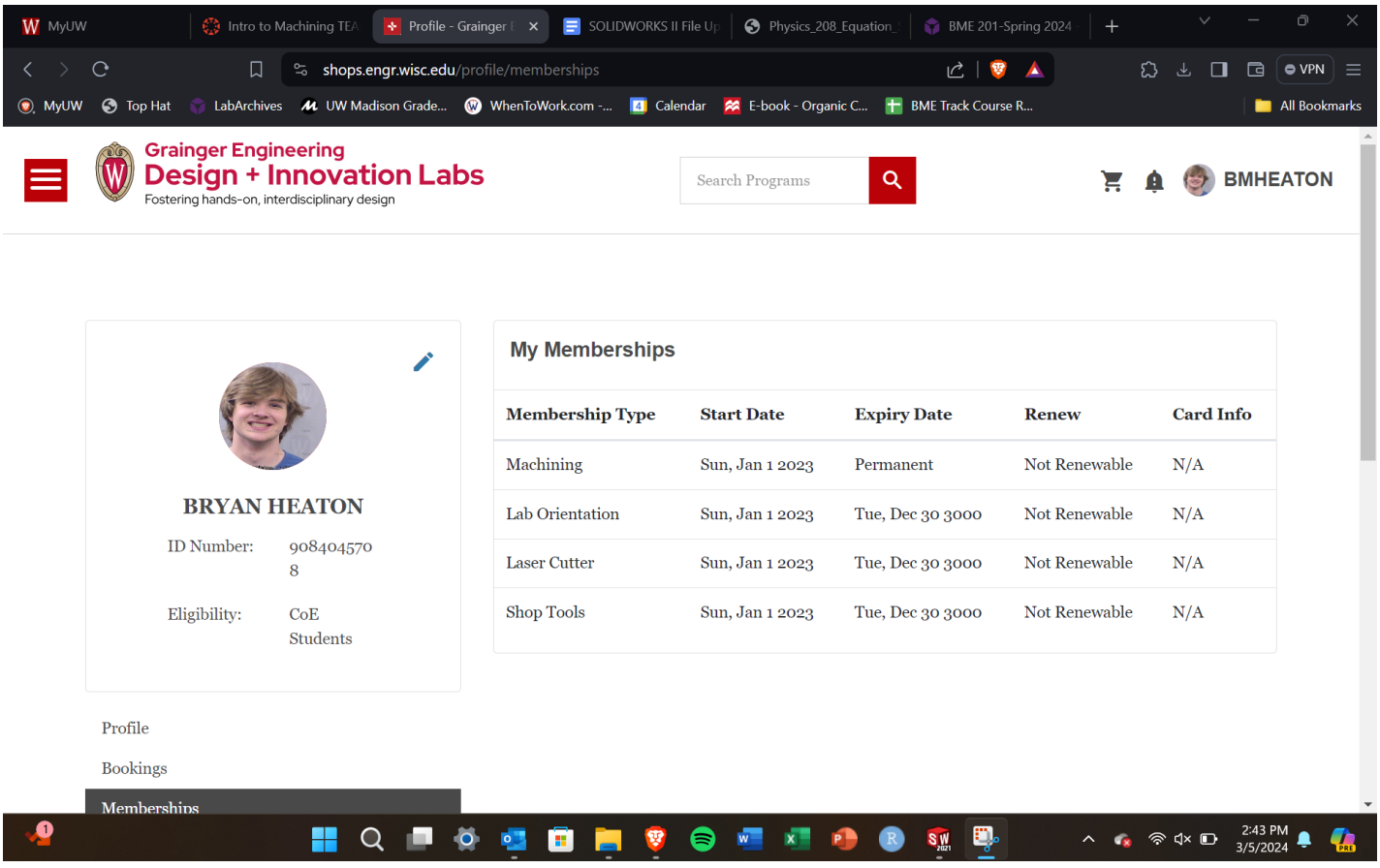
Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

Show my documentation for machining

Content:



Conclusions/action items:

- Utilizing the lathe and mill in the TEAMlab will be essential for fabrication of our sample holder and other design projects

10/28/2025 - Training Record (Animal Safety)

BRYAN HEATON - Oct 28, 2025, 9:47 AM CDT

Title: Animal Safety Training Record

Date: 10/28/2025

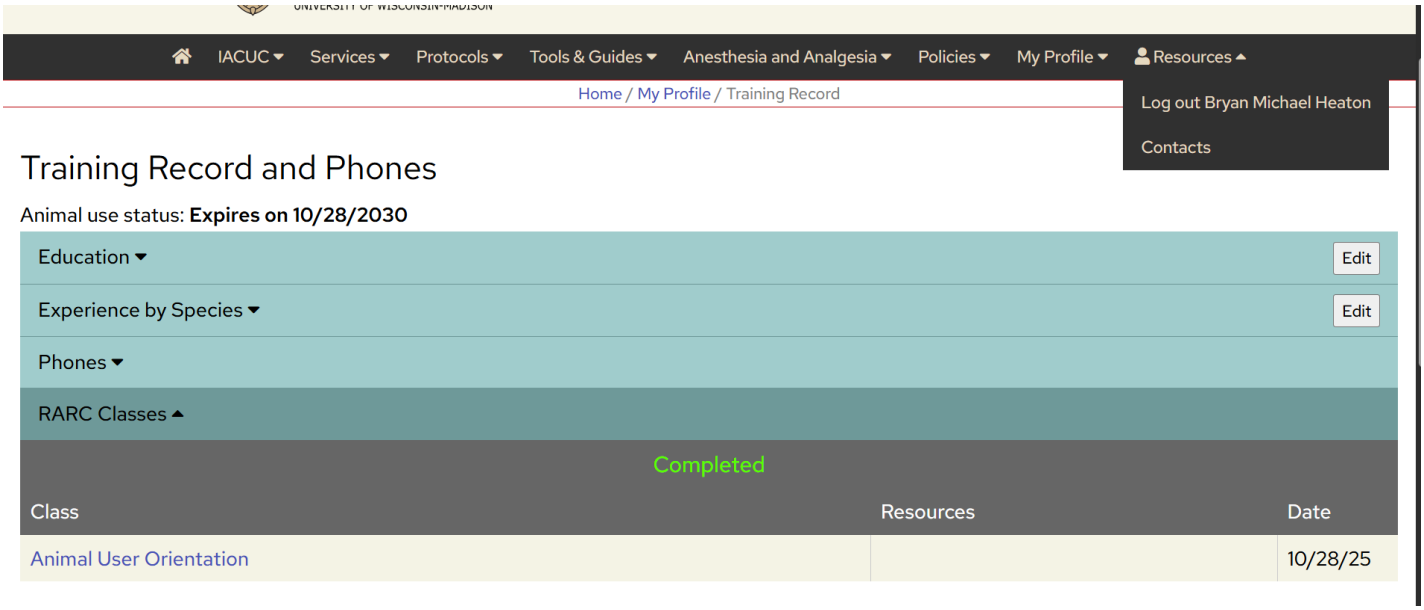
Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Record training completion for animal safety

Content:



Conclusions/action items:

N/A

2024/3/9 - Biosafety & Chemical Lab Safety Training

BRYAN HEATON - Mar 12, 2024, 11:17 PM CDT

Title: Biosafety & Chemical Safety Training Documentation

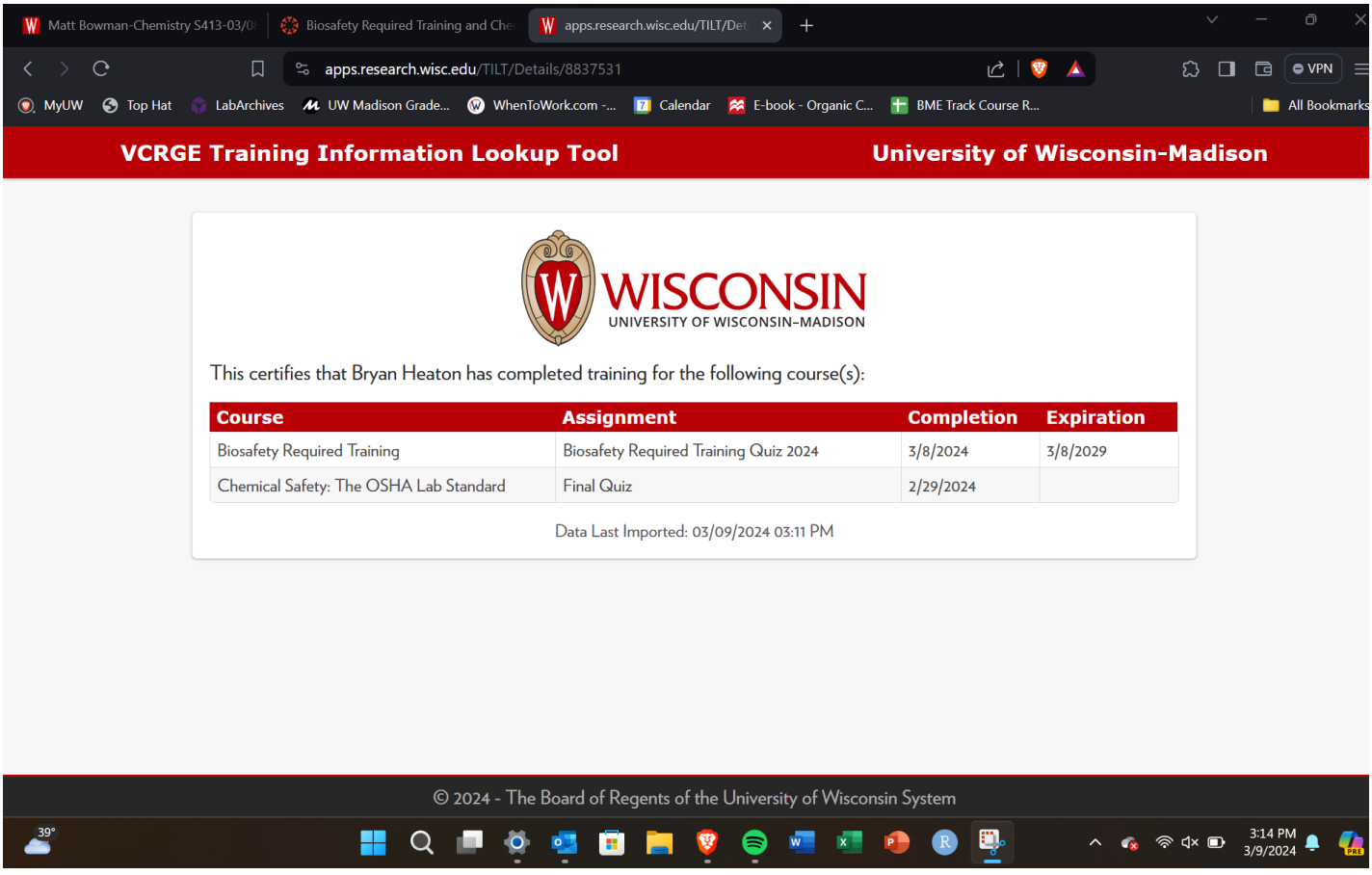
Date: 3/9/2024

Content by: Bryan Heaton

Present: Bryan Heaton

Goals: N/A

Content:



Conclusions/action items:

- Biosafety and Chemical training will be essential for individual and coursework in laboratory settings in the future.

10/28/2025 - OVERALL TRAINING RECORD (minus animal training)

BRYAN HEATON - Oct 28, 2025, 10:01 AM CDT

Title: Animal Safety Training Record

Date: 10/28/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Record overall training completion

Content:

The animal training I just completed does not show up here for some reason, see other entry for that

WISCONSIN
UNIVERSITY OF WISCONSIN–MADISON

This certifies that Bryan Heaton has completed training for the following course(s):

Course	Assignment	Completion	Expiration
2023-24 HIPAA Privacy & Security Training	HIPAA Attestation	5/20/2024	
2024-2025 HIPAA Privacy & Security Training	2024-2025 HIPAA Privacy & Security Training	12/3/2024	
Biosafety 102: Bloodborne Pathogens for Laboratory and Research	Biosafety 102: Bloodborne Pathogens Safety in Research Quiz 2024	5/9/2024	5/9/2025
Biosafety 106: Autoclave Use	Biosafety 106: Autoclave Use: Safety and Efficacy - Verification Quiz	11/21/2024	No Expiration
Biosafety Required Training	Biosafety Required Training Quiz 2024	3/8/2024	3/8/2029
Chemical Safety: The OSHA Lab Standard	Final Quiz	2/29/2024	

Data Last Imported: 10/28/2025 09:24 AM

Conclusions/action items:

N/A

10/2/2025 - Draft NDA for Industry Rep

BRYAN HEATON - Nov 14, 2025, 1:13 PM CST

Title: Draft NDA for Industry Rep

Date: 10/2/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Draft an NDA for the meeting with the industry rep
    1. Ensure the rep cannot utilize design, need, or other information pertinent to designs

Content:

NON-DISCLOSURE AGREEMENT (NDA)

This Non-Disclosure Agreement is entered into as of October 9th, 2025, by and between:

Disclosing Party: Team EarVac (1550 Engineering Drive, Madison, Wisconsin 53706, +1 (630) 549-4521)
Receiving Party: Solventum Corporation (2510 Conway Ave., St. Paul, MN 55144, +1 (612) 842-1263)

1. Purpose
The Disclosing Party intends to share certain confidential information with the Receiving Party for the purpose of evaluating potential collaboration, technical feedback, or business opportunities related to medical vacuum device technology.

2. Definition of Confidential Information
“Confidential Information” means any non-public information disclosed by the Disclosing Party, whether written, oral, or electronic, including but not limited to research data, project concepts, technical designs, prototypes, intellectual property, business strategies, and related materials.

Confidential Information does not include information that:
(a) is or becomes publicly available through no fault of the Receiving Party;
(b) is rightfully received from a third party without breach of any obligation of confidentiality;
(c) is independently developed by the Receiving Party without reference to the Confidential Information.

3. Obligations of Receiving Party
The Receiving Party agrees to:
(a) maintain the confidentiality of the Confidential Information with at least the same degree of care it uses to protect its own confidential information (and no less than a reasonable degree of care);
(b) not disclose the Confidential Information to any third party without prior written consent of the Disclosing Party; and
(c) not use the Confidential Information for any purpose other than the Purpose stated above.

4. Term
This Agreement shall commence on the date first written above and remain in effect for two (2) years. The obligations of confidentiality shall survive termination of this Agreement for five (5) years thereafter.

5. Return or Destruction of Materials
Upon written request, the Receiving Party shall promptly return or destroy all materials containing or derived from the Confidential Information.

6. Ownership
All Confidential Information remains the sole property of the Disclosing Party. Nothing in this Agreement grants the Receiving Party any rights or licenses to the Confidential Information except as expressly stated herein.

7. No Warranty
All Confidential Information is provided “as is.” The Disclosing Party makes no representations or warranties, express or implied, regarding its accuracy or completeness.

8. Governing Law
This Agreement shall be governed by and construed in accordance with the laws of the State of Wisconsin, without regard to its conflict of laws principles.

9. Entire Agreement
This Agreement constitutes the entire understanding between the parties regarding the subject matter herein and supersedes all prior discussions or agreements.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

Disclosing Party:
Signature: _____

Name (printed): _____

Date: _____

Receiving Party:
Signature: _____

Company: Solventum

Name: _____

Date: _____

Conclusions/action items:

- Continue to investigate the necessary components to make an NDA legally binding
- Deploy the NDA at meeting with industry representative

11/7/2025- Tong Lecture

BRYAN HEATON - Nov 07, 2025, 12:50 PM CST

Title: Tong Lecture

Date: 11/7/2025

Content by: Bryan Heaton

Present: All

Goals:

Content:

- 15% (!!) of GDP spent on healthcare per year
  - A lot of it (25%) wasted
- advice: follow hard problems and you don't need to know your end outcome
- Challenges of healthcare system:
  - IT is not ideal
  - Patent system being so slow
  - Fragmented financing
  - Misaligned incentives ? (fee for service)
  - Inequities between regions in US
- Telehealth could be a big solution for a lot of these problems
- Clinicians being rewarded for OUTCOMES instead of time spent with patients key
- Thinking about system design is what healthcare needs right now
- Work hard and build range
  - Take on the hardest projects, classes, experiences
- Explore diverse opportunities
- Choose people wisely
- Know and protect your values
- Embrace challenge

Conclusions/action items:

10/23/2025 - Team Delegation Ideas

BRYAN HEATON - Oct 23, 2025, 5:57 PM CDT

Title: Team Delegation Ideas

Date: 10/23/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Compartmentalize the remaining project into different modules
2. Identify people most fit for each module
3. Prepare for delegation meeting (10/24)

Content:

Ideas for project compartmentalization:

1. Headphone part
    - Current phase: fabrication (v1)
    - Need to fabricate, identify issues, refabricate
    - Align with headband part team mate to ensure correct connection
        - Try not to alter connection too much after created unless necessary
2. Headband part
    - Current phase: modeling
    - Need to design in CAD, align with headphone teammate, refabricate
3. Y-connector (if necessary)
    - Current phase: research
    - 3D print if we need to make a custom part, could look online to see options with varying tube size
    - Fluid dynamics? Check with Serena
    - Need to figure out sizing of tubing for drain and woundvac
        - Is this changeable or very standard?
        - Let's start with concrete numbers so we can get headphone part correctly sized, change if necessary
4. Sticker
    - Current phase: research
    - Need to come up with plan
        - Based on 3M prevena from solventum email?
        - What would we need to change from that design?
    - Likely requires the most research still
5. Foam configuration
    - Current phase: Ready to fabricate?
    - Need to align with final product to ensure no crushing of auricle
    - Start with oval w/ slit to fit front and behind ear?

- headband / headphone: SolidWorks experience could be especially useful: me and dhruv / Meghan and dhruv?
- y-connector: Serena has done research already
- Sticker & foam: Meghan and me / Meghan and Shad

Conclusions/action items:

- Continue to consider team strengths for delegation
- Discuss plans with team, identify target dates for next steps for everything
- Make master doc with progress on everything?

11/20/2025 - Initial Dressing Prototyping

BRYAN HEATON - Dec 10, 2025, 5:48 PM CST

Title: Initial Dressing Prototyping

Date: 11/20/2025

Content by: Bryan Heaton

Present: Bryan, Harshad, Meghan, Serena

Goals:

1. Being cutting foam and securing duoderm inside
2. Confirm proof of concept for slit in foam idea

Content:

- The team met and cut into the given foam and duoderm samples
- Determined that this should work, especially when negative pressure is applied

Conclusions/action items:

- Need to make headphone interior deeper / wider to accommodate dressing
- Make document outlining how we think dressing will be applied after surgery, steps to do so

12/4/2025 - Dressing Prototyping for Poster Presentation

BRYAN HEATON - Dec 10, 2025, 5:48 PM CST

Title: Dressing Prototyping for Poster Presentation

Date: 12/4/2025

Content by: Bryan Heaton

Present: Bryan Heaton

Goals:

1. Recreate the dressing from our initial prototypes, with cleaner more measured cuts

Content:

- The dressing is shown below.
- All head models in the BME fab lab did not have protruding ears, therefore the model did not fit on them
    - The model heavily relies on the protruding structure of the ear to be stable when applied
- The dressing (foam, duoderm) measures 110mm (l) x 72 mm (w) x 29 mM (t)
    - 38mm max depth of cut out (crescent shape)
    - Cut into foam for ear fit goes until risk of perforating other side

Notes post-fabrication

- The adhesive is extremely sticky and tedious to work with.
- We will have to see how much of the adhesive layer is minimal to ensure stickage to desired surface, hopefully area around ear is enough.

Conclusions/action items:

- N/A

2025/09/25 - Long-term complications of microtia reconstruction

Dhruv Nadkarni - Sep 25, 2025, 10:23 PM CDT

Title: Long-term complications of microtia reconstruction: A systematic review

Date: 2025-09-25

Content by: Dhruv Nadkarni

Present: N/A

Goals: Understand microtia and current solutions to the defect

Content:

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

- Microtia is a congenital malformation where an absence of the external ear occurs.
  - Ranges from minor defects to complete absence of the ear.
- Current methods for reconstruction include autologous costal cartilage (AAC) and porous polyethylene (PPE) implants.
- AAC is the most common technique and the "golden standard" of today.
  - Steep learning curve
- PPE have become slightly more common, but are less favored due to high exposure rates.
- Holistic review of numerous studies performing both AAC and PPE found inconsistent results.
  - AAC had a sub 10% long term complication rate.
  - PPE had a sub 15% complication rate.
  - However many studies left out certain comparable traits.
- When developing a test methods, we should consider the following for our solutions:
  - framework extrusion or exposure, graft loss, framework resorption, wire exposure and scalp/auricular scar complications

Conclusions/action items:

For the next client meeting, bring up the aforementioned test parameters and how relevant it is for microtia in children. Also consider these parameters to test when we develop test methods in the spring.

2025/09-25 - Salvaging exposed microtia cartilage framework with NPWT

Dhruv Nadkarni - Sep 25, 2025, 10:55 PM CDT

Title: Salvaging exposed microtia cartilage framework with NPWT

Date: 2025-09-25

Content by: Dhruv Nadkarni

Present: N/A

Goals: Understand application of NPWT with the new defined problem.

Content:

[1]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.

- Analyzed 7 cartilage exposure wounds in 6 patients treated with NPWT after auricular reconstruction for microtia.
- Used the KSI negative pressure wound therapy with VAC
    - All wounds healed within 8 to 39 days
    - All frames survived but partial cartilage atrophies remained in 4 cases.
- Outcomes assessed:
    - duration of NPWT
    - wound surface at the end of NPWT
    - Final cartilage frame atrophy
- Atrophy defined by G0-3 (no atrophy to second layer and base frame affected)
- Conclusion was that:
    - NPWT under restricted conditions is useful.
    - Fluid removal effect of NPWT is useful for wounds with dead space as a continuous external drainage system (unused space by the wound)
    - BAD: Granulated tissue formation is impacted due to lack of soft tissue via NPWT
    - BAD: Secondary infection rate increased.

Conclusions/action items:

When designing our device, we have to ensure a tight seal to combat the secondary infection. A tight seal will protect this. Also, when testing our device we can use the assessed outcomes as validation.

2025/10/07 - ASTM F1980

Dhruv Nadkarni - Oct 07, 2025, 10:19 PM CDT

Title: ASTM F1980

Date: 2025-10-07

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document research regarding accelerated aging.

Content:

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

NOTE: I already perform accelerated aging (AA) preconditioning as part of my co-op, but I wanted to understand it a little more as it is relevant to what we are attempting to do.

- AA follows Arrhenius' law, in which any chemical reaction will double its rate with each 10C increase.

- Most common AA settings are 55C for 92 days. This prevents material degradation whilst allowing a 2 year shelf life.

- "Medical devices need to be able to be stored for an extended period without any decrease in performance that may influence safety and efficacy when used."

- FDA ISO 11607 requires that packaging systems must provide physical protection that maintains sterile conditions.

$$AAF = Q_{10}^{[(T_{AA}-T_{RT})\div 10]}$$

- Tensile properties and physical tests are measured and conducted respectively.

Conclusions/action items:

Include AA tensile testing methods in the test section that I am working on.

2025/09/15 - De Novo Classification for PREVENA PLUS 125

Dhruv Nadkarni - Sep 18, 2025, 8:40 PM CDT

Title: De Novo Classification for PREVENA PLUS 125

Date: 09/15/2025

Content by: Dhruv Nadkarni

Present: N/A

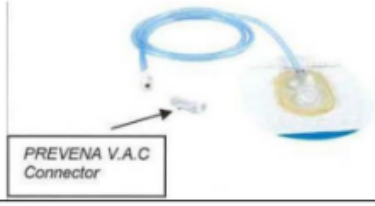
Goals: Research current NPWT units on the market.

Content:

[1] “DE NOVO CLASSIFICATION REQUEST FOR PREVENA 125 AND PREVENA PLUS 125 THERAPY UNITS.” Available: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180013.pdf

- Continuous -125 mmHg to manage the environment of closed surgical incisions.
- The device is not intended to treat surgical site infection or seroma.

Table 1. Device Description

	PREVENA 125	**PREVENA PLUS 125**
1x Disposable non-sterile therapy unit (including compatible non-sterile carrying case)	PREVENA 125 Therapy Unit  • Powered by 3 “AA” batteries • Visual and audible alarms: ○ Leak ○ Canister full ○ Low battery ○ Critical battery ○ System error	PREVENA PLUS 125 Therapy Unit  • Powered by rechargeable lithium battery or power cord • Visual and audible alarms: ○ Leak or canister missing ○ Blockage in tubing or canister full ○ Batteries need to be recharged ○ 8 hours of therapy time remain ○ System fault
1x Sterile canister	45 mL canister	150 mL canister
1x Sterile tubing set	PREVENA Tubing Set – single-lumen, integrated tubing set for direct connection to the PREVENA 125 Therapy unit. Comes with PREVENA V.A.C. Connector, which is necessary for connection to a V.A.C. Therapy Unit 	SENSAT.R.A.C. Tubing Set – multi-lumen, non-integrated tubing set for direct connection to the PREVENA PLUS 125 Therapy Unit and to a V.A.C. Therapy Unit 

- The device has no direct patient contact so no materials / biocompatibility needed to be considered.
- The shelf life is 3 years. Done via AA (accelerated aging) --> If we want to go further with this, I know how to setup Accelerated aging methods.
- Other testing included performance testing - bench, human factors / usability testing, software testing, electrical safety and electromagnetic compatibility.
    - We can consider this when developing our test methods.

Conclusions/action items:

The device components are really helpful. It matches up with what Nada was saying about what we needed to focus on in development. The mentioned tests done can also be taken into consideration when we start planning for those.

2025/09/10 - Negative pressure wound therapy: past, present and future

Dhruv Nadkarni - Sep 10, 2025, 9:30 PM CDT

Title: Negative pressure wound therapy: past, present and future

Date: 09/10/2025

Content by: Dhruv Nadkarni

Present: N/A

Goals: Understand current applications of negative pressure wound therapy (NPWT)

Content:

[1] D. P. Orgill and L. R. Bayer, “Negative pressure wound therapy: past, present and future,” International Wound Journal, vol. 10, no. s1, pp. 15–19, Nov. 2013, doi: https://doi.org/10.1111/iwj.12170.

Background:

- First introduced as a commercial product: V.A.C.® Therapy in response to the rise of complex wounds as medical problems across the nation.
    - Design consisted of open-pore polyurethane foam that is placed in the wound, covered by a semi-occlusive dressing, and connected by a tube to a vacuum source.
- In 2013, the cost of treating a wound like a diabetic foot ulcer would be anywhere from $9000 (simple ulcer) to $45000 (full amputation).

Physics of NPWT:

- Follows ideal gas equation: PV=nRT
    - In an absolute vacuum, pressure is 0mmHg.
    - Negative pressure is incorrectly used, as it really only applies to the gauge pressure being negative / difference between applies and atmospheric pressure.
- Closed suction drainage
    - Facilitates mass transport of liquids from the body
- "Combines suction with a foam dressing and a semi-occlusive drape to keep the wound moist, facilitate fluid removal and stimulate healing at both macrocellular and microcellular levels"

Mechanisms of Action:

- Primary Effects:
    - Macrodeformation: Brings wound edges closer together depending on the mobility of tissue surrounding the wound.
    - Microdeformation: Stretches cells, facilitating division and proliferation
    - Fluid Removal: Removal large amounts of fluid from the extracellular space

    - Environmental control of the wound: Moist/warm/insulated environment to promote growth
- Secondary Effects:
    - Granulation Tissue Formation: Microdeformation effect
    - Cell proliferation: Secondary effect due to being a result of many primary effects
    - Modulation of inflammation: Mast cells (inflammatory chemical releasers) are critical for NPWT success.
    - Change in neuropeptides: upregulates neurotransmitters
    - Change in bacterial levels: varies

Conclusions/action items:

The paper was released in 2013, so I need to read a more updated paper with new advances with this technology. Furthermore, I will begin research on face lift surgeries and areas of fluid build up on the face.

Dhruv Nadkarni - Sep 10, 2025, 10:03 PM CDT

international wound journal

REVIEW ARTICLE

Negative pressure wound therapy: past, present and future

Dennis P Orgill & Lauren R Bayer

Abstract

Introduction

Key Messages

Download

Negative_pressure_wound_therapy_past_present_and_future.pdf (705 kB)

2025/09/10 - The prevention of haematoma following rhytidectomy

Dhruv Nadkarni - Sep 10, 2025, 11:24 PM CDT

Title: The prevention of haematoma following rhytidectomy

Date: 09/10/2025

Content by: Dhruv Nadkarni

Present: N/A

Goals: Determine parameters associated with haematoma formation during facelifts and possible preventative measures.

Content:

[1] R. Grover, B. M. Jones, and N. Waterhouse, “The prevention of haematoma following rhytidectomy: a review of 1078 consecutive facelifts,” British Journal of Plastic Surgery, vol. 54, no. 6, pp. 481–486, Sep. 2001, doi: https://doi.org/10.1054/bjps.2001.3623.

Background:

- Haematoma is the most common major complication following a facelift.
- Size of haematoma poses the biggest issue
    - Larger sizes can exert more pressure on the facelift flap, leading to skin necrosis, prolonged facial oedema and bruising.
    - Pressure left untreated and lead to deeper structures and lead to neurapraxia / respiratory distress.
    - Smaller sizes can cause morbidity through hyperpigmentation and skin irregularities.

Study:

- 1016 females and 62 males, all under the care of the same team.
- Following face lift, data was collected for all the patients and all variables.
    - Information such as operating surgeon, patient age, gender, pre-op blood pressure, smoking, etc..
- Risk factors include: age, gender, smoking, preop blood pressure, cardiovascular or lung disease, non-steroidal anti-inflammatory intake, type of facelift, anterior corset platysmaplasty, primary or secondary facelift, tisseal.
    - The most significant risk factor determine from the study was anterior corset platysmaplasty.
        - Out of the 194 patients undergoing the procedure, 26 developed a haematoma.
        - Out of the 884 who were treated without anterior corset platysmaplasty, only 19 developed haematoma.
    - Pre-op blood pressure, gender, and history of non-steroidal anti-inflammatory intake also were significant associate with haematoma incidence. More stats in the document.

    - All others had no significant risk.
- Predicting haematomas:
    - " An anterior platysmaplastymade a patient 4.3 times more likely to develop a haematoma. A high preoperative systolic pressure (more than 150mmHg) and being male increased the risk by 3.6 and 2.8 times, respectively, whilst aspirin intake and smoking both roughly doubled the risk of haematoma formation. Patients with two or more significant factors had a cumulative risk, which could be estimated by adding the relative risk ratios together. Thus, a patient who underwent anterior platysmaplasty and was a smoker would have 6.4 times the average risk of haematoma formation."

Conclusions/action items:

The team could ask the client wether this data is collected, as this could help the team develop a more customized solution for patients. People with higher risks can be treated to a stronger NPWT, while those without a high risk can be treated with a lighter NPWT.

Dhruv Nadkarni - Sep 10, 2025, 10:43 PM CDT

BRITISH JOURNAL OF PLASTIC SURGERY

The prevention of haematoma following rhytidectomy: a review of 1078 consecutive facelifts

Download

The_prevention_of_haematoma_following_rhytidectomy.pdf (669 kB)

2025/09/11 - Negative pressure wound therapy in complex cranio-maxillofacial and cervical wounds

Dhruv Nadkarni - Sep 11, 2025, 9:58 PM CDT

Title: Negative pressure wound therapy in complex cranio-maxillofacial and cervical wounds

Date: 09/11/2025

Content by: Dhruv Nadkarni

Present: N/A

Goals: Evaluate outcomes of NPWT in treating complex cranio-maxillofacial and cervical wounds

Content:

[1] G. Novelli et al., “Negative pressure wound therapy in complex cranio-maxillofacial and cervical wounds,” International Wound Journal, vol. 15, no. 1, pp. 16–23, Nov. 2017, doi: https://doi.org/10.1111/iwj.12802.

Challenges:

- Frequent dressing changes
- long healing times
- risk of infection
- bone or fixation exposure
- patients comorbidities
- high cost
- biological burden.
- NPWT evolved to combat these challenges, namely the frequent dressing changes, long healing times, and risk of infection.

NPWT

- Mechanisms help with:
  - removal of exudate
  - reducing oedema
  - more listed in the other NPWT research article.

Study:

- 16 patients with complex wounds in cranio-maxillofacial and cervical regions.
- NPWT: -75 to -125 mmHg, dressing changed every 48-72 hours

Results:

- 12/16 patients achieved complete healing. 4 remaining had partial healing, but still showed improvements.
- Patients with cervicofacial infectious disease also achieved complete healing.

Conclusions/action items:

The client mentioned during the client meeting that incisions only occur around certain contours. Further research into studies focusing on those contours (around the ears) would help us better understand infection rate and other issues.

Dhruv Nadkarni - Sep 10, 2025, 10:36 PM CDT

cranio-maxillofacial and cervical wounds

Giorgio Novelli[1], Francesco Deleffe[1], Gisella Biro[1], Gabriele Canzi[2], Fabio Mazzoleni[3], Pietro Boni[3], Clara Maino[3], Carlo Giussani[4], Davide Sozzi[1] & Alberto Bozzetti[1]

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Key words
Negative pressure wound therapy; NPWT
Therapy cervical wounds;
Cranio-maxillofacial wounds;
Vacuum-assisted closure

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doi: 10.1111/iwj.12802

Novelli G, Deleffe F, Biro G, Canzi G, Mazzoleni F, Boni P, Maino C, Giussani C, Sozzi D, Bozzetti A. Negative pressure wound therapy in complex cranio-maxillofacial and cervical wounds. Int Wound J 2018; 15:16–23

Abstract

The care and the management of the healing of difficult wounds at the level of the skull-facial face many problems related to patient compliance and the need to perform multiple dressings, with long periods of healing and, occasionally, a very long hospitalization period. The introduction and evolution of negative pressure wound therapy (NPWT) in the treatment of difficult wounds has resulted in better healing, with a drastic reduction in terms of time and biological costs to the patient and cost to the health care system. The main aim of this study is to describe and discuss, using our experience, the usefulness of NPWT in the cranial-facial-cervical region. We enrolled 16 patients with complex wounds of the cranial-facial-cervical region treated with NPWT. We divided clinical cases in four groups: cervicofacial infectious disease, healing complications in oncological-reconstructive surgery, healing complications of injury with exposure of bone and/or internal fixations and healing complications in traumatic injury with loss of substance. We evaluated complete or incomplete wound healing, application time, related also to hospitalization time (days of intensive care unit (ICU) stay; management of the upper airways; timing of medication removal; and patient comfort and compliance (on a scale of 1–5). Depression values were always between −75 and −125 mmHg in a continuous aspiration pattern. For every patient, we used the Ad VAC Therapy Unit, derived from the vacuum-assisted closure system (KinetiConcepts Inc., San Antonio, TX). Medication removals were performed every 48–72 hours. The NPWT application time ranged from 4 to 22 days (mean of 11.97 days). Therapy was effective in gaining complete restitutio ad integrum in every patient included in the group of cervicofacial infectious disease. Therapy has, however, been well tolerated in our series; this is probably due to the decreased number of applications, the ease of use and the comfort of the system relative to traditional dressing. Results were satisfactory for most of cases treated; faster and more effective wound healing was achieved. The lower number of NPWT applications, relating to standard dressings, led to an increase in patient comfort and compliance and a decrease in the use of medical, and in some cases economic, resources according to international literature.

Introduction

'Bone heals all wounds' is a sentence-serving but quite true assertion due to the adaptabilities of the human body.

Historically, the management of complex wounds included thorough cleansing, surgical preparation of the infected site and removal of necrotizing tissue, as well as postoperative accurate dressing. Although cleansing, debridement, frequent removal of

Key Messages

- this study evaluated outcomes of NPWT in cranio-maxillofacial-cervical regions in different types of lesion and the comorbidity of the subject
- results were satisfactory for most of cases treated; a faster and more effective wound healing was achieved

[Download]

Negative_pressure_wound_therapy_in_complex_cranio-maxillofacial_and_cervical_wounds.pdf (1.49 MB)

2025/09/11 - Evidence of Hematoma Prevention After Facelift

Dhruv Nadkarni - Sep 11, 2025, 10:25 PM CDT

Title: Evidence of Hematoma Prevention After Facelift

Date: 09/11/2025

Content by: Dhruv Nadkarni

Present: N/A

Goals: Understand current methods in minimizing hematoma risk during facelift surgery

Content:

[1] C. M. Stewart, B. Bassiri-Tehrani, Hannah Elizabeth Jones, and Foad Nahai, “Evidence of Hematoma Prevention After Facelift,” Aesthetic Surgery Journal, Aug. 2023, doi: https://doi.org/10.1093/asj/sjad247.

Background:

- Haematoma is the most common face lift complication, occuring in 8% of cases.
- Risk factors included are mentioned in a NPWT entry from 2025-09-10.

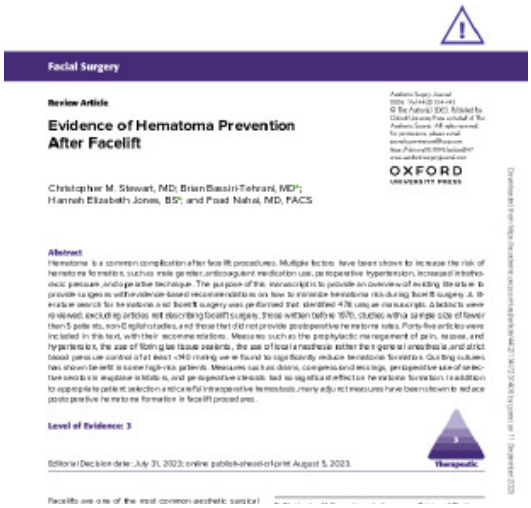
Research Review:

- Additional risk factors were determined:
  - High BP raise haematoma risk nearly 4x.
  - Increased OR time, skin necrosis, delayed bleeding after removal
  - platysmaplasty
- Potential benefits to lower risk factors:
  - Clonidine and atenolol reduce haetoma
  - Local anesthesia
- Most critical factors are meticulous hemostasis and BP control.
- Drains and compression dressings do not prevent hematomas.

Conclusions/action items:

NPWT can replace a drain and compression dressing. Further research into current NPWT designs is needed.

Dhruv Nadkarni - Sep 10, 2025, 10:40 PM CDT



Facial Surgery

Review Article

Evidence of Hematoma Prevention After Facelift

Christopher M. Stewart, MD; Brian Bassiri-Tehrani, MD*; Hannah Elizabeth Jones, BS*; and Foad Nahai, MD, FACS

OXFORD UNIVERSITY PRESS

Abstract

Level of Evidence: 3

Therapeutic

Download

Evidence_of_Hematoma_Prevention_After_Facelift.pdf (588 kB)

2025/09/17 - 820.30 Design Controls

Dhruv Nadkarni - Sep 18, 2025, 8:57 PM CDT

Title: 820.30 Design controls.

Date: 09/17/2025

Content by: Dhruv Nadkarni

Present: N/A

Goals: Understand design controls and the relevance when deciding safety of the product.

Content:

[1] “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

- Design development and planning
  - Establish and maintain plans that describe or reference design and development and define responsibility for implementation.
- Design input
  - procedures to ensure the design reqs relating to device are appropriate and address intended use of the device.
- Design output
  - "Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements."
- Design review
  - reviews of the design must be documented and all previous versions recorded.
- Design verification
  - procedures for verification must be in place.
- Design validation
  - procedures for validation must be in place to confirm user needs and intended uses.
- Design transfer
  - "Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications."
- Design changes
  - All design changes must be recorded prior to implementation and a system of approval must be in place.
- Design history file
  - "Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part."

Conclusions/action items:

All design steps must follow guidelines listed by the FDA. When considering our project, we need to ensure proper verification and validation of the device to protect patients.

2025/09/15 - Negative-pressure wound therapy for management of diabetic foot wounds

Dhruv Nadkarni - Sep 18, 2025, 8:27 PM CDT

Title: Negative-pressure wound therapy for management of diabetic foot wounds

Date: 09/15/2025

Content by: Dhruv Nadkarni

Present: N/A

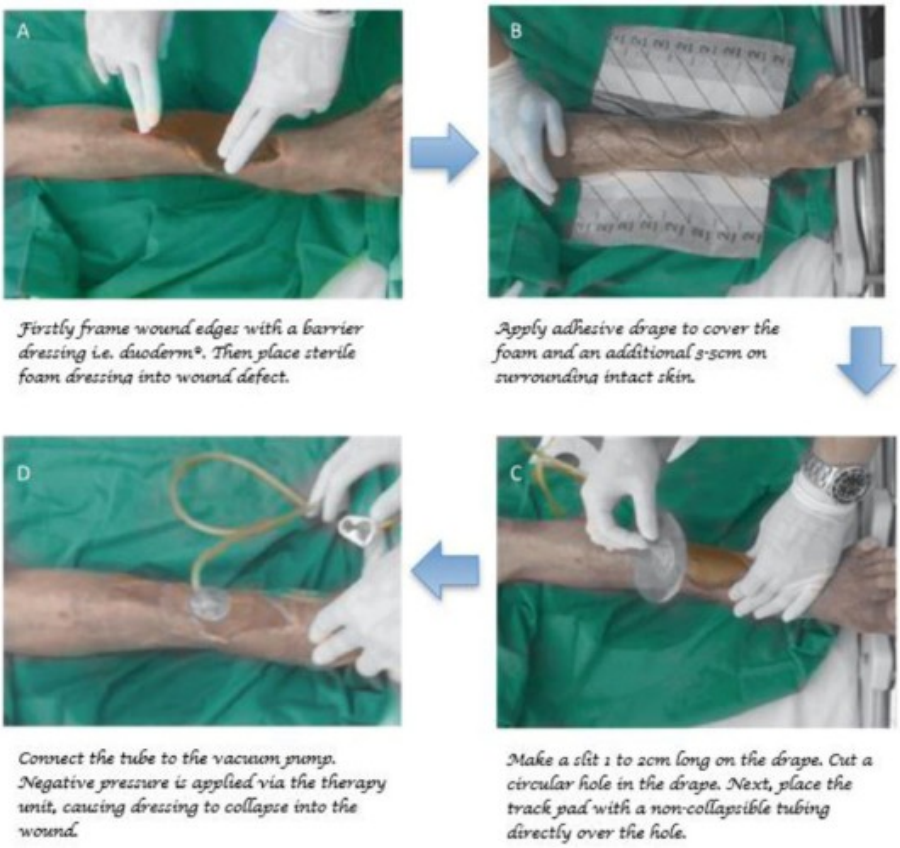
Goals:

Content:

[1]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.

- Standard negative pressure is 125mmHg
- Levels can vary between 50 and 150 mmHg.
- Variable mode between 10 to 80 mmHg. Allows for the interval cycling as mentioned in a previous entry.

- Diabetic Case Study:
  - "Morykwas showed that negative pressures of up to 125 mmHg resulted in an increased blood flow in swine wound models" --> fourfold increase of blood flow.
  - Patient was on NPWT for 4 weeks. Healed completely in 6 weeks.
- Setup attached below.



Conclusions/action items:

What interested me the most here was the variable mode, lower mmHg levels, and the setup. The lower mmHg at variable levels could help stimulate the blood flow at a lower rate, which will prevent haematoma while also allowing for blood to flow at a rate which can promote growth. Further discussion with the client is needed regarding the mmHg levels.

2025/09/16 - Negative Pressure Wound Therapy – A Review of its Uses in Orthopaedic Trauma

Dhruv Nadkarni - Sep 18, 2025, 7:09 PM CDT

Title: Negative Pressure Wound Therapy – A Review of its Uses in Orthopaedic Trauma

Date: 09/16/2025

Content by: Dhruv Nadkarni

Present: N/A

Goals: Understand NPWT applications in orthopedic surgeries and relevance to face lift.

Content:

[1] 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.

- NPWT widely used in acute and chronic wounds since the 90s.
- Major use case in orthopedic trauma
    - open fractures, wounds, skin grafts, etc...
- Current NPWT device set up includes
    - a) foam and gauze around the wounds
    - b) semi-occlusive dressing
    - c) suction tubing and NPWT unit delivering continuous suction
        - -80 mmHg to -125 mmHg
- Mechanisms of action are as mentioned in preliminary research
    - "Macrodeformation of the wound when, depending on the deformability of the surrounding tissues, the wound edges are brought closer together by the suction distributed through the foam sponge. This reduces the space required to be healed by primary closure or secondary granulation."
    - "Microdeformation of the wound surface at the microscopic level. Finite element computer models have shown that NPWT produces 5-20% strain across the healing tissues, that promotes cell division and proliferation, growth factor production and angiogenesis."
    - "Extraction of oedematous fluid and exudate from the extracellular space, removing inflammatory mediators and cytokines whose prolonged effect can hinder the ability of the microcirculation to support damaged tissue. This can lead to further tissue necrosis frequently seen at further debridement."
    - "A warm and moist environment that prevents desiccation of the wound and enhances formation of granulation tissue."
- Components of a NPWT Sytem:
    - Foam can provide rapid granulation.
    - "Wounds with high drainage require continuous suction and lower pressure settings tend to be indicated when wound edges are fragile, have low perfusion, are painful, or where a skin graft is being used" --> this is 125mmHg.

Conclusions/action items:

Use the pressure values provided to include in PDS. Research which of either continuous or intermittent would be better and talk to client about it.

2025/09/24 - Design idea

Dhruv Nadkarni - Sep 25, 2025, 9:43 PM CDT

Title: Preliminary Design Idea

Date: 2025-09-24

Content by: Dhruv Nadkarni

Present: N/A

Goals: Share my design idea with the team.

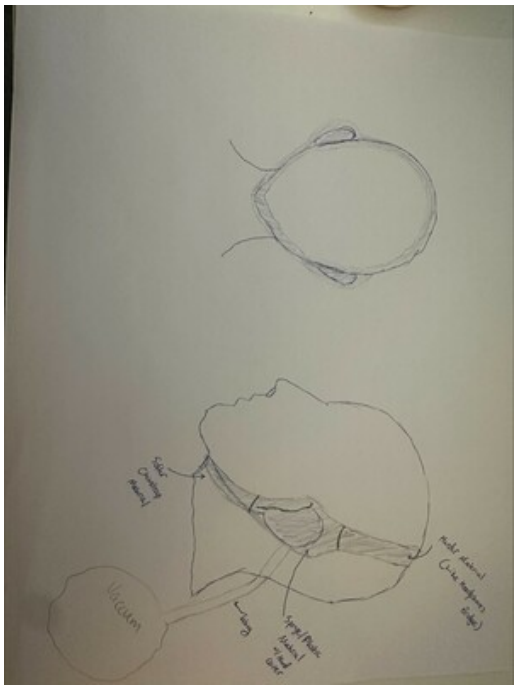
Content:

Image is attached.

Conclusions/action items:

Share design idea with team and create design matrix.

Dhruv Nadkarni - Sep 23, 2025, 7:07 PM CDT



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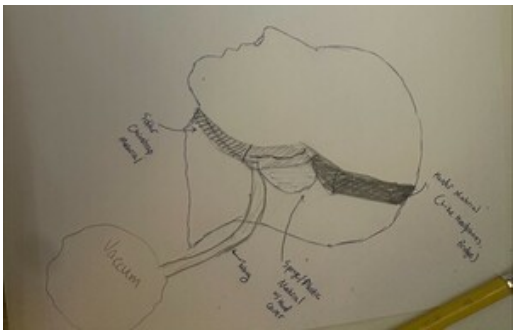
Dhruv Nadkarni - Sep 23, 2025, 7:16 PM CDT



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2025/10/01 - Design idea Hat

Dhruv Nadkarni - Oct 02, 2025, 9:13 PM CDT

Title: Preliminary Design Idea

Date: 2025-10-01

Content by: Dhruv Nadkarni

Present: N/A

Goals: Upload updated preliminary design

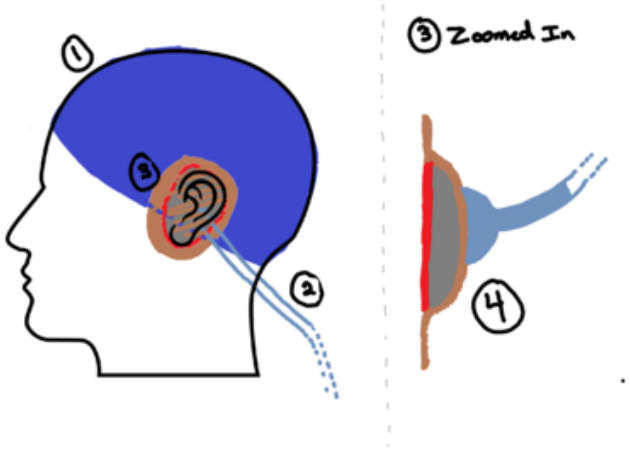
Content:

Image is attached.

Conclusions/action items:

Share design idea with team and create design matrix.

Dhruv Nadkarni - Oct 02, 2025, 9:15 PM CDT



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2025/10/01 - Design idea headphone

Dhruv Nadkarni - Oct 02, 2025, 9:13 PM CDT

Title: Preliminary Design Idea

Date: 2025-10-01

Content by: Dhruv Nadkarni

Present: N/A

Goals: Upload updated preliminary design

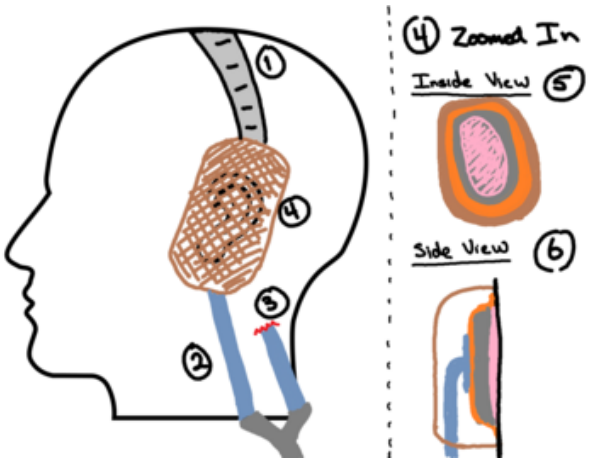
Content:

Image is attached.

Conclusions/action items:

Share design idea with team and create design matrix.

Dhruv Nadkarni - Oct 02, 2025, 9:15 PM CDT



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IMG_8950.png (226 kB)

2025/10/01 - Design idea headband

Dhruv Nadkarni - Oct 02, 2025, 9:14 PM CDT

Title: Preliminary Design Idea

Date: 2025-10-01

Content by: Dhruv Nadkarni

Present: N/A

Goals: Upload updated preliminary design

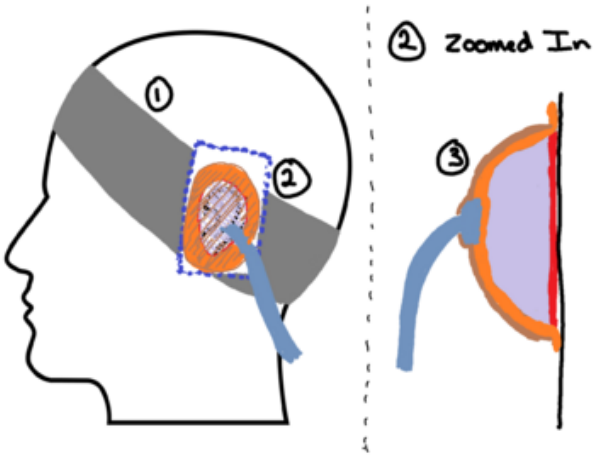
Content:

Image is attached.

Conclusions/action items:

Share design idea with team and create design matrix.

Dhruv Nadkarni - Oct 02, 2025, 9:15 PM CDT



Download

IMG_8951.png (200 kB)

2025/10/23 - Negative Pressure Transmission Protocol

Dhruv Nadkarni - Oct 23, 2025, 7:14 PM CDT

Title:

Negative Pressure Transmission Test Protocol

Date: 2025-10-23

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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 a minimum of 8 hours. 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.
3. Should the displayed pressure and measured pressure exceed +/- 5mmHg of the intended pressure, the test would fail. Additionally, if the vacuum does not continuously suction for 1 hour, the test will fail.
4. Repeat the test for 80, 100, and 120 mmHg below atmospheric pressure.

Conclusions/action items:

Continue writing other test procedures.

2025/10/23 - Consistent Vacuum Seal Protocol

Dhruv Nadkarni - Oct 23, 2025, 7:15 PM CDT

Title:

Consistent Vacuum Seal Protoco

Date: 2025-10-23

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.

Conclusions/action items:

Continue writing other test procedures.

2025/10/28 - Male Connection SolidWorks Model

Dhruv Nadkarni - Oct 28, 2025, 6:09 PM CDT

Title: 1/2 SolidWorks Model

Date: 2025-10-28

Content by: Dhruv Nadkarni

Present: Meghan Kaminski

Goals: Create the connection points for the headphones

Content:

Attached is solidworks model.

Conclusions/action items:

Create an assembly once both sides are created.

Dhruv Nadkarni - Oct 28, 2025, 6:09 PM CDT

Download

DhruvSolidWorksMaleComponent.SLDPRT (486 kB)

2025/12-09 - Strength of Seal Test

Dhruv Nadkarni - Dec 09, 2025, 8:59 PM CST

Title: Strength of Seal Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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 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 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.
    1. Attach a 100N load cell into the machine.
    2. Setup a tensile pull method.
    3. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Strength of Tube/Seal Connection Test

Dhruv Nadkarni - Dec 09, 2025, 9:01 PM CST

Title: Strength of Tube/Seal Connection Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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 5N. 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.
    1. Attach a 100N load cell into the machine .
    2. Setup a tensile pull method.
    3. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Fluid Removal Rate Test

Dhruv Nadkarni - Dec 09, 2025, 9:01 PM CST

Title: Fluid Removal Rate Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.
    1. 10ml
    2. 20ml
    3. 40ml
    4. 80ml
    5. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - Retrograde Fluid Prevention Test

Dhruv Nadkarni - Dec 09, 2025, 9:02 PM CST

Title: Retrograde Fluid Prevention Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.
    1. 10ml
    2. 20ml
    3. 40ml
    4. 80ml
    5. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/12-09 - SOLIDWORKS Deformation Test

Dhruv Nadkarni - Dec 09, 2025, 9:03 PM CST

Title: SOLIDWORKS Deformation Test

Date: 2025-12-09

Content by: Dhruv Nadkarni

Present: N/A

Goals: Document steps for a test procedure.

Content:

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.
    1. 5N
    2. 20N
    3. 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.

Conclusions/action items:

Continue writing other test procedures.

2025/10/24 - Client Meeting Notes

Dhruv Nadkarni - Oct 24, 2025, 12:02 PM CDT

Title: Client Meeting Notes

Date: 2025-10-24

Content by: Dhruv Nadkarni

Present: Entire Team

Goals: Discuss questions with client and get feedback from report

Content:

Technical questions:

- How do you currently dress the ear to accommodate pressure being put on the flap
    - Would a sponge around the ear and behind provide enough support
- Do you foresee NPWT doing damage to the cartilage of the ear
- How much pressure would be ideal for the wound drain, could you foresee there being contradictions between the pressure
    - Our research indicates varying pressures with the average being about 80mmHg sub atmospheric, but the worry stems from crushing the newly built ear. Would they happen to know if 50 or 60 mmHg sub atmospheric would be enough?
- Wallvac/do they have anything we can use to create a negative pressure environment

Resource requests:

- Do they have the Prevena wound vac specifications sheet at the hospital?? (otherwise email solventum guy)
- CAN WE GET PREVENA TUBING CAD FILES?
- Can we get a human model?
- Structure/parameters of wound drain/ example of typical wound drain
- Any skin-like materials we can use for testing?
    - Silicone

Notes:

- Solventum meeting:
    - Bolster (Ball of gauze) typically
        - Cotton with oil to get into crevices, bolster is applied on top of that
        - Some foam behind the ear, so
        - HOT DOG BUN
            - Ear is the hot dog
            - KELOID EARING (inspiration)
- Design:

    - Beats headphones, outside
    - Replaceable adhesive on the outside of the headphone circumference to prevent buildup of Natural oils
    - Nada likes the foam on the outside of to headphones
        - Foam + Adhesive = Difficult to seal
    - Imagining the sticker on the headphone like a goggle-like material
    - Mastazol
    - Avoid skin touching to skin
- **In current bolsters, they use a “hot dog bun” type of design for the foam**
    - Good! This aligns our current thoughts
- Foam behind ear should be good to prevent damage to the ear, necrosis, breakdown of skin
    - Score the inside part of the “hot dog”, allowing flexible adhesion to the intricate outer ear
- Wall Vac:
    - Similar to vacuum tubes in chem labs, only know of manual ones though
    - UW OR - Gauge for pressure desired
        - Could just use manual wall vac with pressure sensor for testing
    - Proof of concept: Use wall vac to prove it works
    - ECB Lab, Portable Suction generator(Expensive), Giant syringes to create some suction as well
        - For testing
        - Controlling how the VAC sucks would be great for the demo
    - NADA WILL FIND MANNEQUIN WOOOOOHOOOOOOOOOOOOOOOOO
        - Silicone very close substrate to ear cartilage
        - Styrofoam head (Silicone Ear)
            - Similar to human skin → *FOR DHRUV TO REMEMBER: Make the test methods that require skin like material based on silicone.*
- WOUND DRAIN
    - Surgeon preference in tubing size
    - Universal tubing size?
    - 8 or 10 french (Fr) size tube (10 is largest)
        - Proceed with 10 french
    - Can build in one way valve into the drain
        - Check with my blood lab at JnJ
        - We might have a way to prevent backflow. It’s an addition to the Y connector that will help with the backflow issue.
    - 100 mmHG instead of 125,
- Could add stopcock to the tubes
- 2 wound drains - both under skin pocket
    - 1 in front of cartilage

    - 1 behind cartilage
- Interference with headphones
    - NON-EXISTENT DESIGN IS GOOD

- TESTING
    - 4 hours a day
    - After testing - Should
    - Week-long vs day-long test, no difference according to nada
        - For the long durability tests, we can have a tension and compression movement form the MTS machine to simulate a child jumping, running, etc…
    -
    - Dr. Cho is okay with a week long, I think we should still include the MTS compression and tension movements to add some variability.
    - SHOP VAC with adjustable Pressure for testing
    - SILICON EAR MODEL

- ADHESIVE
    - Skin glue, Dermabond
        - Might be our answer
    - Research alternative gluing methods
        - Dermabond is heat-activating **, NO DERMABOND**
        - Mastacol would be used by surgeon if needed for extra adhesion of headphone to adhesive layer
- Consider NOT RIGID headband, safari drawstring hat
    - Combats kids being kids
- Mastisol

EAR MOLDING Technology - EAR WELL

Infant ear - use as inspiration

- Ear Well vs InfantEar Device

- Theoretically could make both tubes same diameter
    - 10 French for both?
    - Def look into this
- Flow rate doesn't matter

    - 10 ccs of fluid at most
    - WoundVac tube inner diameter ~ 3.5mm, wound drain = 10 french = 3.3mm □ □ □□□□ □ □□□ □ □ □□□□

Action items:

- Research any relevant pressure sensor compatible with wall vacuum (as found in chem lab, BME design lab)
- Begin design of foam in “hot dog” design
- Look into models for ear, silicone is ideal
- Look into Earwell - could be huge inspo for inner headphone design, could create sticker via this design
    - Inspo for adhesion to skin, allowing device to stick to ear
    - InfantEar more modular

Conclusions/action items:

Implement all testing advice into test protocols.

10/3/25-Salvaging exposed microtia cartilage framework with negative pressure wound therapy

MEGHAN KAMINSKI - Oct 03, 2025, 4:23 PM CDT

Title: Salvaging exposed microtia cartilage framework with negative pressure wound therapy

Date: 10/3/25

Content by: Meghan

Present: N/A

Goals: Look into applications of NPWT on microtia

Link: Salvaging exposed microtia cartilage framework with negative pressure wound therapy - PubMed

Citation:

[1] 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.

Content:

- Background and Purpose
  - Exposure of the cartilage framework is a severe complication after auricular reconstruction for microtia.
  - Negative Pressure Wound Therapy (NPWT) has become popular for managing complex wounds.
  - Limited reports exist on NPWT use specifically for cartilage exposure in microtia reconstruction.
  - The study aims to detail the use, protocol, and outcomes of NPWT for this complication.
- Study Design
  - Retrospective analysis of 7 cartilage exposure wounds in 6 patients after auricular reconstruction with costal cartilage.
  - Wounds appeared between postoperative days 3 and 30.
    - Locations included antihelix (3), helix (2), triangular fossa (1), and scaphoid fossa (1).
    - Skin defects ranged from 1 to 24 mm^2.
    - Causes of exposure: 5 due to flap necrosis, 2 due to suture failures without skin necrosis.
    - Two cartilage frameworks were infected at onset (one MRSA, one MSSA).
- NPWT Protocol
  - Used KCI Negative Pressure Wound Therapy system with V.A.C.Ⓡ GranuFoam Black™ or Silver™.
  - Continuous suction applied between 25 and 125 mmHg.
  - Dressings changed every 1 to 3 days.
  - Therapy continued until granulation covered exposed cartilage or dead space disappeared.
  - Conventional ointment therapy applied after NPWT if needed.
- Treatment Course
  - NPWT was applied as primary or adjunct therapy; all cases eventually required additional surgery.
  - Additional surgeries included debridement and flaps (mastoid fascia flap, local flaps) or direct closure.
  - Vacuum pressures were adjusted depending on wound characteristics.
  - Duration of NPWT ranged from 8 to 39 days.

    - No significant hematomas observed during surgeries.
- Outcomes
    - All wounds healed with granulation tissue formation.
    - All cartilage frameworks survived.
        - Partial cartilage atrophy remained in 4 cases (grades G1 and G2).
    - One case developed secondary infection during NPWT but was managed effectively.
    - Follow-up ranged from 8 to 84 months.
- Mechanisms and Effects of NPWT
    - NPWT removes exudate and fluid from dead spaces, reducing tissue compression and bacterial load.
    - Promotes granulation tissue formation critical for healing exposed cartilage.
    - Particularly important in microtia reconstruction due to the concavo-convex shape of cartilage frames and thin skin envelope.
    - 75 mmHg identified as an optimal vacuum pressure balancing drainage and tissue growth.
    - Lower pressures (e.g., 25 mmHg) may drain inadequately; higher pressures (125 mmHg) may hinder granulation.
- Indications and Limitations
    - Small wounds, good soft tissue coverage, good blood circulation, concave cartilage shapes, and low skin tension favor healing with NPWT alone.
    - Larger wounds or poor soft tissue coverage may require early surgical intervention.
    - Improvement in wound condition should be seen within 7 days of NPWT.
    - If no improvement occurs, additional surgery is recommended to prevent secondary infection.
- Clinical Recommendations
    - NPWT is useful as a continuous external drainage system for wounds with dead space.
    - Surgeons must monitor closely for signs of secondary infection.
    - Prolonged NPWT without improvement may increase infection risk.
    - Additional surgical procedures, such as flap coverage, should be considered promptly if wounds do not improve.
- Conclusion
    - NPWT is a valuable tool under restricted conditions for managing exposed cartilage after microtia reconstruction.
    - It effectively removes fluid and promotes granulation but may be limited by insufficient soft tissue.
    - Vigilance and timely surgical intervention are key to successful outcomes.

Conclusions/action items:

The article highlighted the sensitivities to be aware of when working with NPWT. This is especially important when creating a new device.

How was NPWT applied? Did this cause any damage on the ear?

10/3/25-Microtia Reconstruction

MEGHAN KAMINSKI - Oct 03, 2025, 4:10 PM CDT

Title: Microtia Reconstruction

Date: 10/3/25

Content by: Meghan

Present: N/A

Goals: Understand microtia and reconstruction associated with it.

Link: Microtia reconstruction - PubMed

Citation:

[1] G. H. Wilkes, J. Wong, and R. Guilfoyle, “Microtia Reconstruction,” *Plastic and Reconstructive Surgery*, vol. 134, no. 3, pp. 464e479e, Sep. 2014, doi: https://doi.org/10.1097/prs.0000000000000526.

Content:

- Overview of Microtia Reconstruction
  - Microtia reconstruction is a highly complex and evolving area of plastic surgery.
  - It remains controversial due to differing opinions on optimal techniques, timing, materials, and goals.
  - Progress has been made in understanding genetics, refining surgical methods, improving outcomes, and expanding treatment options.
- Epidemiology and Genetics
  - Microtia affects 0.83 to 17.4 per 10,000 births, with variability across populations.
  - No single genetic mutation has been identified, though over 18 microtia-related syndromes exist.
  - Syndromic cases often involve Mendelian inheritance
    - sporadic cases are likely polygenic or multifactorial.
  - Environmental risk factors may include vascular disruption, altitude, and neural crest cell disturbances.
  - Microtia is frequently associated with oculoauriculovertebral spectrum (OAVS), including conditions like Goldenhar syndrome.
  - Diagnostic criteria for OAVS remain unclear, and it should be considered distinct from isolated microtia.
- Surgical Techniques
  - Creating a three-dimensional ear framework from costal cartilage is traditionally considered the most difficult aspect.
  - Techniques differ in rib harvest location and method:
  - contralateral rib
  - ipsilateral rib
- Postauricular Sulcus Creation
  - Elevating the ear framework and creating a defined sulcus is technically challenging.
  - Earlier methods using only grafts often failed due to poor projection and variable healing.
  - Modern approaches incorporate cartilage.
    - Flaps include postauricular fascia, temporoparietal fascia, or SMAS flaps.
    - SMAS flap is easy to perform and avoids secondary defects.
    - Good skin healing is crucial to avoid contraction and loss of projection.
- Rib Harvest and Chest Wall Concerns

- Rib Harvest and Chest Wall Concerns
    - Chest wall deformity is a known risk of rib cartilage harvest.
    - Leaving posterior perichondrium intact or using cartilage regeneration techniques can reduce deformity.
    - Some surgeons use absorbable sleeves filled with cartilage remnants to regenerate ribs.
    - Chest wall morbidity can also be minimized by pain control, scar placement, and harvesting methods.
- Use of Soft-Tissue Expanders
    - Soft-tissue expanders help generate more skin for better framework coverage.
    - Benefits include improved color and texture match and reduced need for grafts.
    - Challenges include increased risk of necrosis, infection, and added surgical stages.
    - Complication rates are higher in posttraumatic or scarred skin cases and should be avoided.
- Medpor (Porous Polyethylene) Frameworks
    - Medpor frameworks are a valid option, especially for adults unwilling or unable to undergo rib harvest.
    - Complication rates have decreased with improved soft tissue coverage using temporoparietal fascia flaps.
    - Satisfaction rates are high, but long-term concerns about fracture and exposure remain.
    - Revision surgeries are more common than with autogenous reconstructions but typically minor.
- Osteointegrated Auricular Prostheses
    - Offer a high-satisfaction, low-risk alternative, particularly for patients with poor surgical candidacy or failed reconstructions.
    - Attach using implanted abutments with magnets or clips.
    - Minimal implant failure rate and high patient acceptance.
    - Downsides include minor chronic skin issues, required maintenance, and periodic replacement every 2–5 years.
- Treatment Selection Considerations
    - Choosing between autogenous, Medpor, or prosthetic reconstruction depends on:
    - Patient age, anatomy, preferences, surgical risk tolerance, and hearing needs.
    - Patients rarely change their decision once all options are fully explained.
    - Informed consent is essential and should include pros, cons, risks, and long-term expectations.
- Hearing Restoration Strategies
    - Hearing loss in microtia typically involves external canal and middle ear anomalies.
    - Traditional canal reconstruction has risks like restenosis and nerve injury, with variable success.
    - For unilateral microtia, standard practice has been no intervention if the opposite ear has normal hearing.
    - Recent studies challenge this, showing cognitive and educational impacts from monaural hearing.
    - Bone-anchored hearing aids (BAHA, Ponto) are now widely used for both unilateral and bilateral conductive hearing loss.
    - Bilateral aids may restore spatial awareness, improve speech understanding, and enhance quality of life.
- Surgical Timing Conflicts: Otologist vs. Reconstructive Surgeon
    - Otologists prefer early BAHA implantation (age ~5) to support early hearing development.
    - Reconstructive surgeons prefer to delay until after autogenous reconstruction (age 8–10) to avoid scarring key areas.
    - Compromise can be achieved through multidisciplinary planning and thoughtful BAHA placement.
- Surgeon Training and Education

    - Modern training tools now include:
        - Realistic synthetic rib cartilage simulators
        - Digital training modules (apps and videos)
        - Physical trainers developed by expert surgeons (e.g., Firmin)
    - Emphasis has shifted toward mastering both framework carving and soft tissue management.
- Future Directions: Tissue Engineering
    - Tissue engineering aims to grow cartilage on 3D scaffolds using autologous cells or stem cells.
    - Natural scaffolds (hydrogels, chitosan, collagen) degrade quickly or lack strength.
    - Synthetic scaffolds offer customizability but have immune response issues.
    - Major hurdles include:
        - Creating durable, flexible cartilage
        - Sourcing enough viable cells
        - Avoiding dedifferentiation and tumor formation
    - Pilot clinical trials have demonstrated possible success in multi-stage constructs using injected cultured cells.
- 15. Conclusion
    - Ear reconstruction is becoming more consistent and sophisticated but remains technically demanding.
    - Hearing rehabilitation is advancing with implantable devices and growing recognition of early intervention benefits.
    - Tissue engineering holds long-term potential to revolutionize treatment, though clinical application is still emerging.
    - Multidisciplinary, patient-centered care with individualized treatment planning remains key to success.

Conclusions/action items:

Microtia is universally diverse in techniques for surgery and post-operative care. Our device will have to specialize on one method of reconstruction and post-operative care techniques.

10/3/25-The anatomy and application of the postauricular fascia flab in auricular reconstruction for congenital microtia

MEGHAN KAMINSKI - Oct 03, 2025, 3:47 PM CDT

Title: The anatomy and application of the postauricular fascia flab in auricular reconstruction for congenital microtia

Date: 10/3/25

Content by: Meghan

Present: N/A

Goals: Understand different microtia surgical techniques

Link: The anatomy and application of the postauricular fascia flap in auricular reconstruction for congenital microtia - PubMed

Citation:

[1] Y. Wang *et al.*, "The anatomy and application of the postauricular fascia flap in auricular reconstruction for congenital microtia," vol. 61, pp. S70–S76, Jan. 2008, doi: https://doi.org/10.1016/j.bjps.2008.07.008.

Content:

- Background:
  - Proper soft tissue coverage is crucial in ear reconstruction to avoid framework exposure and failure.
  - The postauricular fascial flap offers a reliable, thin, neurovascular layer for better coverage.
- Anatomy:
  - The postauricular area is well-vascularized by branches of the posterior auricular and occipital arteries.
  - It is innervated by the great auricular and lesser occipital nerves.
  - The flap provides a good balance of vascularity and sensation for ear reconstruction.
- Patient group:
  - 428 patients (438 ears) were reconstructed between August 2006 and August 2007.
  - Age range was 6 to 14 years (mean 7 years, median 10 years).
  - 280 male and 158 female patients; most cases involved microtia.
- Surgical technique:
  - A two-stage procedure was used:
    - Stage 1: insertion of a postauricular tissue expander.
    - Stage 2: removal of expander, lobule transposition, harvesting of postauricular fascia flap, cartilage framework fabrication, and coverage using the flap and a skin graft.
  - A suction drain helped the skin adhere to the cartilage framework.
  - Skin grafts were taken from the same site as the rib cartilage harvest.
- Results:
  - No flap failures occurred; all patients healed uneventfully.
  - No cartilage infection or exposure was reported.
  - Minor complications included:
  - Haematoma in 23 patients during tissue expansion.
  - Hypertrophic scars in 32 cases.
  - Thick fibrous tissue in 4 cases affecting ear detail.
  - All flaps survived, and early edema resolved within weeks.
  - Final aesthetic outcomes were:
    - 279 ears rated as excellent

        - 156 as fair
        - 3 as poor
    - Sensation to touch and temperature was preserved in all cases.
- Discussion:
    - Adequate skin and soft tissue coverage are essential for successful long-term outcomes.
    - The fascia flap improves vascularization and helps prevent cartilage resorption.
    - Tissue expansion provides sufficient non-hair-bearing skin for full coverage.
    - The flap allows clear definition of ear contours after edema subsides.
    - The method avoids many complications associated with temporoparietal fascial flaps, such as alopecia and visible scarring.
    - The postauricular fascial flap is easier to raise, leaves inconspicuous scars, and is sensate.
    - Knowledge of vascular and nerve anatomy is vital for surgical planning.
    - If this method fails, a temporoparietal fascial flap is a reliable alternative.
    - Reconstruction is ideally performed around age 6, when the contralateral ear is nearly fully grown.
- Conclusion:
    - The postauricular fascial flap with skin graft provides safe, effective coverage for autologous cartilage frameworks in microtia reconstruction.
    - This technique improves vascularization and reduces complication rates.

Conclusions/action items:

The usage of this technique gives an outlook to the post-operative complications that may occur.

What are typical post-operative care methods currently used?

10/3/25- Microtia Stanford Ear Institute

MEGHAN KAMINSKI - Oct 03, 2025, 3:33 PM CDT

Title: Microtia Stanford Ear Institute

Date: 10/3/25

Content by: Meghan

Present: N/A

Goals: Understand the technicalities of microtia to better understand the application of our device

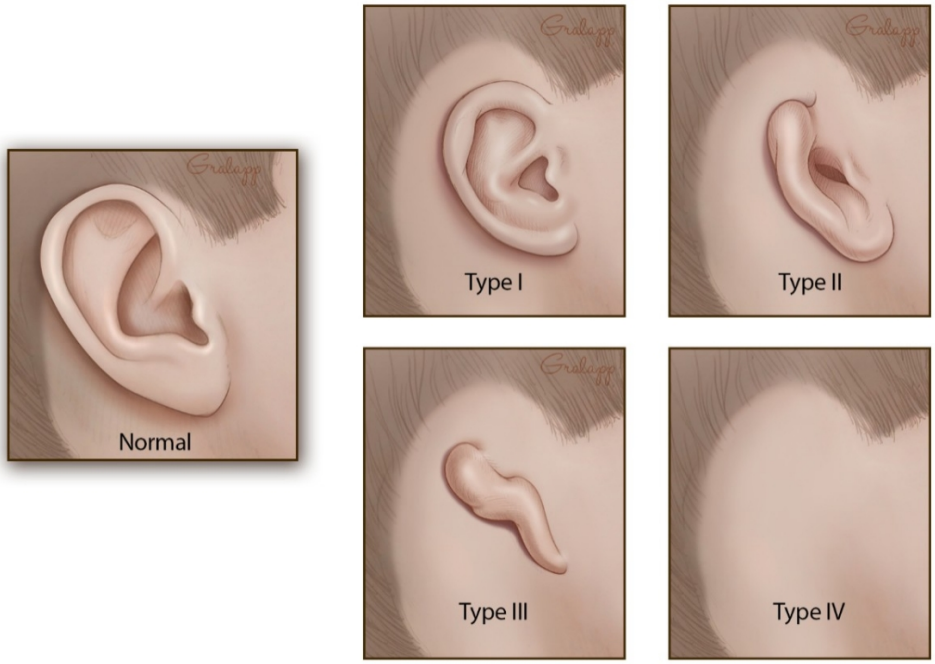
Link: [Microtia | Otolaryngology — Head & Neck Surgery | Stanford Medicine]

Citation:

[1] "Microtia," *Otolaryngology — Head & Neck Surgery*, 2025. https://med.stanford.edu/ohns/OHNS-healthcare/earinstitute/conditions-we-treat/microtia.html

Content:

- Microtia occurs in about 1 in 5,000 births; more common in males and usually affects the right ear.
  - Over 90% of cases are unilateral (one ear affected).
  - Often associated with absence (atresia) or narrowing (stenosis) of the ear canal.



  -
- Four grades of microtia:
  - Grade 1: Small ear with normal structures.
  - Grade 2: Partial ear with missing features; narrow canal often present.
  - Grade 3: Most common type; peanut-shaped lobe only; no ear canal.
  - Grade 4: Complete absence of the ear (anotia); very rare.
- Microtia is usually not inherited; 95% have no family history.
- About 5% of cases may have a genetic cause; recurrence risk is about 5%.
- 50% of patients have underdeveloped tissues on the same side of the face (hemifacial microsomia).
  - Up to 15% may have facial nerve weakness.

    - May be associated with craniofacial syndromes like Treacher Collins and Goldenhar Syndrome.
- Causes often unknown; possible factors:
    - Reduced blood flow or oxygen in early pregnancy
    - Pressure on the fetus or umbilical cord
    - Drug/alcohol exposure (e.g. Accutane, methamphetamines, alcohol)
- Evaluation includes:
    - Kidney ultrasound
    - Hearing tests by pediatric audiologist
    - ENT consultation
    - Genetics consult if other abnormalities present
- CT scans are delayed until age 9-10 to reduce radiation exposure and allow better imaging.
- Treatment does not occur at birth
- Reconstructive options:
    - Rib cartilage graft (most common, long-lasting, uses patient's own tissue)
        - Done in 2–4 stages
        - Typically performed between ages 8–10
        - Uses Firmin technique at Stanford
            - Durable, living tissue, good long-term outcomes
            - Disadvantages: chest scar, stiffness, initial pain
    - Medpor graft (synthetic implant)
        - Can be done as early as age 3
        - Only one surgery required
        - Not a living structure; lifelong risk of trauma/infection
        - Not performed at Stanford due to long-term risks
    - Prosthetic ear
        - Realistic appearance, easy surgery
        - Can detach or need replacement
        - May require glue or implanted anchors
    - Reconstruction of ear canal (atresia repair) is done *after* external ear reconstruction with rib graft, or *before*if Medpor is used.
        - Ideal age for surgery is 8–10 years to allow for:
            - Full growth for better symmetry
            - Stronger cartilage for better framework
            - Greater child maturity and consent
            - Easier and safer rib cartilage harvest

Conclusions/action items:

Microtia is separated into four types. Stages 2-4 are the target stages for our project, as they are when rib cartilage grafts are performed.

What is the average size ear formed from rib cartilage?

9/24/25: Minimal Coverage Face Mask- Mid Neck- Style No. FM100-B

MEGHAN KAMINSKI - Sep 24, 2025, 3:24 PM CDT

Title: Minimal Coverage Face Mask- Mid Neck- Style No. FM100-B

Date: 9/24/25

Content by: Meghan

Present: N/A

Goals: Gain a better understanding of devices currently used in rhytidectomy post-operative care.

Link: FM100-B | Plastic Surgery Face Mask | Face Compression Garment - The Marena Group, LLC

Citation:

[1] The, “Minimal Coverage Face Mask - Mid Neck - Style No. FM100-B,” *The Marena Group, LLC*, 2025. https://marena.com/collections/womens-post-surgical-face-masks/products/fm100-face-mask-mid-neck (accessed Sep. 24, 2025).

Content:

- FM100-B features hook and look closures and mid-neck coverage
- Sizes range from small to extra large
- Variations of the mask are available with no neck and no long neck coverage

Conclusions/action items:

The compression brace is currently an important step of recovery in rhytidectomies. The brace is utilized after the head is wrapped for multiple days.

How will we combine both aspect of the brace and gauze wrapping?

9/24/25- Jackson-Pratt (JP) Drain

MEGHAN KAMINSKI - Sep 24, 2025, 3:41 PM CDT

Title: Jackson-Pratt (JP) Drain

Date: 9/24/25

Content by: Meghan

Present: N/A

Goals: Gain a better understanding of devices currently used in rhytidectomy post-operative care.

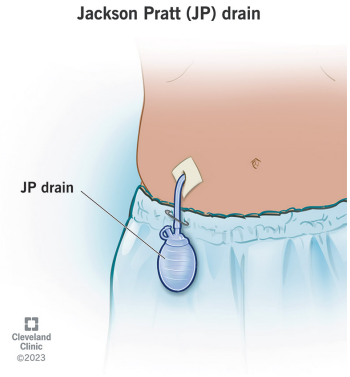
Link: Jackson-Pratt (JP) Drain: What It Is, Care & Removal

Citation:

[1] Cleveland Clinic, “Jackson-Pratt (JP) Drain: What It Is, Care & Removal,” *Cleveland Clinic*, Oct. 23, 2023. https://my.clevelandclinic.org/health/articles/21104-jackson-pratt-jp-drain

Content:

Overview:



- The JP drain is a thin, flexible tube with a bulb on the end that drains fluid away from the wound after surgery
- The fluid moves form the wound to the bulb on the outside of the body

How does a JP drain work?

- JP drain utilizes suction to draw fluid from the would
- 3 parts of the device:
  - flattened end with holes that enters the inside of the wound
  - tubing allows fluid from the wound to travel
    - tubing is typically secured via suture
  - The bulb which will draw fluid out when compressed
    - the bulb has a topper that create an airtight seal

When are JP drains needed?

- JP drains are utilized in many types of surgery, as they are the most common type of surgical drain
- Procedures such as abdominal surgery, breast surgery, chest surgery, thyroid surgery, cosmetic and plastic surgery, and lymph node removal
- JP drains hold from 20 to 50 milliliters at a time

Conclusions/action items:

The JP drain is commonly used in cosmetic surgeries currently.

Why should we move towards NPWT on the ears, opposed to this solution?

Are there any hematoma formation possibilities with the usage of a wound drain?

10/16/25-3M Prevena

MEGHAN KAMINSKI - Oct 22, 2025, 3:46 PM CDT

Title: 3M Prevena

Date: 10/16/25

Content by: Meghan

Present: N/A

Goals: Understand how Solventum utilizes NPWT in their devices.

Link: 3M Prevena Therapy patient information | Solventum

Citation:

[1] "Prevena for patients," *Solventum.com*, Feb. 05, 2025. https://www.solventum.com/en-us/home/medical/advanced-wound-care/negative-pressure-wound-therapy/prevena-therapy/prevena-for-patients/

Content:

- The therapy system is a portable, disposable unit prescribed for managing a closed surgical incision.
- It applies continuous negative pressure (-125 mmHg) to the incision area and removes fluids away from the surgical site.
- It's intended to help reduce the incidence of seroma (fluid build-up under the skin) in closed incisions.
- For patients at high risk of post-operative infection and with Class I or II closed wounds, it's designed to help reduce superficial surgical-site infections (SSIs).
- The unit is to be worn for the full duration prescribed by the healthcare provider; for many closed-incision uses, the system runs up to 7 days.
- Dressings for closed incisions typically are *not* changed frequently, only when instructed, unless the system covers open or more complex wounds.
- The unit can be worn under or over clothes and includes features (carrying strap, etc) for mobility; care must be taken to avoid kinks in tubing or mishandling.
- tips:
    - Keep the unit turned on as instructed.
    - Place the unit so tubing isn't kinked or pulled.
    - If the unit uses batteries, ensure you have extras; if rechargeable, bring the charger when away from home.
    - Quick, light showering may be allowed only if approved by your provider, but do not submerge the dressing or spray the unit directly with water.
- Limitations and conditions:
    - It is not intended to treat an already established surgical-site infection or seroma, it is prophylactic/management, not remediation.
    - Safety and efficacy in pediatric patients under 22 years old have not been evaluated.
    - The system's effectiveness has not been demonstrated for Class III (contaminated) or Class IV (dirty/infected) wounds.
    - It has not been shown to reduce deep-incisional or organ-space surgical-site infections.
    - It has not been shown to be effective in all surgical procedures and patient populations, so it is not necessarily recommended for routine use in every case.
    - If any alarm or alert appears from the unit, the patient should refer to the system's alert guide or patient guide and contact their healthcare provider or the technical support line as instructed.

- As with all medical devices, the patient should discuss with their doctor whether this therapy is right for them, understand how to use it properly, and follow all instructions and precautions.

Conclusions/action items:

The Prevena is a device created by Solventum. The NPWT device is a premade assembly of the dressings.

What materials do they use in manufacturing?

9/12/25- Negative Pressure Wound Therapy

MEGHAN KAMINSKI - Sep 12, 2025, 4:09 PM CDT

Title: Negative Pressure Wound Therapy

Date: 9/12/25

Content by: Meghan

Present: N/A

Goals: Complete preliminary research to understand all aspects of the project.

Link: [Negative Pressure Wound Therapy]

Citation:

[1] C. Clinic, “Negative Pressure Wound Therapy,” *Cleveland Clinic*, 2024. https://my.clevelandclinic.org/health/treatments/17313-negative-pressure-wound-therapy

Content:

- Negative Pressure Wound Therapy
  - Pulls fluid and bacteria out of the wound
  - Creates suction
  - treatment utilized to heal soft tissue
  - Encourages healthy tissue formation
- Procedure
  - Clean and dry wound
  - Place special foam pad to cover the wound
  - Cover with a film to allow fluids through
  - Seal
  - Secure suction tube on top
  - attach suction tube to a canister to collect fluid drainage
  - use pump to apply negative pressure
- Usage
  - NPWT is used on any of the following wounds:
    - Complex
    - acute
    - reopened
    - chronic
- Risks and Benefits
  - Benefits
    - reduced swelling
    - increased blood flow
    - fewer dressings
    - device portability
  - Risks
    - Pain
    - Infection
    - Foam sticking to wound
    - Device failure

Conclusions/action items:

Negative Pressure Wound Therapy is a reliable source for a faster recovery. NPWT is versatile in application.

- What is the standard pressure level on NPWT and is this something suitable for rhytidectomies?
- How flexible is the size of a standard NPWT device? Will the standard materials of the device be malleable/adjustable?

9/12/25- Facelift (rhytidectomy)

MEGHAN KAMINSKI - Sep 12, 2025, 4:44 PM CDT

Title: Facelift (rhytidectomy)

Date: 9/12/25

Content by: Meghan

Present: N/A

Goals: Complete preliminary research to understand all aspects of the project.

Link: Facelift (Rhytidectomy): What Is It, Recovery & What to Expect

Citation:

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

Content:

- Rhytidectomy
  - Surgical procedure that improves signs of aging in the face and neck by removing/repositioning skin, fat, and muscle
  - Cosmetic restorative surgeries
  - Traditional facelift:
    - incisions around the hears, hairline, and below chin
    - Surgeon separates skin from underlying tissues and tightens the muscles
    - Surgeon removes excess fat if needed
    - Skin is then repositioned over the face
  - SMAS facelift:
    - superficial musculoaponeurotic system- the muscular layer of the face
    - targets the lower two-thirds of the face
    - surgeon tightens the muscle and trims excess skin
  - Deep plan facelift:
    - Surgeon will life the SMAS, fat, and skin as a single unit
    - Addresses multiple areas of the face at once
  - Mid-facelift:
    - Cheek area of the face
    - Repositions and tightens the fat and skin in cheeks
  - Mini facelift:
    - lifting lower face and neck area
    - quicker and less invasive
    - recommended for younger patients
  - Cutaneous facelift:
    - skin facelift
    - skin only
    - focused on the neck and lower face
  - Population
    - physically fit, nonsmoker, mental wellness
    - significant facial aging

        - 40s to 60s typically
    - During the surgery
        - Depending on the type of facelift, the incision varies in placement
            - hairline
            - around the ears
            - at the lower scalp
            - under the chin
            - in the mouth
        - Incision is closed with any of the following:
            - dissolvable stiches
            - Removable stitches
            - skin glue
    - Side-effects
        - infection
        - hematoma
        - changes in skin sensation
        - facial nerve injury
        - scarring
        - prolonged swelling
    - Recovery time
        - recovery time without additional therapy ranges from two to three months

Conclusions/action items:

Rhytidectomies vary in multiple ways. Grasping the variability or understanding the most common rhytidectomy is an essential portion of the design of the HeadVac.

Should we design a device applicable for one type of facelift?

If making a more adjustable design, how do we adjust both size and surface area?

9/12/25- Common Complications in Rhytidectomy

MEGHAN KAMINSKI - Sep 24, 2025, 4:58 PM CDT

Title: Common Complications in Rhytidectomy

Date: 9/12/25

Content by: Meghan

Present: N/A

Goals: Understand why hematomas form in rhytidectomies

Link: [Common Complications in Rhytidectomy - ClinicalKey]

Content:

- Introduction
  - One of the most popular surgical cosmetic procedures, reported by American Society for Aesthetic Plastic Surgery
  - 2017: Ranked 6th among women and 5th among men
- Pre-op assessment
  - Complete history and physical examination is completed
    - will anticipate potential complications following
- Local Anesthetic
  - Local anesthesia with epinephrine is commonly used regardless of whether general anesthesia is administered
  - Dosages must be calculated carefully to prevent toxicity, especially when combining agents
  - Signs of local anesthetic toxicity include lightheadedness, tremors, and seizures, followed by cardiovascular symptoms
  - These signs may be masked under general anesthesia
- Complications
  - Hematoma
    - Hematoma is the most frequent postoperative complication in facelift surgery
    - Most commonly develops within 24 hours after surgery
    - Reported in 1 to 15 percent of cases, usually in the 1 to 5 percent range
    - Presents with pain, swelling, bruising, tight skin, trismus, and sometimes anxiety
    - In severe cases, can cause airway compromise if occurring in the neck
    - Expanding hematomas require urgent surgical evacuation to control bleeding and prevent skin loss
    - Prompt management usually preserves the final aesthetic result
    - Prevention strategies include:
      - Meticulous hemostasis during surgery
      - Application of cold compresses and pressure dressings postoperatively
      - Adequate control of intraoperative and postoperative blood pressure
      - Avoidance of medications and supplements that increase bleeding risk
      - Common supplements to avoid include ginkgo biloba, ginseng, garlic, St. John’s wort, vitamin E, licorice, and kava
      - All herbal supplements should be stopped at least two weeks before surgery

        - Patients on anticoagulants (warfarin, rivaroxaban, clopidogrel, heparin) require coordinated management with their physicians
        - Hypertension is a major risk factor and should be controlled preoperatively and postoperatively
        - Blood pressure spikes over 150 mm Hg are frequently associated with hematoma development
        - Smooth emergence from anesthesia helps avoid blood pressure surges and physical strain like coughing or vomiting
        - Hypotensive anesthesia may increase hematoma risk by masking bleeding during surgery
        - Male patients have a higher risk due to increased facial vascularity
        - Use of tissue sealants has been shown to reduce hematoma rates significantly
        - Tissue sealants do not affect seroma formation or drain use
        - Deep plane facelifts have a slightly higher hematoma risk than SMAS plication but the difference is not clinically significant
        - In smokers, deep plane techniques may reduce hematoma risk by preserving skin flap perfusion
        - Use of suction drains is common but their effectiveness in reducing hematoma is not proven
        - Postoperative instructions to avoid physical strain and maintain head elevation are important to minimize bleeding risk
    - Facial Nerve Injury
        - Occurs in 0.5 to 2.5 percent of cases, with permanent injury in about 0.1 percent
        - Most commonly affects the frontal and marginal mandibular branches
        - Stretching, cautery injury, or edema are common causes of temporary nerve weakness
        - Proper knowledge of anatomy and conservative use of cautery helps reduce risk
        - Temporary asymmetry may result from anesthesia and usually resolves in hours to days
        - Neuromodulators like Botox can help manage bothersome asymmetry during recovery
    - Great Auricular Nerve Injury
        - Occurs in up to 7 percent of cases
        - Results in numbness or pain in the lower ear and surrounding area
        - Caused by deep dissection over the sternocleidomastoid muscle
        - Most sensory loss resolves over time, but neuromas may require medications or surgical excision
        - Cold sensitivity due to numbness may require patient education on ear protection
    - Skin Flap Necrosis
        - Often caused by vascular compromise due to hematoma, tension, or cautery
        - Most commonly seen in preauricular and postauricular areas
        - Smoking increases risk up to 20 times
        - Patients should stop smoking four weeks before and after surgery
        - Management includes wound care, avoiding tension, and possible use of topical nitroglycerin
        - Healing is usually acceptable over time
    - Scarring

        - Proper incision placement and closure technique are critical
        - Men and women require different incision patterns to preserve natural hairlines and beard lines
        - Hypertrophic scarring may be treated with steroid injections, laser therapy, or other nonsurgical interventions
        - Broken line incisions can help camouflage scars in bald patients
        - Sun protection reduces the risk of hyperpigmentation and scar discoloration
    - Ear Deformity
        - Includes tragal displacement and pixie ear deformity
        - Caused by tension during closure or poor skin redraping
        - Proper surgical planning and tension-free closure help prevent these issues
        - Corrective surgery can be performed after 6 to 12 months
    - Seroma
        - Typically occurs between days 2 to 7 postoperatively
        - Most common around the postauricular area
        - Treated with needle aspiration and pressure dressings
        - Tissue sealants may reduce healing time but not the incidence of seromas
    - Parotid Duct Injury
        - Rare but more likely with deep dissections
        - Duct injuries may require stenting and surgical repair
    - Hair Loss
        - Reported in up to 8 percent of cases, but usually temporary
        - More common in the temporal region due to tension or cautery
        - Risk is higher in patients with preexisting hair thinning
        - Minoxidil may aid recovery and prevention
        - Permanent alopecia is rare
    - Poor Aesthetic Outcomes
        - Edema and bruising distort early results and may take weeks to resolve
        - Patients should be warned about limitations based on anatomy such as low hyoid or prominent submandibular glands
        - Common complaints include residual jowling, nasolabial folds, and platysma bands
        - Most refinements are delayed at least 12 months to allow full healing
        - Treatments may include fat grafting, fillers, neurotoxins, or laser therapy
    - Infection
        - Infection rate is less than 1 percent
        - Early antibiotic treatment is effective
        - Pseudomonas coverage is needed if chondritis is suspected
    - Deep Vein Thrombosis
        - Rare but serious complication with a 0.1 percent incidence
        - Preventative measures include compression stockings and early mobilization
        - Chemical prophylaxis is controversial due to increased hematoma risk
        - Risk increases with operative time over 5 hours

Conclusions/action items:

Hematomas are the largest risk in rhytidectomies.

How can NPWT reduce the number of hematomas formed?

Would NPWT work in reducing hematomas during standard use?

9/19/25- What are example of NPWT? Exploring different types of negative pressure wound therapy devices

MEGHAN KAMINSKI - Sep 19, 2025, 12:39 PM CDT

Title: What are example of NPWT? Exploring different types of negative pressure wound therapy devices

Date: 9/19/25

Content by: Meghan

Present: N/A

Goals: Understand NPWT devices

Link: [What Are Examples of NPWT Devices? Types and Benefits of NPWT]

Content:

- Bluemed: leading medical consumables manufacture, offers range of NPWT solutions
- NPWT devices help accelerate healing, reduce risk of infection, and improve patient outcome
- Device promotes healing by:
  - Removing excess exudate
  - reducing tissue edema
  - stimulation blood flow and granulation tissue
- Portable NPWT devices
  - lightweight, compact, battery-operated, offer flexibility to patients to continue daily life
- Stationary NPWT device
  - designed for continuous wound therapy
  - used in clinical settings and hospitals for complex wounds
- Single-use NPWT
  - cost-effective, disposable systems
  - Emergency use, outpatient care, or home car
  - pre-packaged for easy use
- Wounds:
  - Chronic (diabetic foot ulcers, pressure ulcers, venous ulcers), surgical (post-surgical incisions, grafts, donor sites), traumatic (burns, lacerations, and exposed bone), complication (deep wounds)

Conclusions/action items:

The single-use NPWT device is most similar to what our clients are requesting.

What do they look like?

What is the cost to manufacture one of these devices?

9/24/25- Exploring Different Types of Medical Adhesives

MEGHAN KAMINSKI - Sep 24, 2025, 4:17 PM CDT

Title: Exploring Different Types of Medical Adhesives

Date: 9/24/25

Content by: Meghan

Present: N/A

Goals: Understand how dressings are chosen in order to apply the knowledge to dressings needed for rhytidectomies

Link: Exploring Different Types of Medical Adhesives | PolarSeal

Citation:

[1] polarseal, “How can AI advance Cancer research?,” *PolarSeal*, Aug. 27, 2024. https://www.polarseal.net/blog/exploring-different-types-of-medical-adhesives/

Content:

- Introduction:
  - Selecting adhesives for medical devices is critical for both patient comfort and profitability of the product
  - Various types of medical-grades adhesive available
- Understanding Adhesive Performance: Tack, Peel Adhesions & Shear Strength:
  - Tack: measurement of immediate stickiness when adhesive comes into contact with a surface. Adhesives with high tack have a quick bond, crucial for immediate adhesion
  - Peel Adhesion: Measures the strength of the bond when the adhesive is peeled away. High peel adhesion is required in devices that are required to remain secured over long periods of time
  - Shear strength: Measures the adhesives ability to resist sliding or shifting under pressure. High shear strength is required for products where the adhesive will experience prolonged stress
- Acrylic:
  - strong adhesion, environmental resistance
  - Range of application including wound care and wearable medical devices
  - Characteristics:
    - Tack: moderate to high
    - Peel adhesion: very good, suitable for long-term use
    - Shear: high shear strength
  - Suitable body parts:
    - Chest and back: flat and stable surfaces
    - Arms and legs: wearable devices for prolonged use
  - Not suitable for: face due to strong bonding
- Silicone:
  - softer and gentler, ideal use on sensitive skin
  - Characteristics:
    - Tack: lower tack, ease of repositioning
    - Peel Adhesion: moderate, effective bonding
    - Shear: adequate, focus on comfort rather than durability
  - Suitable body parts:
    - Face: idea for attaching dressings or devices

        - Neck and shoulders: suitable for application where flexibility is prioritized
    - Not suitable for high-swear areas and high-friction areas
- Natural rubber:
    - High tensile strength and high tack
- Characteristics:
    - Tack: high
    - Peel adhesion: strong
    - Shear: Good, degradation under UV
- Usage declines due to latex allergies and environmental degradation
- Synthetic rubber:
    - viable alternative to natural rubber
    - Characteristics:
        - Tack: high, similar to rubber
        - Peel adhesion: strong
        - Shear: very good

Conclusions/action items:

Silicone adhesive products should be used for our device.

Can silicone products stick to hair?

Can they create a seal for NPWT to be used?

9/24/25-Application of Negative Pressure Therapy on Skin Grafts after Soft-Tissue Reconstruction: A Prospective Observational Study

MEGHAN KAMINSKI - Dec 07, 2025, 5:18 PM CST

Title: Application of Negative Pressure Therapy on Skin Grafts after Soft-Tissue Reconstruction: A Prospective Observational Study

Date: 9/24/25

Content by: Meghan

Present: N/A

Goals: Understand the uses of negative pressure wound therapy

Link: Application of Negative Pressure Therapy on Skin Grafts after Soft-Tissue Reconstruction: A Prospective Observational Study - PMC

Citation:

[1] Aeshah Mandili *et al.*, "Application of Negative Pressure Therapy on Skin Grafts after Soft-Tissue Reconstruction: A Prospective Observational Study," *Clinics and practice*, vol. 12, no. 3, pp. 396–405, Jun. 2022, doi: https://doi.org/10.3390/clinpract12030044.

Content:

Introduction

- Split-thickness skin grafts (STSGs) are widely used to treat skin defects from trauma, surgery, burns, or chronic wounds.
- Proper postoperative dressing is critical for graft success because the graft must attach, revascularize, and avoid complications like infection or hematoma.
- Negative-pressure wound therapy (NPWT) is commonly used to stabilize grafts and remove fluid, theoretically improving graft survival.
- Despite its popularity, research comparing NPWT to conventional dressings after grafting is limited and inconsistent.
- This study aimed to prospectively evaluate whether NPWT improves graft outcomes compared to standard dressings.

Methods

- Prospective observational study including adult patients receiving STSGs for soft-tissue defects.
- Excluded: grafts on face/neck/genitals, active bleeding, sepsis, or loss to follow-up.
- Patients were placed in one of two groups:
    - NPWT group: received negative-pressure therapy dressing for 5–7 days post-op.
    - Conventional dressing group: received non-adherent gauze dressings with routine changes.
- All grafts were harvested at the same thickness and meshed using the same technique.
- Outcomes assessed at weeks 1, 2, and 3:
    - Graft take percentage
    - Wound healing progress
    - Pain levels
    - Infection
    - Hematoma
    - Need for re-grafting
- Wound assessments included standardized scoring tools and photographic documentation.

Results

- 18 total patients: 10 received NPWT, 8 received conventional dressing.
- Graft take rate: The conventional group had slightly higher take rates in weeks 2 and 3, but the difference was not statistically significant.
- Wound healing: Both groups showed similar healing progression.
- Pain: No meaningful difference between groups.
- Infection: Rates were low and similar in both groups.
- Hematoma: No significant differences observed.
- Re-grafting: No patient in either group required a second graft.

Discussion

- Although NPWT is believed to improve graft survival by immobilizing the graft and removing fluid, this study did not find evidence of superior outcomes.
- Conventional dressings performed comparably and, in some areas, slightly better, though not significantly.
- NPWT is more complex and more expensive, and these added burdens did not result in measurable clinical benefit.
- The findings suggest NPWT may not need to be used routinely for all graft patients and that conventional dressing remains an effective option.

Limitations

- Small sample size limits the strength and generalizability of conclusions.
- Not a randomized controlled trial; group assignment was not random.
- No blinding, which may affect outcome assessments.
- Short follow-up period (three weeks), which limits ability to evaluate long-term graft quality or complications.

Conclusion

- NPWT did not demonstrate a significant advantage over conventional dressing after STSG for soft-tissue reconstruction.
- Conventional dressings are simpler, cheaper, and performed equally well in this study.
- Larger randomized studies with longer follow-up are needed to determine whether NPWT provides meaningful benefits in specific patient groups.

Conclusions/action items: Utilize the knowledge within this article and apply it specifically to the ear's curvature.

10/16/25- What is the real difference between positive and negative pressure pumps?

MEGHAN KAMINSKI - Oct 22, 2025, 4:12 PM CDT

Title: What is the real difference between positive and negative pressure pumps?

Date: 10/16/25

Content by: Meghan

Present: N/A

Goals: Understand negative and positive pump differences.

Link: [Positive vs Negative Pressure Pumps: Key Differences Explained]

Citation:

[1] "China Micro Diaphragm Pump Factory," *Micro diaphragm pump mini compressor maufacturer*, 2021. https://bodenpump.com/positive-vs-negative-pressure-pumps/ (accessed Oct. 22, 2025).

Content:

- Overview of Pumps:
  - Pumps are categorized based on the type of pressure they generate positive pressure (above atmospheric pressure) or negative pressure (below atmospheric pressure, i.e., vacuum).
  - The distinction is based on the function of the pump in a system: whether it is pulling (suction) or pushing (pressurizing) air or fluid.
- Negative Pressure Pumps
  - Also known as vacuum pumps.
  - Function by drawing fluid or gas inward through their inlet.
  - Create a vacuum or low-pressure environment by reducing pressure inside a space.
- Common applications:
  - Vacuum suction devices
  - Gas sampling systems
  - Laboratory and analytical instruments
  - Medical suction
  - Evacuation systems
- Positive Pressure Pumps
  - Often referred to as blowers or pressure pumps.
  - Operate by forcing fluid or gas outward through their exhaust.
  - Create pressure higher than the ambient environment.
- Common applications:
  - Inflating devices
  - Pressurizing sealed systems or tanks
  - Air and gas transfer
  - Pneumatic tools
  - Water pressure boosting
- Key Differences
  - Flow direction:
    - Negative pressure pumps pull in.
    - Positive pressure pumps push out.
  - Effect on system:
    - Negative pressure pumps lower internal pressure

        - Negative pressure pumps lower internal pressure.
        - Positive pressure pumps raise internal pressure.
    - Both types of pumps may have minor effects in the opposite direction (e.g., slight positive pressure from a vacuum pump's exhaust).
- Dual-Function Pumps
    - Some micro or miniature pumps can provide both suction and pressure, depending on configuration.
    - These are useful in compact systems where space and cost efficiency are needed.
- Design & Selection Considerations
    - Choose based on:
        - The direction of required flow.
        - The target pressure range (how much vacuum or pressure is needed).
        - The application (whether suction or pressurization is needed).
        - Always review technical specifications to ensure the pump meets the required pressure output, flow rate, and durability.

Conclusions/action items:

How is the flow affected by these differences?

10/22/25-Understanding the Relationship Between Flow and Pressure

MEGHAN KAMINSKI - Oct 22, 2025, 4:01 PM CDT

Title: Understanding the Relationship Between Flow and Pressure

Date: 10/22/25

Content by: Meghan

Present: N/A

Goals: Better understand pressure and flow rates to apply it to our project.

Link: [Understanding The Relationship Between Flow And Pressure | Atlas Scientific]

Citation:

[1] Atlas Scientific, "Understanding The Relationship Between Flow And Pressure," *Atlas Scientific*, Feb. 27, 2023. https://atlas-scientific.com/blog/relationship-between-flow-and-pressure/

Content:

- In fluid systems (pipes, plumbing), the flow rate, the volume of fluid passing through per unit time, is driven by the pressure difference (gradient) between two points (e.g., inlet vs outlet).
- For a given piping system, once the system geometry (diameter, length, roughness) is fixed, the flow rate is approximately proportional to the square-root of the pressure difference: larger pressure difference - higher flow.
- What is flow?
  - Flow refers to how much fluid passes through a system over time.
  - In a pipe, wider diameter - can carry more fluid -higher potential flow (if pressure allows).
  - Narrower pipes or higher friction paths reduce flow.
- What is pressure?
  - Pressure is the force exerted by the fluid inside the system, pushing it through the pipe.
  - In plumbing or piping, pressure can be influenced by elevation (head), gravity, fluid density, and the source height.
- Does pressure affect flow rate?
  - Yes: an increase in pressure (or in the pressure difference) generally yields an increase in flow rate, all else constant.
  - But it's not simply "flow = pressure × constant" because the system geometry (diameter, pipe length, friction) matters significantly.
- Why are flow and pressure important?
  - They're critical for applications like water taps, chemical dosing to treatment systems, leakage detection, measuring water consumption, flow between reservoirs, etc.
  - Types of pipe pressure to consider:
    - The source-to-destination pressure: force required to push fluid through the system.
    - Pressure related to head / elevation: fluid at higher elevation means more pressure to move it downwards / maintain flow upwards.
    - Pressure due to friction: as fluid moves through pipe, friction losses (from pipe walls, bends, fittings) reduce effective pressure and reduce flow.
- Relationship of pipe diameter, pressure, and flow:
  - The inner diameter of the pipe strongly affects how much fluid can flow: smaller diameter means more friction, lower flow, and potentially greater pressure drop (for same pump).

    - Always ensure the pipe is sized adequately to allow desired flow without causing the pump/system to exceed its pressure rating.
- Quantitative relationships / formulas (for ideal/in-simple conditions):
    - Resistivity of pipe **s=0.001736/d^5.3**
    - Head difference **H=P/(ρg)+h**
    - Flow rate **Q = (H/sL)^(1/2)**
    - Flow velocity **V = 4Q/(3.1416 * d^2)**
    - These show how diameter, length, and pressure difference combine to determine flow.
- Bernoulli's principle / equation:
    - For incompressible, frictionless fluid along a streamline: **p+1/2ρv2+ρgh=C**
    - This implies that if velocity increases (fluid moves faster), the static pressure tends to decrease — inverse relation in ideal case.
- What is a pressure drop (or loss)?
    - Pressure drop/loss refers to how much pressure is "lost" moving fluid through the system (due to friction, fittings, elevation change, etc).
    - A large pressure drop means more energy (stronger pump) is required to maintain given flow.
    - Lower pressure drop - less power needed - more efficient system.
- What affects the pressure drop?
    - The fluid's nature (viscosity, density).
    - The pipe system (length, diameter, material, bends, fittings, valves).
    - Elevation changes: lifting fluid increases required pressure; dropping fluid may recover head but still has losses.
- Relationship between flow rate and pressure drop:
    - high flow typically causes larger pressure to drop; conversely, reducing flow yields smaller pressure drop.
    - if you attempt to push more fluid through a given pipe, you'll encounter more friction, more pressure drop and require more input pressure to maintain it.
- Summary takeaway:
    - To get higher flow in a system, you need either a higher-pressure difference or reduce losses (increase diameter, shorten pipe length, reduce friction, reduce elevation head).
    - Similarly, if you hold pressure constant but increase system resistance (smaller diameter, longer pipe, more bends), flow will decrease.
    - Designing a piping/plumbing system means balancing pressure, flow, geometry, and cost/power.

Conclusions/action items:

The article gave insights as to how pressure and flow are related.

How will we apply this to our tubes being connected?

Can this apply to negative pressure flow?

10/22/25-Wounds edge microvascular blood flow during negative pressure wound therapy

MEGHAN KAMINSKI - Oct 22, 2025, 4:29 PM CDT

Title: Wounds edge microvascular blood flow during negative pressure wound therapy

Date: 10/22/25

Content by: Meghan

Present: N/A

Goals: Understand which pressure level is most effective.

Link: Wound edge microvascular blood flow during negative-pressure wound therapy: examining the effects of pressures from -10 to -175 mmHg - PubMed

Citation:

[1] O. Borgquist, R. Ingemansson, and M. Malmsjö, “Wound Edge Microvascular Blood Flow during Negative-Pressure Wound Therapy: Examining the Effects of Pressures from −10 to −175 mmHg,” *Plastic and Reconstructive Surgery*, vol. 125, no. 2, pp. 502–509, Feb. 2010, doi: https://doi.org/10.1097/prs.0b013e3181c82e1f.

Content:

- The study investigated how different levels of negative pressure applied during Negative Pressure Wound Therapy (NPWT) influence microvascular blood flow near the edges of wounds.
- Researchers tested pressures from -10 mmHg up to -175 mmHg in an animal model using eight pigs weighing about 70 kg each.
- The wounds were surgically created, and blood flow was measured at various distances from the wound edge: 0.5 cm (very close), 2.5 cm (moderate distance), and 5 cm (farther away).
- Laser Doppler velocimetry, a technique for measuring blood flow in small vessels, was used to obtain precise data from the subcutaneous tissue and muscle beneath the wound.
    - Findings near the wound edge (0.5 cm):
        - Blood flow decreased progressively as the negative pressure increased.
        - At -10 mmHg, blood flow dropped by about 15%.
        - At -45 mmHg, the decrease was 64%.
        - At -80 mmHg, blood flow nearly stopped, with a 97% reduction.
        - This suggests that higher negative pressures close to the wound edge could cause significant local ischemia (lack of blood flow).
    - Findings at 2.5 cm from the wound edge:
        - Blood flow actually increased with the application of negative pressure, which may enhance healing in the surrounding tissue.
        - At -10 mmHg, flow increased by 6%.
        - At -45 mmHg, flow increased by 32%.
        - At -80 mmHg, flow increased substantially, by 90%.
        - This indicates a beneficial effect of NPWT on microcirculation a bit farther from the wound edge.
    - Findings at 5 cm from the wound edge:
        - Blood flow remained essentially unchanged across all tested pressures.
        - This means the negative pressure effects are localized primarily near the wound edge and surrounding tissue.
    - Steady-state blood flow:

        - At each pressure level, blood flow reached a stable value over time, meaning the tissues adapted to the applied negative pressure after an initial response.
        - Increasing pressure beyond a certain point didn't further alter blood flow significantly.
    - Clinical implications:
        - The commonly used NPWT pressure setting of around -125 mmHg may be higher than necessary to achieve beneficial blood flow changes.
        - Pressures around -80 mmHg might offer similar positive effects on tissue perfusion with less risk of causing ischemia near the wound edge.
        - Tailoring negative pressure settings to individual wounds could optimize healing and minimize potential damage from excessive suction.
        - This understanding can guide clinicians in adjusting therapy parameters based on wound size, location, and patient-specific factors.

Conclusions/action items:

This study shows the implications of applying different pressure levels to a wound.

How can we apply this to the amount of pressure used in our device?

10/10/25-TPU in Medical Devices: Properties, Applications, and Catheter Design

MEGHAN KAMINSKI - Oct 10, 2025, 2:29 PM CDT

Title: TPU in Medical Devices: Properties, Applications, and Catheter Design

Date: 10/10/25

Content by: Meghan

Present: N/A

Goals: Research materials that can be used in the fabrication of the EarVac

Link: [TPU in Medical Devices: Properties and Applications]

Citation: [1] “TPU in Medical Devices: Properties and Applications,” cathetermelt.com, Jun. 05, 2025. https://cathetermelt.com/tpu-in-medical-devices/

Content:

- What is TPU (Thermoplastic Polyurethane):
  - A flexible plastic material combining elasticity and strength
  - Made from soft and hard segments for customizable properties
  - Medical-grade TPU meets safety standards like ISO 10993 and USP Class VI
  - Available in a wide range of hardness levels
  - Resistant to abrasion, chemicals, and sterilization
  - Easy to process into complex shapes (extrusion, molding, forming)
- Key Benefits for Medical Use:
  - High mechanical strength and stretchability
  - Adjustable flexibility depending on application
  - Surface can be modified (e.g. hydrophilic or antimicrobial coatings)
  - Often a better balance of cost, performance, and processability than silicone
- Common Applications in Medical Devices:
  - Vascular catheters (e.g. central lines, PICCs)
  - Urinary catheters
  - Respiratory tubing (e.g. endotracheal tubes)
  - Dialysis tubing
  - General flexible, biocompatible tubing
- Processing Temperatures:
  - Extrusion: around 180–220 °C
  - Injection molding: around 190–230 °C
  - Heat forming: around 160–200 °C
  - Melting point: varies between 150–200 °C
- TPU Catheter Tips:
  - Softer TPU grades (Shore 60A–80A) used for catheter tips to reduce trauma
  - Tips are shaped using heat or radio-frequency forming
  - Often bonded to the shaft for a smooth transition
  - Can include low-friction or antibacterial coatings
- Comparison to Other Materials:
  - TPU offers excellent biocompatibility and flexibility
  - Stronger and more durable than PVC
  - Easier to manufacture than silicone
  - Less long-term implant data than silicone

    - More expensive than PVC, but cheaper than silicone
    - PVC has plasticizer concerns; silicone is softer but harder to process
- Hardness Guidelines for Catheters:
    - Tips: Shore 60A–80A
    - Transition zones: Shore 75A–85A
    - Shafts: Shore 80A up to Shore D (for stiffness)
- Limitations and Considerations:
    - More costly than PVC
    - Not ideal for high-stress or long-term implants compared to silicone
    - Needs high-purity formulations to avoid plasticizer issues
    - Best suited for disposable or high-performance catheters needing strength and flexibility

Conclusions/action items:

TPU is the material we will use for the earmuff section of the design. This should provide a protective soft layer.

What hardness should we use in our application?

10/10/25-What is the role of Nylone in additive Manufactuing for medical applications?

MEGHAN KAMINSKI - Oct 10, 2025, 2:33 PM CDT

Title: What is the role of Nylone in additive Manufactuing for medical applications?

Date: 10/10/25

Content by: Meghan

Present: N/A

Goals: Research materials that can be used in the fabrication of the EarVac

Link: [What is the role of Nylon in additive manufacturing for medical applications?]

Citation: [1] 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).

Content:

What Nylon Brings to Medical 3D Printing

- Strength and Flexibility
  - Nylon, especially PA12, offers high tensile strength, good elongation, and excellent fatigue resistance
    Suitable for prosthetic sockets, orthotic braces, and wearable medical supports
- Biocompatibility and Sterilizability
  - Medical-grade nylon complies with ISO 10993 and USP Class VI standards
    Safe for skin contact and compatible with sterilization methods like ethylene oxide and low-temperature steam
    Ideal for surgical guides, diagnostic device housings, and anatomical models
- Lightweight and Durable
  - Combines strength with low weight
  - Resists wear and repeated mechanical stress
  - Used in surgical jigs, tool holders, and rehab device components
- Customization and Personalization
  - Enables cost-effective, patient-specific device production via 3D printing
  - Common in prosthetics, orthotics, and dental applications
  - Enhances comfort, fit, and patient outcomes
- Support Services and Material Considerations
- Typically processed with Selective Laser Sintering (SLS) or Multi Jet Fusion (MJF) 3D printing methods
- Uses certified nylon materials (like PA12) for medical safety and durability
- Post-processing steps such as surface finishing or CNC machining improve fit, smoothness, and cleanliness

Conclusions/action items:

Nylon will be used to create the headband structure of the design. The utilization in braces and wearable medical devices makes this an ideal choice.

What are the limitations of nylon?

10/10/25-PVC PhthalateFree Medical Grade Tubing

MEGHAN KAMINSKI - Oct 10, 2025, 2:35 PM CDT

Title: PVC PhthalateFree Medical Grade Tubing

Date: 10/10/25

Content by: Meghan

Present: N/A

Goals: Research materials that can be used in the fabrication of the EarVac

Link: PVC PhthalateFree ® Medical Grade Tubing – Ormantine USA, Ltd. | Environmental Monitoring Division | Peristaltic Pump Tubing Division

Citation: [1] “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).

Content:

- Ormantine’s medical-grade PVC tubing is phthalate-free, using TOTM as a plasticizer that’s tightly bound to reduce leaching
- Offers strong chemical and acid resistance
- Transparent for visual monitoring of fluid flow
- Very low gas permeability
- Good durability under pumping; designed for long life in peristaltic pump applications
- Temperature tolerance roughly from –50 °C to +74 °C
- Sterilization methods supported: ethylene oxide, autoclave, gamma irradiation (though gamma may cause discoloration)
- Hardness around 59 Shore A
- Elongation at break about 409%
- Certified to USP Class VI and meets European pharmacopoeia and BS2463 standards
- Applications include laboratory, pharmaceutical, peristaltic pumps, low-toxicity, and general-purpose fluid transport contexts

Conclusions/action items:

This is a company example of PVC tubing and its' properties. PVC is commonly used in tubing for medical devices.

Will we need to adjust the tubing in our design?

10/10/25-Negative Pressure Wound Therapy: Our Adhesive Solutions

MEGHAN KAMINSKI - Oct 10, 2025, 2:40 PM CDT

Title: Negative Pressure Wound Therapy: Our Adhesive Solutions

Date: 10/10/25

Content by: Meghan

Present: N/A

Goals: Research materials that can be used in the fabrication of the EarVac

Link: **Negative pressure wound therapy: Our adhesive solutions | Avery Dennison**

Citation: [1]"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).

Content:

- Avery Dennison provides adhesive drapes designed for Negative Pressure Wound Therapy (NPWT)
- Drapes are skin-friendly, breathable, waterproof, and act as a bacterial barrier
    - These drapes must conform to body contours while maintaining a tight, reliable seal over the wound
- Two standard drape types: MED 9530S and MED 9531S
    - MED 9530S: higher moisture vapor transmission rate (good for skin protection)
    - MED 9531S: higher initial tack (helps with hard-to-dress wound areas)
- The material is a flexible polyurethane film with a skin-compatible acrylic adhesive
- The drapes are transparent, flat in appearance (no gloss), and easily cut for custom sizing
- They support a reliable vacuum seal, crucial for consistent negative pressure delivery

Conclusions/action items:

Avery Dennison is a company that provides adhesive dressing that could be utilized in the fabrication of our product.

What different suppliers provide a similar product?

9/23/25- Design 1

MEGHAN KAMINSKI - Sep 24, 2025, 10:40 AM CDT

Title: Design Idea 1

Date: 9/23/25

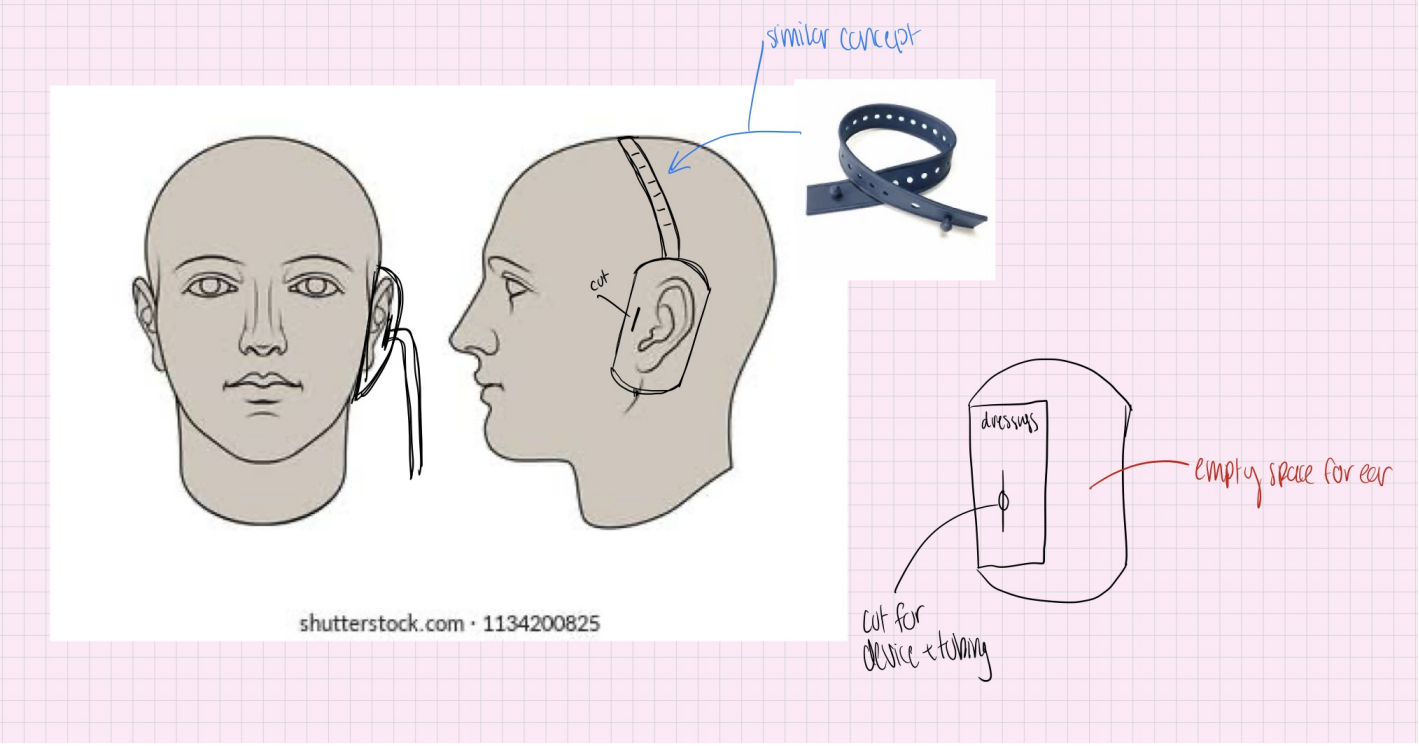
Content by: Meghan

Present: N/A

Goals: Create preliminary design ideas before team meeting.

Content:

- The concept below is inspired by headphones/earmuffs
- Along the top of the head, there would be a stiff plastic material to secure the 'muffs' location
  - The plastic material can be adjusted through a notch system
- Due to incision placement, bandages will only be in the anterior direction
- On the anterior section of the muff, a hole is made to secure the placement of the wound vac while attached to the bandages



Conclusions/action items:

The design above would combat the uncomfortable placement of gauze around the head.

How will the dressings be configured in the muffs?

Are there limitations due to ear size?

9/23/25- Design 2

MEGHAN KAMINSKI - Sep 24, 2025, 10:46 AM CDT

Title: Design Idea 2

Date: 9/23/25

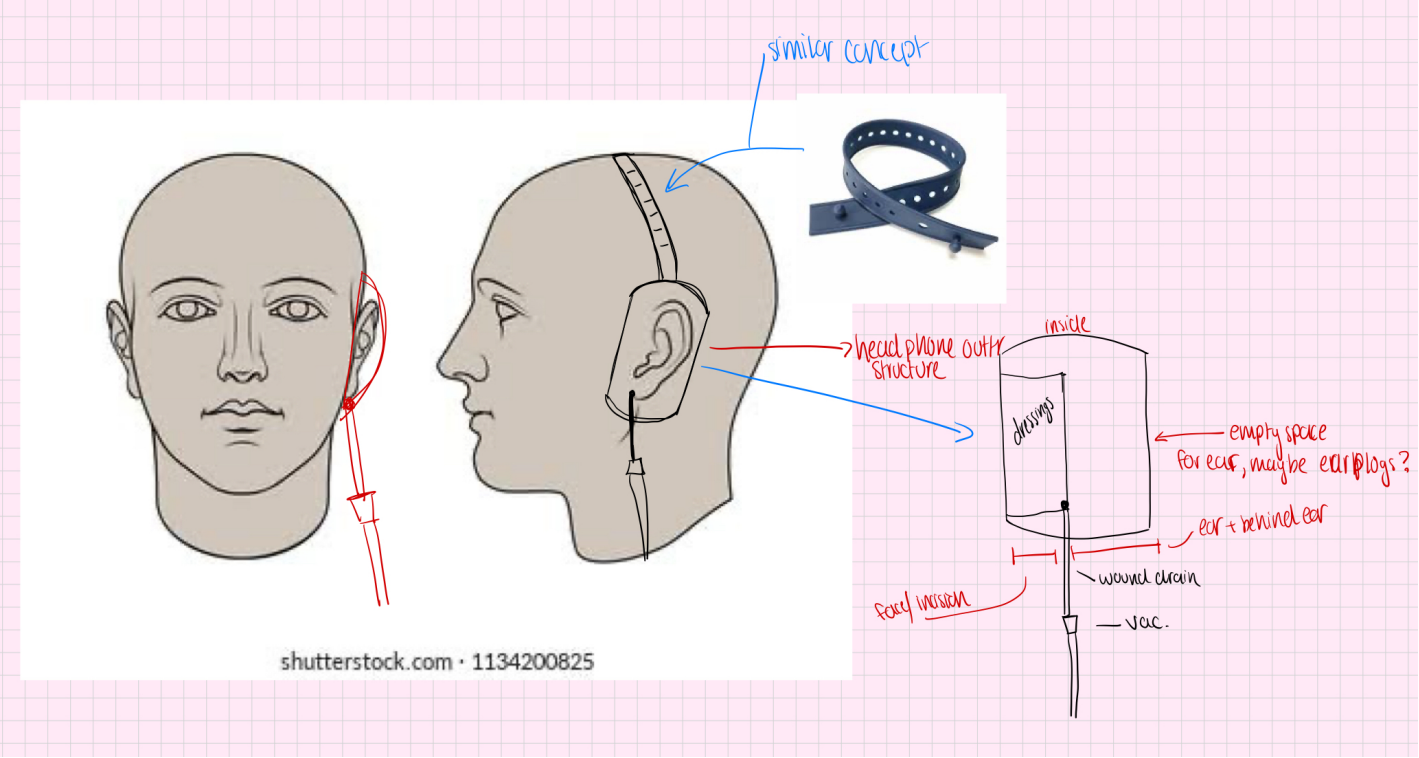
Content by: Meghan

Present: N/A

Goals: Create preliminary design ideas before team meeting.

Content:

- The concept below is inspired by headphones/earmuffs
- Along the top of the head, there would be a stiff plastic material to secure the 'muffs' location
  - The plastic material can be adjusted through a notch system
- Due to incision placement, bandages will only be in the anterior direction
- On the end section of the muff, a hole is made to insert a wound drain
  - At the end of the wound drain, a vacuum is then attached to apply pressure



Conclusions/action items:

The design above would combat the uncomfortable placement of gauze around the head.

How will the dressings be configured in the muffs?

Are there limitations due to ear size?

Is there a certain angle the wound drain needs to be inserted relative to the incision?

10/3/25- CAD design

MEGHAN KAMINSKI - Oct 03, 2025, 4:29 PM CDT

Title: CAD design

Date: 10/3/25

Content by: Meghan

Present: N/A

Goals: Create a CAD design of headphone inspired model for preliminary presentations

Content:

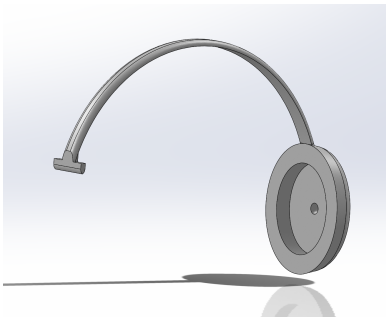


Figure 1. CAD model of headphone inspired design, interior included

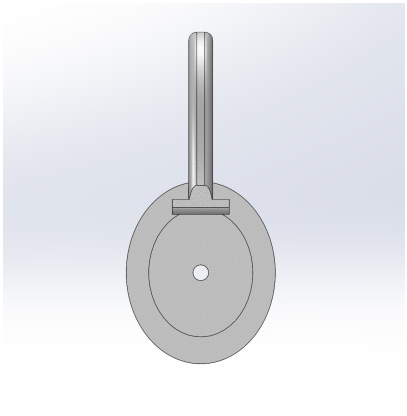


Figure 2. CAD model of headphone inspired design, right plane view

Figure 3. CAD model of headphone inspired design, exterior included

Conclusions/action items:

The CAD model is the shell of our design.

Next steps are to compile material choices, run simulation testing, and begin fabrication technique protocols.

10/9/25- Updated CAD design

MEGHAN KAMINSKI - Oct 10, 2025, 12:30 PM CDT

Title: Updated CAD design

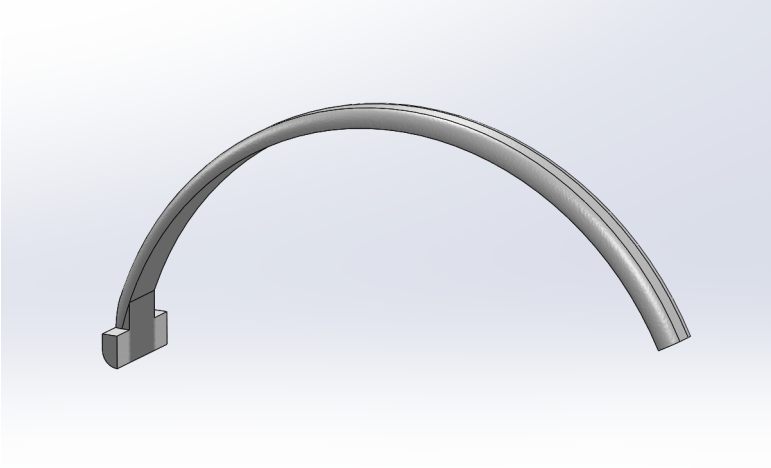
Date: 10/9/25

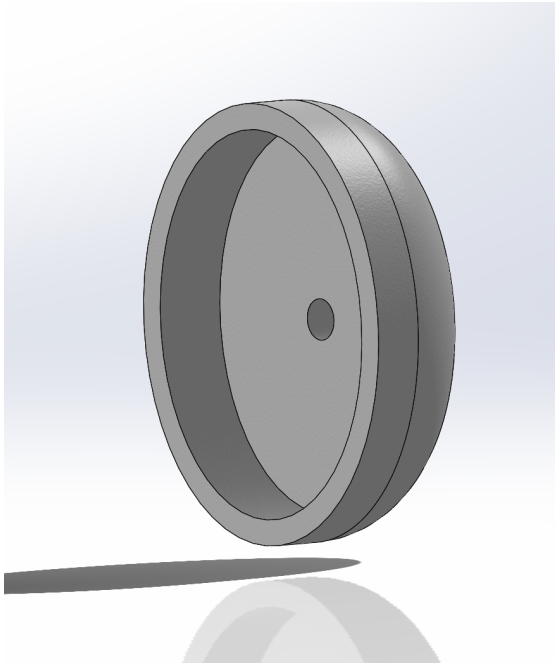
Content by: Meghan

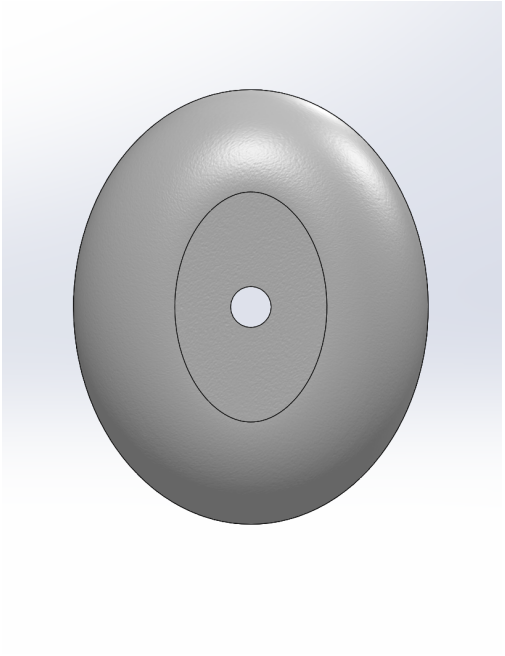
Present: N/A

Goals: Update the CAD design of headphone inspired model for preliminary presentations

Content:







Conclusions/action items:

The CAD model is the shell of our design.

Next steps are to compile material choices, run simulation testing, and begin fabrication technique protocols.

10/28/25- Update 2: CAD Design

MEGHAN KAMINSKI - Nov 05, 2025, 4:31 PM CST

Title: Update 2: CAD design

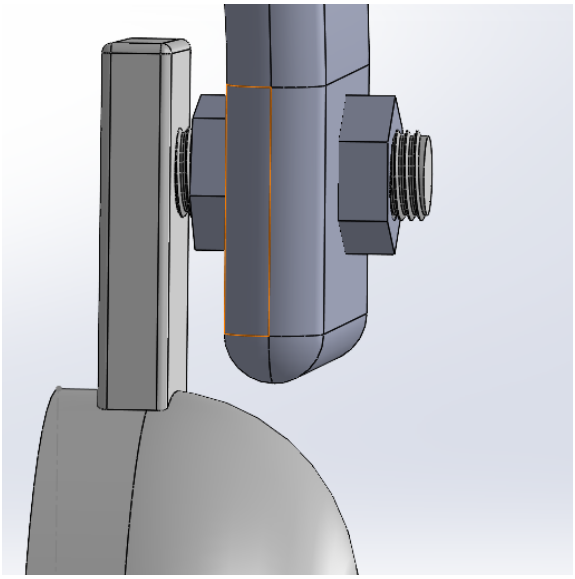
Date: 10/28/25

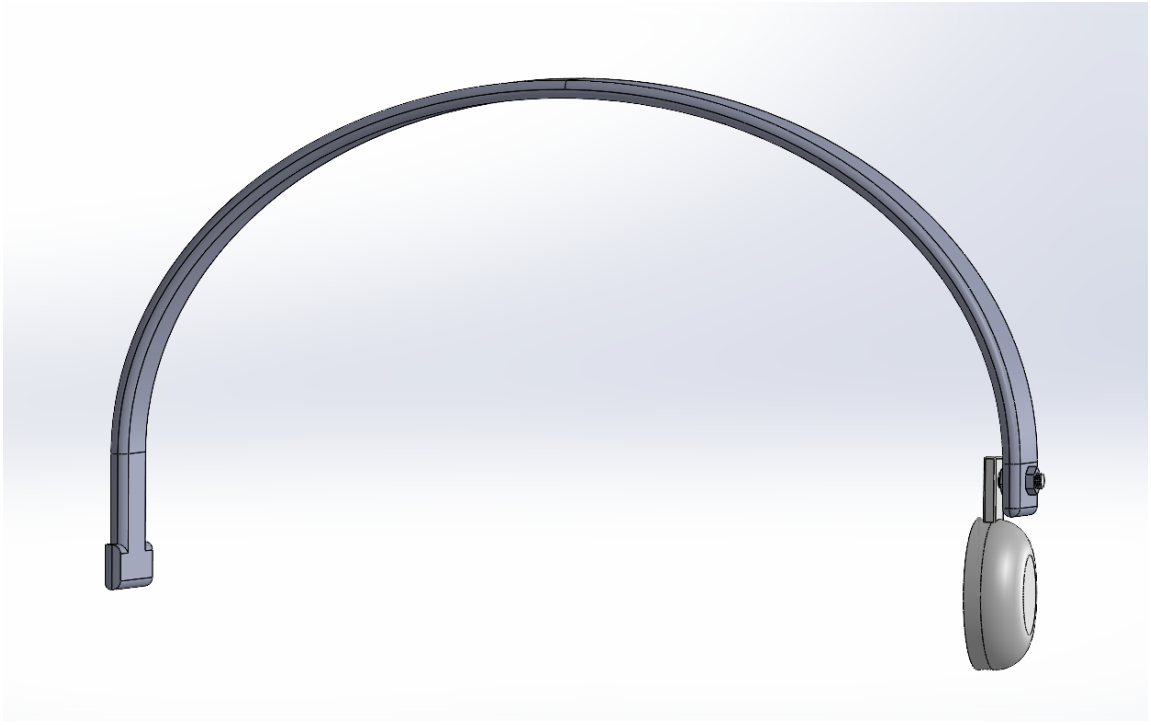
Content by: Meghan/Dhruv

Present: Meghan/Dhruv

Goals: Create dimensioned design with female and male attachment

Content:





Conclusions/action items:

The headband is incorrectly dimensioned in the figure. The dimensions were fixed after the picture was taken.

3D print the SolidWorks design in the Makerspace.

12/3/25- Update 3: CAD Design

MEGHAN KAMINSKI - Dec 07, 2025, 4:51 PM CST

Title: Update 3: CAD Design

Date: 12/3/25

Content by: Meghan

Present: N/A

Goals: Update the SolidWorks model with dimensions and design changes.

Content:

Figure 1. SolidWorks model of final design, interior of earmuff included

Figure 2. SolidWorks model of final design, exterior of earmuff included

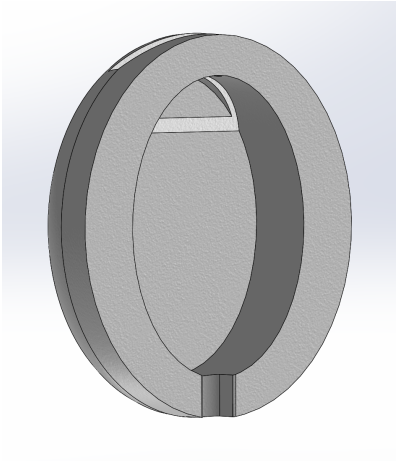


Figure 3. SolidWorks model of earmuff

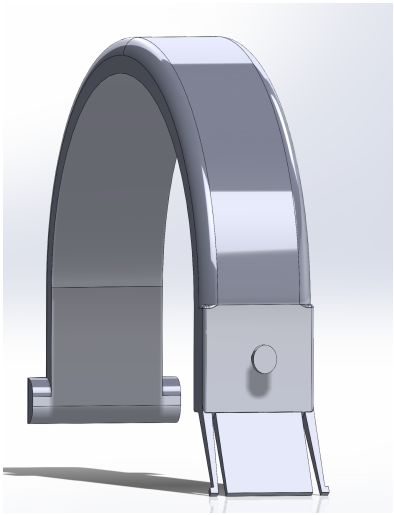


Figure 4. SolidWorks model of headband

Conclusions/action items: 3D print the design using the makerspace.

12/4/25-3D printed prototype

MEGHAN KAMINSKI - Dec 07, 2025, 4:51 PM CST

Title: 3D printed prototype

Date: 12/4/25

Content by: Meghan

Present: N/A

Goals: 3D print SolidWorks model in thermoplastic polyurethane at the makerspace

Content:

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

Conclusions/action items: Evaluate the design and identify changes that need to be made in the design.

3/10/24: Biosafety and Chemical Safety

MEGHAN KAMINSKI - Mar 19, 2024, 10:30 PM CDT

Title: Bio safety and Chemical Safety training

Date: 3/10/24

Content by: Meghan

Present: Meghan

Goals: Complete all canvas modules and tasks to pass the bio safety and chemical safety training necessary for the labs in coming weeks.

Content:

Conclusions/action items: The image above shows the completion of my biosafety and chemical safety training. The training is necessary to understand the processes and potential dangers that come with unsafe practices in the lab. The next step is to use the skills in the biomaterial fabrication.

3/13/24: TeamLab training

MEGHAN KAMINSKI - Mar 19, 2024, 10:28 PM CDT

Title: TeamLab training

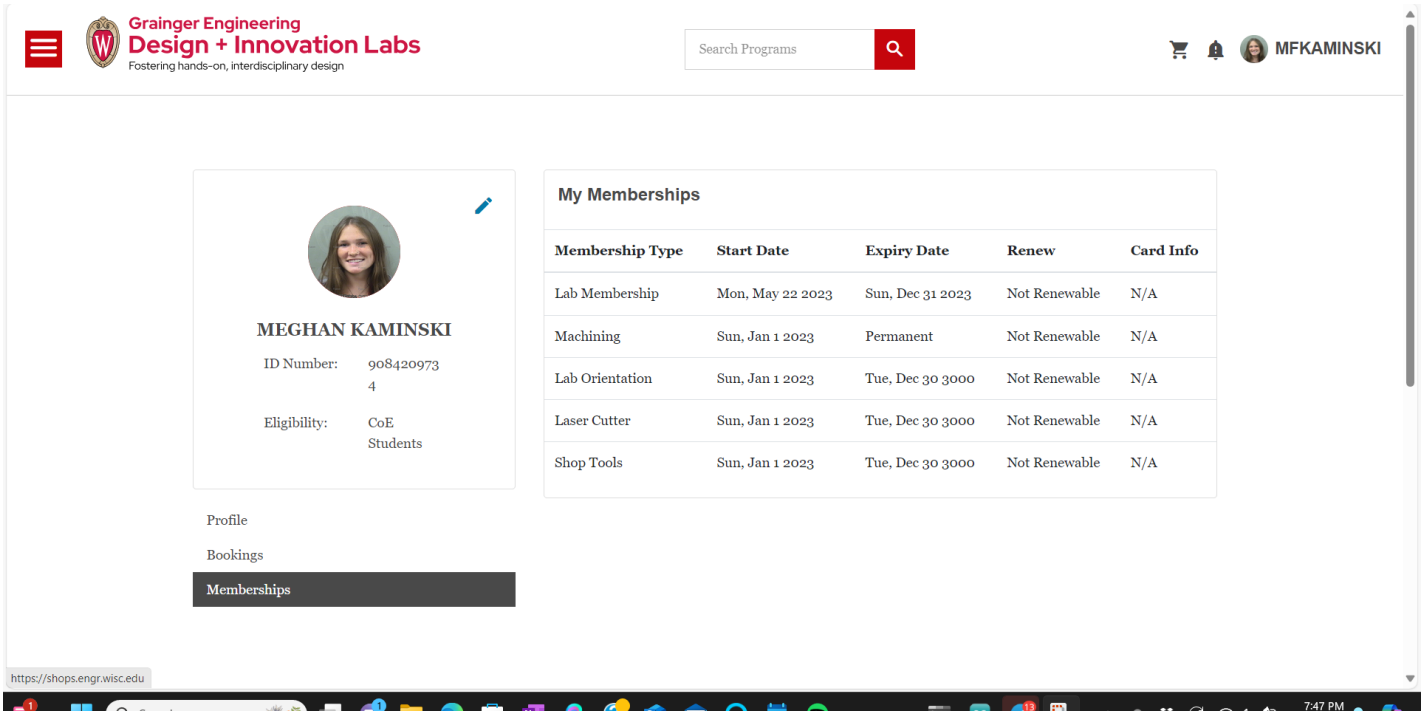
Date: 3/13/24

Content by: Meghan

Present: Meghan

Goals: Complete mill and lathe training to pass the intro to machining training necessary for fabrication of the sample holder.

Content:



Conclusions/action items: The screenshot above contains proof of my completion of the intro to machining in the Team Lab. It is necessary to continue to practice these new skills to improve my techniques. The next steps will be to use the certificate in the team lab with fabrication of the sample holder.

10/28/25- Animal user orientation training

MEGHAN KAMINSKI - Oct 28, 2025, 11:51 AM CDT

Title: Animal user orientation training

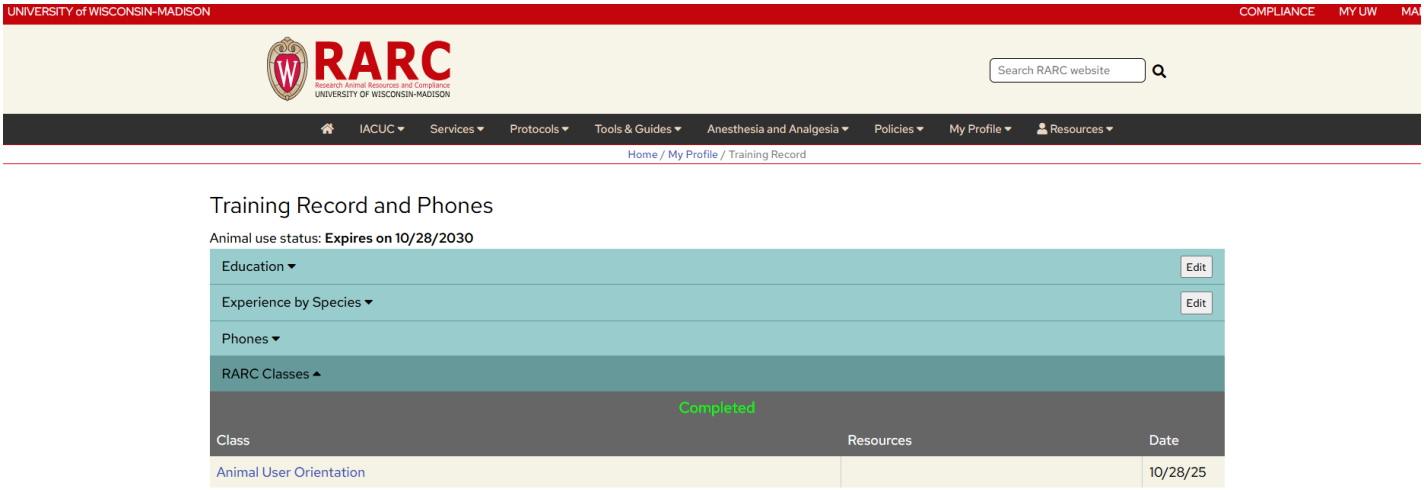
Date: 10/28/25

Content by: Meghan

Present: N/A

Goals: Required training

Content:



Conclusions/action items: N/A

11/7/25-Tong Lecture: Building a Career of Impact

MEGHAN KAMINSKI - Nov 07, 2025, 2:02 PM CST

Title: Building a Career of Impact

Date: 11/7/25

Content by: Meghan

Present: N/A

Goals: Run towards the hard problems, they are the ones that change the world

Content:

Why healthcare needs more engineers

- Kristen Myers
- Run towards the hard problems, they are the ones that change the world
- Career journey: foundation, growth curve, build and transform
- Foundation
    - Four internships: financial company, Abiomed, Guidant, and Gap
    - Medtronic: Engineering marketing/product launch technical sales
    - Harvard MBA
    - Skyline venture; investor in healthcare startup
    - Arboretum venture; investor in healthcare startup technology
- Climb the growth curves
    - Combine EQ with IQ to multiply impact and reach
    - Aetna- gave helpful leadership experience; 100+ team
    - Infield women's healthcare – leading a network of obgyn's
        - Challenge due to pandemic
    - Figuring out how to work through teams and make a larger impact
- Build and transform
    - Drive system-level impact through innovation and scale
    - Hopscotch health: founder and CEO, advance primary care for rural communities
    - Blue cross blue shield association: chief operating officer enable access, affordability, outcomes, and experiences for 1 in 3 Americans
        - Attempting to improve patient experience in healthcare
- Healthcare system
    - Quadruple aim: affordable outcomes, positive outcomes, improved provider experience, improved patient experience
    - Spending on healthcare in US: 18
    - Ranked last on equity access
    - Misaligned incentives, fragmented financing and regulation, data and legacy IT, inequities
- The future of healthcare is an integrated ecosystem of health and care
    - Rewards to continuum of care
    - Requirements: interoperable data infrastructure, human centered design, aligned incentives and measurement, connected care and deliver platforms, simplified and automate infrastructure
- Work hard and build range
    - Take on the hardest projects, classes and experience found. Effort and range are you foundation
- Seek diverse exposure

    - Explore different sectors, teams and geographies. Gain perspectivity and learn how systems connect, not just how parts work.
- Choose your people wisely
    - Surround yourself with curious, driven, high-integrity people. They will shape who you become.
- Know your values and protect them
    - Define what matters most – family, friends, health, career, impact, values and make decisions that align
- Embrace challenge and keep growing
    - Run towards hard problems. Growth lives on the edge of discomfort- where big impact starts

Conclusions/action items:

Use the information from Kristen to apply to my professional career.

10/1/25 Ear

SERENA EVERS - Oct 01, 2025, 9:02 PM CDT

Title: Ear

Date: 10/1/25

Content by: Serena

Present: n/a

Goals: learn about the ear

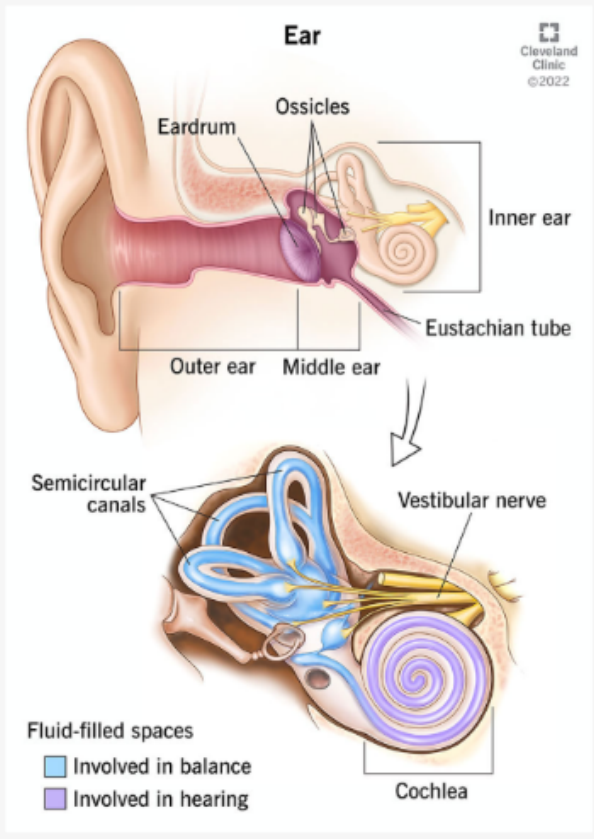
Content:

search term: ear anatomy

search location: google

link: Ear: Anatomy, Facts & Function

Ear - Anatomy, Structure, Function, Location, Diagram



- ears have two main functions: hearing and balance
- Hearing
  - sound waves enter ear canal--> tympanic membrane (eardrum) vibrates-->vibration passes to ossicles (three tiny bones) in middle ear---> ossicles amplify and transmit these sound waves to you inner ear--> stereocilia transform vibrations into electrical energy and send it along nerve fibers to brain
- Balance
  - semicircular canals filled with fluid and hair like sensors
  - when you move your head the fluid inside canals sloshes around and moves the hairs
  - hair transmits information along the vestibular nerve to brain
  - brain sends signals to muscles to stay balanced
- Anatomy

- tympanic membrane (eardrum) separates your outer ear and middle ear: thin semi-transparent membrane. Vibrates in response to sound waves
- outer ear
  - visible portion
  - primary role to collect and direct sound waves into the ear
  - also called auricle or pinna
  - elastic cartilage, skin, glands that secrete earwax
  - canal leads to eardrum or tympanic membrane
- middle ear
  - begins on other side of eardrum
  - ossicles: malleus, incus, and stapes
  - also house eustachian tubes which help equalize the air pressure in your ears
- inner ear
  - cochlea (hearing)
  - semicircular canals (balance)

Conclusions/action items:

I now know more about the ear anatomy, structure, and function.

10/10/25 Microtia reconstruction

SERENA EVERS - Dec 10, 2025, 3:31 PM CST

Title: Microtia Reconstruction

Date: 10/10/25

Content by: Serena Evers

Present: n/a

Goals: learn about the difference between Flap pocket method versus expansion method

Content:

link: Auricular reconstruction in microtia for soft tissue coverage: Flap pocket method versus expansion method - ScienceDirect

search term: microtia reconstruction

search location: PubMed

The flap pocket method basically uses local tissue to wrap and protect a cartilage framework, and it's the more traditional approach. It tends to have higher patient satisfaction, fewer complications, and a much shorter overall treatment period.

The expansion method relies on a skin expander to create more soft-tissue coverage before placing the cartilage, which can help with limited mastoid skin but also introduces extra steps, longer treatment time, and a higher rate of expander-related issues.

Conclusions/action items:

The flap pocket method is the method our client uses.

10/20/25 Retained NPWT foams

SERENA EVERS - Dec 10, 2025, 4:10 PM CST

Title: Retained NPWT foams

Date: 10/20/25

Content by: Serena E

Present: n/a

Goals: Research into retained foam as a complication of using NPWT

Content:

link: Retained Negative Pressure Wound Therapy Foams as a Cause of Infection Persistence - PMC

In 19 samples of foam from NPWT dressings, 26 different microorganisms were found. microorganisms that were not present in the deeper wound tissue itself. This raises a concern: retained foam in NPWT systems might harbor bacteria, potentially undermining wound hygiene or even seeding infection. For our design project, that finding is important, it underscores the need for a vacuum-system design that ensures complete, safe removal of foam and minimizes bacterial retention.

Conclusions/action items:

Optimizing foam structure, drainage efficiency, and interface materials could therefore be just as critical as maintaining proper negative pressure, to reduce microbial risk and ensure safe wound healing.

10/23/25 Severe Diesel Injection Injury to the Face, Neck and Orbit: Surgical Management and Critical Care Considerations

SERENA EVERS - Dec 10, 2025, 4:13 PM CST

Title: Severe Diesel Injection Injury to the Face, Neck and Orbit: Surgical Management and Critical Care Considerations

Date: 10/23/25

Content by: Serena

Present: n/a

Goals: Get more background on surgical management of facial injuries

Content:

link: Ophthalmic Plastic & Reconstructive Surgery

This case report describes a high-pressure diesel injection injury to the face, neck, and orbit that led to rapid tissue destruction and severe liquefactive necrosis. The patient required eight surgical debridements and eventually a subtotal orbital exenteration because of the extent of contamination and damage. After the acute surgical management, NPWT was used to help control fluid, stabilize the wound bed, and support healing in an extremely complex soft-tissue defect.

Conclusions/action items:

For our project, this highlights how NPWT systems need to reliably manage high bioburden and heavy exudate while maintaining consistent suction, since even in catastrophic injuries, the therapy plays a key role in promoting granulation and preparing the wound for reconstruction.

10/23/25 Developing Evidence-Based Algorithms for Negative Pressure Wound Therapy in Adults with Acute and Chronic Wounds: Literature and Expert-based Face Validation Results

SERENA EVERS - Dec 10, 2025, 4:14 PM CST

Title: Developing Evidence-Based Algorithms for Negative Pressure Wound Therapy in Adults with Acute and Chronic Wounds: Literature and Expert-based Face Validation Results

Date: 10/23/25

Content by: Serena

Present: n/a

Goals: More NPWT background

Content:

link: Developing Evidence-Based Algorithms for Negative Pressure Wound Therapy in Adults with Acute and Chronic Wounds: Literature and Expert-based Face Validation Results

This article outlines how researchers reviewed more than 330 publications on NPWT and found that only 25 met high-quality evidence standards, which shows how uneven the clinical guidance has been despite the therapy's widespread use. Earlier recommendations were mostly wound-specific and lacked clear criteria for when to start, continue, or stop NPWT, so the authors created three validated algorithms for adult acute and chronic wounds. These algorithms reached a content-validity index of 0.96, meaning experts strongly agreed on the decision steps and safety considerations.

Conclusions/action items:

For our project, this reinforces that a good NPWT device is not just about generating suction but supporting safe, appropriate use by making pressure delivery, wound assessment, and therapy adjustments more intuitive and harder to misuse.

10/1/25 Customized negative pressure wound therapy for intractable auricular defects using alginate dressings and feeding tubes

SERENA EVERS - Oct 20, 2025, 12:39 PM CDT

Title: Customized negative pressure wound therapy for intractable auricular defects using alginate dressings and feeding tubes

Date: 10/1/25

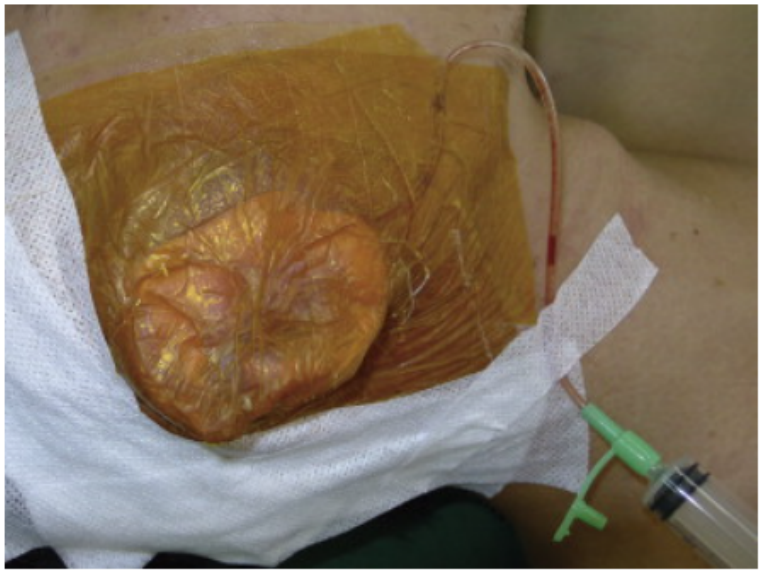
Content by: Serena

Present: n/a

Goals: Document an existing use of NPWT to teat auricular defects

Content:
Customized negative pressure wound therapy for intractable auricular defects using alginate dressings and feeding tubes - ScienceDirect

Negative pressure wound therapy was planned. A non-adherent impregnated dressing was used as the wound contact layer and alginate dressings were applied as wound filler material. A feeding tube with multiple holes was inserted between the layers of alginate dressing. The whole system was enclosed in an occlusive dressing. In the operating theatre the feeding tube was temporarily connected to a syringe providing negative pressure.



*main disadvantage of their system is the necessity of hospitalization due to the connection to wall suction. SNAP™ therapy adds a sticky hydrocolloid dressing that achieves total sealing even in irregular surfaces.

Conclusions/action items:

This design used a syringe as the supply of negative pressure, therefore isn't something we need to take into consideration for our design.

9/10/25 Negative Pressure Wound Therapy (NPWT)

SERENA EVERS - Oct 20, 2025, 12:40 PM CDT

Title: Negative pressure wound therapy

Date: 9/10/25

Content by: Serena

Present: n/a

Goals: Research NPWT

Content:

search term: negative pressure wound therapy

Source: National Library of Medicine

link: Negative Pressure Wound Therapy: Mechanism of Action and Clinical Applications - PMC

System: polyurethane foam sponge, semiocclusive adhesive cover, and a fluid collection system, & suction pump

four main mechanisms of action:

- macrodeformation of the tissues
  - reduces sponge size by 80% and therefore the wound surface area
  - shrinkage dependent on the deformability of surrounding tissues; wounds with more loose skin shrink faster vs the scalp
- drainage of extracellular inflammatory fluids
  - removes fluid which decreases edema
    - edema causes swelling that leads to cellular compression and diminishes proliferative cellular response necessary for wound healing
  - releases pressure caused by fluid around blood vessels
  - flow of fluid causes:
    - shear forces on the cells
    - movement of ions establishing electric fields
  - ^^^^^both promote a cellular proliferation response
  - helps remove toxic materials such as TNF-alpha and matrix metalloproteases (MMP) (https://pmc.ncbi.nlm.nih.gov/articles/PMC8432996/#JR01315-6)
    - MMPs are known to disrupt the connective tissue matrix which inhibits wound healing
- stabilization of the environment of the wound
  - less frequent dressing changes (2-3 days)
    - usual gauze dressings must be removed daily
  - VAC sponge covered by polyurethane drape
    - impermeable to proteins and microorganisms -- prevents bacterial colonization in wound
  - semiocclusive membrane has limited permeability to gases and water vapor
    - limits heat transfer secondary to water evaporation- keeps wound moist and warm
  - decreases bacterial count inside the wound
    - study found bacterial count decrease from 10^8 to 10^3 organisms in 4 to 5 days (https://pmc.ncbi.nlm.nih.gov/articles/PMC8432996/#JR01315-13) ctrl group w standard gauze dressing reported a significant increase in bacterial count
- microdeformation
  - promote cellular proliferation, angiogenesis, and granulation tissue formation
    - in pig models granulation tissue formation increased more than 60% when using NPWT vs gauze dressings (https://pmc.ncbi.nlm.nih.gov/articles/PMC8432996/#JR01315-13)
  - mechanotransduction (mechanical forces modifying cell function)
    - negative pressure disrupts integrin bridges--> intracellular messengers are released that alter gene transcription---> cellular proliferation (https://pmc.ncbi.nlm.nih.gov/articles/PMC8432996/#JR01315-9)

    - standard gauze dressings result in more cell death and less fibroblast proliferation compared to NPWT (https://pmc.ncbi.nlm.nih.gov/articles/PMC8432996/#JR01315-10)

Complications are rare (most attributed to poor technique or inadequate patient selection):

- toxic shock syndrome
    - to prevent ensure wound in clean and healthy before installing NPWT device
- enteric fistula
    - incidence increase significantly when the VAC foam dressing is applied over the exposed organ
    - absorbable biologic or synthetic mesh must be placed between the foam and the organ to precent fistulation
- hemodynamic instability
    - occurs when large amounts of fluid are suctioned during the first days of therapy
    - important to monitor patients and offer fluid and electrolyte resuscitation when needed
- bleeding
    - major bleeding can occur if vac is placed directly over major blood vessel or a wound bed that has not undergone adequate surgical hemostasis
    - when removing the sponge the capillary buds are disrupted which can lead to bleeding
    - electrocoagulation or surgical interventions may be needed, otherwise most cases of bleeding can be controlled with manual pressure
    - effective method to prevent bleeding is to increase frequency of foam dressing changes
    - VAC sponge should be changed every 48 hours in adults and every 24 hours in children
- pain
    - diminished by starting with -50 mmHg and increasing gradually to -125mmHg
    - continuous suction leads to less discomfort than intermittent
    - pain caused by dressing changes can be alleviated by saline or xylocaine
- odor
    - sign of infection
    - cleaning and hydrotherapy when dressing is being changed
- infection
    - prevented by debridement of nonviable tissue prior to VAC installation & respecting sterilization techniques during sponge changes

DEVICE PLACEMENT: to prevent adjacent tissues from being damaged tubes must not be placed on skeletal pressure points to prevent the formation of pressure ulcers, foam must be trimmed to fit the geometry of the wound

Various clinical settings:

-diabetic foot ulcers

-pressure ulcerations

-chronic wounds

-skin grafts

Concept of using controlled subatmospheric pressure initially described by Fleischmann et al:

https://pmc.ncbi.nlm.nih.gov/articles/PMC8432996/#JR01315-1

-vacuum-assisted wound closure (VAC) or NPWT device for improving secondary intention wound healing

- one of the most powerful tools for plastic surgeons
- provides subatmospheric pressure across the entirety of the wound site
- foam pores 400 to 600 micrometers-- trimmed to fit the size and geometry of any wound
    - foam cell structure ensures equal distribution of negative pressure
    - different kinds of sponges
- chosen foam is sealed to skin with an adhesive membrane and connected to a suction pump
    - neg press between -50 and -200mmHg
    - pressure applied continuously or intermittently

NPWT changes the biochemistry of the wound

- MMP decrease
- decrease in peripheral blood monocytes, neutrophils, proinflammatory cytokines, and other compounds

Conclusions/action items:

Negative pressure wound therapy heals open and closed wounds through four main mechanisms of action, as well as changes the biochemistry of the wound, and reduces complications.

9/10/25 Facelift (Rhytidectomy)

SERENA EVERS - Sep 10, 2025, 7:18 PM CDT

Title: Facelift (Rhytidectomy)

Date: 9/10/25

Content by: Serena Evers

Present: n/a

Goals: Research the rhytidectomy procedure, patient demographic, treatment details, surgery preparation, recovery, and risks/benefits

Content:

search term: rhytidectomy

source: Cleveland Clinic

link: Facelift (Rhytidectomy): What Is It, Recovery & What to Expect

Rhytidectomy:

- A cosmetic surgery to address signs of aging in the face and neck, such as sagging skin, jowls, deep wrinkles, and double chin
- It involves removing or repositioning skin, fat, and/or muscle.
- Highly individualized: each surgery depends on the patient's unique face and goals.

Types of facelifts:

- Traditional Facelift: Targets full face and neck. Involves extensive incisions (ears, hairline, chin).
- SMAS Facelift: Tightens the muscle layer (superficial musculoaponeurotic system) – relevant for deep tissue healing.
- Mini-Facelift: Less invasive, used for early signs of aging.
- All types involve incisions, typically around the ears and hairline, areas the headband will need to accommodate.

Patient demographics:

- Most common among adults aged 40–60s with some skin elasticity.
- Over 131,000 facelifts performed annually in the U.S.
- Patients are generally healthy, non-smokers, and seeking youthful appearance and self-esteem boosts.

Post-Op:

- Hematoma is a common and serious complication: pooling of blood under the skin after surgery.
    - Can require urgent treatment if not controlled.
    - Caused by poor drainage, vessel bleeding, or pressure build-up.
- Bruising and swelling last 2–3 weeks, sometimes longer.
- Bandages and small drainage tubes are used immediately after surgery.
- Surgeons give precise instructions for post-op care.
- Patients should avoid strenuous activity for 3+ weeks.
- Patients often leave the hospital same day.
- Healing occurs mostly at home, with self-care or assistance.

- Home recovery setup includes bandages, creams, thermometers, and often manual drains.

Financial considerations:

- Surgery is not covered by insurance (cosmetic).
- Patients are already investing significantly in their appearance and recovery.
- Many may be willing to purchase supportive recovery tech if it improves outcomes and convenience.

Conclusions/action items:

Current rhytidectomy recovery tools are basic and passive. A NPWT device could improve outcomes, enhance comfort, support faster recovery, and appeal to a cosmetic surgery population highly motivated by results and comfort.

9/11/25 Hematoma formation in rhytidectomy

SERENA EVERS - Sep 11, 2025, 9:52 AM CDT

Title: Hematoma formation in deep plane rhytidectomy

Date: 9/11/25

Content by: Serena E

Present: n/a

Goals: Further research on hematoma formation after rhytidectomy procedure

Content:

search term: hematoma formation following rhytidectomy

source: PubMed

link: Hematoma formation in deep plane rhytidectomy - PubMed

-various reports cited hematoma formation using SMAS technique

-no report of hematoma following deep plane rhytidectomies

-medical records of 451 deep plane rhytidectomies performed at one institution by one surgeon: incidence of major hematoma 2.2% (10/451) and minor hematoma 6.65% (30/451)

-all hematomas that did occur occurred in the subcutaneous plane of dissection

-no facial hematomas

Conclusions/action items:

These reports support the motivation for the project.

9/18/25 VAC therapy clinical guidelines

SERENA EVERS - Sep 22, 2025, 5:55 PM CDT

Title: VAC therapy clinical guidelines

Date: 9/18/25

Content by: Serena Evers

Present: n/a

Goals: Complete my PDS sections

Content:

Solventum™ V.A.C.® Therapy Clinical Guidelines

I was confused about the dressing changes involving the headband and how that affects accessibility for the size section of the PDS I was working on.

From the VAC therapy clinical guidelines: "In a monitored, non-infected wound, Solventum™ V.A.C.® Peel and Place Dressings may be left in place for up to 7 days with the frequency adjusted by the clinician as appropriate. Infected wounds must be monitored often and very closely. For these wounds, dressings may need to be changed more often than indicated, taking into account local and systemic signs of infection. The dressing change intervals should be based on a continuing evaluation of wound condition and the patient's clinical presentation, rather than a fixed schedule. "

Our client Ms. Nada told us the headband will be worn for 7 days following the surgery and that is the guidelines limit.

Conclusions/action items:

Dressing changes will not be a concern for our design.

9/18/25 Some motivation and more guidelines

SERENA EVERS - Oct 20, 2025, 12:41 PM CDT

Title: Some motivation and more guidelines

Date: 9/18/25

Content by: Serena E

Present: n/a

Goals: Look at clinical guidelines provided by our client

Content:

Smtih+Nephew Negative Pressure would therapy systems Clinical Guidelines

NPCE9-42082-0125-NPWT Clinical Guidelines-FINAL APPROVED.pdf

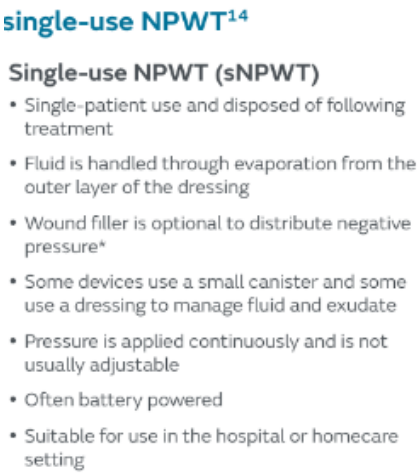
Clinical guidelines for surgeons and mid-level providers to support effective use of NPWT for optimal patient outcomes

Motivation: " In the US over 8.2 million people annually are affected by chronic wounds, costing the healthcare system between 28.1 and 96.8 billion. (based on Medicare beneficiaries)."

NPWT has been shown to:

- Promote granulation tissue formation
- Protect the wound from the outside environment
- Promote moisture balance within the wound bed

Our device will be single use:



For dressings: " Clinical studies have shown that gauze and foam dressings yield comparable healing rates, with similar percentages of wound volume or surface area reduction per week. Therefore, healthcare professionals can expect similar results from either type of dressing material."

Conclusions/action items:

Continue researching motivation for our design.

10/1/25 Salvaging exposed microtia cartilage framework with negative pressure wound therapy

SERENA EVERS - Oct 01, 2025, 10:03 PM CDT

Title: Salvaging exposed microtia cartilage framework with negative pressure wound therapy

Date: 10/1/25

Content by: Serena

Present: n/a

Goals: Research NPWT used for microtia

Content:

Salvaging exposed microtia cartilage framework with negative pressure wound therapy - ScienceDirect

-used same NPWT vac as our client provided us: KCI Negative Pressure Wound Therapy with V.A.C.® GranuFoam Black™ or Silver™

-continuous suction applied in range of 25-125mmHg

- one of the most severe complications of auricular reconstruction for microtia is exposure of the cartilage framework

-only two case reports that used NPWT for exposed microtia cartilage framework and both details and proper protocols remain unknown

-analyzed 7 cartilage exposure wounds in 6 microtia patients that were treated with NPWT after auricular reconstruction with costal (rib) cartilage

-wounds appeared on postoperative days ranging from 3 to 30

-skin defect sizes at onset ranged from 1 to 24 mm^2

-causes of cartilage exposure were 5 cases of flap necrosis(lack of blood and oxygen to the tissue) and 2 suture failures without skin necrosis

-two cartilage frames were infected at onset

-infections: MRSA, methicillin-resistant Staphylococcus aureus & MSSA, methicillin-sensitive Staphylococcus aureus

-NPWT dressings were changed every 1-3 days and continued until cartilage exposure was covered with proliferated granulation or the dead space had disappeared

-durations of NPWT ranged from 8 to 39 days

-all patients experienced granulation with full recovery and cartilage frames survived in all cases but partial cartilage atrophies remained in all 5 locations in 4 cases

-a higher pressure (125mmHg) was used for cases where NPWT purpose was just granulated tissue formation. When the NPWT was used for fluid removal or both fluid removal and granulated tissue formation a negative pressure of 75mmHg or less was used.

-fluid removal for small skin defect cases regardless of dead space

-granulated tissue formation for large skin defect wounds

-during microtia reconstruction the exudate fluid is particularly apt to collect in the dead space of the concavo-convex shape of the frame

Important: "During microtia reconstruction, the exudate fluid is particularly apt to collect in the dead space of the concavo-convex shape of the frame. Furthermore, insufficient subcutaneous tissue of the skin envelope is less likely to fill the dead space and subsequent retention of exudate risks infection. NPWT therefore acts as a continuous external drainage system and promotes tissue adhesion. Granulated tissue formation is critical for healing cartilage exposure. These types of wounds after microtia reconstruction have disadvantages for granulated tissue formation because of the insufficient quantity of soft tissue in the thin skin envelope. Our experience showed that 75 mmHg vacuum pressure was a proper setting. However, low settings, such as 25 mmHg, may drain inadequately while 125 mmHg might interfere with granulation."

Conclusions/action items:

This is the only journal article I could find discussing NPWT for microtia reconstruction surgery. We should base our design off of this information since its the best literature there is.

10/1/25 USE OF INNOVATIVE NEGATIVE PRESSURE THERAPY FOR CARTILAGE EXPOSURE IN MICROTIA RECONSTRUCTION

SERENA EVERS - Oct 01, 2025, 11:12 PM CDT

Title: USE OF INNOVATIVE NEGATIVE PRESSURE THERAPY FOR CARTILAGE EXPOSURE IN MICROTIA RECONSTRUCTION

Date: 10/1/25

Content by: Serena

Present: n/a

Goals: Found this through the "Salvaging exposed microtia cartilage framework with negative pressure wound therapy" article and wanted to see what it was about

Content:

j.bjps.2018.10.04420220710-1-9o9wjd-libre.pdf - 2018

"We report a case of an 8 year old woman with a lobular microtia. We planned a two stage reconstruction technique. First stage surgery was performed without complications and the patient was discharged at 5 days postoperatively. Some not well delimited skin suffering was noted at first revision and finally, skin necrosis was clearly established at 15 days postoperatively. Then, surgical debridement was performed showing a defect of 2 x 1 centimetres, where two areas of cartilage exposure were identified (Figure 1). We planned treatment with negative pressure therapy SNAP™ (Acelity®) at -125 mmHg. This is a portable and quite comfortable negative pressure wound therapy that allowed the patient to continue her normal activity (Supplementary figure). Revisions were made once a week and SNAP™ therapy was maintained for 3 weeks leading to complete granulation and total cartilage coverage. Complete epithelization was achieved 2 weeks later (ointment dressings were changed daily by the parents during that period) "

"Negative pressure therapy is difficult to apply to the ear due to its irregular surface and round contour that make it almost impossible achieve vacuum"

Conclusions/action items:

I think this is one of the first reported use of NPWT for microtia reconstructive surgery.

10/1/25 Microtia review

SERENA EVERS - Oct 01, 2025, 11:10 PM CDT

Title: Microtia review

Date: 10/1/25

Content by: serena

Present: n/a

Goals: learn more about microtia

Content:

Microtia - ClinicalKey - 2024

The prevalence of microtia has been reported to vary between 0.8 and 17.4 per 10,000 in different populations, being least common in Western Europeans and Caucasians, and more common in those of Andean, Native American, and Asian descent. 8910 Microtia is more common in male individuals, who comprise 54% to 73% of cases. 4 , 9 , 11 , 12 Involvement is unilateral in 80% to 90% of cases, and the right side is more commonly affected (60%).

In 55% to 90% of cases, microtia is accompanied by CAA, a malformed ear canal that can be stenotic or completely absent with varying grades of middle ear involvement. 13 The degree of microtia and the severity of middle ear dysplasia are usually correlated, with more severe forms of microtia having more severe middle ear involvement.

While 80% to 90% of patients have conductive hearing loss in the affected ear, 10% to 15% of patients can also present sensorineural hearing loss, warranting further workup

Conclusions/action items:

There are good statistics to use for our project motivation.

10/2/25 complications of autologous cartilage microtia reconstruction

SERENA EVERS - Oct 20, 2025, 12:43 PM CDT

Title: complications of autologous cartilage microtia reconstruction

Date: 10/2/25

Content by: Serena

Present: n/a

Goals: Research complications of microtia reconstruction

Content:

Complication Rate of Autologous Cartilage Microtia Reconstruction: A Systematic Review - PMC - 2013

- little agreement in literature regarding risk factors for complications
- overall complication incidence is 16.2% in average with a range of 0-72.9%
- national survey of American society of plastic surgeons: 91.3% choose autologous cartilage staged reconstruction for patients with microtia

Conclusions/action items:

I will use some of these in our background section for our report and presentation.

11/5/25 POISEUILLE'S LAW AND THE VISCOSITY OF FLUIDS

SERENA EVERS - Dec 08, 2025, 10:52 PM CST

Title: POISEUILLE'S LAW AND THE VISCOSITY OF FLUIDS

Date: 11/5/25

Content by: Serena

Present: n/a

Goals: Research for the fluid dynamics of the y connector

Content:

POISEUILLE'S LAW AND THE VISCOSITY OF FLUIDS

For sufficiently small velocities the flow will be laminar i.e. layered. One can show that laminar flow leads to a parabolic distribution of velocities across a pipe with a circular cylindrical cross section. As the velocity increases past a critical value, depending upon the viscosity and density of the fluid, eddies appear and the flow becomes turbulent.

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

The laminar flow through a pipe is described by the Hagen-Poiseuille law, stating that the flow rate (F = volume of fluid flowing per unit time) is proportional to the pressure difference Dp between the ends of the pipe and the fourth power of its radius r.

Conclusions/action items:

We will use the Hagen-Poiseuille law to calculate flow rate for the two branches of the y connector.

11/15/25 Applied Fluid Mechanics

SERENA EVERS - Dec 08, 2025, 10:52 PM CST

Title: Applied fluid mechanics

Date: 11/15/25

Content by: Serena

Present: n/a

Goals: Justification for the use of two 10 Fr tubes to the drain and the dressing in our design instead of the originally different sized tubing

Content:

Fluid mechanics textbook

Applied Fluid Mechanics, 7/e

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

Conclusions/action items:

Use this as justification.

10/15/25 NPWT

SERENA EVERS - Dec 10, 2025, 3:41 PM CST

Title: NPWT

Date: 10/15/25

Content by: Serena

Present: n/a

Goals: Find more background information on NPWT

Content:

search term: negative pressure wound therapy

search location: PubMed

link: Negative pressure wound therapy for surgical site infections: A systematic review and meta-analysis - Gao - 2021 - Journal of Advanced Nursing - Wiley Online Library

This meta-analysis shows that NPWT outperforms standard dressings for surgical site infections. Wounds heal faster, patients spend less time in the hospital, and complication rates are lower. Even though costs are higher, the clinical benefits are strong. For our design project, it reinforces why delivering stable, controlled negative pressure is important, since device performance can directly influence healing outcomes. Patients treated with NPWT also had shorter hospital stays and fewer adverse events, even though overall medical costs were higher. For our design project, this supports why a device that can reliably maintain target negative pressures (like –60 to –120 mmHg) actually matters because consistent suction is tied to faster tissue recovery, reduced complications, and better wound outcomes.

Conclusions/action items:

Useful background information for our report.

10/20/25 negative-pressure wound therapy: emerging devices and techniques

SERENA EVERS - Dec 10, 2025, 3:43 PM CST

Title: negative-pressure wound therapy: emerging devices and techniques

Date: 10/20/25

Content by: Serena

Present: n/a

Goals: More general research on NPWT

Content:

link: Topical negative-pressure wound therapy: emerging devices and techniques: Expert Review of Medical Devices: Vol 17, No 2

This review highlights how chronic wounds place a huge financial strain on healthcare, which is why more efficient wound treatments, like NPWT, matter. NPWT has evolved into multiple applications, all showing improved healing across different wound types, including better perfusion, lower infection rates, and strong potential when paired with instillation for contaminated wounds. The authors also point toward future directions, like using NPWT to deliver stem cells, growth factors, or cold plasma directly to the wound bed, and improving foam materials to optimize microstructure and pore size. For our design project, this reinforces that NPWT isn't just about applying suction, it's becoming a platform for more individualized and biologically targeted wound care, which makes pressure stability, interface materials, and device adaptability even more important.

Conclusions/action items:

NPWT does more than just close the wound, it helps heal it by promoting metabolic processes.

10/7/25 Negative pressure wound therapy: device design, indications, and the evidence supporting its use

SERENA EVERS - Dec 10, 2025, 3:45 PM CST

Title: Negative pressure wound therapy: device design, indications, and the evidence supporting its use

Date: 10/7/25

Content by: Serena E

Present: n/a

Goals: More background on NPWT

Content:

link: Negative pressure wound therapy: device design, indications, and the evidence supporting its use: Expert Review of Medical Devices: Vol 18, No 2

This review explains how NPWT has expanded far beyond its original 1995 vacuum-assisted closure system and is now used for open wounds, closed surgical incisions, and skin grafts. NPWT improves perfusion and granulation, reduces edema, and in chronic lower-extremity ulcers has some of the strongest supporting evidence for improved healing outcomes. Device innovations such as instillation, antimicrobial foams, and portable units have broadened its clinical reach. The authors note that future development should focus on making systems easier for patients to use and adaptable to more anatomical sites, while higher-quality studies are still needed to define the true clinical and cost benefits.

Conclusions/action items:

For our project, this reinforces the importance of creating a device that consistently maintains therapeutic pressures and manages fluid removal effectively, since these are the physiological mechanisms driving the improved healing seen across multiple wound types.

12/1/25 Air properties for y connector calculations

SERENA EVERS - Dec 10, 2025, 4:16 PM CST

Title: Air properties for y connector calculations

Date: 12/1/25

Content by: Serena

Present: n/a

Goals: Find air properties to use for y connector calculations

Content:

link: Air Properties - Density, Viscosity, Heat Capacity, Thermal Conductivity, and more

Air properties were taken as $\mu = 1.81 \times 10^{-5}$ Pa·s and $\rho = 1.2$ kg/m³

Conclusions/action items:

Calculate hydraulic resistance and flow for each branch of the y connector system.

11/12/25 Continuous NPWT Regulates Fibrosis in Murine Diabetic Wound Healing

SERENA EVERS - Dec 10, 2025, 4:35 PM CST

Title: Continuous NPWT Regulates Fibrosis in Murine Diabetic Wound Healing

Date: 11/12/25

Content by: serena

Present: n/a

Goals: understand how NPWT can actively reduce fibrosis and scarring at the cellular level

Content:

link: Continuous NPWT Regulates Fibrosis in Murine Diabetic Wound Healing

This study used a diabetic mouse excisional wound model and showed that NPWT at 125 mmHg for seven days actually shifts the biology of wound healing toward a less fibrotic state. NPWT increased YAP expression with a reported p value of 0.04, while significantly decreasing Engrailed-1 and CD26 expression with p values of 0.0001 and less than 0.0001. These markers are tied to pro-scarring fibroblast lineages, so lowering them suggests reduced fibrosis risk. NPWT also lowered several downstream fibrosis markers such as Vimentin and alpha-SMA, each with a p value of 0.04, as well as HSP47 with a p value of 0.0008, and overall collagen deposition and apoptosis were also reduced.

Conclusions/action items:

For our design project, this reinforces that maintaining consistent negative pressure does more than clear fluid. It can directly influence cellular mechanotransduction and reduce pathways that lead to scarring, which strengthens the argument for a device that delivers stable, uniform suction across the wound bed.

9/23/25 Velcro Head wrap

SERENA EVERS - Oct 20, 2025, 12:29 PM CDT

Title: Velcro Head wrap design

Date: 9/23/25

Content by: Serena

Present: n/a

Goals: Share my design idea

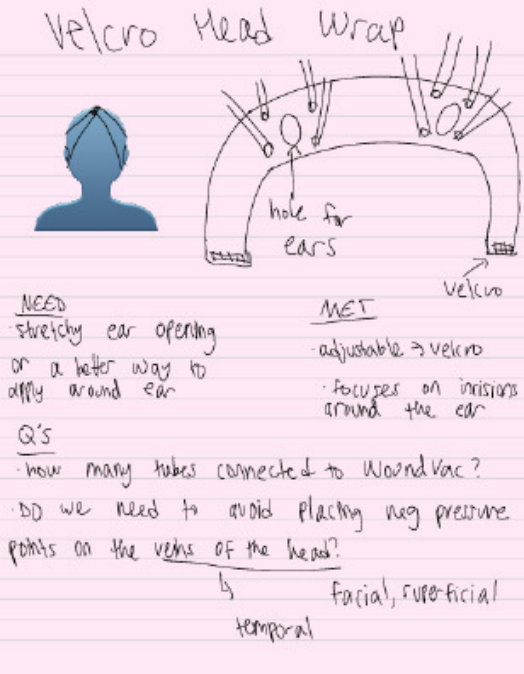
Content:

My velcro head wrap design is attached below.

Conclusions/action items:

The team is meeting to share design ideas with each other.

SERENA EVERS - Sep 23, 2025, 7:00 PM CDT



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Designs.pdf (207 kB)

10/20/25 Preveena specs

SERENA EVERS - Oct 20, 2025, 12:29 PM CDT

Title: Prevena specifications

Date: 10/20/25

Content by: Serena

Present: n/a

Goals: Gather all info about the negative pressure supply possible to figure out how to supply even pressure to the incisions as well as the drain.

Content:

link: msd-ssm-prevena-therapy-overview-brochure-en-gbl.pdf

Compatible with 3M negative pressure wound therapy devices

3M™ Prevena™ Plus 125 Therapy Unit

One single-use negative pressure wound therapy unit compatible with all 3M™ Prevena™ Dressings.

Negative pressure options:

- Pre-set, continuous negative pressure wound therapy at -125 mmHg for up to 7 or 14 days (with dressing changes every 7 days)
- Disposable, single patient use
- Rechargeable battery

Specifications:

- Dimensions: Approx 8.9 × 16.3 × 5.49cm
- Weight with empty canister: 0.64lbs (0.29kg)

Prevena Dressings are also compatible with 3M traditional negative pressure wound therapy devices:
3M™ V.A.C.® Ulta Therapy Unit and 3M™ ActiV.A.C.® Therapy Unit

3M™ Prevena™ Plus 125 Therapy units come with a 3M™ Prevena™ Plus 150 mL canister, a 3M™ Prevena™ Plus 125 Therapy Unit power supply and cord and a patient-friendly carrying case with an adjustable strap.

- Provides up to seven days of continuous NPWT at -125mmHg with the simple push of a button. *
- * Prevena™ Plus 125 Therapy Unit can be continuously applied for up to 14 days, but V.AC.® Dressings should be changed by a medical professional every 48–72 hours, but no less than 3 times per week
- Visual and audible safety alerts notify you and your patients of a low battery, blockage alerts or air leaks.
- Designed with our proprietary 3M™ SensaT.R.A.C.™ Pad Technology to deliver continuous and accurate NPWT to the target site.
- Includes a rechargeable battery — no need for manual battery changes.
- Attach the 3M™ Prevena™ Plus Canister (150ml) to the therapy unit to store fluid and exudate away from the surgical site.
- Use the 3M™ Prevena™ Plus 125 Therapy Unit (7-Day) with 3M™ Prevena™ Dressings, 3M™ Prevena Restor™ Dressings and select 3M™ V.A.C.® Dressings.*

**Prevena Plus 125 Therapy Unit is compatible with small- and medium-sized V.AC.®Dressings or 3M™ V.A.C. Whitefoam™ Dressings*

Suggested Applications

- Designed for closed incisions and small-to-medium open wounds.
- Use with select 3M NPWT dressings.

Conclusions/action items:

These are all the specifications I could find online.

10/29/25 Y connector

SERENA EVERS - Dec 10, 2025, 3:59 PM CST

Title: Y connector

Date: 10/29/25

Content by: Serena E

Present: n/a

Goals: Figure out the fluid dynamics behind the y connector

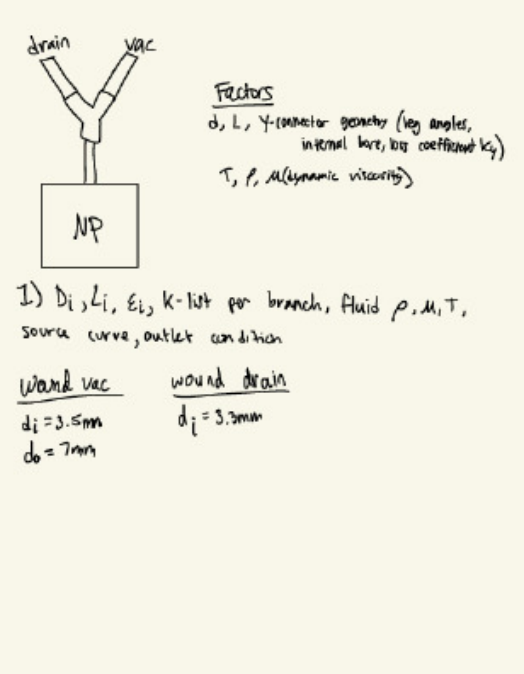
Content:

my work is attached

Conclusions/action items:

Use two 10 Fr tubes for both the drain and the dressings.

SERENA EVERS - Dec 10, 2025, 4:04 PM CST



Download

Y_Connector_Fluid_Dynamics_Problem.pdf (322 kB)

10/29/25 future work notes

SERENA EVERS - Dec 10, 2025, 4:01 PM CST

Title: Future work notes

Date: 10/29/25

Content by: Serena

Present: n/a

Goals: Notes about future directions for our design

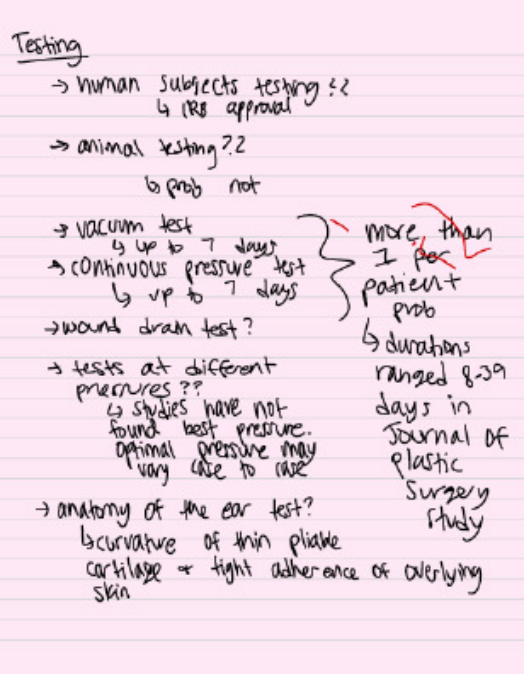
Content:

attached below.

Conclusions/action items:

n/a

SERENA EVERS - Dec 10, 2025, 4:04 PM CST



Download

Future_Work_Notes.pdf (560 kB)

11/15/25 Y connector updated info

SERENA EVERS - Dec 10, 2025, 4:02 PM CST

Title: Y connector updated info

Date: 11/15/25

Content by: Serena E

Present: n/a

Goals: Update y connector info for the report

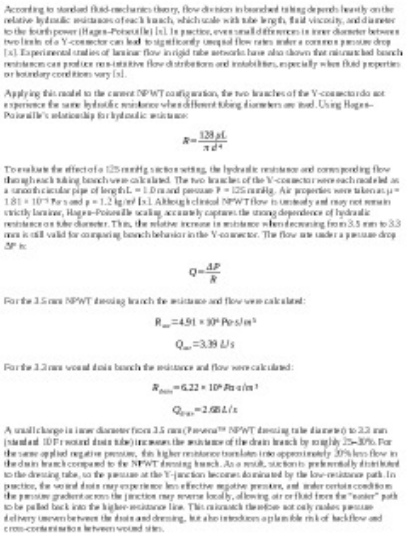
Content:

attached

Conclusions/action items:

Add this to the final report.

SERENA EVERS - Dec 10, 2025, 4:03 PM CST



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) [x]. 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 [x]. 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 [x].

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 [x]. 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:

$$R_{3.5\,mm} = 4.91 \times 10^{9}\ Pa \cdot s/m^3$$

$$Q_{3.5\,mm} = 3.39\ L/s$$

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

$$R_{3.3\,mm} = 6.22 \times 10^{9}\ Pa \cdot s/m^3$$

$$Q_{3.3\,mm} = 2.68\ L/s$$

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.

Download

Y_connector.docx (8.85 kB)

1/29/2024 Biosafety and Chemical Safety Required Training

SERENA EVERS - Jan 29, 2024, 9:03 PM CST

Title: Biosafety and Chemical Safety Required Training

Date: 1/29/2024

Content by: Serena Evers

Present: Serena Evers

Goals: provide documentation for my completed Biosafety training and Chemical Safety: The OSHA Lab Standard training

Content:

pdf with proof of training completion attached

Conclusions/action items:

Utilize these trainings in BME design

SERENA EVERS - Jan 29, 2024, 9:03 PM CST

WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

This certifies that Serena Evers has completed training for the following course(s):

Course	Assignment	Completion	Expiration
Biosafety Required Training	Biosafety Required Training Quiz 2023	4/5/2023	4/5/2028
Chemical Safety: The OSHA Lab Standard	Final Quiz	4/6/2023	

Data Last Imported: 01/29/2024 08:44 PM

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Biosafety_and_Chemical_safety_training.pdf (60.8 kB)

10/28/25 CITI Human subjects course

SERENA EVERS - Dec 10, 2025, 3:46 PM CST

Title: CITI human subjects training

Date: 10/28/25

Content by: Serena E

Present: n/a

Goals: Complete the semester required training

Content:

attached

Conclusions/action items:

n/a

SERENA EVERS - Oct 28, 2025, 2:54 PM CDT

Download

CITI_human_subjects.pdf (77.4 kB)

3/11/2024 Intro to Machining Training

SERENA EVERS - Mar 11, 2024, 7:46 PM CDT

Title: Intro to Machining Required Training

Date: 3/11/2024

Content by: Serena Evers

Present: Serena Evers

Goals: Provide documentation for the Intro to Machining Required training

Content:

pdf with proof of training completion attached.

Conclusions/action items:

Utilize this training when fabricating the Bioreactor for the Bone Biomaterial

SERENA EVERS - Mar 11, 2024, 7:46 PM CDT

Download

Untitled_document_3_.pdf (168 kB)

11/7/25 Kristin Myers "Why Healthcare Needs More Engineers"

SERENA EVERS - Nov 07, 2025, 12:41 PM CST

Title: Building a Career of Impact

Date: 11/7/25

Content by: Serena

Present: n/a

Goals: attend Tong lecture

Content:

- Run towards the hard problems they are the ones that change the world
- UW BME graduate
    - 4 internships & coops
- Chapter 1: Foundation
- Worked at medtronic
    - engineering
    - marketing/product launch
    - technical sales
- then Arboretum ventures
    - investor in healthcare startup technology
- Skyline Ventures
    - investor in healthcare startup
- Chapter 2: Growth curve
- Combine EQ with IQ to multiply impact & reach
- Chapter 3: Build & Transform
    - drive system-level impact through innovation & scale
- Hopscotch Health
    - founder and CEO advanced primary care for rural communities
    - Blue cross blue shield association COO
- The Healthcare System
    - the quadrouple aim
    - US spends 18% of GDP on healthcare
        - 2x more than other high income countries
    - challenges
        - misaligned incentives
        - fragmented financing & regulation
        - data silos & legacy IT
        - inequities
- the future of healthcare is an integrated ecosystem of health and care

Conclusions/action items:

Kristin Myers talk was very thought provoking and her story is inspiring.

9/15/2025 - FaceLift Procedure

HARSHAD GUNASEKAR - Sep 26, 2025, 4:51 PM CDT

Title: FaceLift Research

Date: 9/15/2025

Content by: Harshad Gunasekar

Goals: Research and gain a better understanding of the facelift procedure

Citation: B. S. Raggio, “Deep Plane Facelift,” in *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025. Available: https://www.ncbi.nlm.nih.gov/books/NBK545277/. Accessed: Sep. 15, 2025.

Content:

What a facelift does (concept)

- Goal: reposition ptotic facial soft tissues and redrape skin to restore cervicomental angle, jawline, and mid-lower face contours. Not primarily for fine wrinkles or skin texture.
- Core maneuver is working on the SMAS (superficial musculoaponeurotic system): plication, imbrication/SMASectomy, or deep-plane release and mobilization. Technique selection trades off longevity, vector control, and nerve/vascular risk.

Critical surgical anatomy

- **Layers (superficial → deep):** skin → subcutaneous fat (compartments) → **SMAS** → parotidomasseteric fascia → mimetic muscles → facial nerve branches → retaining ligaments → deep fat/SMAS extensions. The SMAS is a fibromuscular sheet continuous with the platysma and parotid fascia; manipulating it moves the overlying skin more safely and durably than skin-only lifts.
- **Retaining ligaments** (zygomatic, masseteric, mandibular, etc.) tether the face, partition fat compartments, and protect facial nerve branches until released—after release, nerves are more vulnerable. Surgeons selectively release these to allow tissue mobilization.
- **Vascular supply of facelift flaps:** lateral facelift flaps are perfused predominantly by transverse facial artery perforators; ligation reduces preauricular perfusion—relevant in smokers or vascular compromise.
- **Facial nerve risk zones:** zygomatic/buccal branches course deep to ligaments early and become superficial after ligament release—meticulous plane selection prevents neuropraxia.

Aging biology that surgery addresses

- Dermal changes: decreased collagen/elastin quality, reduced fibroblast activity → skin laxity. Fat pads shift/deflate; retaining ligaments relax → jowling and nasolabial folds. Manipulating the SMAS and releasing ligaments counters these mechanical changes.

Conclusions/action items:

Find out the specific steps of a facelift

Research more about the rehabilitation after and what specificities our device has to address.

Design Ideas based on this research for the next group meeting

9/15/2025 - FaceLift Research 2

HARSHAD GUNASEKAR - Sep 26, 2025, 4:56 PM CDT

Title: Facelift Research 2

Date: 9/15/2025

Content by: Harshad

Goals: Research more about Face LIfts and NWPT Applications

Citation: A. J. Yang, “Rhytidectomy,” in *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025. Available: https://www.ncbi.nlm.nih.gov/books/NBK564338/. Accessed: Sep. 15, 2025.

Content:

Typical operative flow (condensed)

1. **Marking & anesthesia.**
2. **Incisions:** usually temporal hairline → preauricular → around lobule → postauricular into occipital hairline; submental if neck addressed.
3. **Dissection plane:** sub-SMAS (deep plane) vs limited subcutaneous with SMAS plication/imbrication. Deep plane elevates skin+SMAS as one unit to reduce skin tension and potentially improve longevity/neck-jawline definition.
4. **SMAS work:** plication (fold/tighten), imbrication/SMASectomy (resect/advance), or deep-plane releases of zygomatic/masseteric ligaments with vectorized suspension.
5. **Hemostasis, drains/quilting sutures as needed;** redrape skin without tension, trim, close in layers; pressure dressing.

Wound-healing physiology (why postop care matters)

- **Phases:** hemostasis (mins–hrs), inflammation (days 1–3), proliferation (days 4–21; fibroblasts, collagen III, angiogenesis), remodeling (week 3 → 12+ months; collagen III→I, tensile strength plateaus ~11–14 weeks, never returns to 100%). Nicotine, hypertension, poor perfusion impair these phases.
- **Flap perfusion:** avoid skin-edge tension and vasoconstriction; preserve perforators; maintain normothermia and BP control to reduce ischemia/necrosis risk.

Key complications & physiology behind them

- **Hematoma (most common):** typically within 24 h; risk ↑ with peri-/post-op hypertension, male sex, and inadequate hemostasis—controlled BP and compressive dressings mitigate. Hematoma compromises perfusion and increases skin-edge necrosis.
- **Skin flap necrosis:** risk ↑ in smokers due to microvascular compromise; smoking cessation weeks before surgery is standard.
- **Temporary facial nerve neuropraxia:** traction/thermal injury risk increases after ligament release; usually resolves over weeks–months.
- **Seroma, infection, alopecia at incision, hypertrophic scar:** minimized by gentle handling, proper closure vectors, and pressure control.

Post-op management (what supports biology)

- **Blood pressure control** first 24–48 h to prevent hematoma; maintain head elevation and compressive dressing to limit dead space.
- **Drains** (selectively): decrease dead space/seroma; remove once output is low.
- **Smoking abstinence** pre-/post-op to improve flap survival and scar quality.

Where negative-pressure therapy (NPWT) may fit (context for head/neck)

- NPWT (VAC) enhances granulation, reduces edema/bioburden, and mechanically stabilizes wounds; head-and-neck use is under-adopted due to sealing challenges around contours but can aid complex/maxillofacial wounds and incisions with high drainage risk when an airtight seal is achieved.

- Mechanisms: microdeformation (mechanotransduction), exudate control, perfusion optimization, and temperature/moisture stabilization. *(Note: NPWT isn't routine after cosmetic rhytidectomy but is relevant to complex wounds or research concepts for adapting seals around pre-/post-auricular regions.)*

Conclusions/action items:

- Determine Design Ideas for how the seal adheres to the skin

- Research existing products on the market that could possibly be adapted for this application

- Make up questions for the upcoming client meeting

10/12/2025 - The WOCA NPWT

HARSHAD GUNASEKAR - Oct 15, 2025, 12:29 PM CDT

Title: The WOCA NPWT

Date: 10/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find our that NPWT Devices are already on the market and what features they include.

Citation: A. J. Knulst *et al.*, "The WOCA negative pressure wound therapy device," *J. Glob. Health Rep.*, vol. 9, art. e2025001, 2025.https://www.sciencedirect.com/science/article/pii/S2468067224001147?utm

Content:

Objective: Create a low-cost, portable NPWT system (WOCA device) suitable for low- and middle-income countries (LMICs) to make negative pressure therapy accessible where commercial systems are unaffordable.

- Core Construction & Components:
  - Pump Housing: Injection-molded ABS plastic — rigid, impact-resistant, and biocompatible for clinical use.
  - Tubing: Medical-grade silicone — highly flexible, sterilizable, and non-reactive, ideal for reusable systems.
  - Seals: Used silicone O-rings and gaskets for airtight connections.
  - Controller: Microcontroller-based feedback loop (Arduino Nano) with analog pressure transducer for live monitoring.
  - Power Source: Rechargeable lithium-ion pack, 10–12 h battery life, with overcharge protection.
- Pressure Range & Regulation:
  - Adjustable between –75 mmHg and –125 mmHg, with auto-shutoff beyond ±10 mmHg error margin.
  - Feedback loop ensures stable vacuum even under leak conditions.
- Geometric & Modular Features:
  - Compact 10 × 6 × 4 cm housing with modular dressings attached through Luer-lock connectors.
  - Designed for easy cleaning and field repair — no proprietary parts.
  - Sound-damped motor compartment reduces pump noise to <45 dB, important for comfort in pediatric use.
- Material Relevance for Design:
  - Combines rigid polymer enclosure for safety with soft silicone interfaces for sealing and comfort.
  - The modular system and pressure safety architecture can inform your earband-mounted micro-pumpsubsystem.

Application in Microtia Reconstruction Surgery

- The WOCA's modular, small-scale NPWT system can be adapted for post-reconstruction healing where exposed cartilage or grafted skin requires stabilization and exudate control.
- The use of flexible silicone tubing and compact pump design is well suited for auricular geometries, as it minimizes pressure points behind the ear.
- The device could be fitted with a micro-dressing interface over the reconstructed ear, connected by short tubing to the pump module clipped behind the head.
- Potential limitations include lack of fine-tuned low-pressure mode (< –50 mmHg) needed for delicate cartilage regions, and a relatively rigid housing that may need adaptation for patient comfort.

- Overall, the WOCA system provides a proven control and pressure stabilization framework that could be miniaturized for microtia-specific NPWT prototype.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our first prototype

10/12/2025 - Difference between Canister-Based and Canisterless NPWT

HARSHAD GUNASEKAR - Oct 15, 2025, 12:32 PM CDT

Title: Difference between Canister-Based and Canisterless NPWT

Date: 10/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find our that NPWT Devices are already on the market and what features they include.

Citation: A. Orlov, E. R. Bowen, and M. S. Jones, “Effective negative pressure wound therapy for open wounds: distinction between canister-based and canisterless single-use NPWT systems,” *Int. Wound J.*, vol. 20, no. 8, pp. 2231–2242, Aug. 2023..https://onlinelibrary.wiley.com/doi/10.1111/iwj.13879?utm

Content:

- Objective: Compare canister-based and canisterless single-use NPWT systems to evaluate performance, drainage, and suitability for various wound types.
- Design Architecture Comparison:

  Canister-Based Systems:

  Canisterless Systems:

  - Components: polycarbonate housing, silicone valves, hydrophobic membranes, and a collection canister(100–200 mL).
  - Best for high-exudate wounds — robust drainage but bulkier and less conformal.
  - Vacuum controlled via pump feedback with one-way check valves to prevent backflow.
  - Utilize absorbent polyurethane (PU) foam combined with superabsorbent polymer (SAP) hydrogel layers for exudate capture.
  - Outer drape: thermoplastic polyurethane (TPU) film coated with silicone-acrylic hybrid adhesive to ensure flexibility and airtight sealing.
  - No rigid components → thinner, lighter, and patient-friendly for smaller wounds.
- Material & Mechanical Design Notes:
  - PU foam pore sizes (400–600 µm) optimized for exudate wicking and pressure distribution.
  - SAP hydrogel layer maintains moisture but risks saturation in high-output wounds.
  - TPU outer layer provides mechanical integrity and gas impermeability under continuous suction.
  - Ideal operating pressure range: –80 mmHg to –120 mmHg, sufficient for granulation without tissue collapse.

Application in Microtia Reconstruction Surgery

- Microtia reconstruction involves thin, curved skin flaps over cartilage, which are susceptible to pressure necrosis and desiccation.
- Canisterless NPWT systems, as described by Orlov *et al.*, are well-suited for auricular wounds because they:
  - Eliminate bulky canisters → improved comfort and mobility for pediatric patients.
  - Allow uniform negative pressure across irregular ear contours through conformal foam dressings.
  - Use soft TPU and silicone-acrylic seals, minimizing risk of air leaks around complex shapes.
- Integration of a micro-scale absorptive layer (PU + SAP) within dressing can emulate this approach while maintaining a compact design.
- Limitation: once the foam saturates, suction weakens — a sensor-based pressure indicator (like in WOCA) could solve this issue in system.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our first prototype

10/12/2025 - Low Resource Region NPWT

HARSHAD GUNASEKAR - Oct 15, 2025, 12:32 PM CDT

Title: Device for Negative Pressure Wound Therapy in Low-Resource Regions: Open-Source Description and Bench Test Evaluation

Date: 10/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out that NPWT Devices are already on the market and what features they include.

Citation: R. Farré, L. G. Montserrat, and F. F. Suárez, “Device for negative pressure wound therapy in low-resource regions: open-source description and bench test evaluation,” *J. Clin. Med.*, vol. 11, no. 18, art. 5417, Sep. 2022.https://www.mdpi.com/2077-0383/11/18/5417?utm

Content:

Objective: Develop an open-source NPWT device with accessible parts and full transparency for replication and clinical adaptation.

- Mechanical Architecture & Materials:
  - Housing: CNC-cut acrylic panels with silicone gasket seals — transparent and inexpensive for prototypes.
  - Pump: 12 V miniature diaphragm pump (medical-grade) with low-noise chamber (≤ 48 dB).
  - Pressure Sensor: MPX5010DP transducer providing analog output for closed-loop feedback.
  - Tubing: Silicone rubber (3 mm ID) for flexibility and ease of sterilization.
  - Filter: PTFE hydrophobic membrane at exhaust to prevent bacterial escape.
  - Reservoir: Small detachable polycarbonate chamber with check-valve system.
- Control & Safety:
  - Arduino-based PID loop maintaining –25 to –175 mmHg, error < ±5 mmHg.
  - Dual safety layers: software shutoff at under/over-pressure, mechanical relief valve.
  - Bench testing showed consistent vacuum recovery under simulated leakage conditions.

Application in Microtia Reconstruction Surgery

- Provides an excellent engineering blueprint for your auricular NPWT prototype.
- Components like the pressure sensor, diaphragm pump, and control algorithm can be reused or miniaturized.
- For microtia patients, where comfort and discreetness are key:
  - Replace acrylic housing with silicone-encased flexible module that can fit under a headband or behind the ear.
  - Use short tubing lengths (≤ 10 cm) to reduce pressure lag and noise.
  - Incorporate the same PID feedback loop to maintain gentle suction (–50 mmHg to –75 mmHg) appropriate for delicate ear grafts.
- Because it’s open-source, it serves as a reference architecture for adapting NPWT to specialized headband designs for pediatric microtia reconstruction recovery.
-
- Material & Ergonomic Takeaways:
  - Acrylic → cost-effective for early prototypes but not ideal for long-term patient wear (rigid, brittle).

- Suggest transitioning to TPU or flexible silicone housing for wearable version.
- Tubing and PTFE membranes demonstrate effective contamination control — critical for post-auricular infection prevention.
- Consider integrating soft silicone manifold between foam and skin to diffuse suction evenly over curved cartilage.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our first prototype

10/15/2025 - Smith and Nephew RENASYS

HARSHAD GUNASEKAR - Oct 16, 2025, 10:09 AM CDT

Title: Smith and Nephew RENASYS

Date: 10/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out that NPWT Devices are already on the market and what features they include.

Citation:

Smith & Nephew, “RENASYS EDGE Negative Pressure Wound Therapy System — Product Overview,” Smith & Nephew, 2023. (Online) Availablehttps://www.smith-nephew.com/en-us/health-care-professionals/products/advanced-wound-management/renasys-touch-global?utm

Content:

Design & Material / Engineering Notes

- Product positioning & key features
  – Designed for acute and post-acute care; marketed as simpler and more streamlined NPWT than legacy systems.
  – Uses RENASYS Soft Port (a flexible interface) to help conform dressing ports on complex body contours with less pain.
  – The EDGE version emphasizes lightweight (≈2 lb) and quiet operation with built-in canister (300 mL) hidden discreetly.

- Materials & construction
  – Pump & housing: durable, maintenance-free plastic (likely ABS or polycarbonate composite) that is wipe-clean and relatively rigid but tough.
  – Canister: 300 mL capacity, likely polycarbonate or similar transparent plastic for visual inspection of exudate.
  – Drape / adhesive / interface: uses soft port technology to reduce shear on skin, thus requiring adhesives / sealing layers that are flexible (likely silicone / soft adhesives) rather than rigid.
  – Tubing & connectors: likely medical-grade silicone or PVC with connectors that interface to Soft Port, engineered to resist kinking and maintain vacuum.

- Performance / user interface & ergonomics
  – Step-by-step guidance UI, simple interface for clinicians.
  – Battery: 24-hour life, silent pump, streamlined design to reduce patient burden.
  – Hidden canister: keeps device compact and less bulky.

Application & Limitations for Microtia Reconstruction

- Potential advantages
  – The Soft Port interface is promising for curved, irregular auricular surfaces; its flexibility could reduce edge leaks or peeling on the ear.
  – The compact pump + hidden canister design is more wearable, which is essential in pediatric patients (behind ear or integrated into a headband).
  – The relatively modest canister capacity (300 mL) is likely more than sufficient for a small microtia wound site, allowing the dressing to remain compact.

- Challenges / limitations
  – The 300 mL canister adds bulk; in an ear-mounted or headband system, integrating that much volume may be infeasible without redesign.
  – The rigid pump housing may not conform to the scalp / behind-ear curvature; for comfort, you might need flexible or segmented casing.
  – The Soft Port and drape adhesives are designed for skin generally—not always for areas with cartilage underlay or fluctuating geometry like the ear, so leakage or delamination is risk.
  – The standard pressure capabilities may be too aggressive for small cartilage exposures; you’d need fine control in lower-negative-pressure ranges specific to auricular tissue.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our first prototype

10/15/2025 - Molnycke Avance Solo

HARSHAD GUNASEKAR - Oct 16, 2025, 10:14 AM CDT

Title: Molnycke Avance Solo

Date: 10/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out that NPWT Devices are already on the market and what features they include.

Citation: Mölnlycke, “Avance Solo NPWT System — Product Information,” Mölnlycke, 2024. (Online) Available:https://www.molnlycke.us/solutions/avance-solo/our-npwt-system/?utm_source=chatgpt.com

Content:

- System architecture & design philosophy
  – Canisterless single-use NPWT system — i.e. no external fluid collection container. Fluid is managed within the dressing (absorbent layers + evaporation).
  – Portable, battery-operated pump (small, lightweight) meant for up to 7 days of therapy.
  – Delivers nominal pressure of –80 mmHg.

- Materials & components
  – Absorbent dressing layers: reticulated open-cell foam, or multilayer nonwoven fabrics with high fluid-wicking capacity.
  – Outer drape: high-moisture vapor transmission rate (MVTR) film + adhesive border (often silicone / hydrocolloid hybrid) to maintain seal while allowing vapor escape.
  – Pump & enclosure: small polymer shell containing microcontroller, small motor, battery, and control electronics.
  – Fixation strips (adhesive tapes) around the dressing periphery to hold drape down.

- Regulatory & performance notes
  – The FDA 510(k) document confirms intended uses: chronic wounds, grafts, dehisced wounds, closed surgical incisions, etc.
  – It’s cleared to manage low to moderate levels of exudate (not heavy exudate).
  – Because there is no canister, dressing saturation becomes the limiting factor — performance depends heavily on absorbent capacity / evaporation rate.

Application & Limitations for Microtia Reconstruction

- Advantages in microtia applications
  – The compact, canisterless design is very appealing for a headband form factor: minimal external bulk.
  – Suitable for low-to-moderate exudate wounds, which aligns well with small auricular wounds.
  – Because it’s single-use, you get a “plug-and-play” dressing which could reduce handling complexity in surgical settings.
  – The lower pressure (–80 mmHg) is gentler and may reduce risk of pressure damage to cartilage or thin flaps.

- Challenges to address / limitations
  – Absorbent capacity is limited; if exudate exceeds capacity, vacuum loss occurs — your design may need a sensor to detect saturation or overflow safety path.
  – The off-the-shelf dressing shapes are rectangular and may not conform well to ear contours; custom shaping or flexible foam is needed to avoid leaks.
  – The pump is designed for planar wounds; microtia geometry may cause pressure gradients or dead zones unless the foam is engineered to distribute suction evenly.
  – The standard –80 mmHg may not provide sufficient granulation stimulation for deeper cartilage exposures; your headband might incorporate adjustable pressure up to –125 mmHg.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our first prototype

11/15/2025 - NPWT for Exposed Microtia Cartilage Framework

HARSHAD GUNASEKAR - Dec 10, 2025, 7:48 PM CST

Title: NPWT For Exposed Microtia Cartilage Framework

Date: 11/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out that NPWT Devices are already on the market and what features they include.

Citation: K. Sasaki *et al.*, “Salvaging exposed microtia cartilage framework with negative pressure wound therapy,” *J. Plast. Reconstr. Aesthetic Surg.*, vol. 74, no. 6, pp. 1355–1401, 2021, doi: 10.1016/j.bjps.2020.11.010. https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2021.766599/full?

Content:

- Retrospective study of 7 exposure wounds in 6 microtia patients whose costal-cartilage ear frameworks became exposed after reconstruction.
- Exposure of the cartilage framework is highlighted as one of the most severe complications in microtia reconstruction because it risks infection, necrosis, and total framework loss.
- NPWT was used as a salvage method instead of immediate flap coverage or framework removal, showing that suction therapy can stabilize very delicate auricular reconstructions.
- The authors report that all wounds ultimately healed with preservation of the cartilage framework, supporting that carefully controlled negative pressure can be safe for cartilage.
- Wound sizes were relatively small (mm-scale), but located on critical surfaces of the ear (helix, antihelix, etc.), making sealing and contour conformity challenging — similar to your project constraints.
- NPWT settings included continuous sub-atmospheric pressure (exact ranges in the full text), demonstrating that continuous, not just intermittent, suction can be used on ear cartilage when pressures are chosen appropriately.
- They emphasize how NPWT reduces edema, removes exudate, and encourages granulation over exposed cartilage, all of which are key mechanisms your ear-specific device is trying to harness.
- Dressing application over the ear required careful protection of the surrounding skin and the cartilage framework, implying the need for geometry-specific foams/films rather than flat dressings.
- The paper notes that reports of NPWT in microtia are still scarce, which frames your device as addressing an underserved design space with high potential impact.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our revised prototype

11/15/2025 - NPWT in the Head and Neck (Techniques & Uses)

HARSHAD GUNASEKAR - Dec 10, 2025, 7:59 PM CST

Title: NPWT For Exposed Microtia Cartilage Framework

Date: 11/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out that NPWT Devices are already on the market and what features they include.

Citation: R. M. Liebman, K. S. Hanubal, and P. T. Dziegielewski, “Negative Pressure Wound Therapy in the Head and Neck: A Summary of Uses and Application Techniques,” *Semin. Plast. Surg.*, vol. 37, no. 1, pp. 9–18, 2023, doi: 10.1055/s-0042-1759562. https://pubmed.ncbi.nlm.nih.gov/36776812/

Content:

- This is a review focused specifically on NPWT in head and neck surgery, making it directly relevant to auricular and facial applications.
- It summarizes NPWT use after free-flap reconstruction, skin grafting, fistula management, and necrotizing infections in complex head/neck wounds.
- A core challenge they highlight is that head and neck anatomy is highly contoured, which makes achieving an airtight seal difficult — exactly the engineering problem your ear-dressing is solving.
- The authors describe practical techniques to maintain a seal (e.g., bridging foam, “window” dressings, use of stoma paste or hydrocolloid strips), showing that clinicians currently improvise with generic materials.
- They conclude NPWT is generally safe and effective in this region, with low complication rates when appropriately monitored, strengthening your safety rationale.
- The paper reviews evidence that NPWT can reduce time to closure, improve granulation, and control infection in head and neck wounds — benefits that would be desirable around an ear reconstruction.
- It notes that compromised patients (irradiated tissue, oncologic resections) still benefit from NPWT, but that more high-quality trials are needed, suggesting an opportunity for future clinical studies of your device.
- They emphasize pressure selection and interface protection to avoid damage to critical structures (nerves, exposed vessels), informing your choice of a gentle pressure range and soft interface materials.
- The authors cite multiple case series where NPWT dressing was used as a bolster for skin grafts in the head/neck, analogous to stabilizing a skin graft over a reconstructed ear.
- For your notes: this article frames your ear device as a specialized head-and-neck NPWT accessory that mechanizes what surgeons are currently doing with manual improvisation.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our revised prototype

9/10/2025 - NWPT Introduction

HARSHAD GUNASEKAR - Sep 24, 2025, 12:27 PM CDT

Title: Negative Pressure Wound Therapy Introduction

Date: 9/24/25

Content by: Harshad Gunasekar

Goals: Gain backround knowledge about Negative pressure Wound Therapy

Citation:

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. 10, 2025).

Content:

Quick scope & updates

- **Purpose:** Optimize management of traumatic soft-tissue wounds using NPWT in the aeromedical evacuation (AE) environment; focuses on device basics, troubleshooting, and bleeding management en route.
- **What’s new:** Impact suction device replaced by **Zoll 330 Multifunction Aspirator**; added troubleshooting algorithms for **leak, obstruction, bleeding**.
- **Approved AE device: KCI VAC Freedom** is the only flight-approved commercial NPWT system (others require waiver; the Zoll 330 can be used as the suction source).

Why NPWT for AE

- Benefits: decreases edema, increases local blood flow, speeds healing; useful for temporary abdominal/chest closures post-damage control surgery. Bacterial count reduction is **not** reliably demonstrated.
- Practical advantages: dressings can stay 24–72 h → **less labor-intensive** and allow **accurate output measurement**(important for resuscitation).

Core components (what’s in the dressing)

- **Porous material:** usually ROCF foam (KCI), sterile gauze, or towels—cut to fit so negative pressure distributes evenly.
- **Occlusive dressing:** airtight seal on intact skin; dry skin + consider benzoin/Mastisol; Ioban/Tegaderm or KCI sheets.
- **Suction conduit:** tubing to pump; KCI uses SensaT.R.A.C. (“lily pad”).

Operating settings you’ll see

- **Mode:** Continuous is standard for most wounds; intermittent cycles between suction and zero.
- **Pressure:** Typically **–125 mmHg** continuous; **–75 mmHg** may be used for skin grafts.
- **Intensity:** 0–10 (how aggressively pump reaches set pressure); tweak for pain while maintaining therapy goals.

PREFLIGHT NPWT checklist (8 things to confirm)

1. **Know the wound:** Incisional VAC (fascia closed) vs **TAC/open abdomen (AbThera)**—failure of incisional VAC can go to wet-to-dry; TAC failure risks **evisceration**.

2. **Airtight seal:** Dressing should look **collapsed/firm** under suction; if not, examine and repair before departure.
3. **Leak risk areas:** Edges, skin folds, creases, hair; address before leaving MTF.
4. **Fluid under dressing:** If fluid is pooling, the dressing will separate → loss of suction and leakage; fix before flight.
5. **Extra supplies:** Ioban/Tegaderm, benzoin, bubble tubing, Y-connectors/“football” connectors, razor, spare canisters, etc.
6. **Canister planning:** KCI canisters are small (**300 mL**) and **not reusable**; estimate needs from prior 24 h output. If using **Zoll 330**, its canister is **larger** and can be emptied/reused if necessary.
7. **Failure plan:** Pre-brief surgeon on acceptable conversion to wet-to-dry (smaller, low-output wounds) if equipment issues arise.
8. **Power/outlets:** ECAS may have only **4–7 outlets per patient**; each VAC Freedom draws ~**1 A**. Rotate charging; Ranger Glidescope power cable is compatible with KCI VAC Freedom if shortages occur.

Conclusions/action items:

- Research further NPWT devices and other standards we need to maintain

- Understand the Ritedectomy more, what type of incisions are popular? How long are they? etc.

- Find the constraints. Why hasn't this been made already to support this procedure? What is holding people back?

HARSHAD GUNASEKAR - Sep 24, 2025, 12:27 PM CDT

https://jts.health.mil/assets/docs/cpgs/NPWT_CCATT_26_Feb_2025.pdf

9/10/2025 - NWPT In Facial Setting

HARSHAD GUNASEKAR - Sep 24, 2025, 12:35 PM CDT

Title: NWPT In a Facial Setting

Date: 9/10/25

Content by: Harshad Gunasekar

Goals: Understand why this has not been introduced for ritedectomies yet. What are the limitations that we have to work around?

Content:

How NPWT promotes healing (mechanisms to remember)

- **Macrodeformation:** foam compresses → **wound edges drawn together**.
- **Microstrain / mechanotransduction:** cells pulled into foam pores → **fibroblast & epithelial proliferation**, ECM production.
- **Fluid removal & edema reduction:** improved **perfusion/lymphatic drainage**; stabilizes wound microenvironment.
- **Bacterial burden:** may be **reduced**, mechanism not fully defined (evidence mixed).
- **Secondary effects:** NPWT supports **VEGF gradients/angiogenesis**, thermal insulation (moist environment), and has been associated with **changes in gene expression** (↑ IL-8, IL-24; MMP1/3/10) and **shorter wound-closure/hospital durations** in some studies.

Why head & neck is tricky (key cautions)

- **Sealing challenges:** complex contours; proximity to **eyes, nose, mouth, ears** → avoid direct negative pressure on these structures; protect them if temporarily covered. **More frequent dressing changes (often daily)** may be needed to maintain seal.
- **Underlying pressure transmission:** sub-atmospheric surface strain can **increase pressure in underlying tissues**; pressure tends to attenuate over ~48 h—**use caution near delicate vasculature or dura/brain** and ensure watertight CSF closure before use.

Where NPWT is used in maxillofacial practice (applications & examples)

- **Upper third (scalp/forehead):** temporization of traumatic/contaminated defects; adjunct for soft-tissue coverage.
- **Complex head/neck soft-tissue defects:** adjunct with **skin grafts, Integra®**, or open debrided wounds; retrospective series (n=69, 73 wounds: **86% cancer**, 8% trauma, 3% infection, 3% burns) reported **minor complications** in 56% (grafts), 33% (Integra), 29% (open wounds), mostly managed with follow-up.
- **Exposed cranial/mandibular hardware or calvarial bone:** case reports support VAC to manage exposure and prepare for reconstruction.
- **Fistulas:**
  - **Salivary/orocutaneous fistula closure:** series using **dental paste intraorally** to help seal achieved closure in **9/10** patients.
  - **Cervical esophageal perforation with abscess:** NPWT used successfully as adjunct management (case report).
- **After oncologic resection / osteoradionecrosis,** NPWT is reported to aid soft-tissue management and fistula control in selected cases.

Practical pearls for head & neck NPWT (technique)

- **Seal strategies:** meticulous skin prep; sculpt foam to contours; use bridging, barrier films, pastes (e.g., **dental paste intraorally**) to achieve airtight occlusion—especially near mucosal openings.
- **Protect critical structures: minimize/avoid direct suction** over eyes and other sensitive areas; pad and shield as needed.

- **Change interval:** consider **daily** changes if seal integrity is tenuous in the head/neck.

Evidence snapshot called out by the review

- Early VAC studies (Argenta & Morykwas) showed accelerated granulation with –75 to –125 mmHg and the now-standard **foam+drape+tubing+canister+pump** architecture.
- Subsequent reports in head/neck are largely **case reports/series**; overall signal supports **safe, effective adjunct use when** seals are achievable, with most complications manageable conservatively.

Conclusions/action items:

- Start designing ideas to get around Ears as main obstacle to create seal

- Research more about NWPT and other ways the same result can be achieved, Wound Drain, etc.

- Research materials for most successful NWPT and how the seal is made with teh skin despite contours and hair

10/1/2025 - Salvaging exposed Microtia cartilage framework with negative pressure wound therapy

HARSHAD GUNASEKAR - Oct 15, 2025, 11:23 AM CDT

Title: Salvaging exposed microtia cartilage framework with negative pressure wound therapy

Date: 10/1/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Understand what needs to be done with the cartilage under the skin using NPWT

Citation: K. Sasaki, Y. Hata, M. Kinoshita, Y. Fukumoto, and N. Matsumoto, “Salvaging exposed microtia cartilage framework with negative pressure wound therapy,” *J. Plast. Reconstr. Aesthet. Surg.*, vol. 74, no. 2, pp. 324–330, Feb. 2021PubMed

Content:

- Retrospective study on 6 patients (7 wounds) with cartilage exposure following microtia reconstruction.
- NPWT applied at continuous pressure between −25 and −125 mmHg.
- All wounds successfully healed within 8–39 days without secondary grafting.
- Device sealed over irregular auricular surfaces using foam dressing and transparent adhesive drape.
- Results: Rapid granulation tissue formation and epithelialization observed.
- Complications: Mild framework atrophy in some cases; one partial loss due to infection.
- Demonstrated NPWT’s ability to maintain local perfusion and remove exudate in delicate auricular tissue.
- Supports the feasibility of NPWT for cartilage exposure where conventional closure is difficult.
- Clinical takeaway: Short-term, low-to-moderate negative pressures can rescue microtia frameworks from failure.

Conclusions/action items:

- Research more ways NPWT can be used in Microsurgical Reconstruction Surgery

- Apply research to design ideas

- Research other possible ways to acheive same result without NPWT? Maybe more Efficient?

10/1/2025 - Salvaging exposed Microtia cartilage framework with negative pressure wound therapy (copy)

HARSHAD GUNASEKAR - Oct 15, 2025, 11:25 AM CDT

Title: Salvaging exposed microtia cartilage framework with negative pressure wound therapy

Date: 10/1/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Understand what needs to be done with the cartilage under the skin using NPWT

Citation: C. Lorca-García, A. Alfaro-Rubio, and J. L. García-Medrano, “Use of innovative negative pressure therapy for cartilage exposure in microtia reconstruction,” *J. Plast. Reconstr. Aesthet. Surg.*, vol. 72, no. 5, pp. 847–850, May 2019.https://www.jprasurg.com/article/S1748-6815(18)30409-1/abstract?utm

Content:

Journal of Plastic, Reconstructive & Aesthetic Surgery (case report)

- Focused on developing a portable NPWT system for pediatric microtia patients.
- Addressed the challenge of maintaining an airtight seal on curved, irregular auricular surfaces.
- Designed a compact device with low-noise pump and flexible silicone dressing.
- Negative pressure promoted angiogenesis and debridement of necrotic tissue over exposed cartilage.
- Advantages noted:
    - Greater patient comfort and mobility.
    - Ability to continue therapy in outpatient settings.
- Provided design insight for portable or wearable NPWT concepts.
- Reinforces that continuous suction (−75 to −100 mmHg) is effective even with small surface areas.
- Highlights engineering considerations: dressing flexibility, seal reliability, tubing orientation, and patient compliance.

Conclusions/action items:

- Research more ways NPWT can be used in Microsurgical Reconstruction Surgery

- Apply research to design ideas

- Research other possible ways to acheive same result without NPWT? Maybe more Efficient?

10/5/2025 - Ploymeric Biomaterials for Wound Dressing

HARSHAD GUNASEKAR - Oct 15, 2025, 11:53 AM CDT

Title: Ploymeric Biomaterials for Wound Dressing

Date: 10/5/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Get an understanding of what direction wound dressings are going in terms of innovations in the industry

Citation: L. G. Fernández, J. C. de la Fuente, S. L. Ferrando, *et al.*, "Use of a novel silicone-acrylic drape with negative pressure wound therapy," *Eur. J. Plast. Surg.* (or equivalent NPWT specialty journal), 2020.https://biomaterialsres.biomedcentral.com/articles/10.1186/s40824-022-00291-5?utm

Content:

- Scope & Motivation
  – This is a review bridging clinical wound-dressing needs and polymer material science.
  – Emphasizes the gap between "what clinicians want" (e.g. conformality, biocompatibility, exudate handling) and "what materials can currently provide."

- Classification of biomaterial types
  – Synthetic polymers (e.g. polyesters, polyurethanes)
  – Natural polymers (e.g. collagen, alginate, chitosan)
  – Inorganic / composite materials (e.g. bioactive glass, ceramics)
  – Hybrid / composite systems (polymer + filler) to combine mechanical strength, bioactivity, and degradation behavior.

- Critical properties for wound dressings
  – Porosity & pore size: optimum pore networks facilitate cell infiltration, fluid drainage, and gas exchange.
  – Mechanical compliance / modulus: must balance being flexible (to conform to curved shapes) and robust (resist collapse under negative pressure).
  – Biocompatibility & non-cytotoxicity: no harmful leachables, minimal foreign body response.
  – Degradation / resorption rates (for biodegradable dressings) tuned to match healing timeline.
  – Surface chemistry / bioactivity: e.g. incorporation of peptides, growth factors, or micro/nano topographies to promote cell adhesion or anti-bacterial behavior.
  – Fluid management / swelling capability: ability to absorb exudate while maintaining structural integrity.

- Material trade-offs & challenges
  – Highly porous scaffolds may be mechanically weak.
  – Adding fillers or cross-linkers can improve stiffness but may reduce pore interconnectivity or increase brittleness.
  – Sterilization, manufacturability, cost, and regulatory constraints often limit lab-ideal materials from translation.
  – Need for materials that can maintain function under *cyclical loading* (pumping, suction) in NPWT.

- Relevance to headband / dressing design
  – For auricular / curved surface design, wewant flexible, conformal polymers or hybrid composites that can bend without delaminating under suction.
  – Consider composites (e.g. polymer + nano-filler) to add antimicrobial or conductive features.

Conclusions/action items:

- Research more biomaterials for the design

- Keep track of possible options to put into another design matrix to evaluate the best options

- Ask clients which materials they recommend going with for the problem, anything past the materials they've already given us?

10/5/2025 - Use of a novel silicone-acrylic drape with NPWT

HARSHAD GUNASEKAR - Oct 15, 2025, 11:45 AM CDT

Title: Use of a novel silicone-acrylic drape with NPWT

Date: 10/5/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Get an understanding of what direction wound dressings are going in terms of innovations in the industry

Citation:

L. G. Fernández, J. C. de la Fuente, S. L. Ferrando, *et al.*, "Use of a novel silicone-acrylic drape with negative pressure wound therapy," *Eur. J. Plast. Surg.* (or equivalent NPWT specialty journal), 2020..https://pmc.ncbi.nlm.nih.gov/articles/PMC7754137/

Content:

- Context / Need
  – In NPWT, an occlusive drape / adhesive seal is critical to maintain vacuum. Conventional drapes use acrylic adhesives over polyurethane films.
  – On complex or curved anatomical sites (like ear contours), standard drapes may leak. This article investigates a silicone-acrylic hybrid drape to improve seal performance.
- Materials & construction
  – The hybrid drape uses a silicone-based interface layer coupled with acrylic adhesive to combine the gentleness / flexibility of silicone with strong adhesion of acrylic.
  – The silicone interface reduces shear damage when removing or shifting the drape, especially important on delicate skin or curved surfaces.
-
- Performance / Results
  – Demonstrated better resilience to shear or traction stresses compared to purely acrylic drapes.
  – Lower incidence of seal loss/leakage in challenging geometries.
  – Compatibility with standard NPWT foam/suction configuration.
- Design implications for our design
  – Using a silicone-acrylic hybrid seal may greatly improve seal reliability on the curved auricular shape of your headband/dressing.
  – Consider optimizing thickness, adhesive strength gradient, and interface shape to reduce edge peeling.
  – Also suggests that the drape is just as important (if not more) than the internal foam/dressing in keeping the vacuum stable.

Conclusions/action items:

- Research more biomaterials for the design

- Keep track of possible options to put into another design matrix to evaluate the best options

- Ask clients which materials they recommend going with for the problem, anything past the materials they've already given us?

10/5/2025 - Polyurethane-Related Dressings for Skin Wound Repair

HARSHAD GUNASEKAR - Oct 15, 2025, 11:54 AM CDT

Title: Polyurethane-Related Dressings for Skin Wound Repair

Date: 10/5/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Get an understanding of what direction wound dressings are going in terms of innovations in the industry

Citation:

W. Liang, H. Xiao, and Y. Bao, “Polyurethane-related dressings for skin wound repair,” *Polymers*, vol. 15, no. 21, art. 4301, 2023.https://www.mdpi.com/2073-4360/15/21/4301?utm_source=chatgpt.com

Content:

- Overview & motivation
  – Polyurethane (PU) is a widely used synthetic polymer in wound dressings, due to its mechanical tunability, biocompatibility, and durability.
  – However, standard PU dressings may lack dynamic adaptability as healing conditions change. This article reviews composite / multifunctional PU dressings enhancements.

- Strategies for functional enhancement
  – Incorporation of natural polymers or bioactive agents: e.g. collagen, chitosan, hyaluronic acid added to PU to improve cell affinity.
  – Addition of fillers / nanoparticles: e.g. silver nanoparticles for antimicrobial action, bioactive ceramics, growth factor carriers.
  – Responsive / stimuli-sensitive modifications: PU dressings that change shape, modulus, or porosity in response to pH, moisture, or temperature changes (to adapt to wound microenvironment).
  – Composite layering: layered PU + hydrogel or PU + foam to integrate different functionalities (mechanical support + fluid absorption).

- Advantages / strengths of PU systems
  – Broad mechanical tunability (soft to stiff) by adjusting polymer chemistry.
  – Durability under cyclic loading (important under alternate suction cycles).
  – Good film-forming properties, potential for thin, conformal dressings.
  – Capability to combine multiple agents (antibacterial, growth factors) in a single scaffold.

- Limitations / challenges
  – Some composite or loaded PUs may degrade or delaminate in moist, enzymatic wound environments.
  – Balancing porosity vs. mechanical integrity is always a trade-off.
  – Ensuring uniform dispersion of functional additives or nanoparticles to avoid weak zones.

- Design relevance / suggestions
  – A PU-based outer shell in your headband dressing could provide structural integrity and support the suction environment.
  – Can embed antimicrobial nanoparticles or microchannels in the PU to manage fluid flow.
  – Use adaptive PU composites that change compliance as the wound heals (so your dressing doesn’t become overly stiff or loose).
  – Benchmark your prototypes against properties (e.g. modulus, tensile strength, swelling) reported in this review.

Conclusions/action items:

- Research more biomaterials for the design

- Keep track of possible options to put into another design matrix to evaluate the best options

- Ask clients which materials they recommend going with for the problem, anything past the materials they've already given us?

11/15/2025 - Biomedical Materials for Wound Dressing

HARSHAD GUNASEKAR - Dec 10, 2025, 8:04 PM CST

Title: Biomedical Materials for Wound Dressing

Date: 11/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out what dressing choices are already on the market and what features they include.

Citation: H. M. Nguyen, T. T. N. Le, A. T. Nguyen, H. N. T. Le, and T. T. Pham, “Biomedical materials for wound dressing: Recent advances and applications,” *RSC Adv.*, vol. 13, no. 8, pp. 5509–5528, 2023, doi: 10.1039/d2ra07673j.https://pubs.rsc.org/en/content/articlelanding/2023/ra/d2ra07673j

Content:

- This review surveys **all major classes of wound dressing materials**: traditional gauze, films, foams, hydrocolloids, alginates, hydrogels, bioactive, and “smart” dressings
- It explains the **phases of wound healing** (hemostasis, inflammation, proliferation, remodeling) and aligns material requirements (moisture, oxygen, mechanical protection) with each phase.
- The paper provides **property comparisons** (e.g., absorption, MVTR, conformability, transparency), which can help you justify why you selected specific materials for the ear vs. what alternatives you rejected.
- Hydrogels and alginate dressings are identified as strong moisture managers but sometimes are **mechanically weak**, which is important when you need a dressing that will not collapse under NPWT suction.
- Foams and films (often PU-based) are reported to have **good cushioning and moderate to high absorbency**, making them suitable as interface layers or backing layers paired with NPWT.
- The authors discuss **antimicrobial strategies** (silver, iodine, PHMB, chitosan, etc.), noting both benefits and cytotoxicity concerns, which is useful if you plan to comment on infection control around the reconstructed ear.
- There is emphasis on **patient comfort and ease of use** (atraumatic removal, flexibility), a key consideration for your auricular device that will sit on mobile skin near hair and cartilage.
- The review points out current trends such as **bioactive dressings and stimuli-responsive materials**, laying conceptual groundwork for future iterations of your design (e.g., dressings that release drugs as pressure or pH changes).
- Limitations of existing dressings include **inadequate customization for patient-specific anatomy** and limited ability to simultaneously handle mechanical load, fluid management, and infection control — exactly the gap your ear-specific NPWT system aims to fill.
- Use this article to build **comparison tables** in your Materials folder (columns: class of dressing, advantages, disadvantages, relevance to ear NPWT) and to show that your chosen material stack is evidence-based.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our revised prototype

11/20/2025 - Conventional vs Silicone-Adhesive PU Foam Dressings

HARSHAD GUNASEKAR - Dec 10, 2025, 8:06 PM CST

Title: Conventional vs Silicone-Adhesive PU Foam Dressings

Date: 11/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out what dressing choices are already on the market and what features they include.

Citation: H. J. Ha, J. Y. Yang, C. W. Kim, S. H. Jeong, and E. Hwang, “Comparison of Satisfaction Levels between Conventional and Silicone-Adhesive Polyurethane Foam Materials in Patients with Skin Wounds,” *J. Wound Manag. Res.*, vol. 17, no. 3, pp. 163–168, 2021, doi: 10.22467/jwmr.2021.01529. https://www.koreamed.org/SearchBasic.php?RID=2521677&

Content:

- Prospective or observational study (n≈100+; exact number in full text) comparing **standard PU foam dressings** vs **silicone-adhesive PU foam** in patients with various skin wounds.
- Patients and clinicians rated **satisfaction, comfort, pain on removal, waterproofness, and ease of application**; silicone-adhesive foam scored higher on most patient-comfort metrics.
- Conventional foam dressings, fixed with strong tape, provided high adhesion but caused **more pain and skin trauma** on removal, especially in sensitive areas.
- Silicone-adhesive PU foams showed **atraumatic removal** and better tolerance in patients with fragile or aging skin, highlighting their value near delicate structures like the ear and face.
- The study found that silicone-adhesive dressings were perceived as **more waterproof**, improving daily-life usability (showering, sweating), which is important for a device sitting around the ear.
- Despite softer adhesion, silicone foams still provided **adequate fixation** for routine wound care — suggesting that, coupled with NPWT suction, they could maintain an ear seal without aggressive tapes.
- Clinicians reported **less periwound maceration and irritation** with silicone adhesives, implying better long-term skin health under your dome.
- From a design standpoint, this supports using a **silicone contact layer or silicone-coated PU film** at the skin–device interface to maximize comfort and minimize dressing-change trauma.
- It also informs your **human-factors section**: patients are more likely to adhere to therapy if dressing changes are less painful and the system feels secure and waterproof.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our revised prototype

11/20/2025 - Multifunctional Polymeric Wound Dressings

HARSHAD GUNASEKAR - Dec 10, 2025, 8:08 PM CST

Title: Multifunctional Polymeric Wound Dressings

Date: 11/15/2025

Content by: Harshad Gunasekar

Present: Harshad Gunasekar

Goals: Find out what dressing choices are already on the market and what features they include.

Citation: Z. Soylu, B. Oktay, A. Erarslan, and E. A. Özerol, “Multifunctional polymeric wound dressings,” *Polymer Bulletin*, vol. 82, pp. 5325–5383, 2025, doi: 10.1007/s00289-025-05753-z.https://link.springer.com/article/10.1007/s00289-025-05753-z?

Content:

- Review paper focusing on **“multifunctional” dressings** that combine structural, biological, and therapeutic functions (e.g., mechanical support + antimicrobial + pro-healing factors).
- It describes how traditional dressings mainly provide **passive coverage**, while newer polymeric systems actively modulate the wound environment (release drugs, respond to stimuli, or support cell growth).
- The authors categorize multifunctional dressings by **base polymer (PU, PCL, chitosan, alginate, PEG, etc.)** and by fabrication method (electrospinning, solution blow spinning, 3D printing).
- They emphasize the importance of **porous architecture and interconnected pores** for fluid management and tissue integration — highly relevant for designing a suction interface that distributes NPWT evenly over an ear.
- Many examples integrate **antimicrobial agents, growth factors, antioxidants, or anti-inflammatory drugs** into the polymer matrix, demonstrating how a single dressing can address infection, inflammation, and regeneration simultaneously.
- Smart dressings discussed can be **stimuli-responsive** (pH, temperature, enzymatic activity), which could theoretically signal infection or loss of seal under an NPWT dome.
- The review notes challenges: **compatibility between multiple additives**, maintaining mechanical strength, achieving controlled release, and ensuring manufacturability at scale.
- For your project, this article is perfect for a **“future directions”** section: you can argue that your current ear dressing focuses on geometry + NPWT integration, while future versions could incorporate **multifunctional polymer layers** to reduce infection and accelerate healing.
- It also supports exploring **solution-blow-spun or electrospun polymer meshes** that conform intimately to the ear’s 3D shape, giving more uniform pressure than a solid block of foam.

Conclusions/action items:

- Implement findings into making our final design

- Draft another design matrix with competing features to evaluate the best option for the team

- Start fabrication of our revised prototype

09/23/2025 -Design Ideas

HARSHAD GUNASEKAR - Sep 23, 2025, 7:31 PM CDT

Title: Design Ideas

Date: 9/23/2025

Content by: Harshad

Present: Whole team

Goals: Come up with Design Ideas for the team meeting coming up

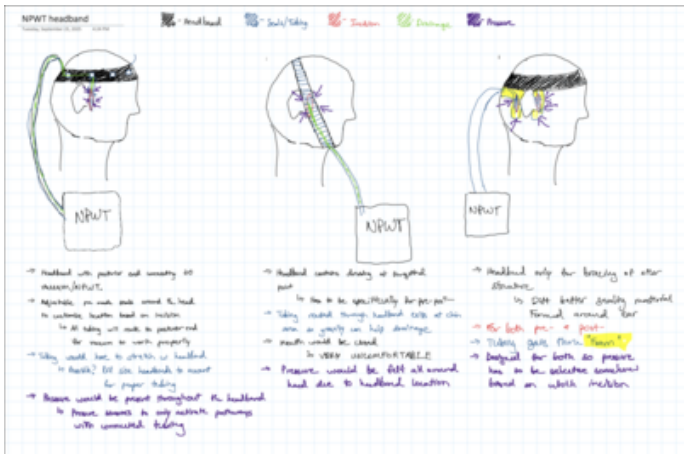
Content:

Design Ideas

Conclusions/action items:

- Present Design Ideas at the team meeting
- Start design matrix
- Make necessary revisions to design matrix

HARSHAD GUNASEKAR - Sep 23, 2025, 7:31 PM CDT



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Screenshot_2025-09-23_at_7.08.38_PM.png (1.53 MB)

10/28/25- New Training Documentation

HARSHAD GUNASEKAR - Oct 30, 2025, 10:04 AM CDT

Title: Animal User Orientation Training

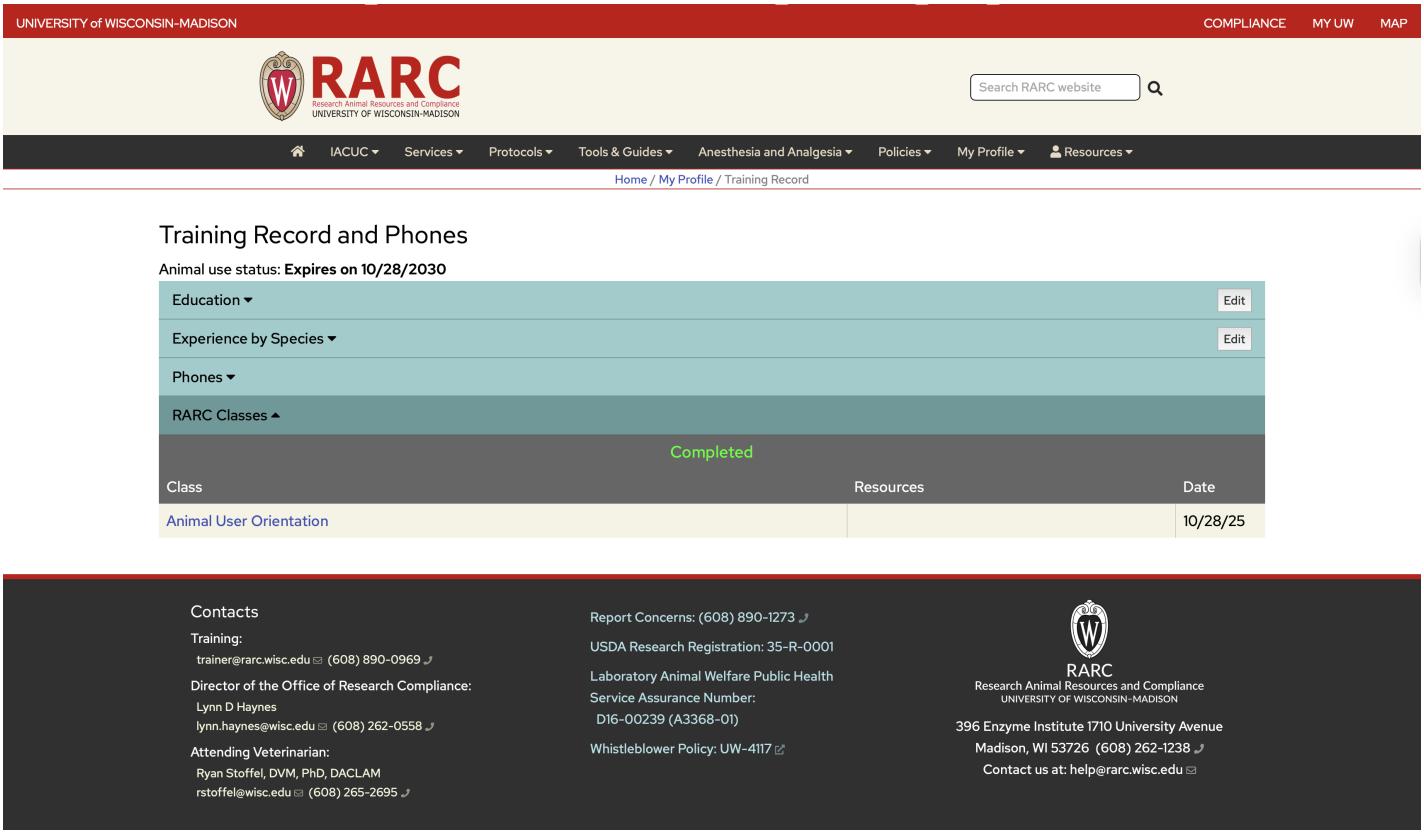
Date: 10/28/25

Content by: Harshad Gunasekar

Present: N/A

Goals: Required Training

Content:



Conclusions/action items: N/A

10/28/25- Overall Training Documentation

HARSHAD GUNASEKAR - Oct 30, 2025, 10:06 AM CDT

Title: Overall Training Documentation

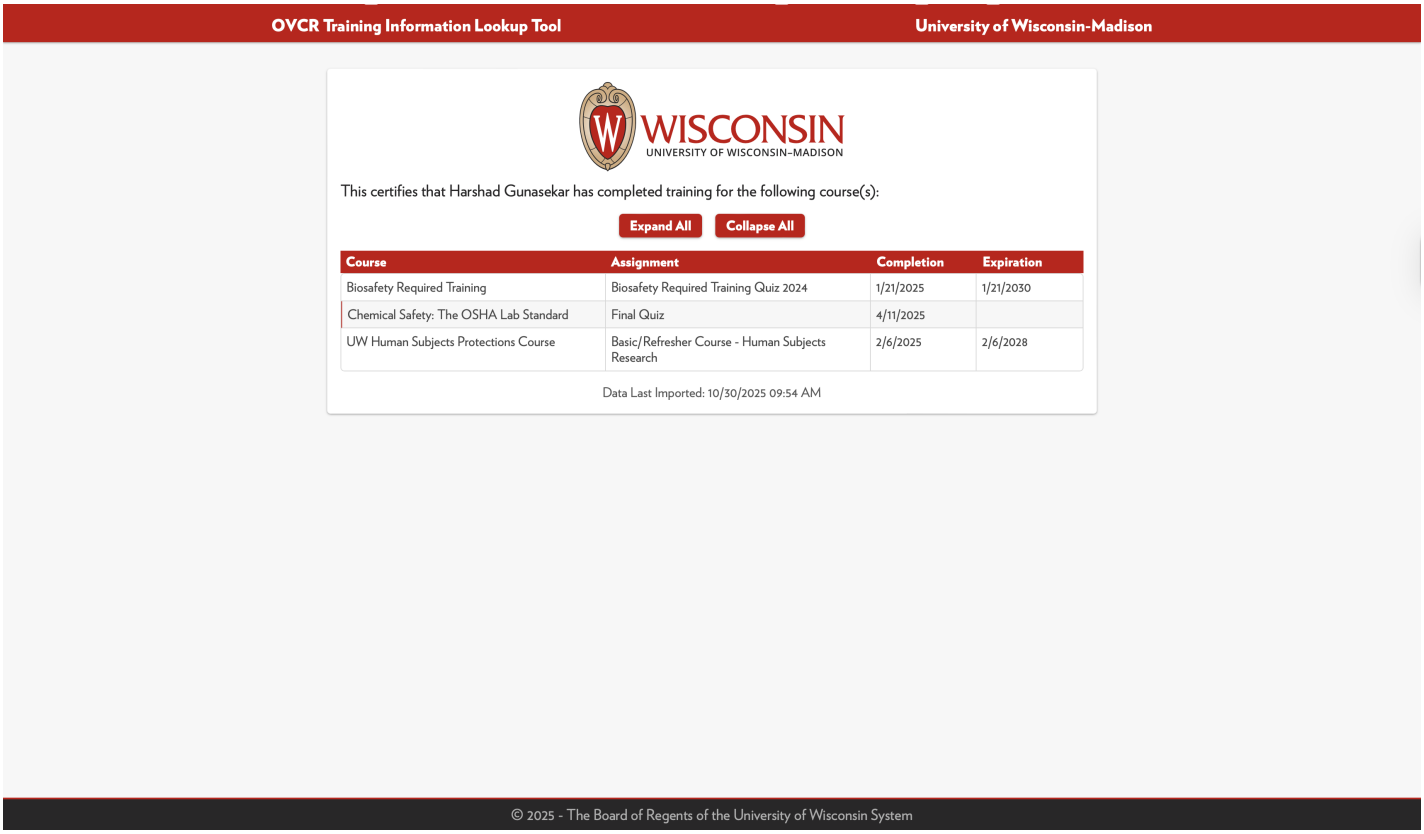
Date: 10/28/25

Content by: Harshad Gunasekar

Present: N/A

Goals: Required Training

Content:



Conclusions/action items:

- RARC Animal Training not showing up on overall record

11/07/2025 - Tong Lecture

HARSHAD GUNASEKAR - Nov 07, 2025, 12:42 PM CST

Title: Tong Lecture - Kristen Myers

Date: 11/7/2025

Content by: Harshad Gunasekar

Present: All of BME Design

Goals: Take notes

Content:

"Run towards the hard problems... they are the ones that change the world"

"Combine EQ with IQ to multiply impact and reach"

"Drive system-level impact through innovation and scale"

"Follow hard problems and build skills that all you to make an impact"

Work Hard and Build Range

- Take on the hardest projects, classes, and experiences you can find. Effort and range are your foundation

Go out and see everything to figure out what you like to do

Seek diverse Exposure

- Explore different sectors, teams,\ and geographies. Gain perspective and learn how systems connect, not just how parts work

Choose your people wisely

- Surround yourself with curious, driven, high-integrity people. They will shape who you will become

Know your values and protect them

- Define what matters most: family. friends, health, career/impact values - and make decisions that align

Embrace challenge and keep growing

- Run towards the hard problems. Growth lives on the edge of discomfort

Conclusions/action items:

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: