BME Design-Fall 2019 - Jurnee Beilke
Complete Notebook

PDF Version generated by

ELIZABETH SCHMIDA

on

Dec 10, 2019 @09:01 PM CST

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▪ Jack Fahy ▪ Dec 03, 2019 @10:29 PM CST

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Project description

▪ Jurnee Beilke ▪ Sep 24, 2019 @09:55 PM CDT

Course Number: BME 400

Project Name: Wound Edge Approximation

Short Name: Wound Edge

Project description/problem statement:

Over 6 million laceration cases are treated in emergency departments each year; during such repairs, skin tension pulls the wound apart while the provider is attempting to approximate the wound edges. Repair is therefore difficult, and imperfect approximation can lead to scarring and poor healing of the wound. This problem is often not an issue within operating rooms on larger wounds; however, it poses a challenge for physicians in emergency rooms, urgent care clinics, and office settings on smaller wounds ranging from 1-5 cm. A clinical tool will be developed to hold the wound edges together while the wound is either sutured or glued, acting as a "second pair of hands" for the physician. The device may consist of a bow-shaped design to pinch the skin together or velcro-like tool that functions by pulling the wound edges together for physicians to repair. The final design must be easy to use by physicians and must not impart any pain or markings onto the patient's skin during use.

About the client: Dr. Charlton specializes in family medicine at the Aurora Health Center in Milwaukee and is an assistant faculty member at the UW School of Medicine and Public Health.

09/17/19 Client Meeting

▪ Jurnee Beilke ▪ Sep 17, 2019 @10:16 PM CDT

Title: Introductory Client Meeting

Date: 09/17/19

Content by: Jurnee

Present: All Team

Goals: To introduce ourselves to the client and gain a background understanding of the project.

Content:

- Problem: lacerations splay apart
    - Need a second person to hold the wound together while the wound is closed by glue or sutures
    - Glue hardens in 30 seconds, so someone is needed to hold the skin edges together for the glue to be applied
    - Important device over a joint to make sure the edges are approximated (wound edges separate wider over a joint)
    - Improper approximation can lead to scarring
    - Small wounds may not spread apart as much as larger wounds (over 1-2 cm)
    - Larger wounds are more likely to splay apart
- Design
    - Plastic (potentially) clips that hold the wound edges together while the wound is closed with glue
    - Possibly redesigning the tips for DermaGlue/DermaBond (new project)
        - Brush end would work better than the drip end where it does not flow out of the device
    - Device must be user friendly - one person to use and close wound
    - Design must be far enough out of the way to not get glue on the device - acetone removes glue
    - Simple sterilization (auto-clave) is needed to reuse the device
        - Heating and repackaged to be used again
    - Spring-loaded design (sextant navigator - engineering how example)
    - Click/lock into position once the skin comes together for gluing/wound closure
- Clinics and UC settings are cheaper for patients with milder wounds than ER or OR
- DermaBond and the new device will be used by people that cannot suture well or are in a rush
    - Glue can gain better outcome from wound healing than sutures (faster)
- Client will send fake skin for us to test and practice on
- Suturing requires numbing - suture ends to stabilize the wound and then suture in between the ends to close the wound
- DermaBond is best for minimal scarring - patient preferred
- Design primarily to be used with glue (DermaBond mini)
- Design - railroad DermaClip design for first round to stabilize the wound and glue at intermittent spaces and then remove device and run another layer of glue (velcro material)
- DermaBond Prineo skin closure system (22cm) video reference
- Target wound size over 2 cm wound - starts to splay/gap (1 cm over a joint) up to 2 inches in size
- 3M Steri-strip skin closure application video reference
- Possible design tape that is impregnated with DermaGlue
- DermaBond is used with 80% of wounds (no numbing needed like with suturing) - check statistic
- Sutures take longer than glue - not preferred in clinic setting
- Budget under thousands of dollars (client did not specify - probably a few hundred)
- Philips plastics - medical devices (option to get materials made)
- Client can supply steri-strips and DermaBond as well as fake skin
- SimLabs - fake skin provider
- Client info
    - Urgent care 140/day in Aurora
    - Family practitioner in MKE but faculty at UW Medical School in Phase 3 (more urban-oriented work)

Conclusions/action items:

The team now has a better understanding about the project, and we can move forward with our research and design brainstorming.

11/6/2019 Client Meeting

▪ ELIZABETH SCHMIDA ▪ Nov 09, 2019 @05:19 PM CST

Title: Client Meeting

Date: 11/6/2019

Content by: Lizzy

Present: All team members

Goals: Obtain client feedback from our rough prototype.

Content:

- Demonstrated how device will work on suture pad
- Patients being treated are usually laying down on the table so doctors have a clear line of sight with the lights above and behind them
    - if getting sutures/glue in arm, limb will be raised outward such that on horizontal plane
- Doesn't seem too keen on including a strap in the design
- Discussed her idea for an adhesive tape with one of the dermabond chemicals and using a brush to paint on the other chemical in order for reaction to take place and seal wound
    - may have to worry about heat from reaction
- DermaBond can sting patient if gets inside wound
- Use a numbing spray to numb the area when necessary
- Different levels to which tools need to be sterilized to--will get back to us as to what level of clean design will need to be
    - Could potentially open up new material possibilities
- Liked Jurnee's idea for using something similar to "cabinet stopper" adhesives
- Client is planning on coming to poster session
- Client mentioned how has discussed wound edge approximation with peers and all agree it's a major issue
    - also complained about how Dermabond oozes everywhere when crack it open to use--thought designing some sort of cap/nozzle (like Elmer's glue cap) would be real useful

Conclusions/action items:

Client was very receptive of our ideas and seems very excited about the direction the design is going in. Asked how she could help and if we needed any additional supplies to be purchased. She plans to attend the poster session in December. The goal now is to fabricate the design using stainless steel, and coat the edges with a silicone rubber for better grip and comfort.

9/13/19 Advisor Meeting

▪ KELLY STARYKOWICZ ▪ Sep 13, 2019 @12:26 PM CDT

Title: Advisor Meeting

Date: 9/13/19

Content by: Kelly

Present: Jurnee, Jack, Lizzy, Kelly

Goals: Figure out client issue and discuss future plans

Content:

- If our client doesn't respond by early next week, Dr. Puccinelli will try to find us another client
    - Regardless we will continue with the project
- Create a time frame for the project
    - Include time to meet with WARF
- We need to be thorough in the notebook if we are to be considered for a patent
    - Keep it very detailed
    - Google Drive is not an ideal method for documenting projects
        - Dr. Suarez-Gonzalez will get a clearer answer for us
- Set up meeting with WARF after client meeting
    - learn about documentation needed
    - learn about everything we need so we can plan the time frame for the year
- Think about patenting throughout the project

Conclusions/action items:

- Set up meeting with WARF after client meeting
- PDS due next week
- Meet with SG after Outreach Seminar: 1:30-2:00 pm Friday, 20th

9/20/19 Advisor Meeting

▪ KELLY STARYKOWICZ ▪ Sep 20, 2019 @01:43 PM CDT

Title: Advisor Meeting

Date: 9/20/19

Content by: Kelly

Present: Kelly, Jurnee, Lizzy

Goals: Discuss client meeting and next steps

Content:

- Gave an overview of client meeting
    - Primarily Dermabond
    - Target size: 1 cm - 2 inches
- Progress Report Feedback
    - in problem statement, add the wound sizes that the device will be used for
- Client Overview
    - will provide fake skin, dermabond
    - budget- include cost in design matrix, run it by the client, and use cost to help decide on design
        - Consider having client order the materials herself and have them be shipped to us
            - rather than us paying out of pocket for the materials
            - make sure she would be able to order in a timely manner
- Learn about autoclave and which heat cycle is used- use this for choosing material
    - if design is reusable

Conclusions/action items:

- In problem statement, add wound sizes that device will be used for!
- Discuss having client order materials and send them to us
    - Make sure she would be able to order in a timely manner
- We WILL be meeting at 12 pm next Friday

9/27/19 Advisor Meeting

▪ KELLY STARYKOWICZ ▪ Sep 27, 2019 @12:18 PM CDT

Title: Advisor Meeting

Date: 9/27/19

Content by: Kelly

Present: All team members

Goals: Discuss PDS and design matrix results. Prepare for preliminary presentations

Content:

- Start planning Outreach
- Presentations next week
  - send slides by Wednesday evening
  - only computer generate final design
- PDS was good
  - very quantitative
- Design Matrix
  - need design that will not block area where suturing will occur
    - if keep this design, reword that criteria of the PDS
  - need dimensions- hard to visualize
    - will we need multiple for a larger wound?
  - redraw all designs for presentation with dimensions and labels
  - only computer generate the final design
- can present these 3 designs Friday if we don't have a better one by then
- if we change our designs, redo design matrix for the presentation only
- Look into WARF patenting

Conclusions/action items:

- Consider another design
- Add dimensions to images
- Computer generate final design
- Send presentation slides to Dr. Suarez-Gonzalez by Wednesday evening
- Look into WARF for patenting!
- Start thinking about Outreach

10/11/19 Advisor Meeting

▪ Jurnee Beilke ▪ Oct 11, 2019 @12:31 PM CDT

Title: Advisor Meeting

Date: 10/11/19

Content by: Jurnee

Present: All

Goals: To receive feedback on the prelim presentation, and update our advisor on project progress.

Content:

- Presentation went well
- Prelim design - nice to be clear how the device stays on the skin
- Elastic band that wraps around the limbs and attaches to the device
- Designs are missing labels - orientation around the wound is unclear
- Mention that device is used on limbs and torso - not facial/scalp
- Start thinking how to make the product broader - can we make the device adjustable to various wounds
- Always be conscious of the audience background - use images and labels
- NOT meeting next week - advisor at BMES
- Delegate activities instead of meeting if the schedule is busy
- Advisor can reach out to upper elementary school
- Meet with TEAM Lab to talk about our design and fabrication

Conclusions/action items:

Start on purchasing materials and begin fabrication - meet with TEAM Lab. Add device use location to problem statement.

11/01/19 Advisor Meeting

▪ Jurnee Beilke ▪ Nov 01, 2019 @06:41 PM CDT

Title: Advisor Meeting

Date: 11/01/19

Content by: Jurnee

Present: All

Goals: To meet with our advisor and show her our preliminary design.

Content:

- Dr. Suarez emailed her son's teacher for us to conduct our outreach activity
- The material is quite light, but the device might fall off the skin
- We need to be more specific about how the device will stay on the patient's skin
  - Possibly elastic bands that wrap around the limb
- Skin prep - place on skin to make the skin sticky - not glue but will increase the tack of the skin
  - Possibly to be used with silicone - test with silicone (may be interaction with silicone and skin prep)
  - Remind Dr. Suarez to bring the skin prep next week
- Feedback - include a future work section in the paper
  - Start to focus on testing - make the section more specific
  - Standards need to be more clearly stated - codes and standards for the device
  - Check access to tensiometer to measure skin tensions around the wound
  - Make the background specific to lacerations
  - Overall a good first draft of the report
  - Dr. Suarez sent a file with more comments

Conclusions/action items:

The team needs to finish the preliminary design and prepare for show and tell next week. Also, we should follow up with the school for the outreach activity.

11/13/19 Advisor Meeting

▪ KELLY STARYKOWICZ ▪ Nov 13, 2019 @06:56 PM CST

Title: Advisor Meeting

Date: 11/13/19

Content by: Kelly

Present: Jack, Lizzy, Kelly

Goals: Show steel pieces to Dr. Suarez-Gonzalez and go over testing ideas.

Content:

- Got skin prep from Dr. Suarez-Gonzalez
- Discussed further fabrication methods
- Discussed client meeting
- Discussed quantitative testing possibilities that Dr. Wille came up with
    - Dr. Suarez-Gonzalez is happy with both ideas
    - Discussed finding a tensiometer with Dr. Suarez-Gonzalez's recommended contact
- Discussed having one team member wear the device and taking pictures of the skin after several time increments to see if it leaves marks or causes pain
- Discussed testing how user-friendly the device is by having multiple different people try to use it
- Consider a time lapse video of the device holding skin together during a prolonged period of time
- Went over Outreach plans

Conclusions/action items:

- Need to order silicone and practice application of it
- Need to touch base with the Outreach teacher about photo release forms to see if theirs complies with the BME department's.
- Need to finish fabrication
- Need to finalize testing plans
- Due dates!
    - Begin final report and final poster
- After Outreach is completed and device is fabricated, reach out to WARF again.

12/02/19 Advisor Meeting

▪ KELLY STARYKOWICZ ▪ Dec 02, 2019 @06:58 PM CST

Title: Advisor Meeting

Date: 12/02/19

Content by: Kelly

Present: Jurnee, Lizzy, Kelly

Goals: Ask questions about the poster and presentations!

Content:

- Statistics on lacerations: ask client
    - if we cannot find anything, no big deal
- Testing questions:
    - Q1: tensile force to pull suture tight in skin is 6.5-10 N; silicone force is 27-40 N
        - send data to Dr. Suarez-Gonzalez
        - find modulus of elasticity of silicon itself!
    - Q2: pain rating scale
        - Test on more people and use scale
        - Don't use scale if everyone says 0 pain level
- Weighed device: 50.81 grams

Conclusions/action items:

- Ask client about laceration statistics
- Send silicone data to Dr. Suarez-Gonzalez
    - Also try to find a modulus of elasticity of silicon
- Test on more people to rate pain
    - Do not use scale if everyone has a pain level of 0
- Add device weight to results section

10/08/19 Design Matrix - Updated

▪ Jurnee Beilke ▪ Oct 08, 2019 @10:14 PM CDT

Title: Design Matrix

Date: 10/08/19

Content by: All

Present: All

Goals: To score our top 4 designs based on the criteria we find the most important for our device.

Content:

The Bow-Shaped Design

The bow-shaped design scored high in effectiveness because the design will offer control over the wound edges and be able to repeatedly approximate wound edges. However, the design lost points because the arms of the apparatus may interfere with the suturing or gluing of the wound as they are directly above the wound. In terms of patient comfort, the design lost points because the design may pinch or hold the patient's skin in a way that is uncomfortable. This pinching is not expected to harm the patient but may provide a sense of discomfort. For safety, the ends of arms are protected with a soft material that will contact that skin to not harm the patient. However, the device lost points because the locking hinge may provide a pinch hazard for the user or could potentially provide excessive force and pinch the patient if used incorrectly. In the category of practicality, the bow-shaped design scored high since it will likely be easy and simple to use by the healthcare professional; but the arms of the design may be awkward to work around. The design scored the highest in novelty, for there are currently no devices on the market with this structure and function. As for cost, this design scored the highest because the equipment is reusable and made of simple parts. The device lost points because it consists of multiple components that will be made from various materials that need to be purchased. For the last category, ease of fabrication, the bow-shaped design requires a simple assembly, but the process may require machining and the hinge may be hard to fabricate.

The Hook & Loop Design

In the category of effectiveness, this design would likely be effective at closing the wound, but once the adhesive patches are placed on the skin, they cannot be adjusted and the hook will cover portions of the wound that cannot be glued/sutured. While the other designs could pinch the skin and cause discomfort, the hook and loop simply adheres to the skin and would cause minimal discomfort to the patient. Therefore, the design scored highest in patient comfort. The hook and loop is also relatively safe, with the only danger being the adhesive patches pulling at the patient's skin/wound or hair (similar to removing a bandage), so it lost some points in the safety category. The hook and loop design lost points for practicality, as it would be more complicated to use than the other designs and more time consuming to apply as there are multiple working components. While there are no products exactly like it, there are other products on the market that use a similar method of wound closure, causing this design to lose points in novelty. In terms of cost and ease of fabrication, the hook and loop design would likely be more expensive and more difficult to produce than the other designs due to its various materials and adhesive quality. The device is also not reusable.

The Barrette Design

The barrette design scored low in the effectiveness category because it would not be very precise when approximating wound edges, as it only has one setting of closure. It also scored low in the categories of patient and safety comfort because it might pinch the skin in the hinge corner of the device and therefore be uncomfortable for the patient. Additionally, the skin nearest the barrette hinge could be damaged more severely and bruising could result. The barrette design lost points in the practicality category because it would require a significant amount of effort to orientate the device so that the wound edges are properly aligned. This apparatus was awarded full points in the category of novelty because it is unlike the other devices that are currently on the market. The barrette design also scored the highest in the cost and ease of fabrication categories because it would require few materials and the assembly would be rather straightforward (simple hinge design). This device would also be reusable, so the cost of repeated use would be minimal.

The Rectangle Design

The rectangle design would score the highest in effectiveness because the design could repeatedly approximate wound edges without impeding the clinician's access to the wound. In the category of patient comfort, the design scored high because the silicone edges would be comfortable against the patient's skin, but the device may provide some level of discomfort when drawing the edges of the wound together. For safety, the design lost points because the regions where the fasteners are located provides potential pinch points if not used carefully. However, for the most part, the design presents minimal risk to the patient and user, scoring the highest for safety. In the category of practicality, the design scored the highest, for it will be easy and straightforward to use by the clinician. The design also scored the highest in the category of novelty since there are no designs currently on the market with the same function and structural design. For cost, the rectangle design scored highly because there are minimal parts to create the design and it is reusable if sterilized. Finally, in the category of ease of fabrication, the design lost points because there are several components of the design that require machining.

Conclusions/action items:

Due to the fact that the rectangle design ranked highest, the team decided to move forward with this design. The team will revise the proposed final design to potentially include a slight curvature in the two shorter sides of the rectangle to better grip the skin. Additionally, the portion of the rectangle in contact with the skin will be textured to guard against slip. Another option the team will further explore is the use of adhesive tape to secure the device to the skin if texturing the metal and the silicone edges do not prove sufficient. The design will be revised based on testing results and client feedback.

▪ Jurnee Beilke ▪ Oct 08, 2019 @10:03 PM CDT

Design Criteria	Bow-shaped Design	Hook & Loop Design	Barrette Design	Rectangle Design
Effectiveness (25)	(4/5) 20	(4/5) 20	(3/5) 15	(5/5) 25
Patient Comfort (20)	(4/5) 16	(5/5) 20	(3/5) 12	(4/5) 16
Safety (20)	(3/5) 12	(3/5) 12	(3/5) 12	(4/5) 16
Practicality (15)	(4/5) 12	(3/5) 9	(4/5) 12	(5/5) 15
Novelty (10)	(5/5) 10	(3/5) 6	(5/5) 10	(5/5) 10
Cost (5)	(4/5) 4	(3/5) 3	(4/5) 4	(4/5) 4
Ease of Fabrication (5)	(3/5) 3	(3/5) 3	(4/5) 4	(3/5) 3
Total (100)	77	73	69	89

Screen_Shot_2019-10-08_at_10.00.49_PM.png(175.5 KB) - download Table 1: Design matrix evaluating the team's top 4 designs.

10/08/19 Rectangle Design Drawing

▪ ELIZABETH SCHMIDA ▪ Oct 08, 2019 @10:30 PM CDT

Title: Rectangle Design Drawing

Date: 10/08/19

Content by: Lizzy S

Present: N/A

Goals: The intention of this entry is to provide a visual idea of the proposed final design and its dimensions. For further details as to how the drawing was constructed see the following entry under Lizzy Schmida>Design Ideas> 9/27/2019 Rectangle Design AutoDesk Files.

Content:

A screenshot of the dimensioned drawing was included in the appendix of the preliminary report (Figure 1). All AutoDesk files are attached to the entry that can be found under Lizzy Schmida>Design Ideas> 9/27/2019 Rectangle Design AutoDesk Files .

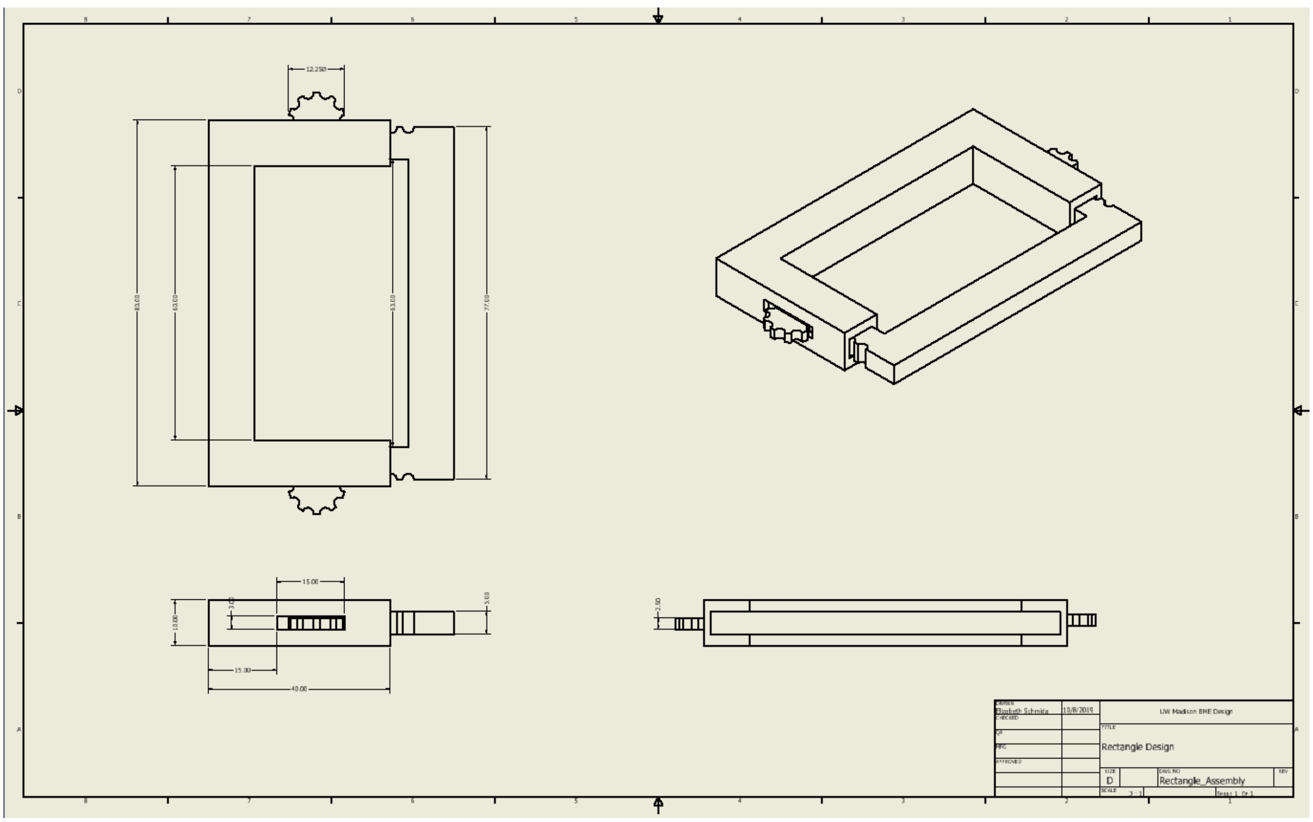


Figure 1. AutoDesk Inventor drawing of the rectangle design.

Conclusions/action items:

The CAD model will be revised based on testing results and feedback from our advisor and client over the course of the semester.

11/08/19 Show and Tell

▪ Jurnee Beilke ▪ Nov 12, 2019 @07:32 PM CST

Title: Show and Tell

Date: 11/08/19

Content by: Jurnee Beilke

Present: All

Goals: To gain feedback from other groups about our design and testing plan.

Content:

- People asked questions about how the device will stay on the skin during use - will the device use adhesive?
- People thinking testing with a tensiometer and the practice suture kit to approximated the wound edges
- We received questions about what types of wound this design would work on - limbs, torso?
    - People thought the device might not be useful for hand wounds
- Mathematic calculations to determine the angles of the device
- Other teams are concerned about being able to push the sides together easily
- laser cutting (check MakerSpace for materials can use), sandblasting, water jet
- Future work--make edges adjustable for different laceration lengths

Conclusions/action items:

The team needs to focus on fabricating our final design and brainstorming for our testing plan. Also, the team should consider ideas to help the device stay on the skin during use.

11/21/19 SolidWorks Drawing of Final Design

▪ Jack Fahy ▪ Dec 03, 2019 @09:18 PM CST

Title: SolidWorks Model of Final Design

Date: 11/21/19

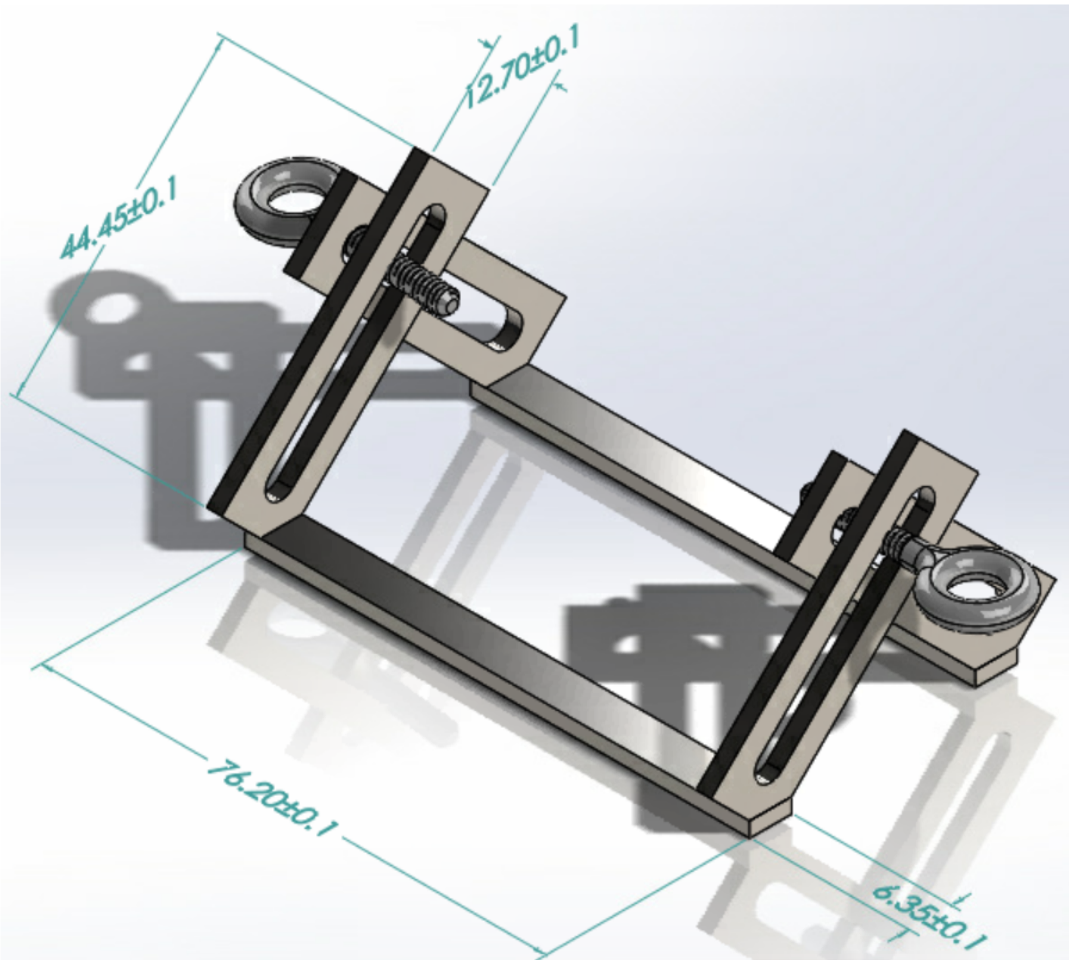
Content by: Jack

Present: Jack

Goals: Assemble a SolidWorks model of the new modified rectangle design

Content:

The SolidWorks model is displayed below with dimensions in mm. A simple 3/16" thumb screw CAD model was pulled from grabcad.com to put through the slotted pieces. Missing from the model are wingnuts, which will be placed on the thumb screws from the inner side (one on each side), and hex nuts, which will be placed on the thumb screws from the outer side (one on each side).



Conclusions/action items:

This model will be included in our final report and poster in place of the previous rectangle CAD design

Expenses Sheet

▪ Jack Fahy ▪ Dec 03, 2019 @09:23 PM CST

Title: Expenses and Materials Sheet

Date: 11/3/2019

Content by: Team

Present: Team

Goals: Record expenses and materials purchased

Content:

Item	Description	Manufacturer	Date	QTY	Cost Each	Shipping + Tax	Total	Link (hyperlinked to Product)
Multipurpose Stainless Steel 304 Strip	1" x 36" x 0.09" (W x L x Thickness)	McMaster-Carr	11/3/2019	1	$18.38	$7.84	$26.22	https://www.mcmaster.com/standard-stainless-steel-sheets
GE Silicone 2+ Sealant Caulk	Liquid silicone rubber	GE	11/14/2019	1	$3.77	$0	$3.77	https://www.amazon.com/gp/product/B000PSE46S/ref=ppx_yo_dt_b_asin_title_o03_s00?ie=UTF8&psc=1
Water Jet Cutting	Assisted by Makerspace staff	N/A	11/15/2019	N/A	$2.53	$0	$2.58	
Sontax 96pc. 1/2" Clear Bumpers	Hard silicone adhesive bumpers	Sontax	11/20/2019	1	$8.79	$0	$8.79	https://www.amazon.com/Sontax-96pc-Clear-Bumpers/dp/B06WW17MC4
Thumb Screws	Part# 80231 6-32 x 1/2	Menards	11/20/2019	2	$0.78	$0	$0.78	N/A
Zinc Plated Wingnuts	Size 6-32	Menards	11/20/2019	6	$0.98	$0	$0.98	N/A
						TOTAL:	$43.07	

Conclusions/action items:

10/28/19 Preliminary Prototype Materials

▪ Jurnee Beilke ▪ Oct 28, 2019 @10:24

Title: Preliminary Prototype

Date: 10/28/19

Content by: Jurnee

Present: NA

Goals: To list the materials used in the preliminary design.

Content:

The preliminary prototype fabrication is outlined in the fabrication folder, but the material used to make the sides of the device was stock sheet aluminum from K&S Precision Metals. This materi was found in ECB as scrap metal. The team thought it was thin enough to make a preliminary design. Each sheet has a price of $2.29 at Fleet Farm.

https://www.fleetfarm.com/store/detail/k-s-precision-metals-aluminum-sheet-metal/0000000228159/5300?gclid=CjwKCAjwo9rtBRAdEiwA_WXcFhRXsRKJVDrtb5PnAO_XW5d1LCL_Eo0haPKml4Z2tZMEivVdPC9_9RoCIVAQAvD_BwE

After each metal component of the design was fabricated, the edges were glued together with JB Weld steel reinforced epoxy. The pack of which costs $4.84 on Amazon.

https://www.amazon.com/J-B-Weld-8265S-Cold-Weld-Reinforced/dp/B0006O1ICE/ref=asc_df_B0006O1ICE/?tag=hyprod-20&linkCode=df0&hvadid=198093606370&hvpos=1o1&hvnetw=g&hvrand=18322841953282600882&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9018948&hvtargi 320192516391&psc=1

The rest of the design will consist of a washer, bolt, and wing nut to secure the device components together. We will likely need to purchase the remaining materials as we could not find any scr ECB or the TEAMLab.

Conclusions/action items:

Once we complete the preliminary prototype, we can ask for feedback from the advisor and client before building and testing the final prototype.

12/04/19 Final Materials List

▪ KELLY STARYKOWICZ ▪ Dec 04, 2019 @07:58 PM CST

Title: Final Materials List

Date: 12/04/19

Content by: Kelly

Present: Kelly

Goals: List the materials used and briefly explain why we used them.

Content:

- **Multipurpose Stainless Steel 304:** Used for the body of the device.
    - Stainless Steel is a popular metal used for medical devices because it is very resistant to corrosion and has a low carbon content.
    - 304 is the most common grade of stainless steel.
    - For more information on the properties and advantages of Stainless Steel 304, see Jack Fahy's entry titled "10/1/2019 Stainless Steel for Medical Devices" in the "Materials" folder under Design Ideas.
- **GE Silicone 2+ Sealant Caulk:** Applied to the parts of the device that are in contact with the patient's skin to allow the device to cling to the skin better.
    - Silicone can often be slightly sticky and therefore assist with gripping surfaces.
    - Stainless steel alone would slide on the skin rather easily upon inspection.
    - Silicone maintains its properties at a variety of temperatures, including up to 300 degree Celsius. Therefore, it would withstand the conditions of an autoclave [1].
    - This specific silicone is a sealant caulk and was purchased because of its low cost and easy application tip. For a true medical device, a medical grade of silicone would be used.
    - While the silicone sealant achieved its purpose, it did not stay on for very long. Therefore, the team plans on finding an alternative application method.
    - For more information on Medical grade silicones, see Lizzy Schmida's entry titled "11/1/2019 Silicone Options" in the Research folder.
- **Sontax 96pc. 1/2" Clear Bumpers:** Placed on the four corners of the wound to have something for the device to grip when approximating the wound edges.
    - The team did not anticipate needing an additional adhesive for the device to grip. When this problem presented itself, the silicone cabinet bumpers were the only potential option that the team had in such a short amount of time.
    - The cabinet bumpers work well for the prototype, but in the future, the team would need to purchase a similar adhesive that is smaller and sterile.
    - These are relatively low cost when purchased in bulk.
- **Thumb Screws #6-32 x 1/2":** Used to fasten the slotted sides of the device, while still allowing it to slide along the slots.
    - The team chose thumb screws because they are easy to fasten quickly.
    - These particular thumb screws are zinc-plated, which makes them more resistant to corrosion. Therefore, they would withstand the autoclave sterilization.
    - Even with the ease of the thumb screw head, the device was still slightly difficult to adjust quickly. The team plans on revising the fastening mechanism.
- **Zinc Plated Wing nuts:** Used to attach to the thumb screws to tighten the device and lock it in place.
    - The team chose wing nuts because they are easy to fasten when compared to other types of nuts.
    - Like the thumb screws, the wing nuts would withstand the autoclave conditions because they are zinc-plated.
    - As mentioned previously, the team plans on revising the fastening mechanism to make it easier for the clinician to adjust.

[1] *Silicone Adhesives*. [Online]. Available: https://www.adhesives.org/adhesives-sealants/adhesives-sealants-overview/adhesive-technologies/chemically-curing/two-component-(2-c)/silicone-adhesives. [Accessed: 04-Dec-2019].

Conclusions/action items:

The costs of the materials listed above can be found in the "Expenses sheet" entry.

The team plans to revise the fastening mechanism and method of silicone application in the next semester.

10/17/19 Fabrication Meeting

▪ Jurnee Beilke ▪ Oct 20, 2019 @10:41 PM CDT

Title: Fabrication Plan Meeting

Date: 10/17/19

Content by: Jurnee

Present: All

Goals: To create a fabrication plan for our device and build a prototype out of cardboard.

Content:

The team met and created a prototype out of cardboard (see the figure below). We then took the prototype to the TEAM Lab to discuss a fabrication plan with the shop staff. Below is the recommended plan of fabrication from the shop staff:

- Start with thin metal strips - cut the strips to the correct dimensions
- To create the hollow strips, a die can be used to punch out the middle of the metal strip
- The corners of the device can be connected by spot welding or riveting
- The shop staff would need to be present and assist with all the fabrication steps
- Additionally, I have an uncle who has a metalworking shop and he said he would be happy to assist with the welding portion of fabrication since no team members are trained in welding

The dimensions of the device will be as follows:

- 3 inch length on the long sides against the patient's skin
- 0.25 inch width for the sides contacting the skin
- 2.5 inch length for the adjustable sides of the device that will be hollowed with a die punch
- 0.5-0.75 inch width for the hollow adjustable sides
- When fully opened, the long edges should be 1.5 inches apart to be places around the wound
- Wounds will be 1 to 5 cm in size

Conclusions/action items:

We now have a plan for fabrication and just need to purchase or find some metal strips that we can use to create a prototype.

▪ Jurnee Beilke ▪ Oct 20, 2019 @10:45 PM CDT

_private_var_mobile_Containers_Data_Application_8527CA1F-1A83-458F-8720-6111AB980B7E_tmp_E321E19B-AA8B-4555-B0AA-40FB095DE6C4_Image.jpeg(1.7 MB) - download Figure 1: Cardboard prototype of the current design. The orange pipe cleaner is the wound location relative to the device. The cardboard prototype was constructed with incorrect dimensions and is not to scale of the final design. The two raised sides of the device are adjustable and can bring the long sides against the skin closer together during approximation. The adjustable sides can then be fastened into position with a wing nut or other fastener (the paperclips in the prototype simulate the fasteners).

10/28/19 Fabrication Meeting

▪ Jurnee Beilke ▪ Oct 28, 2019 @09:56 PM CDT

Title: Fabrication Meeting

Date: 10/28/19

Content by: Jurnee

Present: All

Goals: To fabricate a rough prototype of our device.

Content:

- The team began by cutting out 6 metal rectangles out of aluminum sheets (2 long, slender and 4 wide, shorter)
  - 3 inch length on the long sides by 0.25 inch width for the 2 long rectangles
  - 2.5 inch length for the adjustable sides by 0.5 inch width for the 4 short rectangles
- Next, the team used a whitney punch to punch out 5/32" interconnected holes along the middle of the 4 wide and short rectangles

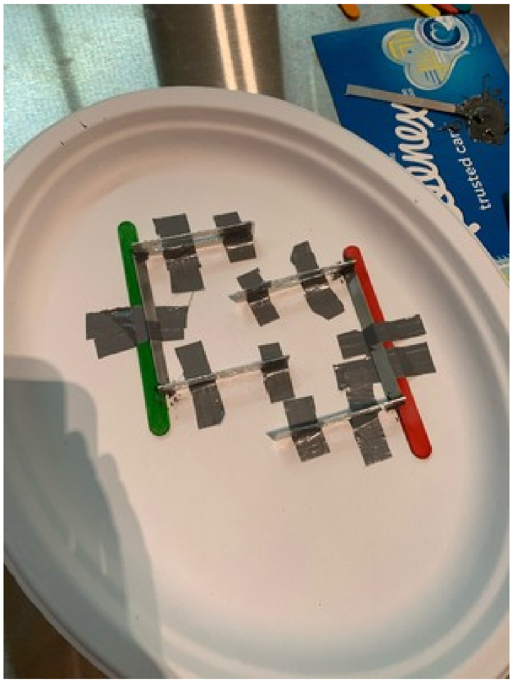
Figure 1: Whitney punch used to hollow out rectangles.

- The interconnect holes were filed down to create a hollow rectangle in the middle of the metal rectangle
  - This would be used for the sliding motion of our device - where the wing nut would be able to move/slide
  - The 4 wide and short rectangles were filed on one corner to create a flat edge that would later be attached to the long, slender rectangles
- The 4 corners of the device were connected with glue (steel-reinforced epoxy) and stabilized for the glue to set

Conclusions/action items:

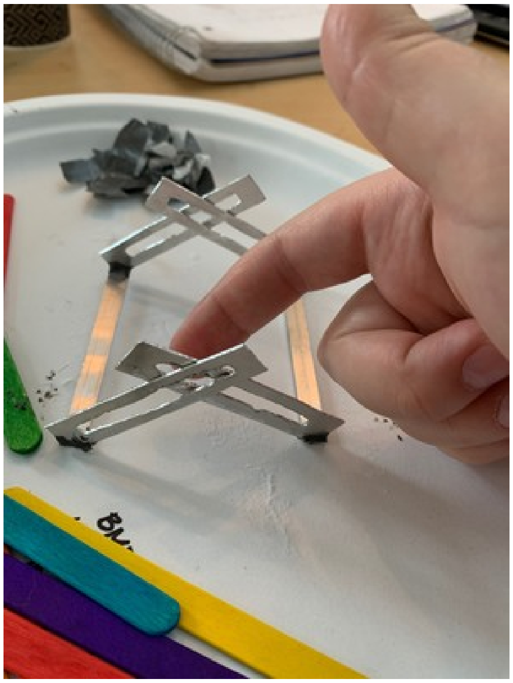
The team must wait for the epoxy to cure before we can handle and examine the design. Once cured, we can assemble the design using wing nuts and show the prototype to the client/advisor for feedback before we fabricate a final design for testing. We also might want to consider purchasing some steel instead of using aluminum, since aluminum is very malleable.

▪ Jurnee Beilke ▪ Oct 28, 2019 @09:59 PM CDT



_private_var_mobile_Containers_Data_Application_D9C41DDB-6253-438A-8D5B-132980E88AC6_tmp_728DC40A-BD69-44A6-B2A6-938DF76 47B6E_Image.jpeg(1.6 MB) - download Figure 2: Stabilized attachment of the metal components while the epoxy is curing. Each popsicle stick is supporting one of the long,slender rectangles that is glued on either end to a wide, short rectangle with a hollow center. The two sides of the device will be connected using one wing nut per side.

▪ Jurnee Beilke ▪ Nov 12, 2019 @10:30 PM CST



_private_var_mobile_Containers_Data_Application_DDBEE7BB-BC1E-42ED-A2B2-3C6810C852E2_tmp_628D0E3D-A1E9-4B2D-9972-059F6E4 61777_Image.jpeg(2.2 MB) - download Figure 3: The preliminary prototype without fasteners.

11/12/19 Fabrication Meeting

▪ Jurnee Beilke ▪ Nov 12, 2019 @10:38 PM CST

Title: Fabrication Meeting

Date: 11/12/19

Content by: Jurnee

Present: All

Goals: To being fabricating the final design, so we can test our device.

Content:

- The team is making some revisions from the preliminary design
  - The sides of the device that extend upwards with hollow slots are going to be made shorter to be less bulky and cumbersome
    - 1.75 inches in length
  - The angle at which the two pieces are connected may also vary from the preliminary design
- To begin, the team measured the pieces to be cut out of stainless steel and spoke with the shop staff about the best approach to complete our design
  - The pieces of the device were cut using a saw in the TEAMLab
- The team consulted with the shop staff to determine the best method for creating the slots in the device
  - The staff recommended using a mill to create the slots along the sides of the device

Conclusions/action items:

The team needs to continue working on the device, so we can begin testing before Thanksgiving break!

11/13/19 Mill Procedure

▪ Jack Fahy ▪ Nov 25, 2019 @12:57 PM CST

Title: Jack Fahy

Date: 11/13/19

Content by: Jack Fahy

Present: Jack

Goals: Layout procedure for milling parts

Content:

1. Place piece in vice with one end sticking out. Set RPM to 1019. Bring endmill in until chip is formed, then zero the x axis.
2. Back part off in y-axis direction, move in .010", cut along edge to finish it.
3. Repeat steps 1 and 2 with other end.
4. With part still in vice, use an edge finder to locate x-axis and y-axis zero. Add radius of edge finder to get the tip of the endmill at the zero location
5. From zero, move 0.25" in x-axis. Move 0.25" direction in y-axis. Move z-axis up until chip is formed and zero it
6. Make passes in y-direction to 1.50", creating a 1.25" long slot. Moving z-axis up 0.0300-0.0400" each time until slot is cut all the way through.
7. Move x-axis to 0.75" and keep y-axis at 0.25" and repeat step 6 to create another slot.
8. Repeat all above steps for other piece.

Conclusions/action items:

With the slots cut, the pieces just need to be cut into their respective parts to complete this part of fabrication.

11/15/19 Water Jet Cutting of Milled Pieces

▪ Jack Fahy ▪ Dec 08, 2019 @11:27 AM CST

Title: Water Jet Cutting of Milled Pieces

Date: 11/15/19

Content by: Jack

Present: Jack

Goals: Use the waterjet cutter in the Makerspace to cut pieces apart

Content:

After consulting the TeamLab's experts, we concluded that the pieces of stainless steel we needed to cut were too small to use on the TeamLab's waterjet cutter. We took the pieces to the Makerspace instead, where there is a smaller waterjet cutter. The waterjet operator helped us cut the 1.75" x 1" milled pieces in half two create the singular slotted pieces we needed. To do this, the water jet coordinates were zeroed on a corner of the piece, then moved over 0.5 inches to the center point of the width. To cut the long sides for the device, the 3" x 1" piece of stainless steel (with no milled slots) was placed in the water jet cutter. The axis was zeroed on a corner and moved 0.25" along the width for the first cut, then to 0.5" for the second cut to create two 3" x 0.25" pieces. The total price for cutting was $2.53.

Conclusions/action items:

The next step of fabrication is to weld two slotted pieces to each long side. We plan on having Jurnee's uncle do this to minimize our cost.

11/19/19 Welding the parts together

▪ Jack Fahy ▪ Dec 03, 2019 @09:09 PM CST

Title: Welding of Parts

Date: 11/19/19

Content by: Jack

Present: Jack, Jurnee

Goals: Weld two slotted pieces to each long side

Content:

The pieces of our device were brought to Jurnee's uncle for welding. He was able to successfully weld the pieces together, completing fabrication of our device.

Conclusions/action items:

Next we need to purchase thumb screws and wingnuts to put through the slotted parts of our device. We can likely get hex nuts from the TeamLab if we deem them necessary.

11/23/2019 Silicone Application

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @02:41 PM CST

Title: Silicone Application

Date: 11/23/2019

Content by: Lizzy

Present: NA

Goals: Carefully apply silicone to the bottom two faces of the device in order to provide a higher coefficient of friction and transitively, better grip.

Content:

Using the purchased silicone and the scrap aluminum and steel from the initial prototypes, various amounts of the silicone were applied to determine the ideal amount to use on the device (Figures 1). The silicone takes 1 hour to become waterproof and 24 hours to completely cure. After these initial trials, it was determined that a thin layer of silicone is ideal as larger volumes can be pried aways from the metal's edge and do not provide a noticeable increase in grip relative to thinner coatings (Figure 2). On the fabricated prototype (Figure 3), a thin bead of silicone was applied longitudinally along the bottom face of one face of the device. This silicone bead was then spread to the edges of the surface using a popsicle stick. Once completely covered, the surface was gently wiped with a final pass of the popsicle stick to achieve a more uniform finish (Figure 4). The process was then repeated for the other bottom face of the device. The two halves were then left to cure for 24 hours.

Figure 1. Silicone to be applied to device to reduce slippage on the skin during approximation.

Figure 2. Testing setup that allowed the silicone to cure for 24 hours. Sample of aluminum with a large volume of silicone coating both faces and edge of the metal.

Figure 3. Bottom face of on side of the device prior to silicone application.

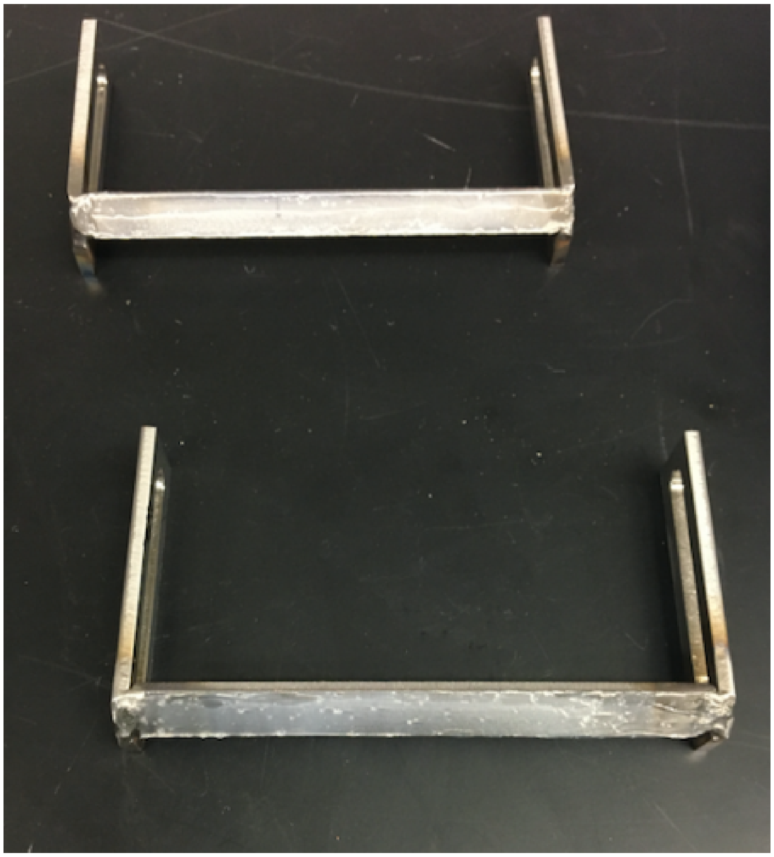


Figure 4. Bottom faces of the device immediately after a thin layer of silicone was applied.

Conclusions/action items:

While a little messy, the silicone was applied with relative ease. Once the design for the device has been fully agreed upon and gone through several iterations, I'd recommend switching to the liquid silicone rubber I described in the entry "Silicone Options" under my Biology and Physiology folder. The liquid silicone rubber can be purchased as medical grade and would have a longer lifetime and would allow a more uniform coverage of the device. For this initial prototype however, this silicone will meet our requirements.

Checking on the silicone status approximately 18 hours later found the silicone to be completely dry, likely due to the how thin the layer applied was.

12/03/19 - Final Design

▪ Jurnee Beilke ▪ Dec 03, 2019 @10:24 PM CST

Title: Final Design

Date: 12/03/19

Content by: Jurnee

Present: All

Goals: To include images of the final design.

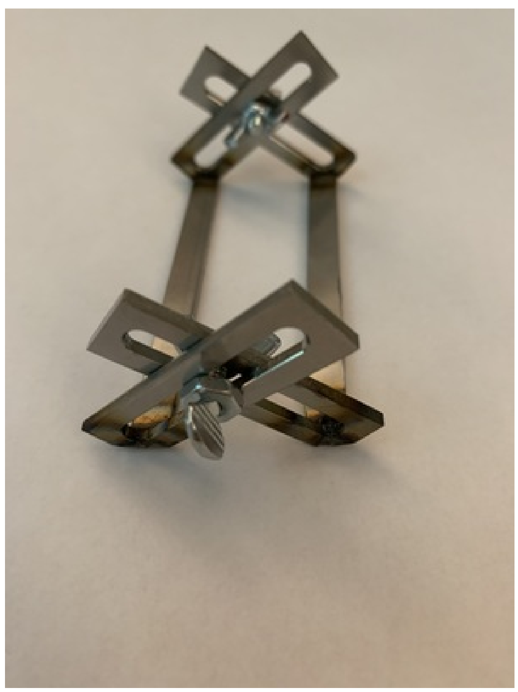
Content:

The prototype is a metal frame consisting of two identical stainless steel sides with three pieces: one long, thin segment with a thin layer of silicone along the bottom and two rectangular slotted segments welded to opposite ends of the long segment at 45 degree angles. The segments of each half are connected via thumb screws and nuts through the slots. The device is assisted by four circular adhesive silicone bumpers, which are placed at the four corners of the wound. The opening of the device is placed around the bumpers, and the thumb screws can be adjusted until the long edges are brought together and the wound is approximated.

Conclusions/action items:

The final prototype is complete and appears to work well. As always, the device needs adjustments/improvements.

▪ Jurnee Beilke ▪ Dec 03, 2019 @10:23 PM CST



IMG_4487.jpg(1.1 MB) - download Figure 1: Side view of the final design including the fastener system.

▪ Jurnee Beilke ▪ Dec 03, 2019 @10:23 PM CST

IMG_4488.jpg(1.1 MB) - download Figure 2: Front view of the final design.

11/12/19 Testing Brainstorming

▪ Jurnee Beilke ▪ Nov 12, 2019 @10:18 PM CST

Title: Testing Plan

Date: 11/12/19

Content by: Jurnee

Present: All

Goals: To brainstorm for the testing/experimentation portion of our design project.

Content:

- I consulted with biomechanics professor Dr. Wille about potential testing methods
- Together, we discussed two ideas for testing

Idea 1: Direct measurement

- For this idea, the silicone fake skin (from the suture kit) can be laid over pre-determined section of the body
- The device can be used to approximate a linear laceration on the silicone skin
- The starting separation of the device edges will be measured and recorded for time zero
- Next, the separation of the device (relative to the starting position) will be measured after a specific unit of time (30 sec for example) over the period of several minutes
- The time period chose can be representative of the time taken to close the wound with DermaBond
- Additionally, several locations on the body can be measured to account for different geometries (forearm, upper arm, thigh, shin, calf...)
- The displacement or separation over time can then be analyzed to determine how accurately and reliably the device approximates wound edges

Idea 2: Spring measurement

- For this idea, silicone fake skin will also be used
- The device will be used to approximate a linear laceration on the silicone
- Once the wound is approximated the device can be held into position while a spring is placed on the device to hold it into position
- This will likely take several attempts as we will need to find a spring that matches the tension required to hold the device in place and approximate the wound
- Once the correct spring is found, we can use the MTS machines in the biomechanics lab to determine the force/tension required to approximate the wound

Conclusions/action items:

After speaking with Dr. Wille and the team, we think one or both of these options are viable for testing our device quantitatively.

12/03/19 Testing Protocols

▪ Jurnee Beilke ▪ Dec 03, 2019 @10:18 PM CST

Title: Testing Protocols

Date: 12/03/19

Content by: Jurnee

Present: All

Goals: To describe the testing protocols used for the final design.

Content:

The first quantitative method was used to determine the force applied by the user and the device to the patient's skin in order to approximate the wound edges

1. A silicone model suture kit was acquired

2. The silicone was cut into roughly 3 cm and 5 cm long strips that averaged about 1 cm wide and 1 cm thick (the sample size was three for each length tested)

3. The stripes were tested in tension using an MTS machine - the silicone strips were secured in the machine using grips (extension rate of 100 mm/min)

4. The strips were stressed in tension until the silicone began to slide out of the grips under the load

5. The data was analyzed using MATLAB to create a stress-strain curve (to convert from load to stress, the force can be divided by the cross-sectional area - to obtain strain, the change in length of the specimen is divided by the original length)

6. An incision was made in the silicone skin that was 3 cm in length

7. The silicone was then draped over a team member's forearm until the wound edges splayed to mimic a real wound

8. Two markings were made on opposite sides of the wound, and the original distance between the two markings was measured

9. The final device was then used to approximate the laceration on the silicone skin

10. Once the skin edges were approximated, the final distance between the markings was measured (the change in length of the silicone could then be computed)

11. The strain of the silicone was calculated using the strain equation

12. With the strain value, the team used the graphs generated from MATLAB to find the stress applied to the silicone skin

A second quantifiable method used was device displacement during life in service

1. Two conditions were used during testing: SkinPrep and bare skin

2. The device was then placed on a team member's forearm until the skin was raised to simulate wound approximation

3. Markings were placed on the skin on either side of the device to denote the starting position

4. A timer was then set for 3 minutes

5. After the three minute interval was completed, new markings were made to denote final position of the device

6. The distance between the original and final markings was recorded

7. This procedure was completed three times for each condition

Another method of testing included a qualitative examination of device functionality

1. The device was applied to the skin as described above and left in place for a three minute duration

2. After which, pictures were taken of the skin to determine what marks were left on the skin by the device

Conclusions/action items:

The team used several qualitative and quantitative methods to determine how well the device met the standards from the PDS.

12/04/19 Pain Scale

▪ KELLY STARYKOWICZ ▪ Dec 08, 2019 @04:59 PM CST

Title: Pain Scale

Date: 12/04/19

Content by: Kelly

Present: All

Goals: Explain the pain scale used to evaluate the device while in service.

Content:

Each team member had the device put on their arm and rated it on the pain scale described below:

0: aware of the device, but no pain

1: uncomfortable

2: slight pain

3: mild pain/pinching

4: moderate pain

5: severe pain

Two team members rated it as 0, one rated it as 1, and one rated it as 2.

Therefore, the average pain rating was 0.75 out of 5.0.

Conclusions/action items:

A rating of 0.75 out of 5.0 corresponds to slight discomfort from the device.

11/27/2019 Data Analysis & Results

▪ ELIZABETH SCHMIDA ▪ Dec 09, 2019 @08:37 PM CST

Title: Testing Analysis & Results

Date: 11/27/2019

Content by: Lizzy S.

Present: N/A

Goals: Process and analyze all data gathered during testing through using Matlab and R (if needed).

Content:

Two different tests were used to quantitatively validate the device required statistical analysis: the tensile force applied to the suture pad and the displacement of the device while wound edges are approximated. A pain scale was also used and individual's ratings were averaged to quantify the pain level inflicted by the device.

Using Matlab, the average moduli of elasticity were found to be 0.4358+-.0738 and 0.6292+-0.0949 MPa for the 3cm and 5cm suture pad sample lengths respectfully. A paired t-test comparing the mean elastic moduli found there to be a significant difference between the two sample lengths tested (p= 0.0494). This p-value is quite close to the 0.05 significance level used for this analysis. Theoretically, the length of the sample put under axial tension should not matter, I think if more samples were tested this p-value would increase, conveying no significant difference in the moduli of the two sample lengths tested. Through combining Hooke's Law and the stress equation, the following model was created to obtain the tensile forces induced by the device in the suture pad during wound edge approximation. We decided to use the average modulus for the 3 cm samples as the cuts we measured displacement on were approximately 3cm in length and their estimated modulus was slightly closer to that of skin. Based on the stress-strain curve generated for the 3 cm samples, this model can be used for measured strains between 0.00 and 0.35 (Figure 1). From this model, tensile forces between 27 and 40N were calculated.

$$F = 0.4358 * e * A$$

Equations used to create mathematical model:

$$\sigma = \varepsilon E$$
$$\varepsilon = \frac{\Delta L}{L}$$
$$\sigma = \frac{F}{A}$$
$$F = \frac{\Delta L}{L} E A$$
$$F = \varepsilon E A$$

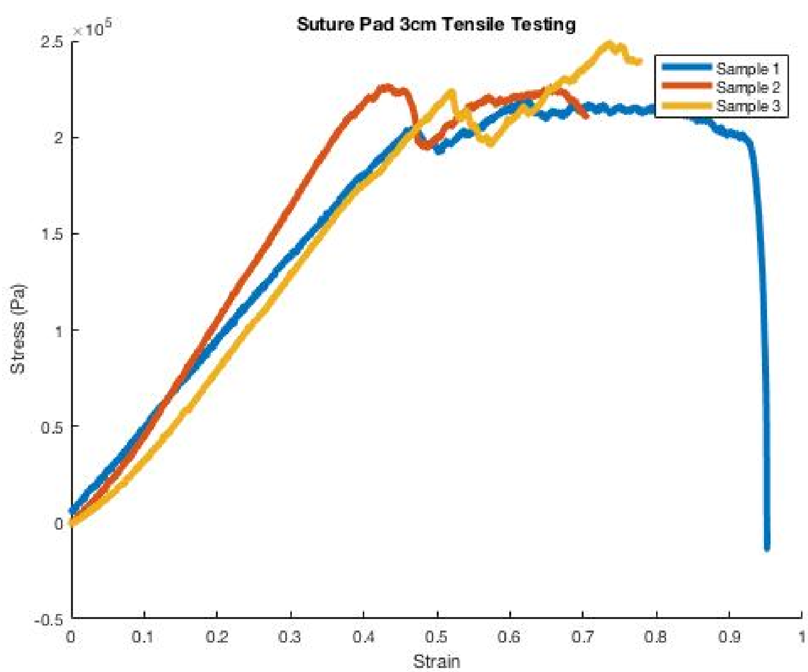


Figure 1. Stress-strain curves from MTS testing for the 3 cm samples.

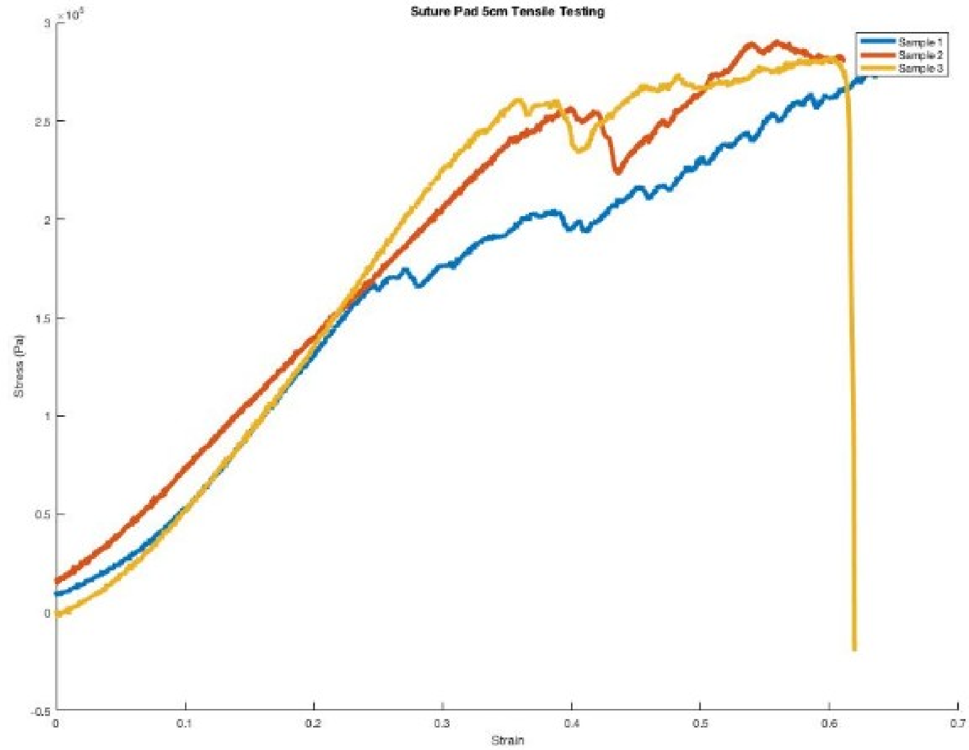


Figure 2. Stress-strain curves generated from MTS testing for the 5 cm test samples.

Table 1. Calculated tensile force based on the measured "fake skin" displacements and the estimated elastic modulus

Test	Length (m)	ΔLength (m)	Strain	Area (m^2)	Elastic Modulus (Pa)	Tensile Force (N)
1	0.01288	0.00357	0.27717	0.000282	435770	34.0611
2	0.00937	0.00297	0.31697	0.000282	435770	38.9514
3	0.00666	0.0015	0.22523	0.000282	435770	27.6773

Upon analyzing the total displacement of the device on skin after a 3 minute period, average displacements of 7.3000e-04 +- 6.3269e-04m and 0.0015 +-7.3736e-04m were measured for skin prep and no skin prep respectively (Table 2). A paired t-test conveyed that no significant difference between these mean displacement values exists (p = 0.2222).

Table 2. Measured device displacements after 3 minutes after different skin treatments

Skin Prep	No Skin Prep
0 mm displacement	1.42 mm displacement
1.07 mm	2.33 mm
1.12 mm	0.87 mm

Pain Scores:

- Jack = 0
- Kelly = 0
- Jurnee = 1
- Lizzy =2

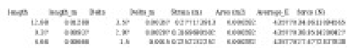
Conclusions/action items:

The calculated tensile forces found using this model are clearly outside the team's target range. I have walked through my Matlab code and have found no errors in the logic. After doing a bit more research, the modulus of elasticity of the samples is far higher than that of skin (0.05-0.15MPa) and that of Eco-Flex 00-30 silicone which the suture pad is primarily made of (0.2 MPa). This testing should be done again using a more accurate model of skin in order to determine if our device meets the tensile force criteria stated in the PDS. See the entry "12/3/2019 Silicone Mechanics Research" under Lizzy Schmida>Research Notes>Biology and Physiology for further details on the tensile force analysis.

With respect to device displacement during use, an overall average slip of 1.12mm was found. The surface treatment (Skin-Prep vs. bare skin) does not effect the amount the device slips during use.

From an observational stand point, shallow indentations in the skin were observed upon removal of the device. These marks faded within 2 minutes. An average pain score of 0.75 out of 5 was found.

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:42 PM CST



length	length_m	Delta	Delta_m	Stress (Pa)	Area (m2)	Average_E	force (N)
12.88	0.01288	3.57	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	1.6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

BME_400_Force_analysis.xlsx(32.1 KB) - download Spreadsheet that calculates the tensile forces

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:44 PM CST

```
1    0.02730    0.01319    0.000972    0.0371    0.01519    0.000943
     0.03546    0.016 0.000014    0.00506    0.01204    0.000675    0.05130
     0.01451    0.000046    0.05907    0.01151    0.00011
```

BME400_sample_data.txt(152 Bytes) - download File containing each sample's gage length, width, and thickness (all in mm). File called by Matlab to calculate areas and original lengths.

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:48 PM CST

```
TR1 = load('/Volumes/Lexar/JDesign/Sample 1/Sample1.txt');
TR2 = load('/Volumes/Lexar/JDesign/Sample2/Sample2.txt');
TR3 = load('/Volumes/Lexar/JDesign/Sample3/Sample3.txt');
TR4 = load('/Volumes/Lexar/JDesign/Sample4/Sample4.txt');
TR5 = load('/Volumes/Lexar/JDesign/Sample5/Sample5.txt');
TR6 = load('/Volumes/Lexar/JDesign/Sample6/Sample6.txt');
sample_info = load('/Users/Lizzy/Desktop/BME400_sample_data.txt');

%Displacement Data (mm)
DTRmm1 = TR1(:,1);
DTRmm2 = TR2(:,1);
DTRmm3 = TR3(:,1);
DTRmm4 = TR4(:,1);
DTRmm5 = TR5(:,1);
DTRmm6 = TR6(:,1);

%Displacement Data conversion into meters (m)
DTR1 = DTRmm1/10^3;
DTR2 = DTRmm2/10^3;
DTR3 = DTRmm3/10^3;
DTR4 = DTRmm4/10^3;
DTR5 = DTRmm5/10^3;
DTR6 = DTRmm6/10^3;

%Force Data
LTR1 = TR1(:,2);
LTR2 = TR2(:,2);
LTR3 = TR3(:,2);
LTR4 = TR4(:,2);
LTR5 = TR5(:,2);
LTR6 = TR6(:,2);

%Calculate Cross section area of samples
thickness = sample_info(:,4);
width = sample_info(:,3);
sample_length = sample_info(:,2);

for i = 1 : length(thickness)
    area(i,1) = thickness(i,1) * width(i,1);
end

%Strain Data for each trial both displacement and length are in m
str1 = (DTR1 / sample_length(1));
str2 = (DTR2 / sample_length(2));
str3 = (DTR3 / sample_length(3));

str4 = (DTR4 / sample_length(4));
str5 = (DTR5 / sample_length(5));
str6 = (DTR6 / sample_length(6));

% %Max Loading Force
% ML1 = max(LTR1);
% ML2 = max(LTR2);
% ML3 = max(LTR3);
% ML4 = max(LTR4);
% ML5 = max(LTR5);
% ML6 = max(LTR6);
%
% %Average of Max Load
% ave_max_load_3cm = (ML1 + ML2 + ML3)/3
% ave_max_load_5cm = (ML4 +ML5 +ML6)/3

%Stress--force/area(Pa)
```

BME400.m(3.8 KB) - download Matlab code that processes and analyzes the MTS data. Performs statistical analysis for skin prep displacements over 3 mins.

11/20/2019 MTS Testing Data

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:32 PM CST

Title: MTS Testing Data

Date: 11/20/2019

Content by: Lizzy S.

Present: Jurnee

Goals: Obtain strain and stress data for samples of the suture pad in order to determine its mechanical properties and how similar it is to actual skin. The modulus of elasticity calculated from this data will be used to determine the tensile force the device applies on the skin edges based on the measured displacement.

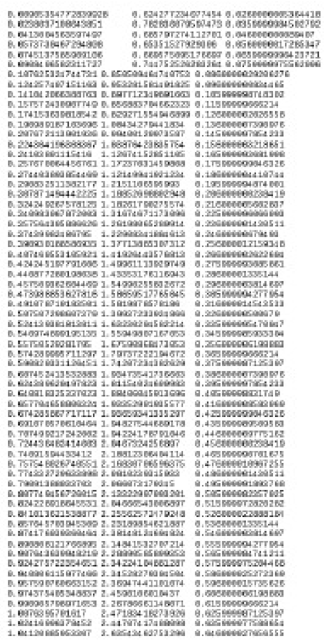
Content:

Six samples were tested, 3 at a gage length of 3cm and 3 at a length of 5cm. These sample lengths were chosen based on the constraints of the MTS machine located in the ECB student lab and the wound sizes Dr. Charleton specified (2-5cm).

Conclusions/action items:

Some slippage was observed during testing. The TA assisting with the testing suggested analyzing the data for the elastic modulus after 1 mm of displacement had occurred. Attached are the text files for each run. The relevant data required for analysis are the first column and second columns as displacement (mm) and tensile force (N) respectively.

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:34 PM CST



Sample1.txt(79.1 KB) - download MTS Raw Testing Data for the suture pad samples

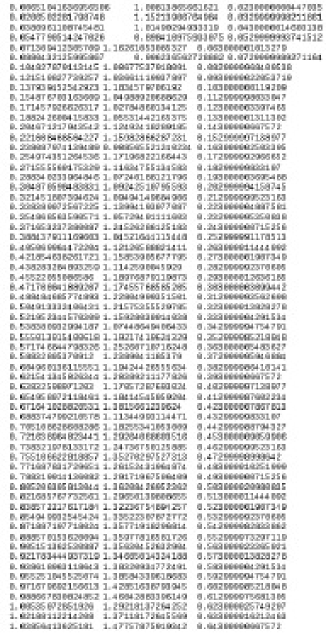
▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:34 PM CST

Sample2.txt(78.8 KB) - download MTS Raw Testing Data for the suture pad samples

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:34 PM CST

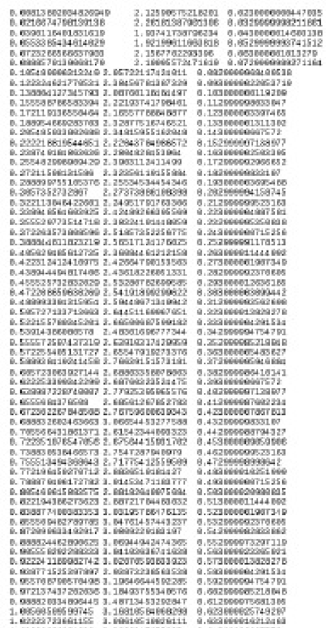
Sample3.txt(84 KB) - download MTS Raw Testing Data for the suture pad samples

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:34 PM CST



Sample4.txt(137 KB) - download MTS Raw Testing Data for the suture pad samples

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:34 PM CST



Sample5.txt(95.4 KB) - download MTS Raw Testing Data for the suture pad samples

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @01:34 PM CST

Sample6.txt(111.7 KB) - download MTS Raw Testing Data for the suture pad samples

PDS

▪ Jurnee Beilke ▪ Oct 08, 2019 @10:05 PM CDT

Wound Edge Approximation

Product Design Specification

Client: Dr. Nicola Charlton

Advisor: Dr. Suarez-Gonzalez

Team:

Lizzy Schmidt (Comm) schmidt@wisc.edu
Jurnee Beilke (Team Leader) jbeilke2@wisc.edu
Kelly Starykowicz (BWIG) kstarykowicz@wisc.edu
Jack Fahy (BSAC/BPAG) jfahy@wisc.edu

Date Updated: 10/05/19

Function:

Over 6 million laceration cases are treated in emergency departments each year; during such repairs, skin tension pulls the wound apart while the provider is attempting to approximate the wound edges [1]. Repair is therefore difficult, and imperfect approximation can lead to scarring and poor healing of the wound. This problem is often solved within operating rooms with wound closure systems for large wounds; however, it poses a challenge for physicians in emergency rooms, urgent care clinics, and office settings on small wounds ranging from 1 cm to 5 cm. A clinical tool will be developed to approximate the wound edges together while the wound is either sutured or glued, acting as a "second pair of hands" for the physician. The final design must be easy to use by healthcare professionals and must not impart any pain or markings onto the patient's skin during use.

Client requirements:

- The device must hold the edges of the wound together for suturing or gluing; however, the tool must not interfere with the wound repair.
- The device must not harm healthy skin by leaving marks or causing pain for the patient during use.
- The device needs to be sterilizable since the tool will be used near open wounds, with the possibility of infection.
- The device should be effective to use for linear wounds 1-5 cm in length located typically on patient limbs or torso, not facial or scalp tissue.
- The device must be easy and simple to use, not cumbersome or difficult to handle.

REVISED_Product_Design_Specification.pdf(158.2 KB) - download

Design Matrix and Criteria

▪ Jurnee Beilke ▪ Oct 08, 2019 @10:06 PM CDT

Wound Edge Approximation

Design Matrix

Client: Dr. Nicole Charlton

Advisor: Dr. Suarez-Gonzalez

Team: Lizzy Schmida (Comm) schmida@wisc.edu
Jurnee Beilke (Team Leader) jbeilke2@wisc.edu
Kelly Starykowicz (BWIG) kstarykowicz@wisc.edu
Jack Fahy (BSAC/BPAG) jfahy@wisc.edu

Date Updated: 09/27/19

Designs

1. Bow-Shaped Design
2. Hook and Loop Design
3. Barrette Design
4. Rectangle Design

Criteria

Effectiveness (25 points):

Effectiveness is a top priority for our design, which is why this category received the highest weighting of 25 points. This criterion is a measurement of how well the device can accurately and consistently approximate the wound edges in order for the wound to be glued or sutured. The device should bring the edges of the wound into contact and not interfere with suture or glue application. Additionally, effectiveness includes the ability of the design to consistently provide wound eversion.

Patient Comfort (20 points):

Patient comfort was given a weight of 20 points, as it is of the utmost importance while the device is in use. Clinicians must be able to utilize the device without the use of local anesthetic on the tissue surrounding the laceration. The wound approximation system must not be uncomfortable while placed on the patient.

Safety (20 points):

Safety is important for this product, as the device must avoid causing more damage to the patient's skin. The wound approximation apparatus must not cause any further damage to the tissue from excessive force or leave any deep skin marks after product removal. Additionally, the device must not harm or pinch the user during application. Since safety is always a vital consideration when designing a product, this category received a 20 point score.

Design_Matrix_.pdf(364 KB) - download

Preliminary Report

KELLY STARYKOWICZ · Dec 04, 2019 @03:52 PM CST

BME Design

Wound Edge Approximation

Preliminary Report

Biomedical Engineering Design 400

Department of Biomedical Engineering

University of Wisconsin

October 9th, 2019

Team Members:

James Beilke (Team Leader)

Lizzy Schmidt (Communicator)

Jack Fahy (BSAC/BPAG)

Kelly Starykowicz (BWIG)

Client:

Dr. Nicola Charlton, Aurora Health Center, Specialty in Family Medicine

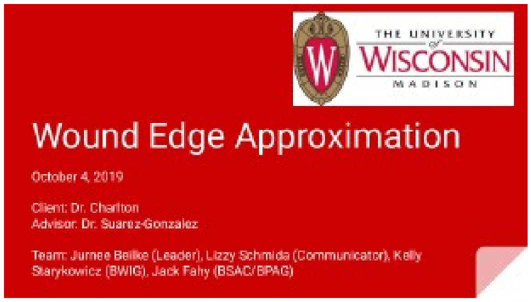
Advisor:

Dr. Darilis Suarez-Gonzalez, Department of Biomedical Engineering, College of Engineering, University of Wisconsin-Madison

Preliminary_Report_2_.pdf(1.2 MB) - download

Preliminary Presentation

▪ KELLY STARYKOWICZ ▪ Dec 04, 2019 @03:53 PM CST



Preliminary_Presentation_2_.pdf(875.7 KB) - download

Revised PDS

▪ KELLY STARYKOWICZ ▪ Dec 04, 2019 @03:53 PM CST

Wound Edge Approximation

Product Design Specification

Client: Dr. Nicola Charlton

Advisor: Dr. Suarez-Gonzalez

Team:
Lizzy Schmidt (Comm) schmidt@wisc.edu
Jamee Beilke (Team Leader) jbeilke2@wisc.edu
Kelly Starykowicz (BWIG) kstarykowicz@wisc.edu
Jack Fahy (BSAC/BPAG) jfahy@wisc.edu

Date Updated: 10/05/19

Function:

Over 6 million laceration cases are treated in emergency departments each year; during such repairs, skin tension pulls the wound apart while the provider is attempting to approximate the wound edges [1]. Repair is therefore difficult, and imperfect approximation can lead to scarring and poor healing of the wound. This problem is often solved within operating rooms with wound closure systems for large wounds; however, it poses a challenge for physicians in emergency rooms, urgent care clinics, and office settings on small wounds ranging from 1 cm to 5 cm. A clinical tool will be developed to approximate the wound edges together while the wound is either sutured or glued, acting as a "second pair of hands" for the physician. The final design must be easy to use by healthcare professionals and must not impart any pain or markings onto the patient's skin during use.

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- The device must be easy and simple to use, not cumbersome or difficult to handle.

REVISED_Product_Design_Specification.pdf(131.4 KB) - download

Final Poster

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @08:35 PM CST

Final_Poster_1_.pdf(2.6 MB) - download

10/09/19 Outreach Meeting

▪ Jurnee Beilke ▪ Oct 09, 2019 @01:51 PM CDT

Title: Outreach Meeting

Date: 10/09/17

Content by: Jurnee

Present: All

Goals: To gain some ideas for the outreach activity this semester.

Content:

- Mechanic ideas may be the route the team wants to go
- Prosthetics
- Mechanics of bones
- K12 Teach Engineering (teachengineering.org/k-12)
- Cite sources from the activity - background information
- Activity guide is online under BME 400 or 402 resources
- Dr. P will send us the activity ideas and will reach out to schools for potential outreach activities
- Demographic information is critical - ask participating schools for statistics
- Children self report
- Meet again once we have a draft
- Focus on activity for middle school or 5th-6th grade for activity
- Photo-release forms need to be sent to the teacher immediately
- Target is after school activity -
- Bring outline of the report - note certain things during the activity
- Note what went well and what went poorly
- Send schedule and draft or guide and presentation to meet again

Conclusions/action items:

We need to find an activity that interests us as a group and is suitable for students in 5th grade. We will then meet again with Dr. P to finalize outreach plans.

09/20/19 Outreach Seminar

• KELLY STARYKOWICZ • Sep 20, 2019 @01:58 PM CDT

Title: Outreach Seminar

Date: 9/20/19

Content by: Kelly

Present: All team members

Goals: Learn about outreach and its requirements

Content:

- Encouraged to do outreach at specified location- grants, free t shirts
  - Submit 1 page proposal with table of materials and costs
  - Form online
- 10-15 min presentation: define BME and introduce activity
- 45 min fun hands-on activity
  - Must have clear learning objectives
- Report after outreach
- Teacher/Leader Evaluation during event
- Due Friday, April 3rd 2020
- Webpage- Outreach Requirements & Submission
- Also include pictures
  - Sent photo release form way in advance
- Consider topics that interest you- up to 5 people
  - Must set up meeting with Dr. Puccinelli once we have an idea
- Past BME activities will be posted online
- Teach Engineering (K-12)- google it

Ex:

- Wear name tags
- Define BME
- Can introduce design project if you want
- Bring stuff to show
- Introduce problem- concussions
- How to solve problem as engineer
- End with rules and keep them up throughout activity

    - Ex: design a helmet- design 5 min, build 20 min

Good aspects:

- Competition
- Prize
    - candy? Think of allergies, classroom restrictions
- Give options- allow for creativity

Have to submit activity guide by the end of the semester!

Conclusions/action items:

- Meet with Dr. P
- Submit activity guide by end of semester
- Outreach due April 3, 2020

11/20/2019 Outreach Practice

• ELIZABETH SCHMIDA • Dec 06, 2019 @05:10 PM CST

Title: Outreach Practice

Date: 11/20/2019

Content by: Lizzy

Present: Design Team

Goals: Run through our presentation and build a prosthetic leg in preparation for Friday.

Content:

The team met in an ME classroom. The presentation was practiced several times and edits to the slides were made throughout. The team then built a practice prosthetic leg in order to ensure enough materials were provided (Figure 1). The created prosthetic worked well, we still have concerns about safety with respect to the testing portion of the activity. We will check with the classroom staff when we arrive on Friday to get their input.

Figure 1. Jurnee testing out a below knee prosthesis without using a shoe.

Conclusions/action items:

The team is ready. We will meet at ECB at 11am on Friday and Jurnee will drive us over to the school. I will have copies of the presentation in multiple formats on a flash drive to ensure we can display the slides properly.

11/27/2019 Outreach Summary

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:00 PM CST

Title: Outreach Summary

Date: 11/27/2019

Content by: Lizzy

Present: Jack, Jurnee, Kelly, Lizzy, Dr. Suarez-Gonzalez, Crestwood Elementary students and staff

Goals: Teach students about the different areas of BME and the design process through building a below knee prosthesis.

Content:

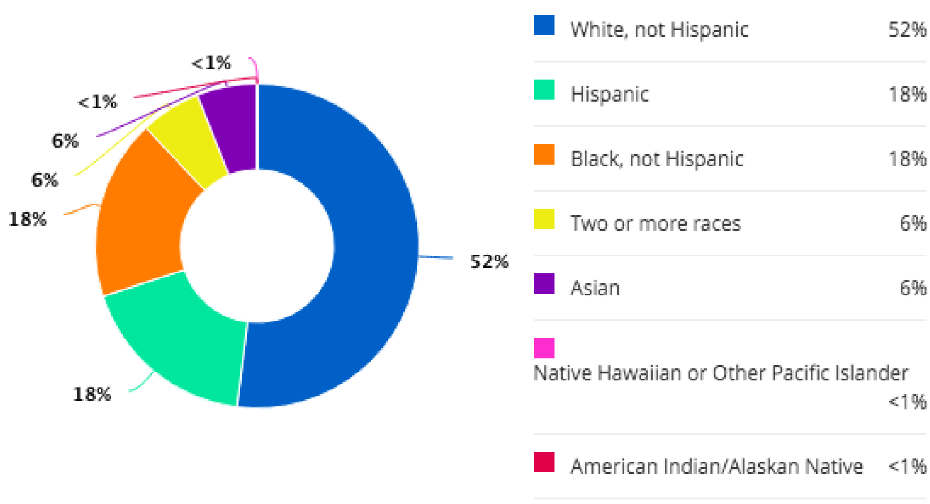
On Friday, November 22nd, we performed our senior outreach activity at Crestwood Elementary (5930 Old Sauk Rd, Madison, WI 53705) in Mrs. McMahon's classroom. Twenty-three 4th grade students (14 females and 8 males) , ages 9-11, participated. Crestwood Elementary has a student demographic of 52% White, 18% Hispanic, 18% Black, 6% Asian, and 6% two or more races. Approximately 23% of students attending Crestwood Elementary are learning English and 41% of students are from low-income families [1].

Our outreach activity consisted of a 15 minute presentation describing biomedical engineering and below knee prosthetics as well as a hands on design activity. Students were split into six groups with the assistance of Mrs. McMahon to design and build their own below knee prosthesis. All materials were sorted out beforehand and delivered in a bag to each group. Students from each group were able to choose their own PVC pipe (lengths varied). After 30 minutes of design and building the teams went to the gym to test their devices. Testing was done based on how far a team member could walk with the device. Once completed, the class regrouped and discussed what they learned. Cupcakes were provided by Dr. Saurez after clean up was complete.

No constraints were placed on the activity; Mrs. McMahon was extremely helpful and flexible throughout our visit. We were very impressed with the student's knowledge level and enthusiasm for the activity. They knew a lot about engineering and were able to break down the word "biomedical" to determine what biomedical engineering is. The students were very attentive; they were not afraid to ask and answer questions throughout our presentation. In the future, it may be best to select a different image as an example of biomaterials engineering in the interest of time (the picture of a rat with an ear being grown on its back generated loads of questions from students). If we were to do the activity again and had more time with the students, it would be great to allow them to test their device, redesign, and test again.

References:

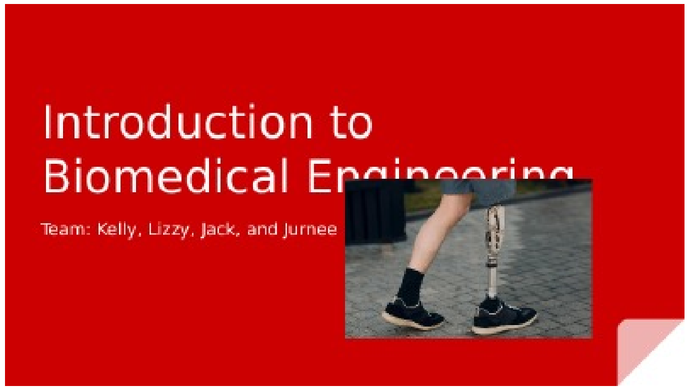
[1] "Explore Crestwood Elementary School in Madison, WI," *GreatSchools.org*. [Online]. Available:https://www.greatschools.org/wisconsin/madison/852-Crestwood-Elementary-School/#Students. [Accessed: 27-Nov-2019].



Conclusions/action items:

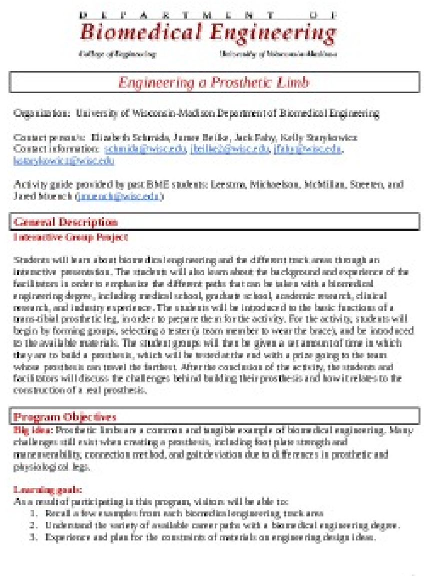
The above content will be submitted as part of our final deliverables for outreach (due 12/11). Attached below are the activity guide and power point presentation used during our classroom visit.

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:01 PM CST



Outreach_Presentation_.pptx(15.4 MB) - download

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:02 PM CST



DEPARTMENT OF
Biomedical Engineering
College of Engineering University of Wisconsin-Madison

Engineering a Prosthetic Limb

Organization: University of Wisconsin-Madison Department of Biomedical Engineering

Contact person/s: Elizabeth Schmida, Jurnee Beilke, Jack Fahy, Kelly Starykowicz
Contact information: schmida@wisc.edu, jbeilke2@wisc.edu, jfahy@wisc.edu, kstarykowicz@wisc.edu

Activity guide provided by past BME students: Leestma, Michaelson, McMillan, Streeter, and Jared Muench (jmuench@wisc.edu)

General Description
Interactive Group Project

Students will learn about biomedical engineering and the different track areas through an interactive presentation. The students will also learn about the background and experience of the facilitators in order to emphasize the different paths that can be taken with a biomedical engineering degree, including medical school, graduate school, academic research, clinical research, and industry experience. The students will be introduced to the basic functions of a trans-tibial prosthetic leg, in order to prepare them for the activity. For the activity, students will begin by forming groups, selecting a tester (a team member to wear the brace), and be introduced to the available materials. The student groups will then be given a set amount of time in which they are to build a prosthesis, which will be tested at the end with a prize going to the team whose prosthesis can travel the farthest. After the conclusion of the activity, the students and facilitators will discuss the challenges behind building their prosthesis and how it relates to the construction of a real prosthesis.

Program Objectives
Big idea: Prosthetic limbs are a common and tangible example of biomedical engineering. Many challenges still exist when creating a prosthesis, including foot plate strength and maneuverability, connection method, and gait deviation due to differences in prosthetic and physiological legs.

Learning goals:
As a result of participating in this program, visitors will be able to:
1. Recall a few examples from each biomedical engineering track area
2. Understand the variety of available career paths with a biomedical engineering degree.
3. Experience and plan for the constraints of materials on engineering design ideas.

1

BME_Outreach.docx(80.1 KB) - download

11/27/2019 Outreach Correspondences

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:12 PM CST

Title: Outreach Correspondences

Date: 11/27/2019

Content by: Lizzy

Present: NA

Goals: Provide a brief overview of the interactions mainly via email that took place in order to facilitate the activity.

Content:

As team communicator, I was in charge of coordinating our visit with Crestwood Elementary and Dr. Tracy Puccinelli the outreach coordinator at UW-Madison. Attached are emails between all parties.

Conclusions/action items:

A surprising amount of time and energy went into coordinating this event, far more than I had originally anticipated. Despite the original rescheduling, the event went smoothly (see the "Outreach Summary" entry for an overview of the event).

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:13 PM CST

Re__Outreach_activity.rtf(16.1 KB) - download Emails with Chris McMahon

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:15 PM CST

Re__BME_400__Outreach_supplies--coordinating_their_return.rtf(18.6 KB) - download Emails with Dr. T Puccinelli

09/09/19 Forces Required for Wound Closure

▪ Jurnee Beilke ▪ Sep 09, 2019 @08:40 PM CDT

Title: Forces Required from Wound Closer

Date: 09/09/19

Content by: Jurnee Beilke

Present: NA

Goals: To gain a background understanding of the forces required for wound closure and how wound closure impacts scar appearance.

Content:

- Introduction
  - The force required to close a wound is related to the appearance of the scar
  - Forces required for edge approximation of mammaplasty wounds were measured and correlated with scar appearances after healing occurred
- Materials and Methods
  - Seven patients studied (27 to 64 years old)
  - A total of 234 measurements of force for wound edge approximation were made
  - Force required for approximation was measured at six locations
    - 1 cm from the medial end of incisions
    - medial midpoint one-half the distance from the breast midline to medial limit of incisions
    - 1 cm medial to breast midline
    - 1 cm lateral to breast midline
    - lateral midpoint one-half the the distance from the breast midline to lateral limit of incisions
    - 1 cm from lateral end of incision
  - Temporary looped suture was passed through the subcuticular tissue at each location on either side of the incision
  - Spring scales were attached to the sutures and the edges brought together until edges were brought into contact
  - Three measurements were taken at each location and averaged
  - One year after surgery, the appearance of the scar was noted and photographed and scar width was measured
- Results
  - Significant correlation between force required for wound closure and the scar width
  - Scars were significantly wider in breast para-median location than in midpoints
  - Midpoints are significantly wider than the ends
- Discussion
  - Numerical correlation between force required for wound closure and scar width/appearance
  - If extreme force is required for wound edge approximation, a wider scar is anticipated
  - If wide scars are unacceptable, techniques such as grafts or flaps must be used to add additional skin or tissue

Conclusions/action items:

I now have a slightly better understanding of the problem posed by the client. Not only is suturing/gluing a wound difficult for a physician when there are signifiant tensions from the skin pulling apart the wound edges, but larger scars can be created from greater forces necessary to close the wound. The device created must make wound approximation easier for physicians and minimize the force exerted on the wound edges to prevent severe scarring.

Wray, R. (1983). Force Required for Wound Closure and Scar Appearance. *Plastic and Reconstructive Surgery*, 72(3), pp.380-382.

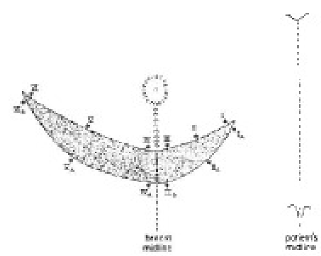
▪ Jurnee Beilke ▪ Sep 09, 2019 @08:42 PM CDT

Force Required for Wound Closure and Scar Appearance

H. Christie Wray, M.D.

[illegible]

[illegible]



[illegible]

[illegible]

00006534-198309000-00021.pdf(116.1 KB) - download

09/11/19 Review of Suturing Techniques

▪ Jurnee Beilke ▪ Sep 11, 2019 @12:03 PM CDT

Title: Review of Sutures and Suturing Techniques

Date: 09/11/19

Content by: Jurnee Beilke

Present: NA

Goals: To gain an understanding of suture types and techniques in order to develop an assist device that works alongside existing techniques.

Content:

- Ideal suture is strong, handles easily, and forms secure knots
  - Causes minimal tissue inflammation and does not promote infection
  - Stretches and accommodates wound edema
  - Proper selection of suturing technique leads to better results in wound healing
- Today - a wide array of suture materials and needles are available
- Sutures function to maintain wound closer and promote wound healing
- Wound healing is affected by amount of suture material, suture type and technique, and amount of tension on the suture
- Process of wound healing
  - Initial lag phase (0 to 5 days)
  - Fibroplasia phase (5 to 14 days)
  - Maturation phase (14 to end)
- Suture materials need to be easy to handle, be able to form secure knots, and possess a high tensile strength
  - Monofilamentous - Prolene or Ethilon
  - Multifilamentous - silk (twisted or braided - harbor bacteria)
  - Smaller the cross sectional diameter, the more zeros the suture size has - greater diameter, higher tensile strength
  - The more suture material implanted, the greater the risk of tissue reaction (natural materials/silk are more reactive than synthetic)
  - Two basic types: absorbable and non-absorbable
  - Absorbable - lose most tensile strength within 60 days - most are synthetic (Dexon, Vicryl, PDS, Maxon)
  - Catgut - derived from sheep or cattle intima
  - Dexon- polyglycolic acid polymer
  - Vicryl - polyglatic acid copolymer
  - PDS - polydioxanone polymer
  - Maxon - polytrimethylene carbonate monofilament
  - Non-absorbable - materials resisten to degradation mechanisms
  - Silk - natural protein filaments spun by silkworm
  - Nylon - synthetic polyamide polymer fiber
  - Polypropylene (Prolene) - plastic suture
  - Braided polyesters (Ethibond, Dacron) - polyester fibers
  - Polybutester (Novafil) - thermoplastic copolymer
- Surgical needles
  - Thickness, accessibility to wound, size, and cost are important factors to consider
  - Eye, body, and the point
  - Eye is attached to suture material
  - Body determines shape of the needle
  - Point determined by type of tissue the needle is required to pass
- Staples
  - Stainless steel and combine highest tensile strengths of sutures with low tissue reactions
  - Close wounds under a great deal of tension
- Wound closure tapes
  - Benefit of tapes is that skin surface is not penetrated while the would edges are held together
  - Maintain integrity of epidermis, less tension to the wound
  - More resistant to infection than sutured wounds
- Suturing Techniques
  - Selection of appropriate suturing technique is essential in order to provide an accurate and secure approximation of skin edges with least scar formation
  - Maximal wound eversion
  - Maintain tensile strength throughout healing process

- Technically simple and fast for surgeons
- Allow for precise wound edge approximation
- Buried suture - reduces dead space, decreases tension along skin edges, provides wound eversion
- Buried vertical mattress suture - buried sutures that gives eversion to the wound, slightly wider needle path
- Running continuous suture - rapid, secure closer with even distributed tension along length of wound
- Interrupted suture - selective adjustments of wound edges can be made
- Vertical mattress suture - greater wound eversion
- Corner stitch - essential for suturing flap tips without compressing the sub-dermal vessels
- Sub-cuticular suture - effective in wound closure
- Horizontal mattress suture - variation of corner stitch

Conclusions/action items:

After reading this article, I now have more background knowledge about suture types and techniques which will prove useful when I am designing a device that will be used alongside these suturing techniques during wound closure.

MOY, R., WALDMAN, B. and HEIN, D. (1992). A Review of Sutures and Suturing Techniques. *The Journal of Dermatologic Surgery and Oncology*, 18(9), pp.785-795.

▪ Jurnee Beilke ▪ Sep 11, 2019 @12:03 PM CDT

A Review of Sutures and Suturing Techniques

Role of Sutures in Wound Healing

Properties of Suture Material

01787395-199209000-00004.pdf(1.4 MB) - download

09/24/19 Autoclave Background

▪ Jurnee Beilke ▪ Sep 24, 2019 @01:18 PM CDT

Title: Autoclave Background

Date: 09/24/19

Content by: Jurnee Beilke

Present: NA

Goals: To gain an understanding of how autoclaves work since our reusable design will need to be sterilized in an autoclave between uses.

Content:

- Fisherbrand SterilElite Tabletop Autoclaves
  - Price - $6,520 to $7,530
  - Device uses the power of steam to kill bacteria, spores, and germs
  - Design - compact design with high performance
    - Reliable and safe
    - Microprocessor control system provides nine fully automatic programs (add water, sterilization, and dry)
    - Eight pre-installed sterilization cycles
    - Two separate water-level check mechanisms - water tank level and chamber water level
    - Auto dry function
    - Pressure door auto-lock device
    - Chamber protected by pressure switch and steam pressure safety valve
    - Vacuum/pressure release buttons will cut off power supply, exhaust pressure of the chamber, and release chamber vacuum
  - Functionality
    - 121-135 degree Celsius

Conclusions/action items:

I now have a better understanding of the use and functionality of an autoclave. This information is important, for our device may be reusable and will need to be sterilized between uses. Understanding how an autoclave functions is important for material selection, since the material will need to withstand the heat and steam power of the machine.

Fishersci.com. (2019). *Sterilizers and Autoclaves | Fisher Scientific*. [online] Available at: https://www.fishersci.com/us/en/products/I9C8JVQ8/benchtop-sterilizers-autoclaves.html [Accessed 24 Sep. 2019].

09/24/19 Anatomy of the Skin

▪ Jurnee Beilke ▪ Sep 24, 2019 @03:41 PM CDT

Title: Anatomy of the Skin

Date: 09/24/19

Content by: Jurnee Beilke

Present: NA

Goals: To gather more background information about the skin, so I can design a device with the team that appropriately interacts with superficial skin wounds without causing further harm to the patient.

Content:

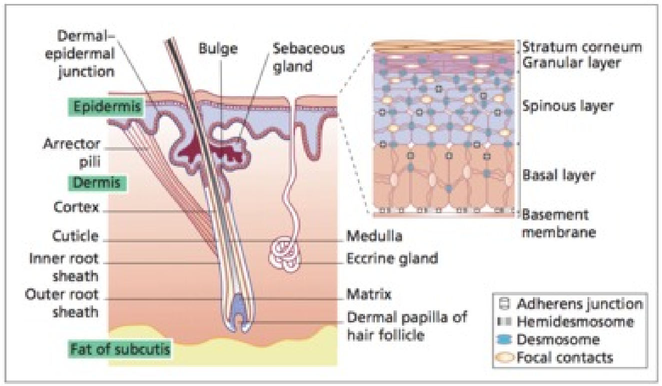
- Human skin consists of stratified, cellular epidermis and an underlying dermis of connective tissue
- The dermal-epidermal junction provides mechanical support for the epidermis and acts as a partial barrier against exchange of cells and large molecules
- Below the dermis is a fatty layer, panniculus adiposus (subcutaneous)
- Two main kinds of human skin
    - Glabrous skin (non-hairy) found on palms and soles is grooved on its surface
        - Characterized by a thick epidermis divided into several well-marked layers and encapsulated sense organs
    - Hair-bearing skin has hair follicles and sebaceous glands
- Superficial epidermis is epithelium composed of keratinocytes formed by cel division in basal layer
    - Melanocytes donate pigment to skin
- Basis of the dermis is a supporting matrix ground substance in which polysaccharides and protein are linked to products macromolecules with capacity for retaining water
    - Collagen and elastin are present in this matrix to supply tensile strength
    - Fibroblasts, mast cells, and histiocytes are cellular constituents in the dermis
    - Dermis has a very rich blood supply
- Epidermis
    - Terminally differentiated, stratified epithelium
    - Major cell is the keratinocyte, which moves from attachment to the epidermal basement membrane towards the skin surface, forming several layers
    - Epidermis can be divided into four distinct layers
        - stratum basale/stratum germinativum
        - stratum spinosum
        - stratum granulosum
        - stratum corneum
    - Cells in epidermis include melanocytes, Langerhan's cells, Merkel cells
    - Intercellular junctions link adjacent keratinocytes - responsible for mechanical, biochemical, and signaling interactions between cells
        - Desmosomes - major adhesion complex anchoring keratin intermediate filaments to cell membrane (allowing cells to withstand trauma)
        - Adherens junctions - electron dense transmembrane structures that associate with actin skeleton (cell motility, shape and interaction)
        - Gap junctions - clusters of intercellular channels known as connexons that form connections between the cytoplasm of adjacent keratinocytes
        - Tight junctions - regulators of permeability in epithelia and present skin with barrier integrity, composed of transmembrane and intracellular molecules
- In adult life, cell division maintains differentiated tissues and replaces lost cells
    - Nerve, skeletal - no cell division
    - Organs - cell division in response to injury
    - Skin - permanently renewing populates of cells (continuous cell turnover)
    - Cell division occurs in the basal layer of the epithelium
    - Cell kinetics are complicated in epidermis by balance between growth, differentiation, and cell death

Conclusions/action items:

After reading this article, I have a better understanding of the components and functions of the skin. This background will be useful when designing a device that interacts with superficial wounds.

J.A. McGrath, R.A.J. Eady & F.M. Pope, *Rook's Textbook of Dermatology*, 7th ed. Oxford: Blackwell Publishers, 2004. ch. 3.

▪ Jurnee Beilke ▪ Sep 24, 2019 @01:49 PM CDT



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09/24/19 Tissue Adhesives

▪ Jurnee Beilke ▪ Sep 24, 2019 @10:24 PM CDT

Title: Tissue Adhesives

Date: 09/24/19

Content by: Jurnee Beilke

Present: NA

Goals: To learn more about tissue adhesives since they will be used primarily in conjunction with our wound edge approximating apparatus.

Content:

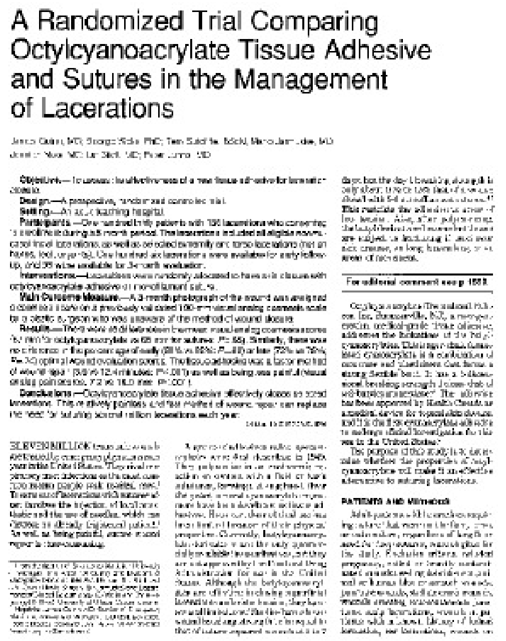
- 11 million traumatic wounds are treated by emergency physicians each year in the United States
- Treatment of lacerations with sutures often involved the injection of local anesthetic and the use of needles which can cause distress to the patient
- Suture repair is also time consuming
- A group of adhesives called cyanoacrylates - polymerize in an exothermic reaction on contact with a fluid or basic substance forming a strong bond
- Butylcyanoacrylates are effective in closing superficial lacerations under low tension
    - Adhesives can become brittle and may fracture is used over skin creases
- Octylcyanoacrylate address limitations - form a strong flexible bond
- Methods
    - Adult patients with lacerations requiring sutures
    - All lacerations assess to whether deep sutures or debridement was needed
    - Subjects were randomized to undergo skin closure with sutures or adhesives
- Clinical outcomes
    - Time of procedure from the start of wound care to complete closure was recorded by physician
    - Patients rated their pain of wound closure
    - Patients were asked to return for a wound assessment and wound healing was given a cometic rating/score
- Results
    - There was no difference in the blinded cosmetic outcome assessment at 3 months with the adhesive vs sutures
    - Similar outcomes between groups on the wound evaluation scale at early and 3 month follow-up
    - Treatment with tissue adhesive was rated less painful by patients
    - Time for repair was short for the tissue adhesive than for suturing
- Conclusions
    - Tissue adhesive can be incorporated into health practices and products cosmetic results similar to those of suturing while providing fast and painless closure
    - Wound needs to be fully apposed so no adhesive gets into the wound edges

Conclusions/action items:

After reading this article, I have a better understanding of tissue adhesives and their benefits over sutures for wound repair. Our device will primary be used with DermaBond tissue adhesives instead of sutures since adhesive is fast and relatively painless for patients.

Quinn, J. (1997). A Randomized Trial Comparing Octylcyanoacrylate Tissue Adhesive and Sutures in the Management of Lacerations. *JAMA: The Journal of the American Medical Association*, 277(19), p.1527.

▪ Jurnee Beilke ▪ Sep 24, 2019 @10:24 PM CDT


A Randomized Trial Comparing Octylcyanoacrylate Tissue Adhesive and Sutures in the Management of Lacerations

jama_277_19_030.pdf(3.3 MB) - download

09/30/19 Force Sensing in Surgical Sutures

▪ Jurnee Beilke ▪ Sep 30, 2019 @08:08 PM CDT

Title: Force Sensing in Surgical Sutures

Date: 09/30/19

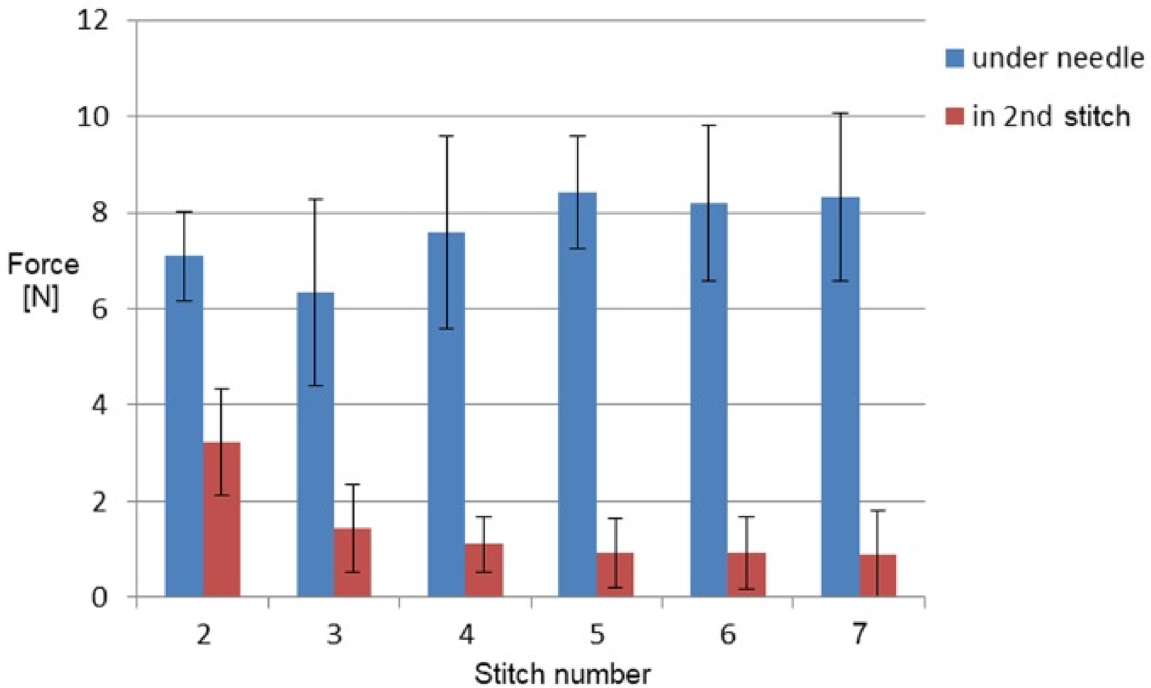
Content by: Jurnee Beilke

Present: NA

Goals: To gain an understanding of the tension in sutures during wound closure, which relates to the tension/forces needed to approximate and close wound edges.

Content:

- Introduction
  - In the process of wound healing, the closure method plays an important role
  - The location of the incision and the tension in the suture are factors that influence the quality of the healed incisions
  - Too high and too low of suture tension can have a negative effect on wound healing
  - Purpose of the paper to describe the design of force sensors for suture threads
    - The relationship between the pulling force and force in one of the stitches of the suture can be determined
- Closing the incision
  - Running stitch is made with one continuous length of suture material used to close tissue layers that requires close approximation
  - During each stitch, the needle is driven through both wound edges and tensioned
  - In previous study, a maximum force of 7N was measured on suture threads (safety factor of new sensors - sensor should withstand up to 15N force)
  - Sensor must not interfere with the hands of the surgeon
- Methods
  - Data recording the user interface for the force sensors was built in Matlab
  - Three different square porcine abdominal wall specimens of 300 by 300 mm were used during the experiments
  - Sutures on each of the four corners of the abdominal wall were used to stretch the abdominal wall
  - Incision was 80 mm long and needed 7 stitches for closure
- Results
  - Both sensors can easily detect force differences of 0.05N
  - Forces per stitch during the wound closure ranged from 6N to 8N
  - The force measurements per stitch remained consistently around 7-8N



- Discussion
    - Force sensors are robust and accurate enough to measure the pulling and stitch force during suturing
    - The tissue has a relatively high resistance during placement of the 5th, 6th, and 7th stitch
    - Every stitch should be pulled through with the same strength to lower the risk of wound failure
- Conclusion
    - Measurement system was developed that could be used to measure forces in suture threads inside and outside the incision
    - Possible to relate thread tension inside sutures to the pulling force applied by the physician
    - Enables comparison of different suture techniques and their impact on wound healing

Conclusions/action items:

After reading this article, I now have a better understanding of the forces required for wound closure using sutures. This information is important because our device will need to exert these forces on the skin to approximate the wound edges.

Horeman, T., Meijer, E., Harlaar, J., Lange, J., van den Dobbelsteen, J. and Dankelman, J. (2013). Force Sensing in Surgical Sutures. *PLoS ONE*, 8(12), p.e84466.

▪ Jurnee Beilke ▪ Sep 30, 2019 @07:37 PM CDT

PLOS

Force Sensing in Surgical Sutures

Tim Horeman, Evert-jan Meijer, Joris J. Harlaar, Johan F. Lange, John J. van den Dobbelsteen, Jenny Dankelman

Abstract

Introduction

pone.0084466.pdf(2.1 MB) - download

09/30/19 Skin Tension Device

▪ Jurnee Beilke ▪ Sep 30, 2019 @08:11 PM CDT

Title: Skin Tension Device

Date: 09/30/19

Content by: Jurnee Beilke

Present: NA

Goals: To understand the tension of skin to estimate the forces required to approximate the wound edges.

Content:

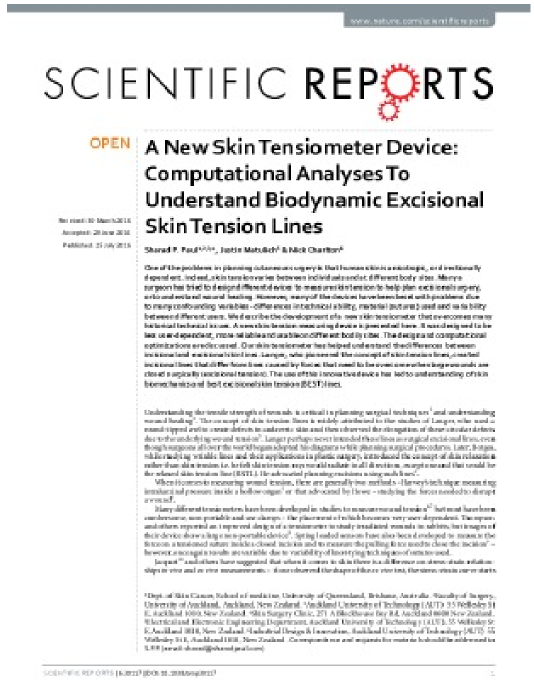
- Introduction
    - Understanding the tensile strength of wounds is critical in planning surgical techniques
    - Skin tensions impact wound healing
    - Tensiometers have been developed in studies to measure wound tension, but more are cumbersome and incorporate clamps
    - Design - bi-directional skin tension measuring device that could measure inherent tension in the skin and the force needed to close the wound
- Methods
    - Prototype based on idea of device operating like a pair of forceps to stretch or compress the skin
    - Current device made up of four main elements
        - Linear actuator
        - Force sensor
        - Signal conditioning hardware
        - Software
    - A calibration reading is taken first
    - The skin is then stretched a predefined distance and the software takes a reading
    - Study began by studying pigskin and later scalp skin to ascertain tension forces
    - Reported that tension needed to approximate skin can be as high as 6.5N
    - Small wounds may have as little tension as 0.5N to 3.2N for larger wounds
    - On scalp tissue, there is a range of tension measurements from 0.5 to 4.6N
- Discussion
    - Device developed on pigskin and adjusted to be used on human skin

Conclusions/action items:

Considering the reported values for the tensions of wounds, our device will need to exert a maximum of 6.5N on the wound edges to approximate the wound edges.

Paul, S., Matulich, J. and Charlton, N. (2016). A New Skin Tensiometer Device: Computational Analyses To Understand Biodynamic Excisional Skin Tension Lines. *Scientific Reports*, 6(1).

▪ Jurnee Beilke ▪ Sep 30, 2019 @08:04 PM CDT


SCIENTIFIC REPORTS

OPEN

A New Skin Tensiometer Device: Computational Analyses To Understand Biodynamic Excisional Skin Tension Lines

Sharad P. Paul, Justin Matulich & Nick Charlton

srep30117.pdf(684.4 KB) - download

09/17/19 DermaBond Mini

▪ Jurnee Beilke ▪ Sep 17, 2019 @09:12 PM CDT

Title: DermaBond Mini

Date: 09/17/19

Content by: Jurnee Beilke

Present: NA

Goals: To gain a background understanding of the wound closure system known as DermaBond since this closure system is the primary method of wound closure to be used with the device the team will design.

Content:

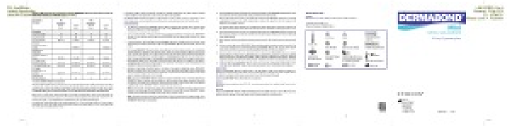
- DermaBond Mini is a topical skin adhesive
- 2-Octyl Cyanoacrylate
- Device comes in a sterile package - single use only
- Applicator composed of crushable glass ampule contained within a plastic vial attached to an applicator tip
- The glue is viscous with a syrup-like texture that polymerizes within minutes
    - The higher viscosity DermaBond is intended to reduce the risk of unintended placement of the adhesive during migration
- DermaBond intended for topical application only on closed, easily approximated skin edges
- Clinical study comparing high viscosity and low viscostiy DermaBond
    - Study included patients of at least one year of age
    - Wounds were closed with either high or low viscosity DermaBond
    - Wounds consisted of small, superficial lacerations (average length = 18.7 mm)
    - Follow up for patients was 14 and 30 days to assess the wound healing
    - Primary measure of device effectiveness was wound closure at day 14
        - Continuous approximations of wound margins
    - High viscosity was as effective as low viscosity DermaBond at day 14
    - High viscosity DermaBond showed significant reduction in liquid adhesive migration at the wound site during application
- Directions for Use
    - Requires thorough wound cleansing
    - Pat the wound dry (moisture accelerates adhesive polymerization and may affect wound closure)
    - The wound should be held in a horizontal position while the DermaBond adhesive is applied from above the wound
    - High viscosity DermaBond should be used immediately after crushing the ampule, for the adhesive will only flow freely from the tip of the vial for several minutes
    - With applicator tip pointed up, use the thumb and finger to apply enough pressure to crush the glass ampule
    - Invert the vial and squeeze slightly to express the liquid adhesive
    - Approximate wound edges with gloved fingers or sterile forceps
    - Apply a thin layer of the adhesive to the wound in at least two layer, waiting 30 seconds between layers
    - Maintain manual approximation of the wound for at least 60 seconds after the final layer
    - Do not apply liquid or ointment onto wounds closed with DermaBond because these substances can weaken the polymerized adhesive
    - Allow top layer to fully dry before applying a bandage
    - Patients should not pick at the polymerized adhesive
    - If removal is necessary, apply petroleum jelly or acetone to loosen the bond

Conclusions/action items:

After reading the instruction manual for DermaBond mini applicators, I now have a better understanding of the use and properties of the DermaBond wound closure system. This background information will be useful when designing a device that will be used simultaneously by the physician.

Jnjmedicaldevices.com. (2019). *DERMABOND® Mini Topical Skin Adhesive | J&J Medical Devices*. [online] Available at: https://www.jnjmedicaldevices.com/en-US/product/dermabond-mini-topical-skin-adhesive [Accessed 18 Sep. 2019].

▪ Jurnee Beilke ▪ Sep 17, 2019 @09:11 PM CDT



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09/17/19 DermaClip

▪ Jurnee Beilke ▪ Sep 17, 2019 @10:34 PM CDT

Title: DermaClip

Date: 09/17/19

Content by: Jurnee Beilke

Present: NA

Goals: To gain a better understanding of current wound closure systems, specifically DermaClip.

Content:

- Non-invasive skin closure device that allows for fast and simple closure of skin surface wounds
- No puncturing or crushing of the skin is necessary for use of this device
- DermaClip has been used to successfully close 10,000s patient wounds - replacing traditional sutures, staples, and glues
- DermaClip can be used in OR, ER, UC, or out in the field
- Singly use, non-invasive device designed to achieve full eversion on each skin closure
- Design incorporates plastic sutures that mate a "living hinge" sandwich between two layers of alkylate-based adhesive to a ratchet mechanism
- DermaClip devices are available as individual units, which makes the closure system versatile for multiple wound types
- Large DermaClip devices are designed for long, straight incisions
- Regular DermaClip devices are designed for slender incisions, possibly with slight curvature
- Adhesive used is strong enough to maintain skin closure for 7 to 10 days, yet remains gentle enough for use on fragile skin
- Directions for use
    - Peel the device off of the backing paper
    - Pinch approximate the wound
    - Place the device around wound edges
    - Pull the tabs closed
- Patented design
    - U.S. Pat. Nos. 8,157,839, 9,028,529, 9,301,760, and 9,603,596
- Images

Conclusions/action items:

After reviewing the DermaClip website, I have a better understanding of this competitive device. I do not believe this device is a direct comparison to our project since the DermaClip approximates and closes the wound, whereas our device will simply approximate the wound edges while a healthcare professional closes the wound with glue or sutures. However, it is helpful to understand existing devices.

DermaClip US, LLC. (2019). *DermaClip Non-Invasive Skin Closure Device, Revolutionizing Wound Care*. [online] Available at: https://www.dermaclipus.com/ [Accessed 18 Sep. 2019].

Additional info: https://academic.oup.com/milmed/article/183/suppl_1/472/4960040

09/17/19 microMend

▪ Jurnee Beilke ▪ Sep 17, 2019 @10:31 PM CDT

Title: mircoMend

Date: 09/17/19

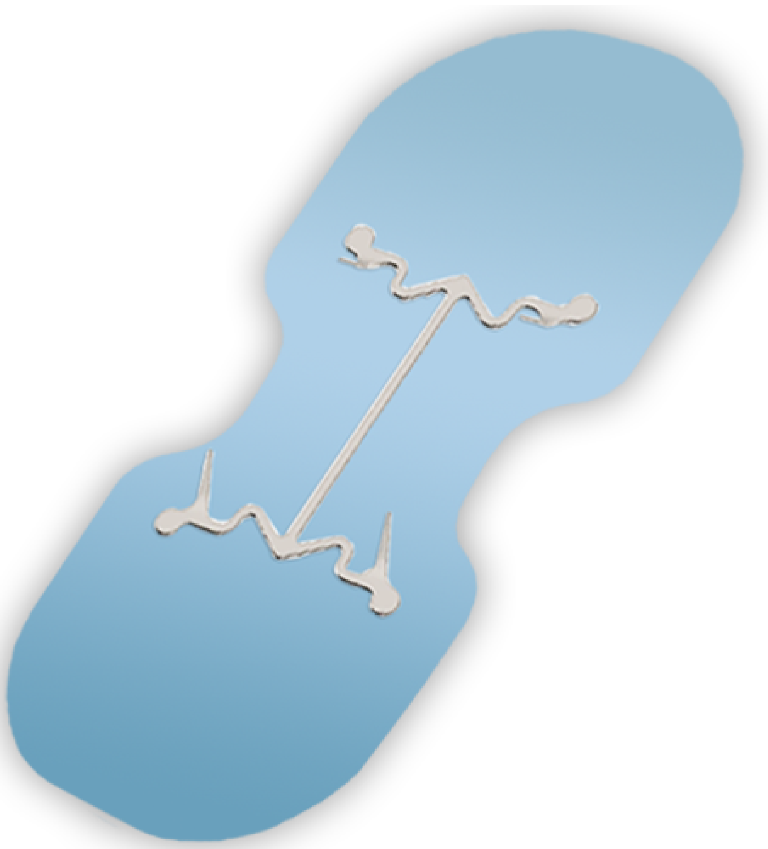
Content by: Jurnee Beilke

Present: NA

Goals: To explore existing devices used for wound approximation, such as the microMend device.

Content:

- Design is conceptually similar to a bandage (Steri-Strip)
- Design
    - Thin adhesive backing with two arrays of microstaples on both sides
    - The device is places across a wound one side at a time
    - Microstaples insert into the skin and approximate the edges of the wound
    - Holding strength of the device is similar to that of sutures
    - Microstaples are said to be painless
    - Device can last as long as the wound takes to heal
- Tensile strength is similar to that of sutures
- microMend can close wounds 2-3 times faster than traditional sutures
- The resultant scar is often smaller than the scars left by sutures
- Patent
    - US20170333039A1
- Images



Conclusions/action items:

After review the microMend website, I now have a clearer understanding of another competitive device for wound closure. While this device is used for approximating skin edges, the device also closes the wound. Our device will simply serve as a second pair of hands to approximate the wound edges while the wound is being sutured or glued.

Kitotechmedical.com. (2019). *microMend | Time-saving skin closure alternative*. [online] Available at: http://www.kitotechmedical.com/ [Accessed 18 Sep. 2019].

09/20/19 Steri-Strip

▪ Jurnee Beilke ▪ Sep 20, 2019 @07:34 PM CDT

Title: Steri-Strip

Date: 09/20/19

Content by: Jurnee Beilke

Present: NA

Goals: To explore existing devices that are used for wound closure, specifically the Steri-Strip adhesive skin closure system.

Content:

- Steri-Strips provides wound support and increases the tensile strength of the wound compared to sutures
- Improved cosmetic outcomes
  - Non-invasive, sterile design reduces the risk of infection and scarring
  - Comfortable to wear compared to sutures
  - Easy removal
  - Less expensive than skin adhesives, sutures, and staples
  - Fast to apply
- Design
  - Sterile, breathable adhesive strip reinforced with polymer filaments for strong closure of the skin laceration
  - Strips used in the closure of lacerations and surgical incisions
  - Adhesive is acrylate-based
  - Strips come in multiple sizes for various wounds
  - For use in emergency department, OR, clinics, and office settings
  - Silicone coated paper liner
  - Polyester and rayon backing
- To use, clean and dry the wound
  - Peel the release paper from the strip
  - Apply one side of the strip to one side of the open wound and secure it in place
  - Approximate the skin edge by pinching the skin together
  - Apply the other side of the strip to the opposite side of the wound and secure it in place

Conclusions/action items:

I now have a better understanding of the Steri-Strip system and how it can be used for wound closure. This device is not an exact comparison to our project because this device is mainly used for wound closure while our device will function only to approximate the wound edges.

3m.com. (2019). *3M™ Steri-Strip™ Reinforced Adhesive Skin Closures | 3M United States*. [online] Available at: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Steri-Strip-Reinforced-Adhesive-Skin-Closures/?N=5002385+3293321968&rt=rud [Accessed 21 Sep. 2019].

11/05/19 Codes and Standards

▪ Jurnee Beilke ▪ Nov 05, 2019 @10:57 PM CST

Title: Codes and Standards

Date: 11/05/19

Content by: Jurnee Beilke

Present: NA

Goals: To learn more about the codes and standards required for our design.

Content:

- Every medical device must follow guidelines from the FDA
- Medical devices have three classes
    - Class I is the most basic (devices that generally interact with the body) while class III is the most complex (usually implanted materials)
- Title 21 is a portion of the federal code of standards that governs food and drugs in the United States
    - The 800 series of the title covers medical devices
    - 803 is medical device reporting
        - General provisions, applicable requirements, user facility reporting, manufacturer reporting
    - 814 is premarket approval
        - Premarket approval application, FDA action, post-approval requirements
    - 820 is quality system regulation
        - Design controls, documenting controls, purchasing controls, identification and traceability, corrective and preventative action, labeling and packaging controls, handling, storage, distribution
    - 860 is a listing of approved devices
- Example medical device: forceps

New Search Back to Search Results

Device	Forceps
Regulation Description	Manual surgical instrument for general use.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	HTD
Premarket Review	Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)
Submission Type	510(K) Exempt
Regulation Number	878.4800
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Recognized Consensus Standard
- 6-268 ASTM F921-10 (Reapproved 2018)
  Standard Terminology Relating to Hemostatic Forceps

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

-
- There are current no devices similar to our design on the market, but forceps have similar surgical uses, so our device will likely need to follow similar codes and regulations
- Part 878 details manual surgical instruments for general use
    - Non-powered, handheld device
    - Reusable or disposable

  - Intended for various surgical procedures
  - Classification is Class I - exempt from premarket notification

Conclusions/action items:

While no devices exactly like our exist on the market, forceps have a similar purpose/service environment, so that example was provided above. The team will need to make sure to abide by the codes and regulations above if we intend on patenting and marketing our design.

Accessdata.fda.gov. (2019). *CFR - Code of Federal Regulations Title 21*. [online] Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1299 [Accessed 6 Nov. 2019].

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1299

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=HTD

09/20/19 Bow Design

▪ Jurnee Beilke ▪ Sep 20, 2019 @10:14 PM CDT

Title: Bow Design

Date: 09/20/19

Content by: Jurnee Beilke

Present: NA

Goals: To brainstorm ideas for a device that approximates wound edges while a healthcare professional can glue or suture the wound.

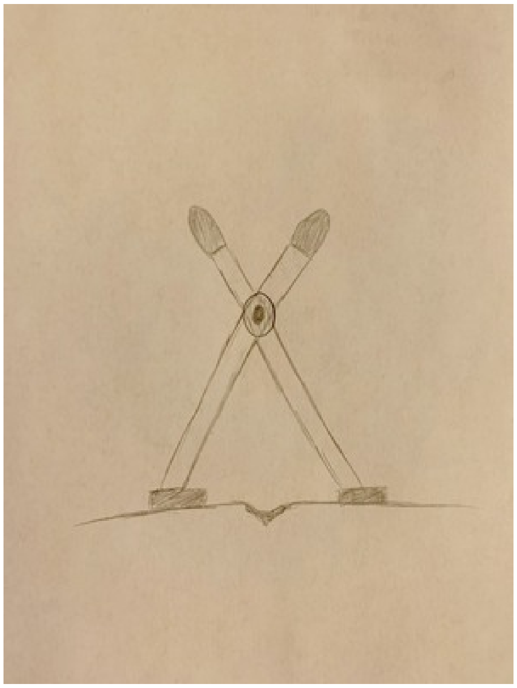
Content:

The bow design consists of two metal, stainless steel, rods connected by a locking hinge system, so the device can be adjusted to approximate different sized wounds. At the ends of the metal rods, there will be rubber bulbs/stoppers that will contact the skin without puncturing or harming the patient. Rubber is softer than metal on the patient's skin, and rubber also has a high coefficient of friction and will maintain stable contact with the skin surrounding the wound. To use the device, the "arms" can be opened far enough for the rubber stoppers to rest on each side of the wound. The arms could then be drawn together until the wound edges are approximated, and the device could be locked into position with the locking hinge system while the wound is glued or sutured.

Conclusions/action items:

I think this device will meet all of the client requirements. The team will need to be considerate over the choice of materials because the device will need to be sterilized between uses. Additionally, this device is quite unique, and there are not devices similar to the bow design on the market.

▪ Jurnee Beilke ▪ Sep 20, 2019 @10:12 PM CDT



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09/20/19 Bandage Design

▪ Jurnee Beilke ▪ Sep 20, 2019 @10:41 PM CDT

Title: Bandage Design

Date: 09/20/19

Content by: Jurnee Beilke

Present: NA

Goals: To brainstorm ideas for a device that approximates wound edges while a healthcare professional can glue or suture the wound.

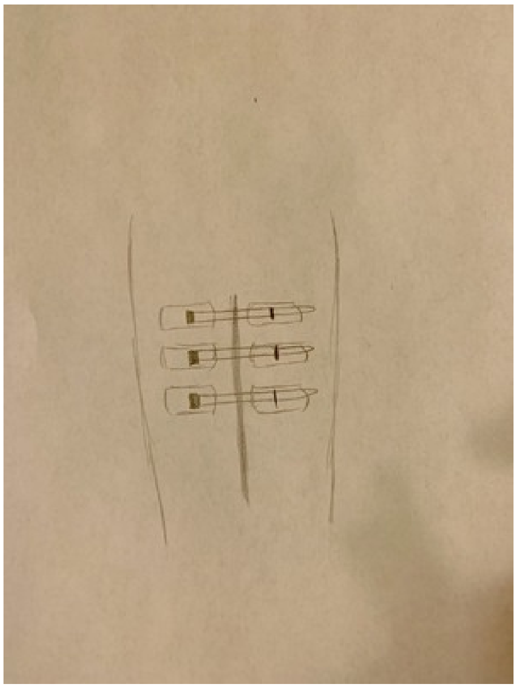
Content:

The bandage design consists of single-use adhesive strips that include a "zip tie" feature that extends across the wound. The bandage will consist of a plastic, possibly PVA, polyethylene, or polyurethane with an acrylate-based adhesive. An adhesive strip with the tie attached will be placed on one side of the wound while another strip with the mating end of the tie will be placed on the other side of the wound. Once all the adhesives are placed, the ties can be tighten, pulling the wound edges together. The healthcare professional can then apply the glue or place the sutures in the intermittent spaces between the adhesives. The device can then be removed, and the remaining spaces can be glued or sutured to complete wound closure.

Conclusions/action items:

I believe this design will meet the client's requirements, for the design will not harm the patient's healthy skin as it is non-invasive. However, this design is similar to designs currently on the market such as DermaCli, but our device is not a wound closure system. The bandage design is simply a device to approximate wound edges.

▪ Jurnee Beilke ▪ Sep 20, 2019 @10:38 PM CDT



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09/29/19 Rectangle Design

▪ Jurnee Beilke ▪ Sep 29, 2019 @10:19 PM CDT

Title: Rectangle Design

Date: 09/29/19

Content by: Jurnee Beilke

Present: NA

Goals: To brainstorm ideas for a device that approximates wound edges while a healthcare professional can glue or suture the wound.

Content:

The rectangle design consists of two metal components (C-shaped with sharp corners) connected by a screw or fastener on both of the short sides of the device. The long edge of the device would be made of a flexible yet sturdy material that possesses a high coefficient of friction against the patient's skin (silicone or rubber); the device could also have small hooks or prongs that feel harmless against the skin to allow the apparatus to draw the wound edges together. The rectangle design would lay flat on the patient's skin with the flexible sides or hooks laying against either side of the wound to be closed. The clinician could then use the screws/fasteners to draw the two sides of the rectangle together until the wound edges were approximated. The clinician could then glue or suture the wound as needed.

Conclusions/action items:

I think this design meets all the client's requirements. Additionally, this design is unique and will not impede the clinician in gluing or suturing the wound as the other designs. The only complication I predict with this design is the material and design chosen for the long edges of the rectangle to make sure the patient is comfortable, but the edges of the wound can be drawn together successfully.

▪ Jurnee Beilke ▪ Sep 29, 2019 @10:20 PM CDT

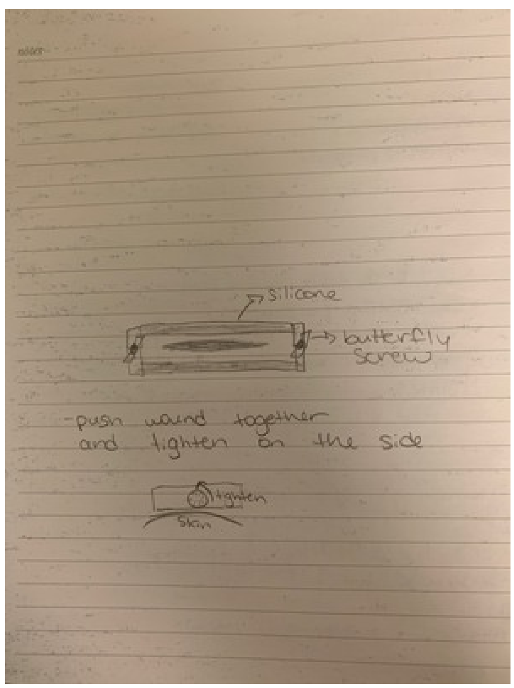


Image-13.jpeg(1.2 MB) - download

▪ Jurnee Beilke ▪ Sep 29, 2019 @10:23 PM CDT

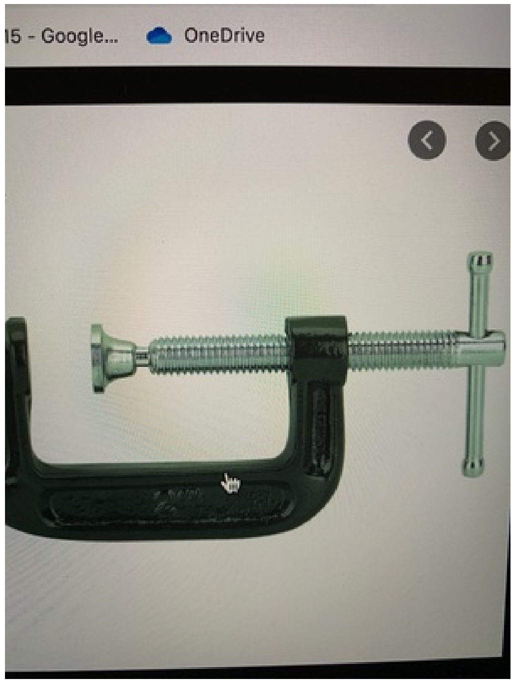
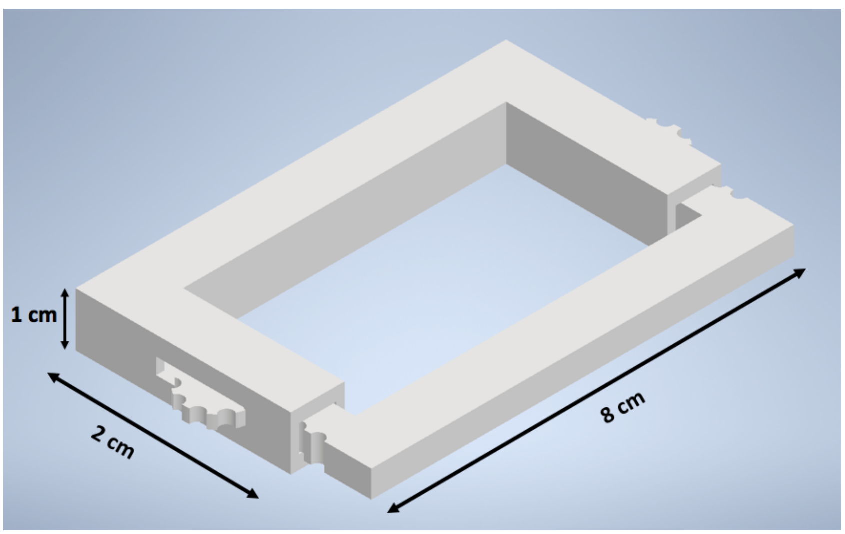


Image-12.jpeg(874.7 KB) - download I think this type of threaded rod and tube might be an interesting design to use to connect the two components of this device. The sides can be drawn together by turning the fastener and moving the threaded rod farther into the tube-shaped component.

▪ Jurnee Beilke ▪ Dec 09, 2019 @05:25 PM CST



Computer-modeled image of the rectangle design.

09/30/19 Skin Tension Forces

▪ Jurnee Beilke ▪ Sep 30, 2019 @08:27 PM CDT

Title: Skin Tension Forces

Date: 09/30/19

Content by: Jurnee Beilke

Present: NA

Goals: To estimate the amount of force from the device needed to overcome the skin tension pulling the wound edges apart.

Content:

The tension of skin wounds can be as high as 6.5N, so the wound edge approximating apparatus would need to exert over 6.5N to bring the wound edges together.

Conclusions/action items:

The fastener or screw aspect of the design would therefore need to exert enough force to pull the edges of the device together and simultaneously approximate the wound edges.

▪ Jurnee Beilke ▪ Sep 30, 2019 @08:27 PM CDT

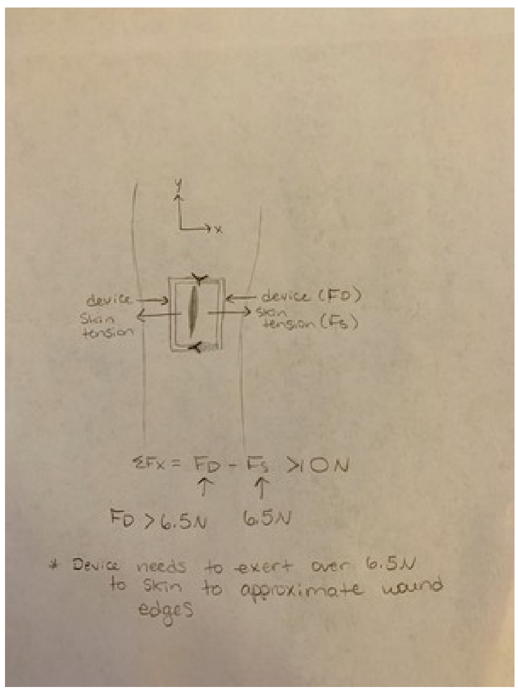


Image-14.jpeg(414.4 KB) - download

10/07/19 Adhesives

▪ Jurnee Beilke ▪ Oct 07, 2019 @10:09 PM CDT

Title: Stick to Skin - Adhesives

Date: 10/07/19

Content by: Jurnee Beilke

Present: NA

Goals: Since the device will need to have a stable and strong interaction with skin, the device will need to have some adhesive aspect in order to pull the skin edges together effectively. The goal is to research materials that temporarily stick to skin.

Content:

- When designing devices that will stick to the skin of patients, several factors need to be considered
    - Balance between a weight bearing adhesive that will hold the device in place yet avoid excessive tack (stickiness)
    - Avoiding skin irritation and discomfort from adhesives or tension from removal
    - Clean and gentle removal of the device for short-term wear
- Skin friendly materials can avoid complications and provide a safe, effective product
- 2-in-1 products are useful for they have an aggressive adhesive for bonding to the device on one side and a gentler adhesive for the skin on the other side - which would be ideal for our design - the stronger adhesive would contact the edges of the device and the gentler adhesive would contact the patient's skin
- Stick to skin materials include
    - Double coated tapes
    - Medical grade foam
    - Hydrocolloids and hydrogels
    - Silicone tapes
    - Clear tapes and adhesives

Conclusions/action items:

After brainstorming, I think our device needs to incorporate an adhesive, tacky, or high friction component in the design in order to provide the tensile force needed to approximate the wound edges. One idea I have now is to fabricate a reusable frame for the device and use single-use adhesives to temporarily attach the device to the patient's skin while the wound is closed. This could include a silicone-based tape/adhesive or possibly a medical grade foam.

Parafix. (2019). *Stick to Skin Wearable Device Tape | Die-Cut Tape | Parafix*. [online] Available at: https://parafix.com/industries/healthcare/device-attachment-to-skin/ [Accessed 8 Oct. 2019].

▪ Jurnee Beilke ▪ Oct 07, 2019 @10:10 PM CDT

Screen_Shot_2019-10-07_at_10.06.08_PM.png(2.4 MB) - download

10/13/19 Fabrication Plan

▪ Jurnee Beilke ▪ Oct 13, 2019 @08:47 PM CDT

Title: Fabrication Plan

Date: 10/13/19

Content by: Jurnee

Present: NA

Goals: To brainstorm idea for device fabrication.

Content:

https://store.buymetal.com/stainless/rectangular-sheared-edge-bar/304-304l/stainless-steel-rectangular-sheared-edge-bar-304-304l-0.125-0.5.html?gclid=CjwKCAjwlovtBRBrEiwAG3XJ-4NJX_KejjJDJtru5r2NY2Cx7MxpfaGGj67JffGmJta0WJbxz5nLAhoCm64QAvD_BwE

Ordering metal strip from the link about (0.125 in thickness, 0.5 in width).

Use a mill to drill out a hollow center of the strip - 0.25 in approximately along the length of the strip (see example below). The edges will be sanded until smooth.

The hollowed strips can be welded to the long edges of the rectangle - also metal strips that can be machined to the proper dimensions. The two hollowed pieces on each short sides of the rectangle can be connected together and tightened with a wing nut.

Additionally, the rectangle design only resembles a rectangle from the top view; the short sides of the device will be angled upward from the skin of the patient - resembling a triangle from the side.

Conclusions/action items:

This design might not be as easy to use with two sides of the rectangle having moving components, but the fabrication seems relatively straightforward and manageable.

▪ Jurnee Beilke ▪ Oct 13, 2019 @08:47 PM CDT

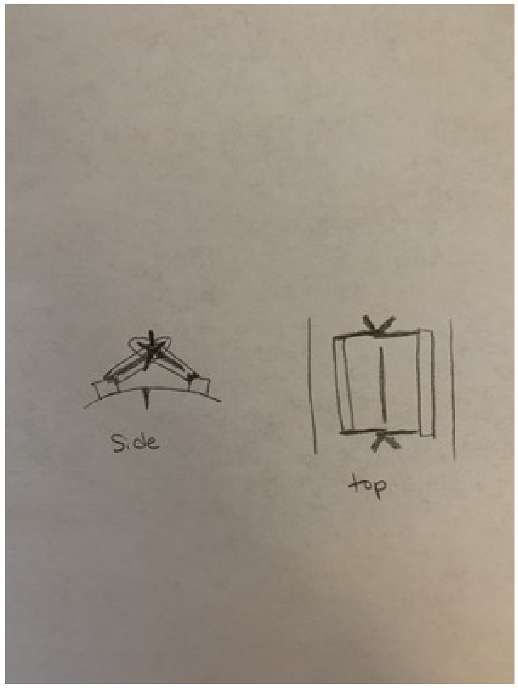


Image-26.jpeg(78.7 KB) - download

10/29/19 Aluminum Research

▪ Jurnee Beilke ▪ Oct 29, 2019 @10:09 PM CDT

Title: Aluminum Research

Date: 10/29/19

Content by: Jurnee Beilke

Present: NA

Goals: To explore aluminum for device fabrication since we found some aluminum scrap metal we could use for our design.

Content:

https://profileprecisionextrusions.com/blog/advantages-aluminum-medical-device-industry/

- One of the biggest benefits of using aluminum for medical devices is its flexibility
- Complex designs cannot be manufactured using metals other than aluminum without investing a lot of time and money into the design
- Extruded aluminum is currently found in several diagnostic and surgical tools
- Aluminum tubes and multi-hollow shapes are found in stethoscopes, trocars, as well as disposable tools
- Aluminum alloys such as 6061, 6063, 3003 are also biocompatible
- Speed, quality, and cost are important factors that make aluminum a viable choice for medical instruments
- Aluminum is also lighter than steel and is stronger as the temperature drops which is not true for steel

https://profileprecisionextrusions.com/blog/advantages-aluminum-medical-device-industry/

- Aluminum oxide coating can be used for medical devices
- The coating creates a microcrystalline barrier to create a long-lasting surface
- A coating can provide chemical corrosion resistance as well as eliminating color fading as a result of steam/heat
- Aluminum is a viable choice for medical devices due to its biocompatibility, weight, thermal conductivity, strength, and cost
- With a protective coating, devices made of aluminum may be preferable to those made of stainless steel as is the industry standard
- However, without the coating, devices can begin to corrode and lose functionality and usefulness

Conclusions/action items:

Aluminum seems to be a viable choice for a device material as long as the device receives a protective coating to prevent corrosion and color fading. Aluminum is lightweight and strong enough to be used in our design. However, the current aluminum material we have is scrap metal - aluminum sheets which appear to be too malleable for use in the final design. If we want to move forward with aluminum, we will need to purchase thicker/stronger materials.

10/29/19 Steel Research

▪ Jurnee Beilke ▪ Oct 29, 2019 @10:24 PM CDT

Title: Steel Research

Date: 10/29/19

Content by: Jurnee Beilke

Present: NA

Goals: To explore steel materials as an option for our final design.

Content:

https://www.azom.com/article.aspx?ArticleID=6641

- Stainless steel is one of the most common materials used for medical devices
    - Particularly, stainless steel 304
    - 304 is regarded as one of the most suitable materials for medical devices in the world (gold standard)
    - 304 has high corrosion resistance which is necessary for sterilization purposes
    - Stainless steel has low carbon content
    - The steel will not react with bodily tissues/fluids, cleaning products, and will maintain function even with repetitive wear
    - 304 is incredibly strong and extremely workable - can be drawn into shape without the need for annealing
    - 304 steel can be work hardened with cold working if the material needs to be harder or stronger
    - Advantages
        - diverse applications
        - rust resistant
        - high corrosion resistance
        - recyclable
        - antibacterial properties
        - material does not stain
        - non-magnetic
        - high heat resistance
    - For surgical steel, specific grades are used - 316 and 316L
    - The steel is alloyed with chromium, nickel, molybdenum
    - Nickel content may cause allergic reactions in some patients
    - Examples of 316(L)
        - Orthopedic implants
        - Bone fixation
        - Medical needles
        - Sensor probes

Conclusions/action items:

After researching both stainless steel and aluminum, I think stainless steel is the way to go. The benefits/advantages indicate that stainless steel 304 or 316 would be "gold standard" material to use for our final design. I think aluminum was viable to use for the preliminary prototype, but the team should use stainless steel for the final design and testing.

11/12/19 Brazing

▪ Jurnee Beilke ▪ Nov 12, 2019 @11:07 PM CST

Title: Brazing Metal

Date: 11/12/19

Content by: Jurnee Beilke

Present: NA

Goals: To explore methods other than welding to connect the pieces of our device together.

Content:

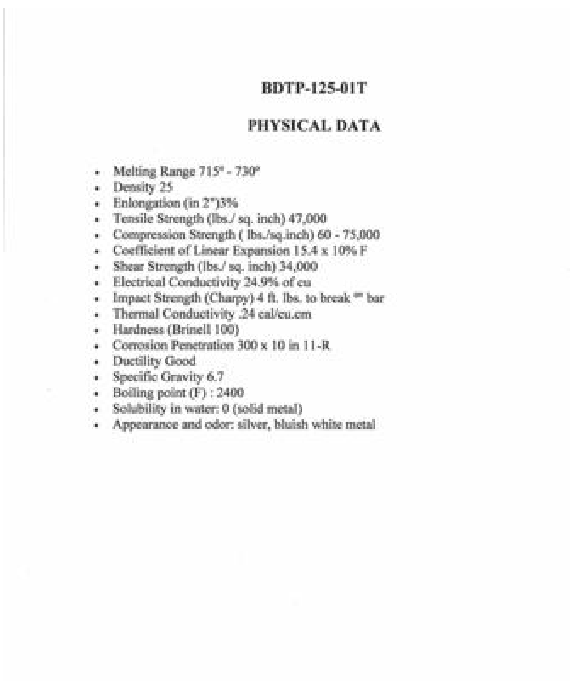
- Low temp - aluminum-zinc brazing rod
- Brazing can be used for materials that can be difficult to weld
- The brazing rod has an extremely low melting point (730 F)
- The rod can be melted with a propane torch
- Brazing can repair and combine many metal components
- The rod has excellent corrosion resistance
- To use
    - Heat up the base material using the torch - not the rod itself
    - Run the brazing rod quickly back and forth along the area to be fixed/welded until enough of the brazing rod has melted to secure the pieces together until the material is cooled

Conclusions/action items:

I think this technique could be a welding alternative to secure the edges of our device together.

https://www.amazon.com/Blue-Demon-BDTP-125-01T-Aluminum-Zinc-Brazing/dp/B01MCTUIUN/ref=sr_1_1?keywords=bdtp-125-01t&qid=1573253594&s=instant-video&sr=8-1&th=1

▪ Jurnee Beilke ▪ Nov 12, 2019 @10:57 PM CST



BDTP-125-01T

PHYSICAL DATA

- Melting Range 715° - 730°
- Density 25
- Enlongation (in 2")3%
- Tensile Strength (lbs./ sq. inch) 47,000
- Compression Strength (lbs./sq.inch) 60 - 75,000
- Coefficient of Linear Expansion 15.4 x 10% F
- Shear Strength (lbs./ sq. inch) 34,000
- Electrical Conductivity 24.9% of cu
- Impact Strength (Charpy) 4 ft. lbs. to break " bar
- Thermal Conductivity .24 cal/cu.cm
- Hardness (Brinell 100)
- Corrosion Penetration 300 x 10 in 11-R
- Ductility Good
- Specific Gravity 6.7
- Boiling point (F) : 2400
- Solubility in water: 0 (solid metal)
- Appearance and odor: silver, bluish white metal

71AdtKASm0L._AC_SL1500_.jpg(107.8 KB) - download Properties of the brazing rods.

▪ Jurnee Beilke ▪ Nov 12, 2019 @10:58 PM CST

81QTuBFe8BL._AC_SL1500_.jpg(84.3 KB) - download Image of the brazing rods.

11/20/19 Testing Ideas

▪ Jurnee Beilke ▪ Dec 09, 2019 @05:19 PM CST

Title: Testing Ideas

Date: 11/20/19

Content by: Jurnee Beilke

Present: NA

Goals: To brainstorm testing ideas.

Content:

- Force require for approximation
  - Test silicone samples in the MTS machine
  - Use MATLAB and the following equations to obtain stress-strain curves
  - Create a wound on the silicone skin and approximate with the device
  - Measure the deformation (change in length) of the silicone
  - Calculate strain from the deformation
  - Use the graph/linear modulus equation to determine stress
  - Calculate force required from stress and area

$$stress = \frac{F}{A}$$

$$strain = \frac{\Delta L}{L}$$

$$E = \frac{stress}{strain} = \frac{F/A}{\Delta l/l_o}$$

- Device displacement (stay in place)
  - Dr. Wille had the idea of measuring device displacement over the period of use
  - Place the device on skin and measure how far the device moves from its initial position over several minutes
  - Device according to PDS must remain in place and approximate the wound edges for the entire time of use
- Pain scale
  - Dr. Suarez had the idea of measuring the pain caused by the device
  - Apply the device to patient's skin and ask them to rank pain on pre-determined and defined scale

Conclusions/action items:

I think these methods of testing - developed by the team and with the assistance of advisors - provide necessary information about device function in comparison to the requirements listed in the PDS.

*Refer to team section of the lab notebook for test protocols, results, and analysis.

12/09/19 Future Work Ideas

▪ Jurnee Beilke ▪ Dec 09, 2019 @05:06 PM CST

Title: Future Work Ideas

Date: 12/09/19

Content by: Jurnee Beilke

Present: NA

Goals: To document ideas for future work.

Content:

- Obtain approval from IRB to test the device on humans
  - List Dr. Suarez and Dr. Charlton
- Purchase or fabricate a new snythetic model for skin
  - Internet providers sell self-assembly gelatin skin mixes that the team could look into
  - Potentially consider animals skin (pig or chicken) for testing force required
- Re-design the fastener
  - The current fastener is too complicated and difficult for older users
  - Include a simpler hinge or locking mechanism
  - Test ease of use with physicians to get feedback

Figure 1: Idea for the locking hinge mechanism that is simpler than thumb screws to use.

- Potentially create/design different sizes and colors for the design to be used on different locations of the body with various age groups
  - Possibly make the design look like an animals for kids
  - Create various sizes/shapes for the hands and face

Conclusions/action items:

I think the team should speak with Dr. Charlton to determine what aspects of the design to improve and test as a priority before pursuing all of these changes. I think obtaining IRB is the most important for the spring semester.

12/09/19 CAD Models of Alternate Designs

▪ Jurnee Beilke ▪ Dec 09, 2019 @05:27 PM CST

Title: CAD Models

Date: 12/09/19

Content by: Jurnee Beilke

Present: NA

Goals: To include the CAD-generated images I created for the alternative designs.

Content:

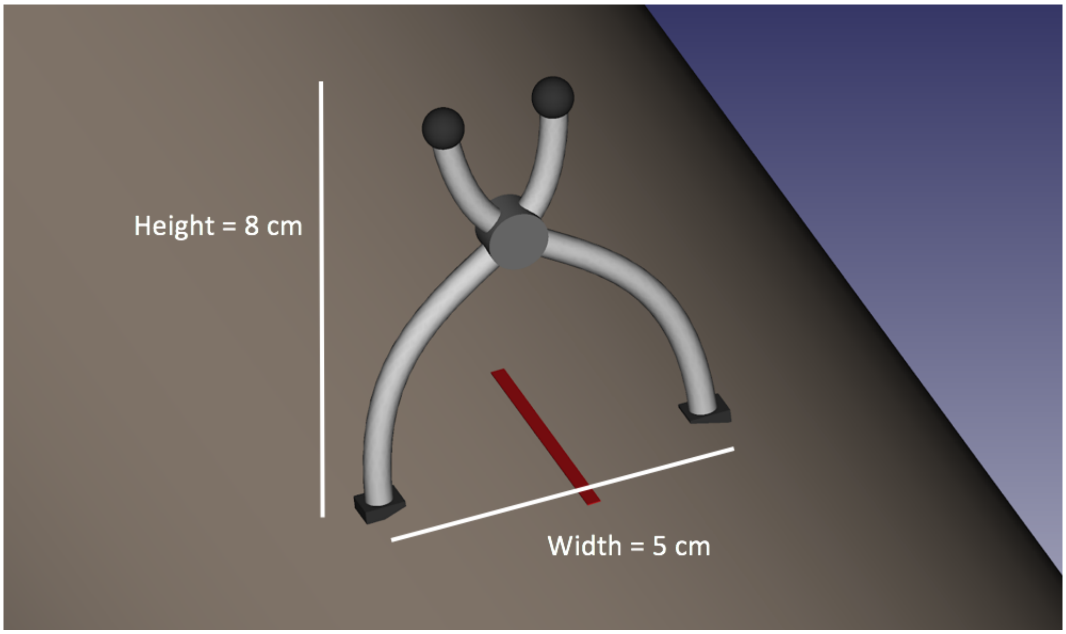


Figure 1: The bow-shaped design.

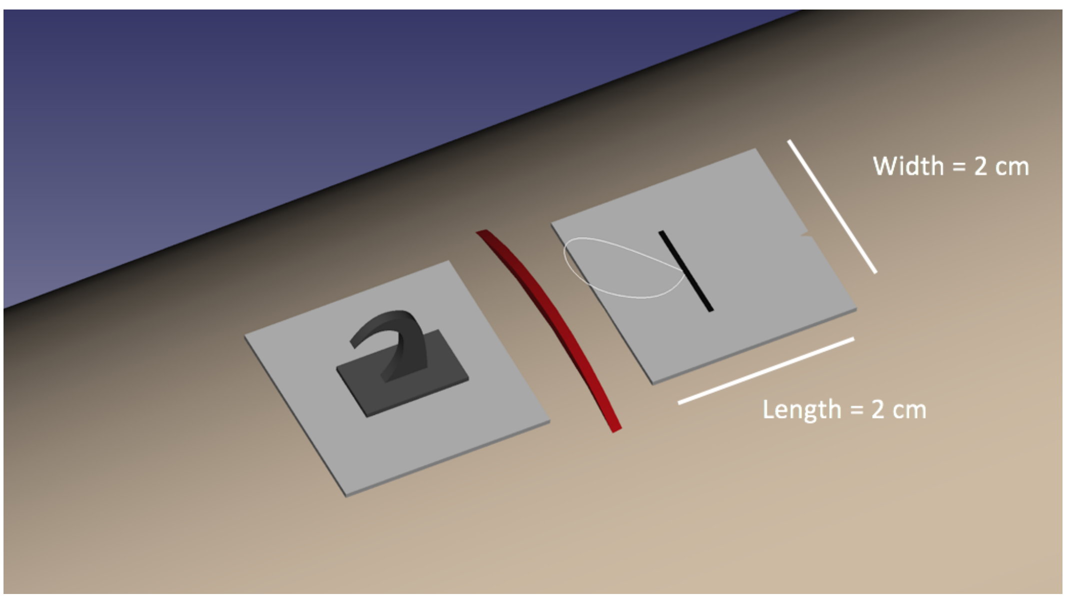


Figure 2: The hook in loop design.

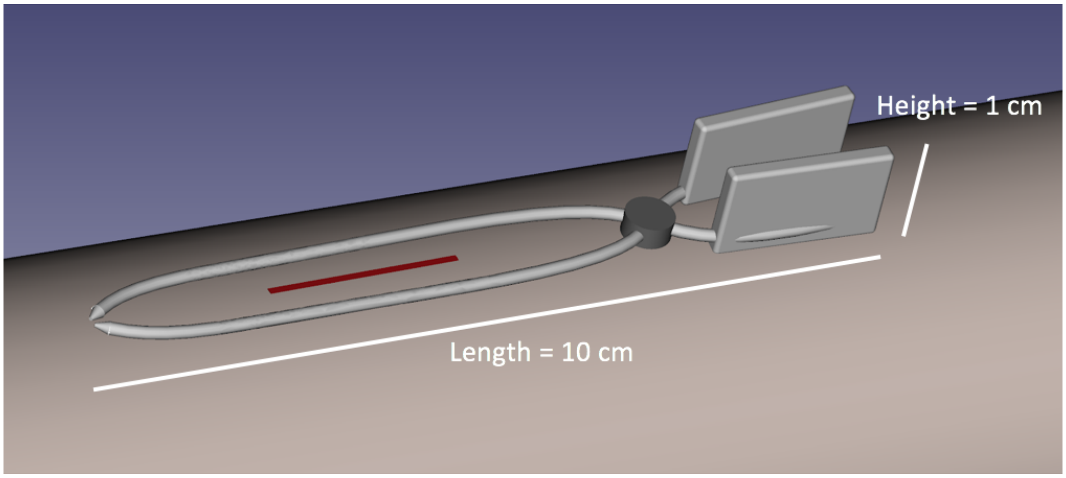
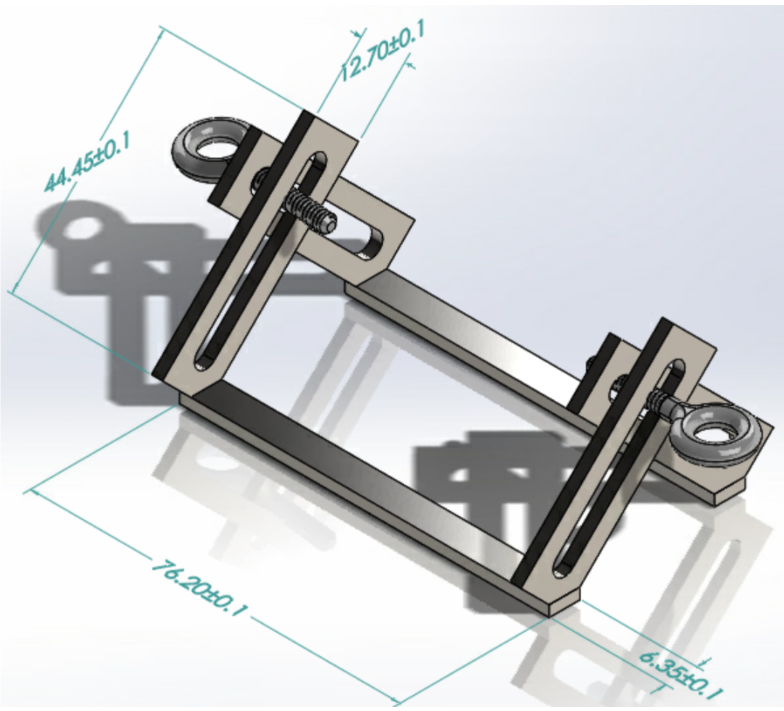


Figure 3: The barrette design.

Conclusions/action items:

I updated the hand-drawn design alternatives to these CAD models of the alternate designs.

The final design was modeled by Jack in SolidWorks (see below).



Green Pass

▪ Jurnee Beilke ▪ Dec 05, 2017 @06:24 PM CST

Image.png(1.7 MB) - download

Tong Lecture

▪ Jurnee Beilke ▪ Nov 21, 2019 @09:06 PM CST

Title: Tong Lecture

Date: 11/21/19

Content by: Jurnee Beilke

Present: NA

Goals: To summarize the aspects of the Tong lecture I am most interested in and highlight what I learned from the lecture.

Content:

- The speaker is Marie Lotto who graduated from biomedical engineering at UW-Madison
- The topic of the lecture is navigating career choices
- One important thing to remember is to be proactive - plan ahead and take your future into you own hands
    - Be aware of your options - industry vs medical school
    - Advocate for yourself
    - Prioritize what is important to you - match up strengths and interests with what job you pick or what company you decide to work for after graduation
- The research and internships you choose in undergrad will impact what job opportunities you have after graduation
- Marie Lotto began her career at Smith and Nephew and worked in sports medicine and orthopedics
- Marie then moved to Hologic - a company focused on women's health
    - A device was developed to treat heavy uterine bleeding
- Marie planned her career path
    - UW-Madison
    - Developmental Engineer
    - Developmental Engineer II
    - Senior Developmental Engineer
    - Manager
    - Director
- A real career will include lateral and promotional moves as well a geographic moves
- The job roles will vary - positions may be more heavily related to engineering (BME) than other positions
- Positions can include various functions
    - Research - setting up experiments and trying to solve a problem or answer a question
    - Product development engineer - help to develop medical devices and innovation
        - What is the clinical need - what problems need to be solved?
    - Project management - leading a cross-function team to develop products
    - Operational excellence - learning how to improve and develop process
        - Reduce waste and increase efficiency
    - Global marketing - creative yet analytical position
    - Business development - external innovation
- To plan your career path
    - Know your strengths and your skills - analytic, learner, logical, problem solver, communicator, creative
    - Explore your options
    - Understand your interests
    - Leverage your degree and expertise
- Engineering options
    - Product development - developing and creating an idea to solve an unmet need
    - Operations engineer - how to actually build the device for the best cost
    - Quality engineer - how to test products to meet the correct requirements, how to manage and resolve complaints
- Beyond engineering
    - Project management
    - Marketing
    - Business development
- Networking will be a great method to explore what options are available
- Don't plan too far in advance because interests and options will likely change - think 5 years ahead
- Plan income - prioritize expenses
- Always be willing to learn

Conclusions/action items:

From hearing Marie Lotta talk about her career path and her advice for students, I have learned that I really need to take the time to explore my interests. I not only should take classes about topics I am interested in, but I should explore what I am curious and passionate about in engineering and beyond. My career path does not need to be solely engineering related. I also learned that I need thoroughly explore my options about where I want to work and what type of work I want to do in the future. I will need to align my beliefs and strengths with the company I work for after graduation. I will additionally try not to plan my life too far in advance since my plans will likely change every few years - I tend to get too far ahead of myself and plan farther than is appropriate.

9/10/19 Preliminary Wound Research

▪ KELLY STARYKOWICZ ▪ Sep 10, 2019 @10:47 PM CDT

Title: Preliminary Wound Research

Date: 9/10/19

Content by: Kelly Starykowicz

Present: Kelly

Goals: Learn more about wounds and suturing

Content:

- tensile strength = "load per cross-sectional area unit at the point of rupture"
  - affects the ability of a tissue to withstand injury
- breaking strength = the force necessary to break a wound (regardless of size)
- burst strength = the force necessary to rupture a large internal organ

Source: http://www.uphs.upenn.edu/surgery/Education/facilities/measey/Wound_Closure_Manual.pdf

Conclusions/action items:

Need to consider these strengths while designing

9/11/19 Types of Wound Repairs

▪ KELLY STARYKOWICZ ▪ Oct 07, 2019 @11:28 AM CDT

Title: Types of Wound Repairs

Date: 9/11/19

Content by: Kelly Starykowicz

Present: Kelly

Goals: Learn about types of wound repairs

Content:

- Primary repair:
    - "requires clean tissue to be approximated without tension"
    - sutures left in for approximately 7 days
    - Deep wounds are sutured in layers; absorbable sutures often used
- Delayed primary closure:
    - contaminated wounds are cleaned and then filled with "damp saline gauze"
    - sutures are used after 2 days
- Secondary healing:
    - Dead, damaged tissue cut away

Source: https://www.who.int/surgery/publications/s16383e.pdf

Conclusions/action items:

Need to ask client if we are only focusing on primary wound repair

9/11/19 Suture Techniques

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:33 PM CDT

Title: Suture Techniques

Date: 9/11/19

Content by: Kelly

Present: Kelly

Goals: Learn about suture techniques

Content:

Overall aim of suturing is to approximate wound edges without gaps or tension

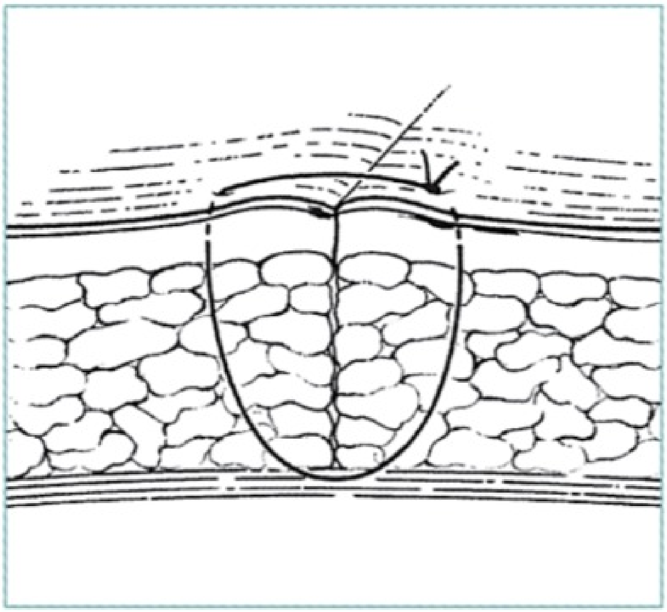
- "Size of suture 'bite' and interval between bites should be equal in length, proportional to thickness of tissue being approximated"
- Suture Techniques:
    - Interrupted Suture:
        - used to repair lacerations
        - allows for "good eversion" of wound edges
        - only used when minimal skin tension
    - Continuous/running sutures
        - less-time consuming than interrupted sutures
        - fewer knots needed
        - less suture material
        - less precise --> poorer cosmetic result
    - Continuous Subcuticular sutures
        - excellent cosmetic result
        - used when skin tension is strong
        - take bits below the dermal-epidermal border to anchor the suture in wound
    - Mattress Sutures
        - relieves wound tension
        - precise wound edge approximation
        - more complex --> takes longer
        - Vertical and Horizontal types
    - Purse String Suture
        - circular pattern that draws together tissue in path of suture
        - used around drain sites
    - Retention Sutures
        - insert through entire thickness of abdominal wall
        - close wound in layers
        - thread suture through rubber tubing before tying off

Source: https://www.who.int/surgery/publications/s16383e.pdf

Conclusions/action items:

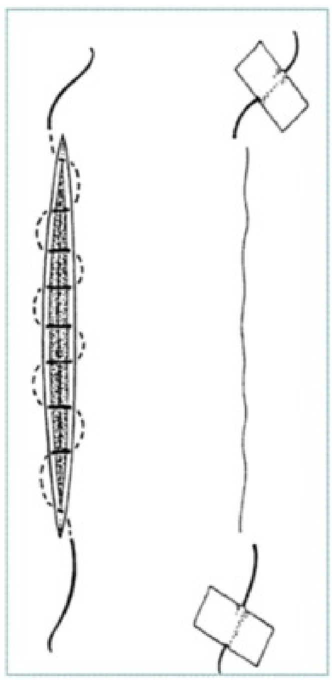
Verify whether our client will be using all of these suturing methods or only some

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:27 PM CDT



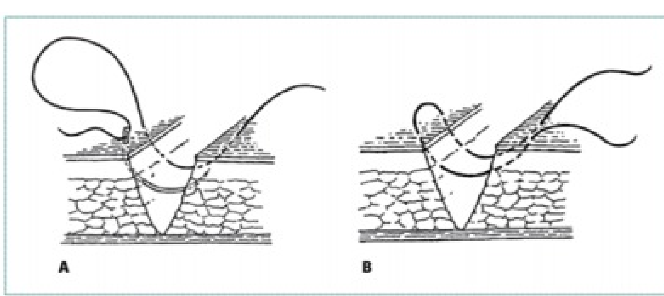
interrupted_suture.PNG(146.4 KB) - download Interrupted Suture

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:28 PM CDT



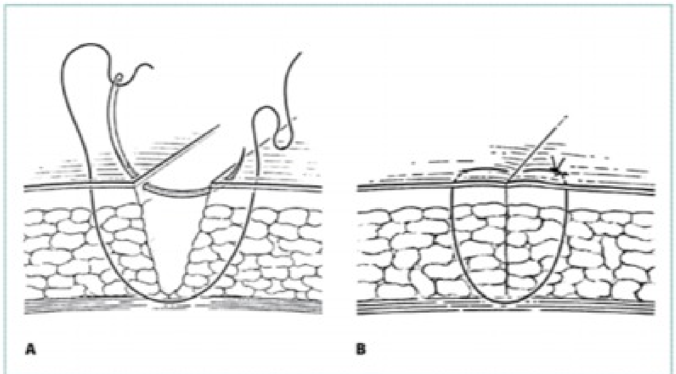
subcuticular_suture.PNG(72.2 KB) - download Subcuticular Suture

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:29 PM CDT



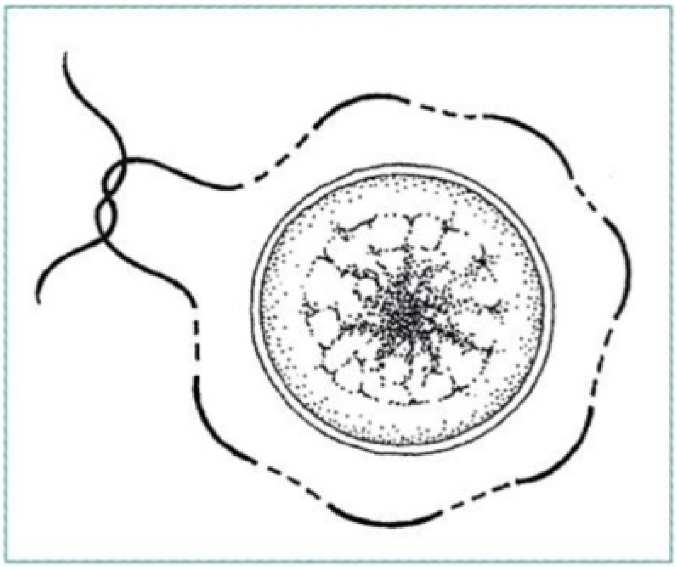
horizontal_mattress_suture.PNG(104.3 KB) - download Horizontal Mattress Suture

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:29 PM CDT



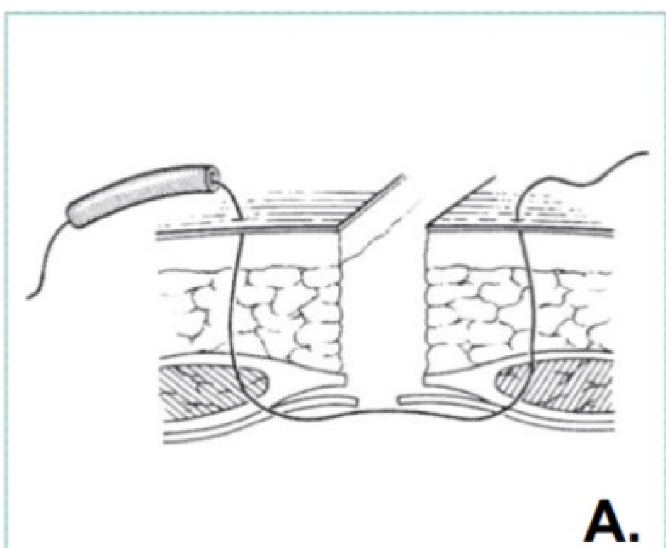
Vertical_mattress_suture.PNG(86.8 KB) - download Vertical Mattress Suture

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:30 PM CDT



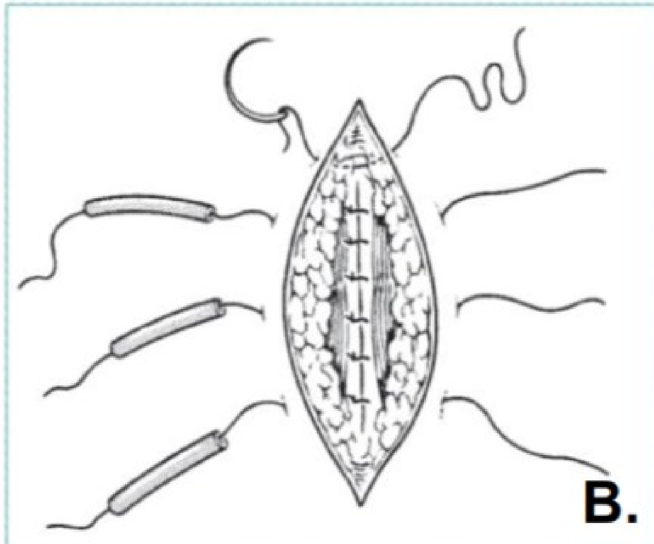
purse_string_suture.PNG(197.7 KB) - download Purse String Suture

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:33 PM CDT



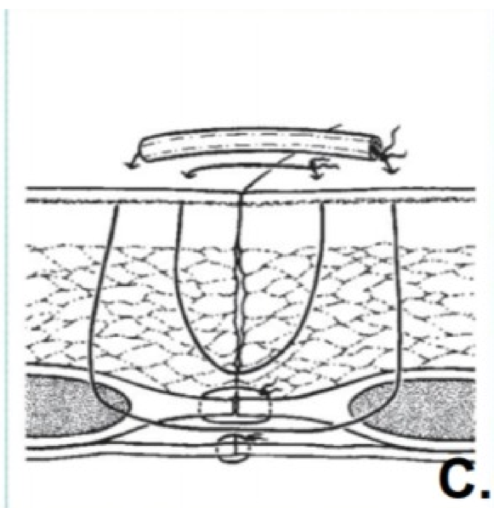
retention_suture_a.PNG(96.8 KB) - download Retention Suture Step 1/4

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:33 PM CDT



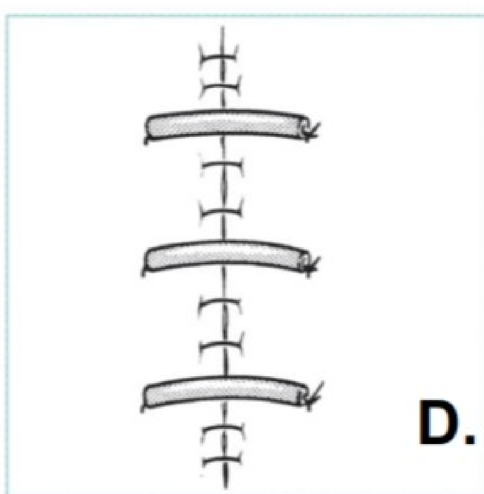
retention_suture_b.PNG(106.1 KB) - download Retention Suture Step 2/4

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:33 PM CDT



retention_suture_c.PNG(110.6 KB) - download Retention Suture Step 3/4

▪ KELLY STARYKOWICZ ▪ Sep 11, 2019 @10:33 PM CDT



retention_suture_d.PNG(44.7 KB) - download Retention Suture Step 4/4

DermaClip Non-Invasive Skin Closure

▪ KELLY STARYKOWICZ ▪ Sep 17, 2019 @09:56 PM CDT

Title: DermaClip Non-Invasive Skin Closure

Date: 9/17

Content by: Kelly

Present: Kelly

Goals: Learn about the DermaClip Skin Closure Device

Content:

DermaClip Non-Invasive Skin Closure

- Alternative to sutures
- Doesn't puncture the skin
- Single-use
- Plastic structure that is attached to a "ratchet mechanism"
- Works on a varying wound sizes
- Very precise
- Works on smaller and curved wounds
- Adhesive will stay put for 7-10 days
- Redistributes the tension across the whole device, not just the wound area
- Works on sensitive skin
- Easy to use: "Pick, place, and pull"
- Safe and gentle removal
    - Patients can do it themselves
- 2 sizes

https://www.dermaclipus.com/pages/the-dermaclip-device

Conclusions/action items:

Discuss with the client why she does not like this method

Steri-Strip Skin Closure

▪ KELLY STARYKOWICZ ▪ Sep 17, 2019 @10:02 PM CDT

Title: Steri-Strip Skin Closure

Date: 9/17

Content by: Kelly

Present: Kelly

Goals: Learn about the Steri-Strip Skin Closure device

Content:

- Secures wound
- "Increases the tensile strength of the wound"
- Non-invasive
- Reduces scarring
- Less-expensive than sutures
- Easy to use
- Comfortable for patients
- One-time use
- Varying sizes
    - varying widths and lengths

https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Steri-Strip-Reinforced-Adhesive-Skin-Closures/?N=5002385+3293321968&rt=rud

Conclusions/action items:

Ask client about opinions on this device

11/2 Medical Device Codes and Regulations

▪ KELLY STARYKOWICZ ▪ Nov 02, 2019 @04:47 PM CDT

Title: Medical Device Codes and Regulations

Date: 11/2

Content by: Kelly

Present: Kelly

Goals: Learn about the codes and regulations that apply to medical devices such as ours

Content:

- Title 21, Volume 8, Part 878, Subpart E: Surgical Devices, Sec. 878.4320: Removable Skin Clip
    - Similar concept to our device
    - removable device that connects skin tissues temporarily to assist with healing
    - classified as a Class 2
- Title 21, Volume 8, Part 878, Subpart E: Surgical Devices, Sec. 878.4495: Stainless steel suture
    - 316L stainless steel suture; nonabsorbable; used for abdominal would closure
    - classified as a Class 2 (special controls)
- Class 2 Special Controls Guidance Doc: Surgical Sutures
    - need to list the tissues that the device can be used on

Conclusions/action items:

There were not a lot of devices similar to ours, but I found ones relating to our device that we can use when we are discussing design requirements and patenting.

9/30 Silicone Research

▪ KELLY STARYKOWICZ ▪ Oct 08, 2019 @10:23 AM CDT

Title: Silicone Research

Date: 9/30/19

Content by: Kelly

Present: Kelly

Goals: Learn about the properties of silicone

Content:

- Silicone retains its properties under various temperatures and stressors
- good at sealing out water
- reduces corrosion

https://www.chemicalsafetyfacts.org/silicones-post/

- most common type is PDMS (poly(dimethyl siloxane))
    - high surface energy
    - low critical surface tension: 20-25 mN/m (similar to Teflon/PTFE)
    - flexible
    - structure of silicone is less dependent on temperature

https://polymerdatabase.com/polymer%20classes/Silicone%20type.html

Conclusions/action items:

Because of its durability under temperature changes and its ability to reduce corrosion, silicone is a viable option for our design.

10/15 Materials Research

▪ KELLY STARYKOWICZ ▪ Oct 15, 2019 @09:37 PM CDT

Title: Materials Research

Date: 10/15

Content by: Kelly

Present: Kelly

Goals: Research the types of metal rods that are sold

Content:

- 304 Stainless Steel Square Tube: https://www.metalsdepot.com/stainless-steel-products/stainless-steel-square-tube?gclid=Cj0KCQjw3JXtBRC8ARIsAEBHg4n99yhJpTo5n83lzfdxVEMgokn-UQD-hBlUOnDGMjf_8QJZ7thsj0gaAhxxEALw_wcB
    - Not slotted
- Plastic square tube: https://www.dickblick.com/products/plastruct-styrene-tubing/?clickTracking=true&wmcp=pla&wmcid=items&wmckw=56922-4014&gclid=Cj0KCQjw3JXtBRC8ARIsAEBHg4mUFZCmuUpsQMBFSxljL0PjZx_KgLPP5CEpB4L1VVjigSwFrWy3NdIaAtWhEALw_wcB
    - Not metal and not slotted

Conclusions/action items:

Ideally, we want a small, perforated or slotted square tube made of 304 Stainless Steel

We need to decide on an ideal size for the tube!

10/23 Materials Research

▪ KELLY STARYKOWICZ ▪ Dec 10, 2019 @09:36 AM CST

Title: Materials Research

Date: 10/23

Content by: Kelly

Present: Kelly

Goals: Learn about the properties of aluminum to see if it would work for our design.

Content:

- Lightweight
  - About 1/3 the weight of steel
  - We want our device to be as light as possible
- Thin oxide coating makes it more resistant to corrosion
  - This would extend the service life of our device
- Low density
- Low melting point
- Ductile
- Tensile strength increases at lower temperatures
  - Would it maintain its strength after being autoclaved?
- Nontoxic

Properties

- Max service temp: 260.33 - 350.33 degrees F
  - Would withstand autoclave sterilization

https://www.azom.com/article.aspx?ArticleID=1446

Conclusions/action items:

Need to see if aluminum would work for this device.

10/29 Silicone Research

• KELLY STARY

Title: Silicone Research

Date: 10/29

Content by: Kelly

Present: Kelly

Goals: Learn about the types of silicone that are available for purchase.

Content:

- Silicone caulk
  - https://www.amazon.com/GE-Silicone-Purpose-Caulk-GE012A/dp/B0000CBIH9/ref=asc_df_B0000CBIH9/?tag=hyprod-20&linkCode=df0&hvadid=198117319585&hvpos=1o1&hvnetw=g&hvrand=18277229494576727038&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9(320585030345&psc=1
  - GE
  - 100% silicone
  - 100% waterproof and weatherproof
  - $4.47 for 10.1 oz
- Silicone rubber
  - https://www.amazon.com/Smooth-Silicone-Making-OOMOO-30/dp/B004BNF3TK/ref=asc_df_B004BNF3TK/?tag=hyprod-20&linkCode=df0&hvadid=216501935499&hvpos=1o6&hvnetw=g&hvrand=18277229494576727038&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9(351422374259&psc=1
  - Used for mold-making
  - low viscosity
  - $27.97 for 2.8 lb
- Silicone fluid
  - https://sciencekitstore.com/silicone-fluid-350-cst/?sku=AK350&gclid=Cj0KCQjwjOrtBRCcARIsAEq4rW7mB_ZlOo0e8YoHV40SgmgXpuz0roR_yn4mH9drgxLV38UySnpQ0FkaAk
  - Only sold in 1 quart
  - $36 for 1 quart
  - Silicone oil
  - Surface tension at 25 degrees C: 0.021 N/m
- Silicone sealant
  - https://www.techtoolsupply.com/ProductDetails.asp?ProductCode=HOL-VC61-2-10&source=googleps&gclid=Cj0KCQjwjOrtBRCcARIsAEq4rW6fZfIfWtxWmEXeqhKrwgh1WLMu6hnBFDc38y5LkPOvZjBFH7BoRW8aAj4fEALw_wcB
  - $11.19 for 10 15-mL tubes
    - have to buy 10 tubes- more than we need
  - clear
- Silicone sealant
  - https://www.walmart.com/ip/LOCTITE-160809-RTV-Silicone-Sealant-80mL-Tube-Clear-Superflex-RTV/26594088?wmlspartner=wlpa&selectedSellerId=2083&adid=22222222227018200973&wl0=&wl1=g&wl2=c&wl3=51805592951&wl4=pla-83208585551&wl5=9018948&wl6=&wl7=&wl8=&wl9=pla&wl10=113509876&wl11=online&wl12=26594088&veh=sem&gclid=Cj0KCQiA2ITuBRDkARIsAMK9Q7MIQgNeiueQSM 8YjtdXTNam5-y61--L_QocC9_gQ_qv8aAtyXEALw_wcB
  - $8.95 for 2.7 fl oz.
  - Loctite
  - clear
  - RTV silicone sealant

Conclusions/action items:

Need to decide which one would work best to coat the metal.

Ordering from Amazon is probably the best way to go- free shipping and fast delivery times.

Need to look specifically at more Amazon options.

11/2 Silicone Options

▪ KELLY STARYKOWICZ ▪ Dec 10, 2019 @09:39 AM CST

Title: Silicone Options

Date: 11/2

Content by: Kelly

Present: Kelly

Goals: Learn about the different silicone options available

Content:

We want a type of silicone to cover the metal pieces and allow the device to "cling" to the skin. We need to figure out what form of silicone we want. Amazon is probably going to be the best purchase option for us because it will ship for free and arrive quickly.

- Silicone Caulk:
    - https://www.amazon.com/GE-GE284-Silicone-Kitchen-Squeeze/dp/B000PSE46S/ref=sr_1_3?keywords=silicone&qid=1572727592&sr=8-3
        - $3.77 for 2.8 oz
        - 100% silicone
        - Clear
        - Squeeze tube
- Silicone Sealant:
    - https://www.amazon.com/Gorilla-Percent-Silicone-Sealant-Squeeze/dp/B01B5RBOA6/ref=sr_1_4?keywords=silicone&qid=1572728716&sr=8-4
        - Gorilla Brand
        - $4.24 for 2.8 oz
        - Squeeze tube
        - Clear
        - 100% silicone
        - 100% waterproof
    - https://www.amazon.com/Loctite-Silicone-Waterproof-2-7-Ounce-908570/dp/B0002BBX3U/ref=sr_1_5?keywords=silicone&qid=1572728716&sr=8-5
        - Loctite Brand
        - $4.24 for 2.7 oz
        - Squeeze tube
        - 100% silicone

Note: In a true medical device, we would use medical-grade silicone. However, we plan to use a less expensive silicone for the prototype to see if it will meet our adhesive needs before we spend more money on the medical-grade type.

Conclusions/action items:

All of these are good options with positive reviews. The first one (silicone caulk) is less expensive, but seems to be a quality silicone to coat metal in. I would recommend that we proceed with that one.

11/2 Stainless Steel Options

▪ KELLY STARYKOWICZ ▪ Nov 02, 2019 @08:50 PM CDT

Title: Stainless Steel options

Date: 11/2

Content by: Kelly

Present: Kelly

Goals: Learn about the different stainless steel options available.

Content:

We want stainless steel sheet metal. It may be easier to purchase in store rather than ordering online.

- Menards:
  - https://www.menards.com/main/hardware/sheet-metal-rods/hillman-reg-steel-plain-sheet/11758/hardware/sheet-metal-rods/hillman-reg-steel-plain-sheet/11762/hardware/sheet-metal-rods/hillman-reg-steel-plain-sheet/11758/p-1444432427498.htm
    - Hillman Steel Sheets
    - Price varies based on size- doesn't seem too expensive
    - smallest size is 6" x 18"
    - made with low carbon steel
    - has a plain finish
    - works well for welding, drilling, machining, sawing, punching, and forming
    - available in 16 or 22 gauge
  - https://www.menards.com/main/hardware/sheet-metal-rods/hillman-reg-galvanized-steel-sheet-metal/11179/p-1444432404070-c-9215.htm?tid=5722618736280902742&ipos=22
    - Hillman Galvanized Steel Sheets
    - Price varies based on size- doesn't seem too expensive
    - smallest size is 12" x 18"
    - made with low carbon steel
    - Galvanized (coated with a protective layer of zinc)
      - makes it corrosion resistant
    - works well for drilling, machining, sawing, and forming
- Home Depot:
  - https://www.homedepot.com/p/Everbilt-1-4-in-x-4-in-x-12-in-Plain-Steel-Plate-800497/204325592
    - Everbilt Steel Plate
    - 1/4" x 4" x 12"
    - $9.87
    - long-lasting durable steel
    - can be cut with a metal saw
    - has a plain finish
  - https://www.homedepot.com/p/M-D-Building-Products-6-in-x-18-in-28-Gauge-Galvanized-Sheet-56072/205058572
    - M-D Building Products Galvanized Steel Sheet
    - Price varies based on size
    - smallest is 6" x 18" - $3.37
    - thickness varies based on size
      - 6" x 18" sheet is 0.0126" thick
    - Galvanized- resistant to corrosion
    - can be cut with tin snips

Conclusions/action items:

Need to decide if we want galvanized or not galvanized.

Need to decide what size we will need.

11/2 Fabrication Methods

▪ KELLY STARYKOWICZ ▪ Dec 10, 2019 @09:40 AM CST

Title: Fabrication Methods

Date: 11/2

Content by: Kelly

Present: Kelly

Goals: Learn about the different options for fabricating our device with stainless steel.

Content:

- Attaching the metal pieces
    - Rivets
    - Welding
        - Need to get certified or have Jurnee's uncle do it
- Making the long slit in 4 metal pieces
    - Drill holes along metal and use a die grinder, file, or use a Dremel
    - Drill-cold chisel-file
    - Dremel

Conclusions/action items:

We need to speak with the workers in the TEAM lab again to see what they recommend and what they have available. If they have a Dremel and allow us to use it on steel, that would probably be the easiest way to cut the slot in the metal pieces. If Jurnee's uncle is available, welding the metal pieces together may be the best option in terms of connecting them.

11/8 Fasteners Research

Title: Fasteners Research

Date: 11/8

Content by: Kelly

Present: Kelly

Goals: Learn about the fasteners available and see which ones would work best for our device.

Content:

Note: I am just researching various types right now, not specific sizes.

- Gibraltar Thumb Screw:
  - https://www.mscdirect.com/product/details/82054560
  - appears easy to fasten and unfasten
- T-shape Thumb Screw:
  - https://www.amazon.com/Cyful-8-Piece-Threaded-Thumbscrew-Machinery/dp/B07PPD64GS/ref=asc_df_B07PPD64GS/?tag=hyprod-20&linkCode=df0&hvadid=343221120696&hvpos=1o16&hvnetw=g&hvrand=6559862950316453953&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9(837693327597&psc=1&tag=&ref=&adgrpid=70737352682&hvpone=&hvptwo=&hvadid=343221120696&hvpos=1o16&hvnetw=g&hvrand=6559862950316453953&hvqmt=&hvd 837693327597
  - similar to Gibraltar, but T-shaped
- Morton Machine Works Thumb Scre:
  - https://www.mscdirect.com/browse/tnpla/06819031?cid=ppc-google-New+-+Fasteners+-+PLA_sVoObsmn0___164124449228_c_S&mkwid=sVoObsmn0|dc&pcrid=164124449228&rd=k&product_id=06819031&gclid=CjwKCAiAwZTuBRAYEiwAcr67ORp6ygZq0fV5z
  - same as Gibraltar, but different material
- Irwin Adjusting Screw
  - https://www.airgas.com/product/Tools-and-Hardware/MRO-&-Plant-Maintenance/Locking-Clamps-&-Pliers/p/VIS2071905?fo_c=306&fo_k=8fd65285112674fa2e14161deb6c1d84&fo_s=cstmc&s_kwcid=AL!10136!3!381225461274!!!g!812980037934!&utm_arg=SEM:Google:GSN_-_Items_-_Tools_ar Locking_Clamps_and_Pliers::pla:pla:Airgas:tools_hardware::VIS2071905::PLA&gclid=CjwKCAiAwZTuBRAYEiwAcr67OUP3Hsb-tRYNzC26hh_cALxyZatON8Uj3GE3Sk-3lu6w3
  - not a thumb screw- unsure if this would be easy to fasten and unfasten
  - seems too long for our needs

Conclusions/action items:

Thumb screws seem to be the best option from what I see in my research. They are the screws used on calipers and, from my experience, are easy to fasten and unfasten as needed.

11/12 Testing Research

▪ KELLY STARYKOWICZ ▪ Nov 12, 2019 @08:47 AM CST

Title: Kelly

Date: 11/12

Content by: Kelly

Present: Kelly

Goals: Learn about different methods of quantitative testing- looking specifically at strain, stress, forces, surface tension, etc.

Content:

- Measure Strain
    - Electrical Strain Gauges [1]
        - commonly used in strain tests
        - "used in Experimental Stress Analysis (ESA), durability testing, and transducer manufacturing"
    - Optical Strain Sensors [1]
        - used in structural monitoring
- Measure surface tension
    - Tensiometer [2]
        - would need to find a way to adapt to skin
        - usually used for liquids
- Measure applied force
    - Force meter [3]
        - Force reading connected to a spring which is connected to a hook
        - As more force is applied, the spring stretches, and the force reading is larger
        - We want something like this but on a much smaller scale (able to read very small forces)
- Possible Equations we will need:
    - Hooke's Law: stress = strain * E (modulus of elasticity)
    - Force = -k (spring constant) * x (displacement)

[1] https://www.hbm.com/en/7074/strain-gauge-fundamentals/

[2] https://www.kruss-scientific.com/services/education-theory/glossary/tensiometer/

[3] https://eschooltoday.com/science/forces/what-is-a-force.html

Conclusions/action items:

We plan on speaking to someone who has a tensiometer in their lab. If that does not work out, we need to look into a small version of a force meter.

11/14 Thumb Screws Research

Title: Thumb Screws Research

Date: 11/14

Content by: Kelly

Present: Kelly

Goals: Find relatively short thumb screws with a diameter of 3/16"

Content:

<u>Note</u>: lengths listed do not include the head of the screw

1. https://www.zoro.com/zoro-select-thumb-screw-knurled-6-32x916-l-stl-z2307/i/G2374154/feature-product?gclid=Cj0KCQiAk7TuBRDQARIsAMRrfUbkpuKAIV0phgjFbnHncyLBLiwc_VP66
    1. 9/16" length
    2. $3.02 for 1
2. https://www.zoro.com/zoro-select-thumb-screw-spade-6-32-38-l-pk25-tsi0-60037s0-025p/i/G2343442/
    1. $7.29 for 25
    2. 3/8" length
3. https://www.mscdirect.com/browse/tnpla/67218685?cid=ppc-google-New+-+Fasteners+-+PLA_sdbznxvcu___164110844574_c_S&mkwid=sdbznxvcu|dc&pcrid=164110844574&rd=k&product_id=67218685&gclid=Cj0KCQiAk7TuBRDQARIsAMRrfUbPc79DksE0FzHmVsye-b
    1. $7.55 for 1
    2. 1/2" length
4. https://www.zoro.com/zoro-select-thumb-screw-knurled-6-32x38-l-18-8-ss-z2364/i/G1172446/
    1. 3/8" length
    2. $2.88 for 1
5. https://www.walmart.com/ip/Computer-Graphics-Card-Round-Head-Knurled-Thumb-Screws-Silver-Tone-6-32-4pcs/795861611?wmlspartner=wlpa&selectedSellerId=571&adid=2222222 276429799869&wl5=9018948&wl6=&wl7=&wl8=&wl9=pla&wl10=111838760&wl11=online&wl12=795861611&veh=sem&gclid=Cj0KCQiAk7TuBRDQARIsAMRrfUboj7icauq0CUGMSJ4d
    1. 0.4" length
    2. Aluminum Alloy
    3. $4.47 for 4
6. https://www.zoro.com/zoro-select-thumb-screw-knurled-6-32x14-l-pk5-wftsss1/i/G1905041/
    1. 0.25" length
    2. Stainless Steel
    3. $9.33 for 5
7. https://www.zoro.com/zoro-select-thumb-screw-knurled-6-32x38-l-pk5-pts6-sl/i/G1972363/
    1. 3/8" length
    2. Stainless Steel
    3. $10.94 for 5

Narrowing down options:

- Anything over 3/8" is probably too long
    - Eliminates #1, #3, and #5
- Reevaluate 2,4,6,7:
    - Thread lengths:
        - #2,4, 7 are 3/8" in length
        - #6 is 1/4" in length, but has a bit of a "neck" (for lack of a better word) that we were hoping to avoid
    - Materials:
        - #4,6,7 are made of stainless steel
        - #2 is made of steel
    - Cost:
        - #2: $7.29 for 25
        - #4: $2.88 for 1
        - #6: $9.33 for 5
        - #7: $10.94 for 5

Conclusions/action items:

Need to show these 4 to the team and see what they think.

According to my research, screws can be cut but it isn't necessarily a simple process.

11/22 Menards Trip

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @11:10 PM CST

Title: Menards Trip

Date: 11/22/19

Content by: Kelly

Present: Kelly

Goals: Purchase fasteners for the device

Content:

Went to Menards to look at the fastener options and purchase some so we can test Monday.

6/32" diameter, 0.25" length screws

Looked at machine screws, hex nuts, wing nuts, lock nuts, thumb screws, and many others.

Decided on thumb screws because they are easier to turn and adjust.

Bought both hex nuts and wing nuts to see which ones would be easier to use.

Conclusions/action items:

Need to assemble the device with the thumb screws and nuts and see how the fastener mechanism works.

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @11:11 PM CST

IMG_20191122_162348036.jpg(479.5 KB) - download Two thumb screws were purchased. Diameter of 6/32" and length of 0.25"

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @11:12 PM CST

IMG_20191122_161414239.jpg(805.6 KB) - download The hex nuts and wing nuts were purchased. Both fit screws with a diameter of 6/32". The machine screws seen on the left part of the image were not purchased because I decided that the thumb screws would be easier to use

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @11:13 PM CST

IMG_20191202_214208859.jpg(676.6 KB) - download Receipt for the thumb screws, hex nuts, and wing nuts.

11/28 Skin Prep Research

▪ KELLY STARYKOWICZ ▪ Nov 28, 2019 @12:26 PM CST

Title: Skin Prep Research

Date: 11/28/19

Content by: Kelly

Present: Kelly

Goals: Learn about Skin Prep

Content:

- Comes as a wipe or spray and forms a thin film when applied [1]
- Assists with adhesion [1]
- Easily washed off [1]
- Reduces the friction between tapes and the skin- makes it easier and less painful to remove adhesives [1]
- Often used before adhesive dressings and drainage tubes are applied [1]

[1] SKIN-PREP◊," *SKIN-PREP Protective Barrier Wipe | Smith & Nephew - US Professional*. [Online]. Available: https://www.smith-nephew.com/professional/products/advanced-wound-management/skin-prep/#. [Accessed: 28-Nov-2019].

Conclusions/action items:

We can use this information to give background on SkinPrep and describe how it may affect the functionality of our prototype.

9/23/19 Bow-shaped Design

▪ KELLY STARYKOWICZ ▪ Sep 24, 2019 @08:56 AM CDT

Title: Bow-shaped Design

Date: 9/23/19

Content by: Kelly

Present: Kelly

Goals: Sketch up and describe a possible bow-shaped design

Content:

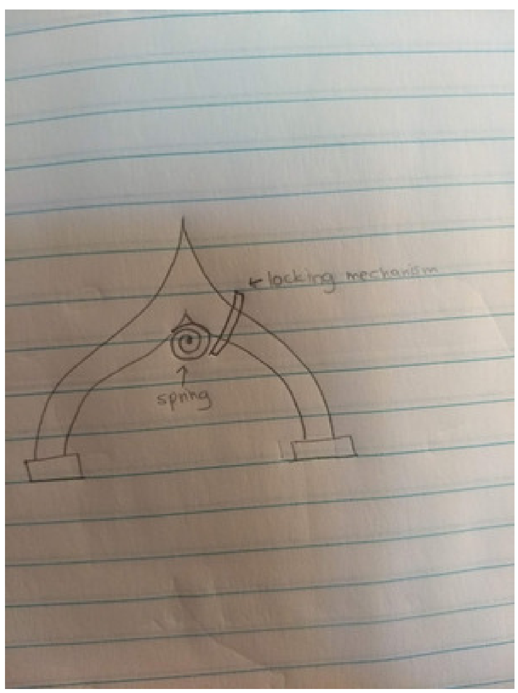
Design Features:

- 2 "feet" to sit on skin and gently move skin into place
    - Must not irritate or rub skin
    - Must grip skin to move it (otherwise, it would merely be sliding along skin)
- Bow-shaped "legs" that attach to each other at the top and to the feet at the bottom
- Spring
    - tightened to bring the feet closer together, therefore guiding the wound edges together
- Locking Mechanism
    - pushed when the spring is tightened the optimal amount- locks the legs and spring in place so the clinician can seal the wound

Conclusions/action items:

- Research a good material for the "feet" of the design

▪ KELLY STARYKOWICZ ▪ Sep 24, 2019 @08:51 AM CDT



bow-shaped_design.jpg(60.2 KB) - download

9/23/19 Railroad Track Design

▪ KELLY STARYKOWICZ ▪ Sep 24, 2019 @09:00 AM CDT

Title: Railroad Track Design

Date: 9/23/19

Content by: Kelly

Present: Kelly

Goals: Sketch up and describe a possible railroad track design

Content:

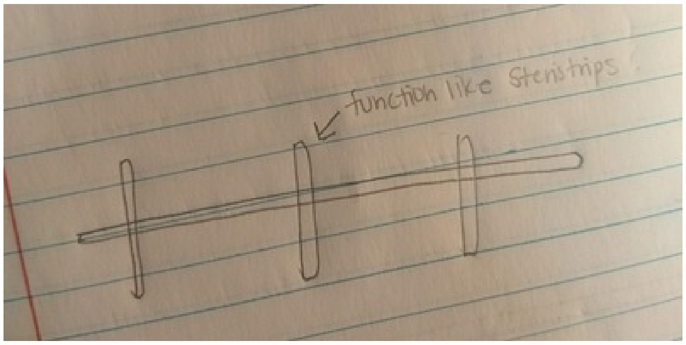
Design Features:

- Thin adhesive strips that function similar to SteriStrips
    - Can be pressed to one side of the wound and pulled to approximate the wound edges
    - Must be thinner than SteriStrips, but with a similar outcome
    - Different material?

Conclusions/action items:

- Research materials that adhere well to the skin without damaging it
    - Research their tension forces and strengths to compare to SteriStrips

▪ KELLY STARYKOWICZ ▪ Sep 24, 2019 @08:51 AM CDT



railroad_design.jpg(138 KB) - download

11/27/19 Future Work

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @11:20 PM CST

Title: Future Work

Date: 11/27

Content by: Kelly

Present: Kelly

Goals: Think of improvements that could be made to the design.

Content:

- Find smaller adhesive bumpers that are sterile
    - Purchase or make
- Improve fastener mechanism
    - Consider a hinge or gear system
- Improve silicone application method
    - It currently comes off pretty easily
- Test on real skin wounds
- Test on a better skin model
- Test ease of use among different users
- Stress Concentration Analysis in Solidworks
- Test on other parts of the body (legs and torso)

Conclusions/action items:

Need to add all of these to the final report and poster to discuss.

12/09/19 Post-Presentation Ideas

▪ KELLY STARYKOWICZ ▪ Dec 09, 2019 @11:25 PM CST

Title: Post-Presentation Ideas

Date: 12/09/19

Content by: Kelly

Present: Kelly

Goals: Note down some of the ideas we had/were given during the poster presentations.

Content:

- Fake skin model: another group created their own
    - Need to research this more
    - Sounds similar to EcoFlex (which was used in the Midfoot Collapse Project briefly)
- Adhesive bumpers: can make our own
    - We can use an existing mold and make them out of PTFE
- Accessing real skin wounds may be too difficult- focus should be on a more accurate synthetic model
- We need to get clearance from the IRB to do any further testing on human skin

Conclusions/action items:

These are things we need to consider as we head into next semester. We will work on getting IRB clearance over winter break.

12/10/19 To Do Next Semester

• KELLY STARYKOWICZ • Dec 10, 2019 @09:49 AM CST

Title: To Do Next Semester

Date: 12/10/19

Content by: Kelly

Present: Kelly

Goals: Make a list of what should be done next semester

Content:

- Research different types of fake skin to see what is closest to skin and would work for our purposes.
    - Needs to feel similar to real skin to test device on.
    - Will be tested in the MTS machine to redo the testing that we performed with the suture kit.
    - Consider making it from a mix
- Research types of sterile adhesives that can replace the silicone bumpers.
    - Need to be smaller than the current bumpers.
    - Need to either be (1) inexpensive and sterile when we buy them, or (2) able to be sterilized in an autoclave.
    - Consider making them in the Makerspace with a mold
        - Dr. Tracy Puccinelli's suggestion from poster presentations
- Brainstorm how a hinge or gear mechanism would work.
    - Instead of fasteners, which we found too difficult to tighten independently of one another.
- Get IRB clearance for human testing

Conclusions/action items:

- Need to research the following:
    - types of fake skin
    - sterile adhesives
    - hinge and gear mechanisms
- Need to get IRB clearance

12/5/2018 Poster Printing Notes

• ELIZABETH SCHMIDA • Dec 06, 2018 @08:23 PM CST

Title: Poster Printing Notes

Date: 12/5/2018

Content by: Lizzy

Present: N/A

Goals: Print the group poster

Content:

The hope is to provide notes from my experience printing a poster to reference in future semesters so I know how to execute it more smoothly.

- Print on the 2nd floor of Helen C. White College Library
- Poster printing takes 3hrs-2days to print
  - Our poster printed in 1hr likely due to the fact that we printed on Wednesday instead of Thursday like most groups do
- Log into windows side on computer in the lab
- download slide from googledocs as a powerpoint
  - if doesn't work resize slide under setup in google docs
  - Sizing: 48inx36in
- zoom into 100% to ensure nothing gets blurry
- save as a TIFF into the library's drop folder for printing
- staff at front desk will check poster over before giving ok to print
- can pay before or after poster prints
  - cost $50

Conclusions/action items:

Although there were a few complications, the whole process went far smoother than I thought it would. Biggest suggestion is to make sure the poster is sized properly BEFORE starting to write and add pictures--very stressful to do that after.

9/8/2019 Suture Material Background Research

• ELIZABETH SCHMIDA • Sep 08, 2019 @11:32 AM CDT

Title: Suture Material Background Research

Date: 9/8/2019

Content by: Lizzy Schmida

Present: N/A

Goals: Gain a better understanding of the current suturing equipment and techniques utilized in operating rooms.

Source: Omar E Beidas, Jeffrey A Gusenoff, Deep and Superficial Closure, *Aesthetic Surgery Journal*, Volume 39, Issue Supplement_2, April 2019, Pages S85–S93.

Link: https://academic.oup.com/asj/article/39/Supplement_2/S85/5377469

Content:

- In relation to surgery, approximation means bringing tissue edges into position for suturing
- Approximation techniques used:
  - traditional smooth suture--most common
  - barbed suture
  - internal and external staples
  - tissue and skin glues
  - negative-pressure wound therapy (NPWT)
- Serve to "reapproximate" wound to relieve tension from skin edges
- Optimal closure characteristics:
  - efficient repositioning of tissue
  - appropriate skin tension
  - eversion of skin edges
  - satisfactory aesthetic result
- Common Suture Problems/Complications:
  - unraveling
  - spitting = suture breaking through the surface of the skin
  - granuloma formation
  - issue ischemia = restriction of blood supply to tissues, low oxygen supply
  - wound infection
  - scarring
- Ideal closure material must hold securely in tissue, be cost effective, cause no foreign body response, offer high tensile strength, and rapid absorption
- Suture Types:
  - absorbable or nonabsorbable
    - Nonabsorbable/permanent made from natural (silk, cotton) or synthetic (polyethylene, polypropylene, polyester)
      - encapsulated by fibroblasts
      - may have to have operation to remove suture if complication arise (could happen years after initial placement)
    - Absorbable/temporary dissolve via hydrolytic or proteolytic processes
      - defined by its time to half tensile strength (THTS)
        - time it takes to lose 50% of strength
      - provides temporary support until the tissue heals sufficiently to maintain its natural tensile strength
  - monofilament or multifilament
    - Multifilament = braided or twisted strands, requires fewer ties to maintain knot security
      - greater risk of infection--could harbor bacteria between strand--usually coat
  - smooth or barbed
    - Barbed = standard suture material with helical pattern of barbs cut into filament
      - Do not require knots to secure (self-lock) which speeds up the suturing process (holds suture in place while working)
- Most important consideration in suture choice is ensuring suture will hold sufficient tension until the tissues able to support themselves
  - Suture retention depends primarily on tensile strength and absorption rate (loss of mass)
- Permanent sutures should be avoided superficial to the muscular fascia because do not dissolve and are bothersome to patients

- Skin Tension Forces:
    - Skin closure required a 6.5-N force (without use of deeper tension-relieving sutures) to approximate wounds
    - To close deep fascia (DF) 10.3 N
    - To close superficial fascia (SF) 7.8 N
    - Force needed to approximate skin after either DF or SF closure was 4.9 or 4.1 N
        - Tension-reduction of 25% or 39%
- Skin glues:
    - composed of liquid monomers
    - polymerize into a strong adhesive once contact moist surface
    - made of a cyanoacrylate base
    - helpful when little wound tension
    - provide an immediate watertight seal--allow patient to shower sooner
    - avoid using on permanent sutures or on external absorbable sutures--will prevent suture removal and lead to long-term scarring

Conclusions/action items:

This article provided a great overview of all the different suture types currently used in operating rooms. I am excited that the article provided tissue tension forces: these will certainly be useful when we test our device. I need to do more research into the types of skin glues used as well as the actual suturing stitches commonly used.

9/8/2019 Suturing Techniques, Background Research

• ELIZABETH SCHMIDA • Sep 11, 2019 @07:37 AM CDT

Title: Suturing Techniques, Background Research

Date: 9/8/2019

Content by: Lizzy Schmida

Present: N/A

Goals: Gain a better understanding of how wounds are closed and the suturing techniques utilized.

Source: https://www.uptodate.com/contents/closure-of-minor-skin-wounds-with-sutures

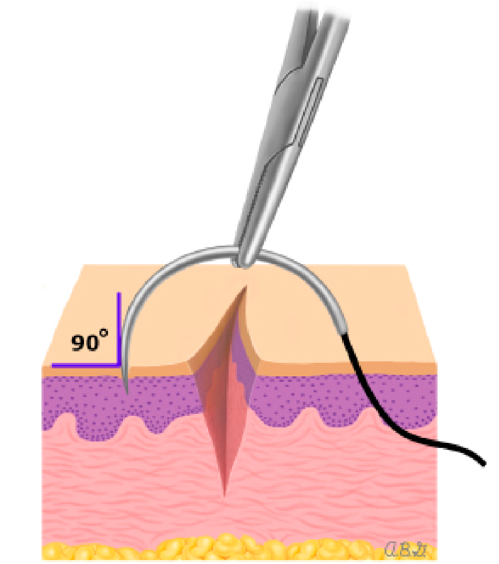
Other sources: https://www.ncbi.nlm.nih.gov/pubmed/29262163

Content:

- Skin Anatomy
    - epidermis, dermis, subcutaneous layer, and deep fascia
    - epidermis and dermis tightly adhered and clinically indistinguishable
        - Dermal approximation provides the strength and alignment of skin closure
    - subcutaneous layer mainly comprised of adipose tissue, nerve fibers, blood vessels, and hair follicles
        - layer provides little strength to the repair, sutures placed in the subcutaneous layer may decrease the tension of the wound and improve the cosmetic result
    - deep fascial layer is intermixed with muscle and occasionally requires repair in deep lacerations
- Healing Process
    - Coagulation begins immediately
    - platelet aggregation and fibrous clot formation occur
    - During inflammatory phase, proteolytic enzymes released by neutrophils and macrophages break down damaged tissue
    - Epithelialization occurs in the epidermis(only layer capable of regeneration)
    - Complete bridging of wound occurs within 48 hours after suturing
    - New blood vessel growth peaks 4 days after injury
    - Collagen formation necessary to restore tensile strength to wound
        - process begins within 48 hours of injury and peaks in first week.
        - Collagen production and remodeling continue for up to 12 months
    - Wound contraction occurs 3-4 days after injury
- Use sutures if wound depth will lead to excess scarring if wound edges not properly opposed
    - Whenever laceration goes through dermis
- Staples frequently used for scalp wounds and wounds in noncosmetic regions (especially when linear and >5 cm)
    - permits faster closure
- Use tissue adhesives if wound <5 cm and not under tension (avoids pain of sutures)
- Wound Preparation/decontamination to prevent tissue infection
    - Surfactant cleaners, wound irrigation, foreign body removal, necrotic tissue debridement
- Useful definitions in relation to sutures:
    - Tensile strength = amount of weight required to break a suture divided by its cross sectional area
        - designation for suture strength is the number of zeros-- the higher the number of zeros (1-0 to 10-0), the smaller the size and the lower its strength
    - Knot strength = measure of amount of force required to cause knot to slip
        - directly proportional to coefficient of friction for the given material
    - Elasticity = suture's ability to hold original form and length after being stretched
        - allows expansion with wound edema and to maintain wound edge apposition during wound contraction
- Suture Needle:
    - Eye = end of needle attached to suture
        - All sutures used for acute wound repair are swaged (the needle and suture are connected as continuous unit)
    - Body = portion grasped by the needle holder during procedure
        - determines shape of the needle and curved for cutaneous suturing
        - curvature can be 1/4, 3/8, 1/2, or 5/8 of a circle
        - 3/8 is most commonly used curvature
            - requires minimal pronation of wrist for large and superficial wounds
        - 1/2 and 5/8 circles used for suturing in confined spaces (ex. mouth)
    - Point = extends from the extreme tip to the maximum cross section of body

        - Use taper needle with round cross section for soft tissue and fascia
- Suture Techniques:
    - Eversion skin closure
        - Needle penetrates skin surface at 90 degree angle
        - Suture loop at least as wide at base as is at skin surface
        - Width and depth of suture loop should be same on both sides of wound and similar to thickness of dermis
        - Number of sutures needed to close wound varies depending on length, shape, and location of laceration
            - Generally sutures placed just far enough from each other so that no gap appears in wound edges

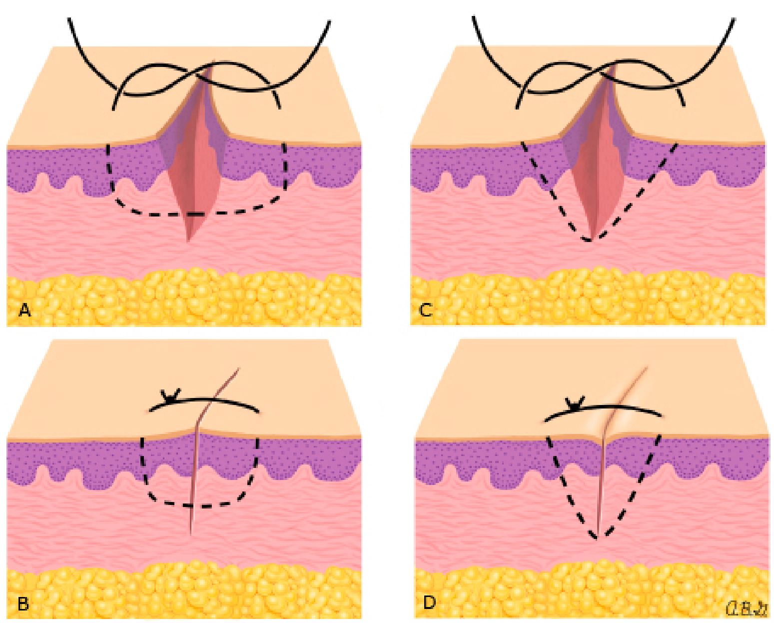
Needle insertion for eversion technique



For proper healing, the edges of the wound must be everted. To accomplish this, the needle should penetrate the skin at a 90 degree angle to its surface.

    -

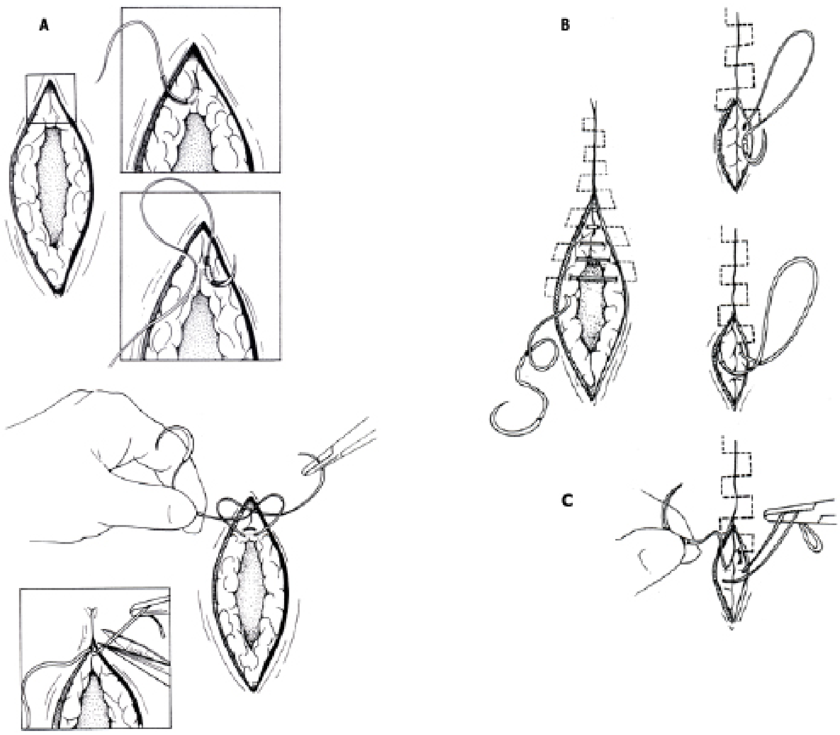
Proper technique for wound edge eversion



Proper technique Improper technique

- The proper technique for everting the edges of a wound is illustrated in the panels on the left.
- Running suture

  - used for rapid closure of longer wounds. It
  - provides even distribution of tension along the length of the wound--preventing excess tightness in any one area
  - best reserved for wounds at low risk of infection with edges easily align
  - closure is started with standard technique of a percutaneous simple interrupted suture, but the suture is not cut after the initial knot is tied
  - needle then used to make repeated bites, starting at the original knot and making each new bite through the skin at 45 degree angle to wound direction
  - final bite made at angle of 90 degrees, left in a loose loop, which acts as a free end for tying the knot
- Subcuticular running suture
  - used by plastic surgeons to close straight lacerations on face--use absorbable suture
  - suture anchored at one end of laceration
  - plane chosen in dermis or just deep to the dermis in the superficial subcutaneous fascia
  - Mirror image bites taken horizontally in plane for full length of the laceration
  - Final bite leaves trailing loop of suture to tie final knot
  - Wound is then reinforced with adhesive tape



"The suture is anchored at one end of the laceration (A). The plane chosen is either the dermis or just deep to the dermis in the superficial subcutaneous fascia. While maintaining this plane, "mirror image" bites are taken horizontally the full length of the wound (B). The final bite leaves a trailing loop of suture, as shown, so that the knot can be fashioned for final closure (C). This technique is commonly supplemented with wound tapes, particularly if there remains some degree of gapping of the edges."

Conclusions/action items:

There were several other alternative suturing methods described, but they are mainly utilized in operating rooms, not in ERs or offices. This article gave a great overview of the different types of suturing techniques and the criteria for which technique to use.

9/21/2019 Autoclave Background Research

• ELIZABETH SCHMIDA • Sep 21, 2019 @01:42 PM CDT

Title: Autoclave Background Research

Date: 9/21/2019

Content by: Lizzy S.

Present: N/A

Goals: Gain a better understanding of what temperatures/chemical reactions the device will need to withstand during the sterilization process between uses.

Source: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html

CDC.gov. (2008). *Steam Sterilization: Guideline for Disinfection and Sterilization in Healthcare Facilities*. [online] Available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html.

https://consteril.com/how-does-a-laboratory-autoclave-work/

Content:

- Autoclave = Steam Sterilizer
    - Autoclave more often in laboratories
    - Sterilizer more commonly heard in hospitals/pharmaceutical settings
- uses steam heat to kill microbial life
- Different types of goods must be sterilized for different times and different temperatures
- Number of microorganisms left alive over time at fixed temperature expressed by logarithmic curve (Figure 1)

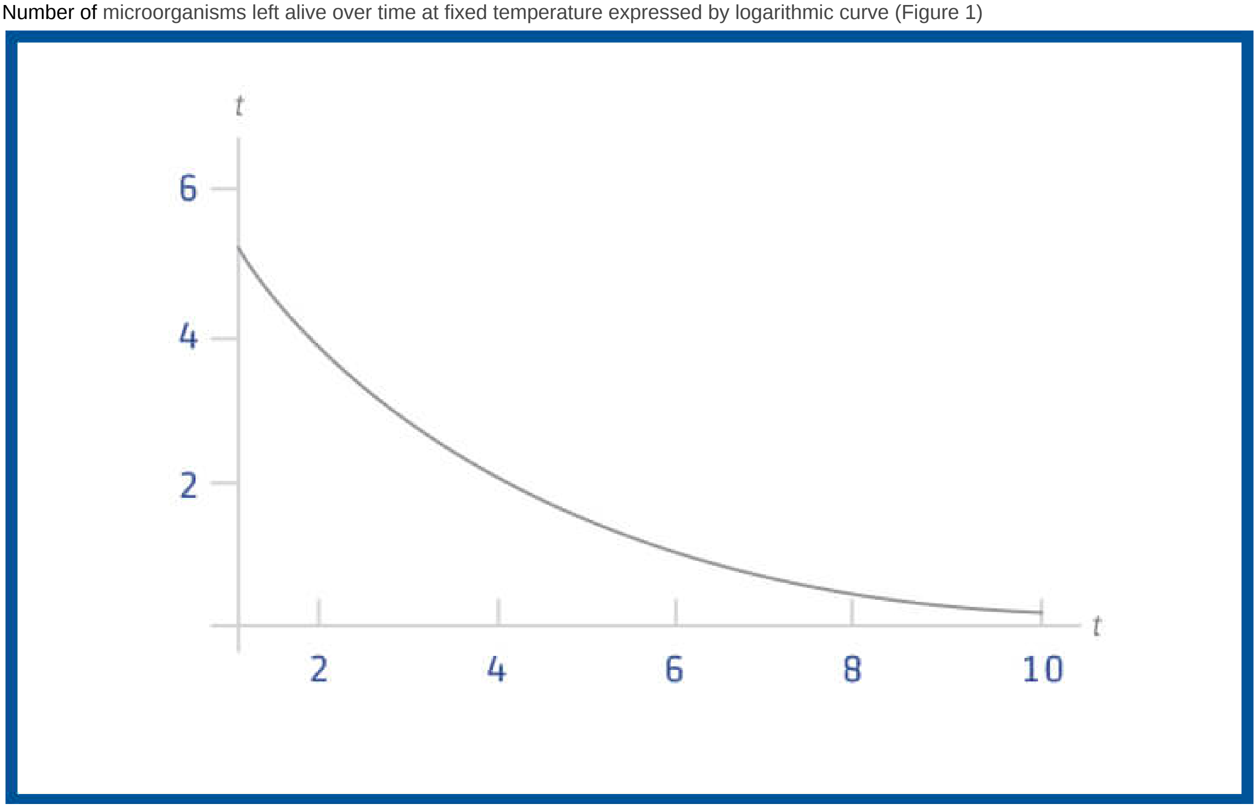


Figure 1. Function of the number of microorganisms left overtime.

As function approaches zero, level of confidence (called Sterility Assurance Level or SAL) chosen for odds that the last microorganism present will survive. General standard for SAL is 10-6, (one in a million chance of a single viable microorganism).

- Process Steps:
    - door locked to form sealed chamber
    - all air within the chamber is replaced by steam
    - steam is pressurized to reach desired sterilization temperature and time

- steam then exhausted

Compatible/Incompatible Materials

AUTOCLAVE-COMPATIBLE MATERIALS	AUTOCLAVE-INCOMPATIBLE MATERIALS
• Tissue Culture Flasks • Surgical Instruments • Glassware • Pipette tips • Media Solutions • Animal food and bedding • Waste • Polypropylene (Secondary containers) • Stainless steel • Gloves	• Acids, bases and organic solvent • Chlorides, sulphates • Seawater • Chlorine, hypochlorite, bleach • Non-stainless steel • Polystyrene(PS) • Polyethylene(PE) • Low density (LDPE) and High density polyethylene(HDPE) • Polyurethane

Never autoclave:

· Flammable, reactive, corrosive, toxic or radioactive materials

· Household bleach

· Any liquid in a sealed container.

· Any material contained in such a manner that it touches the interior surfaces of the autoclave.

· Paraffin-embedded tissue.

Conclusions/action items:

This article by the CDC provided a great overview of how steam sterilization works as well as the typical settings used for autoclaves. Based on the minimum exposure periods and temperatures required, it is fair to infer that our device will be subjected to these temperatures when it is sterilized. We will therefore have to select materials that are compatible with steam sterilization. The article also provided a great overview of some of the materials that can go in an autoclave.

9/21/2019 Tissue Adhesives Background Research

• ELIZABETH SCHMIDA • Sep 21, 2019 @06:27 PM CDT

Title: Tissue Adhesives Background Research

Date: 9/21/2019

Content by: Lizzy S.

Present: N/A

Goals: Based off of the client meeting, it sounds like the designed device will be primarily used in with some form of tissue adhesive versus sutures. My goal is to gain a better understanding of how these glues work and their applications.

Source: Mattick A. Use of tissue adhesives in the management of paediatric lacerations *Emergency Medicine Journal* 2002;**19:**382-385.

Link: https://emj.bmj.com/content/19/5/382

Content:

- 30%–40% of all paediatric injuries are from lacerations that require suturing/gluing
- ideal method of wound closure in children should be painless, rapid, easy to perform, safe, with few complications, and result in minimal scarring
- Cyanoacrylate adhesives have common chemical structure but subtle variations in their alkyl group that can change the properties of each individual tissue adhesive (Figure 1)
- Cyanoacrylates are liquid monomers that can polymerise to form rapid and strong adhesives
    - Process occurs when come into contact with anions (those found in skin moisture or wound exudate)
    - when applied to edges of wound a strong bond will develop

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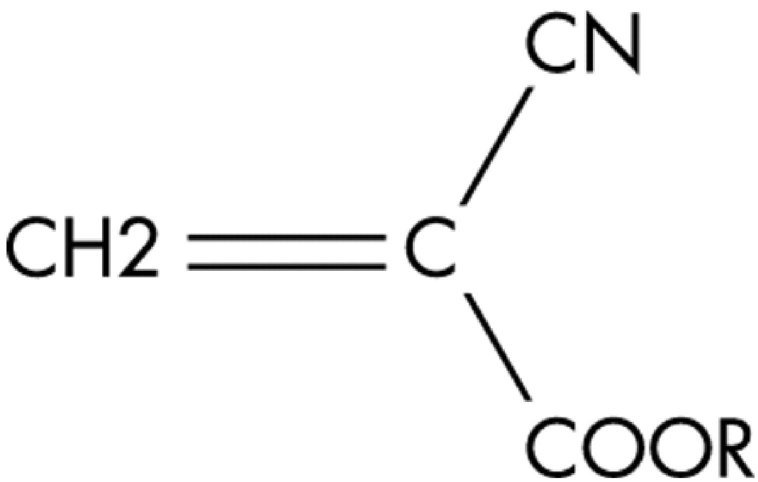


Figure 1. **The chemical structure of cyanoacrylates. R represents the variable alkyl group.**

- Application Process
    - edges of wound held together with forceps or operator's fingers before adhesive applied
        - Histoacryl Blue applied as beads intermittently along edge of laceration
        - Dermabond painted on in layers
    - Edges of wound held together for up to a minute to enable sufficient polymerisation and bond formation
    - Maximum strength usually achieved within 2 minutes
    - important that adhesives are placed topically onto the wound edges and not allowed to enter wound --will impair healing
- Proficiency in adhesive application technique shown to be rapidly learned

Conclusions/action items:

This journal article gave a brief overview of the chemistry behind Dermabond and how it is applied to wounds. I will need to do further research to determine how the decision is made to use glue versus sutures as well as look at how the glue interacts with other materials (i.e. how it would interact if came into contact with designed device).

9/29/2019 Methods for Testing Skin Tension

▪ ELIZABETH SCHMIDA ▪ Sep 29, 2019 @11:14 AM CDT

Title: Methods for Testing Skin Tension

Date: 9/29/2019

Content by: Lizzy S

Present: N/A

Goals: Brainstorm potential testing methods to evaluate the effectiveness of our design in terms of the force it exerts on the skin during wound edge approximation.

Source: S. P. Paul, "Biodynamic Excisional Skin Tension Lines: Using a New Skin Tensiometer Device and Computational Analyses to Understand Excisional Skin Biomechanics," *Biodynamic Excisional Skin Tension Lines for Cutaneous Surgery*, pp. 35–42, Jul. 2016.

Content:

- Skin tension lines
- New skin tensiometer developed
- two current methods for measuring skin tension
  - Harvey's technique = measuring intraluminal pressure inside hollow organ
  - Howe's technique = studying forces needed to disrupt a wound
- Many different tensiometers have been developed in studies to measure wound tension
  - most cumbersome, non-portable and use clamps
    - clamp placement is very user-dependent (figure 1)
- Spring loaded sensors have been developed to measure force on tensioned suture inside closed incision and to measure pulling force used to close the incision

Figure 1: Skin tensiometer being used to measure scalp tension.

Conclusions/action items:

While this article was mainly describing a new skin tensiometer created, it did give a brief overview of the current skin tension measurement methods currently available. While most discussed are likely too sophisticated for our purposes, it did help me start to think of way we could easily measure tension. For instance, we could use some form of strain gage placed on the fake skin, or maybe use a fish scale--we could attach a string from the scale (fixed) to the edge of the rectangle device and close it around the fake wound--the displacement of the string would show up on the fish scale as a force.

▪ ELIZABETH SCHMIDA ▪ Sep 29, 2019 @10:40 AM CDT

SCIENTIFIC REPORTS

OPEN

A New Skin Tensiometer Device: Computational Analyses To Understand Biodynamic Excisional Skin Tension Lines

Sharad P. Paul[1,2,3,4], Justin Matulich[2] & Nick Charlton[3]

Skin_Tensiometer.pdf(684.4 KB) - download

9/30/2019 Skin Mechanics

▪ ELIZABETH SCHMIDA ▪ Oct 04, 2019 @05:50 PM CDT

Title: Skin Mechanics

Date: 9/30/2019

Content by: Lizzy S.

Present: N/A

Goals: Obtain background knowledge on the mechanics of the skin and an idea of how it will

Content:

Sources: Pawlaczyk, Mariola et al. “Age-dependent biomechanical properties of the skin.” *Postepy dermatologii i alergologii* vol. 30,5 (2013): 302-6. doi:10.5114/pdia.2013.38359 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3858658/

Tepole, Adrián Buganza et al. “Stretching skin: The physiological limit and beyond.” *International journal of non-linear mechanics* vol. 47,8 (2012): 938-949. doi:10.1016/j.ijnonlinmec.2011.07.006 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3583021/

- Skin protects from external environment and mechanical injuries
- Skin is largest organ in body--surface area of two square meters and weighs about four kg
    - consists of three layers:
        - epidermis = thin protective outer layer
        - dermis = thick elastic inner layer, main source of skins mechanical strength
        - hypodermis = subcutaneous base layer of fatty tissue
- Within physiological limits, behaves almost like rubber --mechanical response highly nonlinear, initially weak, but much stiffer at higher stretch levels
- skin is highly anisotropic
    - larger stiffness along pronounced collagen fiber orientations (Langer’s lines)
        - Langer = static lines corresponding to lines of maximum tension
        - Kraissl's lines correspond to movement of skin during muscle work
        - Borges lines = relaxed skin tension lines
- When stretched beyond physiological limit skin increases surface area to reduce the mechanical load
- Biomechanical skin parameters change with time
    - Young's modulus increases linearly with age
    - Aging is reason why skin becomes thinner, stiffer, less tense and flexible
    - Skin thickness varies based on anatomic location, fluid content and age
    - Anisotropy increases with age
        - skin shows anisotropic properties and ability to stretch and contract in different directions varies
- Elasticity
    - Deformation marks the skin in response to applied forces
    - perfectly elastic when skin returns to initial state after termination of force
    - When exceed elastic limit, termination of external force does not permit skin to return to initial shape = residual deformation
        - Related to change of stability and position of skin elements
    - modulus of longitudinal elasticity – the Young's modulus (E) – defines the relation between stress (σ) and strain (ε) in skin

        - modulus characterizes skin resistance to elastic elongation : Hooke's Law: $\varepsilon = E/\sigma$
            - Young's modulus (E) of the skin fluctuates between 0.42 MPa and 0.85 MPa (torsion tests) between 0.05 MPa and 0.15 MPa (suction tests)
    - Young's modulus increases linearly with age
        - Skin resistance described by yield limit and elongation
        - Plastic elongation: $Ar = (L1 - L0)/L0 \times 100\%$ (L0 = section of sample before deformation and L1 =section of the sample after deformation).
        - Yield point = point of stress when notable plastic deformations become visible
        - Poisson's ratio = determines proportionality of mutually perpendicular linear elongations

Conclusions/action items:

The introduction sections of these articles provided great background information into the mechanics of skin and provide some great ideas in terms of how to quantify the deformations that could result from using our wound edge approximation device. I will definitely have to include some of the basic equations such as Hooke's law in the background section of our preliminary report. As I am in Advanced Mechanics of Materials this semester, I can use what I have learned in that course to hopefully expand on the ideas put forth in the articles.

10/5/2019 Potential Impacts of Device (ER overcrowding)

ELIZABETH SCHMIDA • Oct 05, 2019 @01:26 PM CDT

Title: Potential Impacts of Device

Date: 10/5/2019

Content by: Lizzy S

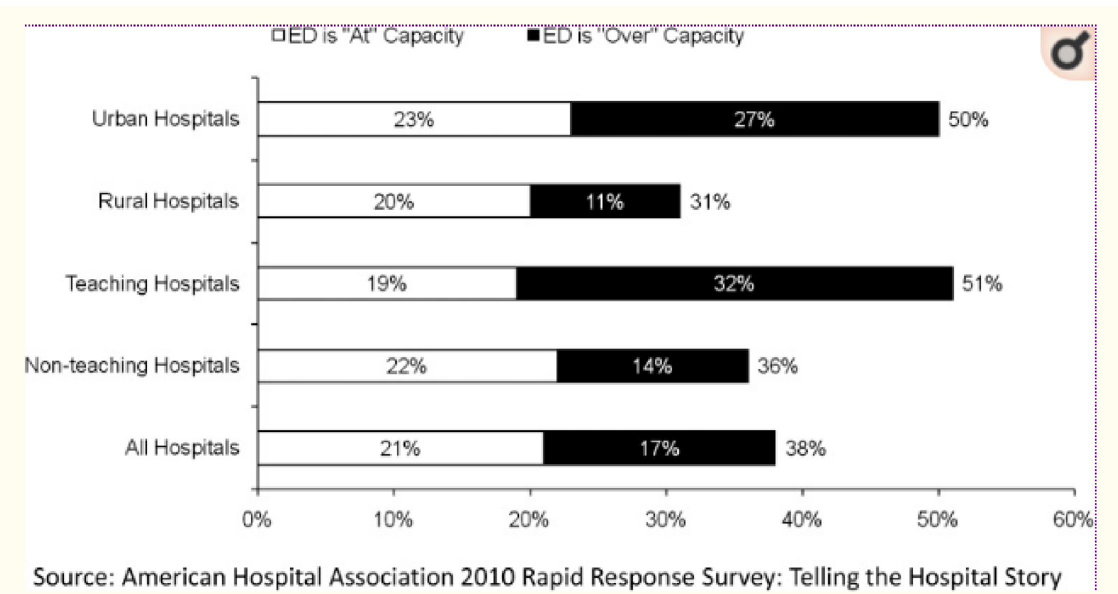
Present: N/A

Goals: Develop a better comprehension of how a wound edge approximation device will impact the hospital setting in relation to understaffed, and overcrowded ERs and doctor's offices.

Source: Barish, Robert A et al. "Emergency room crowding: a marker of hospital health." *Transactions of the American Clinical and Climatological Association* vol. 123 (2012): 304-10; discussion 310-1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3540619/

Content:

- ER visits account for 11% of outpatient encounters, 28% of acute care visits, and 50% of hospital admissions
    - "the safety net of the safety net"
    - it is now a place of last and first resort
- Hospital-based emergency care is only medical treatment to which Americans have legal right, regardless of ability to pay
    - Emergency Medical Treatment and Active Labor Act (EMTALA) passed in 1986
        - Requires hospitals and ambulance services to provide care to anyone needing emergency treatment regardless of citizenship, legal status, or ability to pay
- Crowding problem most severe in urban and teaching hospitals
    - More than 50% of surveyed urban and teaching hospitals had ERs "at" or "over" capacity (figure 1)



- trend of decreasing number of ERs and an increasing numbers of ER visits
    - 1990 - 2009, number hospital-based ERs in non-rural areas decreased by 27%
    - number of ER visits increased 44%
    - increase is not just due to population increases--utilization rate increased 18%
- ER crowding affects certain populations disproportionately
    - "uninsured" patients are three times more likely to use ERs and are sicker than their "insured" counterparts
- ERs employ only 4% of the active physician workforce
    - account for 38% of all acute care visits
- medical specialists account for 60% of the active physician workforce
    - manage 43% of acute visits

Conclusions/action items:

This article provided great statistics and an overview of how short-staffed hospitals are. The short-staffing issue is demonstrated directly by the need for a "hands free" wound edge approximation device. Currently, many clinicians rely on a second individual to hold to edges of the wound together while they suture/glue the wound closed. This presents challenges when no other staff is available to assist during wound closure. While hospital overcrowding is a problem that must be addressed at multiple levels, a wound edge approximation device could help provide some reprieve and free-up staff to assist with other treatments.

11/1/2019 Codes & Standards

• ELIZABETH SCHMIDA • Nov 01, 2019 @04:57 PM CDT

Title: Codes and Standards

Date: 11/1/2019

Content by: Lizzy S.

Present: N/A

Goals: Gather additional background knowledge and standards to include in the final report.

Source: https://www.fda.gov/industry/regulated-products/medical-device-overview

Content:

- Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines medical device as "any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, diagnose disease in man"
- Center for Devices and Radiological Health (CDRH) of FDA is responsible for overseeing medical device program
- Link for determining if medical device: https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device

Medical device classification

- Three Classes (I, II, & III)
- class device assigned to determines type of premarketing submission required for FDA clearance
- Device classification depends on the *intended use* of device and *indications for use*.
- classification is risk based = risk the device poses to patient and user
- Class I includes devices with the lowest risk and Class III includes those with the greatest risk

When searched "approximation" in FDA product classification database, 3 devices relating in use to our design came up, the device that was most similar was an adhesive for topical wound approximation.

Link to product classification database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

New Search	Back to Search Results
Device	Tissue Adhesive For The Topical Approximation Of Skin
Regulation Description	Tissue adhesive.
Definition	Docket number: 2006p-0071 - may 5, 2008 - reclassified from class 3 pma to class 2 510(k).
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	MPN
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	878.4010
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Figure 1. Screen shot of search result relating closely to wound edge approximation.

Based on the devices that appeared in the search, our device would be considered either a Class I or Class II medical device. Regulations 878.4010 and 880.5240 (attached) relate to our design.

Conclusions/action items:

The above medical device search in the FDA database provides a solid basis for the regulations the team needs to keep in mind while designing the device. I believe we can use the classifications found for the topical skin approximation device to search for further standards. I will update this page as I find further information.

▪ ELIZABETH SCHMIDA ▪ Nov 01, 2019 @04:57 PM CDT

Regulation_Number_880.5240_Code_of_Federal_Regulations_Title_21.pdf(437.6 KB) - download

▪ ELIZABETH SCHMIDA ▪ Nov 01, 2019 @04:57 PM CDT

Regulation_878.4010_Code_of_Federal_Regulations_Title_21.pdf(445.9 KB) - download

11/1/2019 Silicone Options

▪ ELIZABETH SCHMIDA ▪ Nov 01, 2019 @06:24 PM CDT

Title: Silicone Options

Date: 11/1/2019

Content by: Lizzy S.

Present: N/A

Goals: Determine potential silicone materials the team could use to coat the edges of the device that will be in contact with the skin for better grip.

Content:

Source: Bodor, R. (2019). *The Importance Of Liquid Silicone Rubber In Medical Device Development*. [online] Meddeviceonline.com.

Link: https://www.meddeviceonline.com/doc/the-importance-of-liquid-silicone-rubber-in-medical-device-development-0001

- Non-implantable medical silicone should be rated as Class VI liquid silicone
  - The silicone we use would only have limited exposure to human skin (less than 24hrs)
- Benefits of medical-grade Liquid Silicone Rubber (LSR):
  - Bio-inert material in compliance with ISO 10993, USP Class VI and RoHS standards
  - Ability to be sterilized with a variety of methods such as Autoclave, ETO, E-beam and Gamma radiation processes
  - Low viscosity that allows flow to all parts of the mold
  - Excellent stability over a broad range of temperatures 150°F to 450°F
  - Low compression set
- overmolding is one technique that may be useful for our device is use liquid silicone rubber
  - overmold metal shaft with LSR to form the desired shape
- LSR available in multiple degrees of hardness (durometers)
  - soft, tacky LSR available
    - Ex) used as feet or a base for a device to keep it from sliding when in use.
    - Tackiness might make surface of device hard to clean if stored in dusty environment

Conclusions/action items:

Based on a preliminary search, for silicones used in medical grade devices, it sounds like LSR is a great option, especially because it is compatible with autoclaves. I believe the techniques for this are outside of our skill level and would require special equipment for fabrication. Perhaps once a finalized design has been fully developed this will be something the team can explore more.

Ideally, we are currently looking for some type of silicone the team can apply on our own to test the grip of the device and cover the potentially sharp edges that would be in contact with the skin. I will update this page as I find more silicone options.

12/3/2019 Silicone Mechanics Research

• ELIZABETH SCHMIDA • Dec 06, 2019 @05:34 PM CST

Title: Silicone Mechanics Research

Date: 12/3/2019

Content by: Lizzy

Present: NA

Goals: Investigate the mechanical properties of the silicone used in suture pads in order to determine the validity of our MTS results.

Content:

From MTS testing of the suture pad samples, I found an average modulus of elasticity of 0.43MPa. Using this value and the measured areas and strains of the suture pad during wound edge approximation, tensile forces ranging from 27 to 40N were calculated. This is clearly way outside our target range. I have walked through my code by hand and can confirm that all my programming is correct.

There was initially great concern with these readings as I had originally stated that the modulus of skin was between 0.24 and 0.85MPa. Based on these values my findings do not make sense. However, I revisited the journal article and noticed that this modulus range is from *torsion tests*, we needed to use the range from *suction tests* as it more simulates the pulling the skin will undergo during wound edge approximation. Therefore the modulus for skin to compare to should be 0.05 to 0.15MPa[1]. This makes sense as a higher modulus of elasticity implies that the material is stiffer and therefore requires more force to deform.

The suture pad is primarily made of Silicone Eco-Flex 00-30. Based on a brief literature review, the 00-30 version of Eco-Flex has a modulus of elasticity of approximately 0.2MPa[2]. While this value is higher than that of skin, it is still significantly lower than the modulus I found using my Matlab program. However, taking a second look at the MTS samples and the suture kit description, it can be seen that the suture pad has an embedded mesh to increase its durability. While this mesh increase the lifetime of the suture pad, it unfortunately makes it a poor skin model to use from our testing purposes. This embedded mesh and its resistance to stretching explains why the modulus was found to be so high.

Sources:

[1] Pawlaczyk, Mariola et al. "Age-dependent biomechanical properties of the skin." *Postepy dermatologii i alergologii* vol. 30,5 (2013): 302-6. doi:10.5114/pdia.2013.38359 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3858658/

[2]J. Dargahi and A. Atieh, "Design, Fabrication and Testing of a Piezoresistive-Based Tactile Sensor for Minimally Invasive Surgery," *International Journal of Advanced Research in Engineering*, vol. 1, no. 2, p. 17, 2015. https://pdfs.semanticscholar.org/f00b/d67fcc429ceda2eb5323a3bfbc3b7c01519f.pdf

Conclusions/action items:

These findings will be added to the final report and poster. I will be sure to explain these results during our final presentation. Moving forward, I think the team would benefit from redoing this testing using a more accurate synthetic skin model.

12/6/2019 Poster Presentation Reflection

▪ ELIZABETH SCHMIDA ▪ Dec 07, 2019 @01:42 PM CST

Title: Poster Presentation Reflection

Date: 12/6/2019

Content by: Lizzy

Present: Design team, advisors, client

Goals: Note some of the feedback received from the client and judges during our presentation.

Content:

- Dr. C was very excited about the device and the poster event as a whole
  - she has many other ideas for other products she would like to see invented--we mentioned that she could propose additional project ideas to the BME department if she wanted to
  - she arrived shortly after presentations started and would regularly circle back to our poster all excited about an idea/designs other BME students had come up with, on several occasions she would have 2 members of our team walk with her so that she could point out a particularly interesting design
  - With her enthusiasm I think the BME department would really benefit from having her as a client for additional design projects if she decides to submit additional project proposals
  - Dr. C offered up having us come visit her in Milwaukee, WI where she teaches to test the device out with her students
    - Once we get IRB approval this could be a great resource for feedback
  - We also gave Dr. C our poster after the event--she seemed pretty excited to share it with her staff
- Dr. T Puccinelli mentioned we need IRB approval to test the device on human subject
  - this is something the team can do over winter break, we also need to include Dr. C on this
- Device appearance was also discussed
  - To make less intimidating could make colorful or make in the shape of animals
    - mentioned some buzzy bee device at the hospital that vibrates the skin to make shots less painful
    - could have multiple models/animals such that a child could choose
- Recommended making own silicone adhesives using molds

Conclusions/action items:

Overall, I felt the poster presentation went well. As usual it was a bit stressful, but everything went smoothly. While it has not sunken in yet, I will be disappointed not to be able to continue working on the project next semester.

9/11/2019 Top Closure S3 System

▪ ELIZABETH SCHMIDA ▪ Sep 21, 2019 @11:40 AM CDT

Title: Top Closure S3 System

Date: 9/11/2019

Content by: Lizzy S

Present: N/A

Goals: Obtain an overview of wound edge approximation devices already on the market.

Source: IVT Medical Ltd. (2010). *TopClosure® 3S System - Skin Stretching and Secure Wound Closure System*. P-70723-USP, 48418, 48419.

See attached PDF for more information

Content:

- Top Closure S3 Device is not reusable

- Comprised of two attachment plates (Figure 1) and approximation strap
- System can be adhered to skin by gluing (non-invasive) or by using staples or sutures
- attachment plates and the approximation strap made of Polypropylene
    - double sided tape at the bottom of the attachment plates is hypoallergenic, non-toxic medical grade adhesive tape (FDA approved)
- system enables skin closure for low to high tension wounds (Figure 2)
    - intended to temporarily stretch skin tissues to aid closure and healing
    - can be used as reinforcement for securing wounds after early suture or staple removal

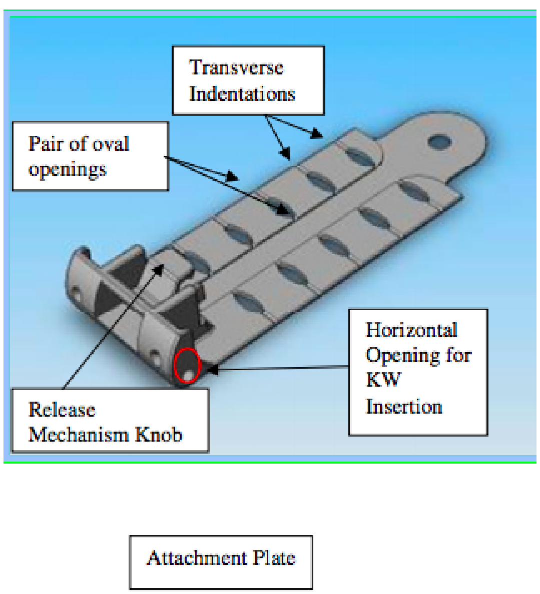


Figure 1. Attachment Plate with adhesive tape on bottom.

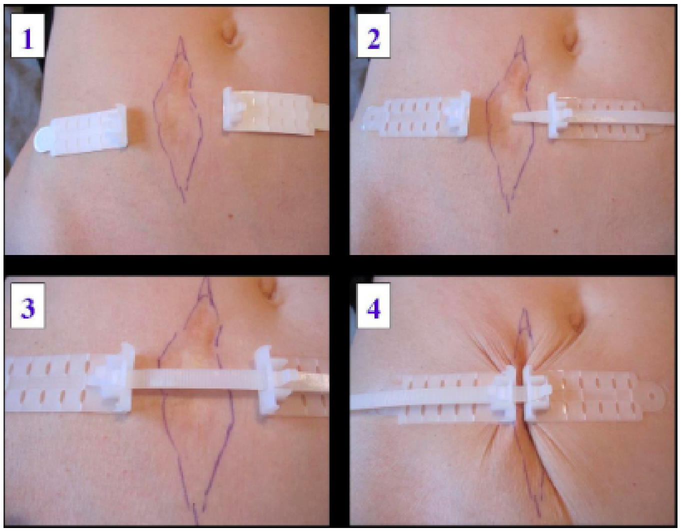
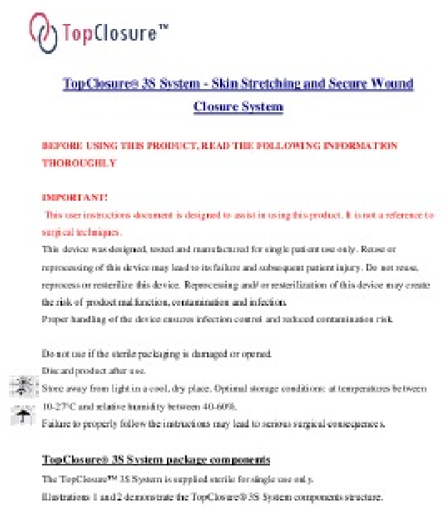


Figure 2. The four steps of using S3 System to close wound.

Conclusions/action items:

This device provides good insight into the types of materials are generally used for wound approximation. The client did however specify a device that could be reusable, therefore, I am not sure if a material such as polypropylene would be ideal--further research must be done to determine if can withstand the heat of an autoclave.

▪ ELIZABETH SCHMIDA ▪ Sep 11, 2019 @07:39 AM CDT



TopClosure™

TopClosure® 3S System - Skin Stretching and Secure Wound Closure System

BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT!

This user instructions document is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Do not reuse, reprocess or resterilize this device. Reprocessing and/or resterilization of this device may create the risk of product malfunction, contamination and infection.

Proper handling of the device ensures infection control and reduced contamination risk.

Do not use if the sterile packaging is damaged or opened.

Discard product after use.

Store away from light in a cool, dry place. Optimal storage conditions: at temperatures between 10-27°C and relative humidity between 40-60%.

Failure to properly follow the instructions may lead to serious surgical consequences.

TopClosure® 3S System package components

The TopClosure™ 3S System is supplied sterile for single use only.

Illustrations 1 and 2 demonstrate the TopClosure® 3S System components structure.

M-IFU-US_revision_002.pdf(412 KB) - download

9/11/2019 DermaClip Skin Closure Device

• ELIZABETH SCHMIDA • Sep 21, 2019 @12:01 PM CDT

Title: DermaClip Skin Closure Device

Date: 9/11/2019

Content by: Lizzy S

Present: N/A

Goals: Obtain an overview of the different products already available.

Source: J. S. Freed and J. Ko, “An Innovative Advance in Non-invasive Wound Closure: A New Paradigm,” *Military Medicine*, vol. 183, no. suppl_1, pp. 472–480, Jan. 2018.

Link: https://academic.oup.com/milmed/article/183/suppl_1/472/4960040 (PDF also attached below)

Content:

DermaClip Website: https://www.dermaclipus.com/

- DermaClip device applied to the approximated edges of wound and closed by pulling the polypropylene tabs in opposing directions
  - pulled until a “click” is heard --> indicating the device is locked (Figure 2)
- As DermaClip closes, angled faces of the polypropylene bridge encounter each other and create lifting action of the wound edges,
  - pushes dermis on each side of the wound into contact with each other
  - wound eversion essential for minimizing scarring
    - maximizes chance of proper epidermal approximation
- wound alignment is maintained without forceping or other skin manipulation
- Comes in two sizes (regular and large)
  - Regular = 11 mm in width
  - Large = 20 mm in width
  - Multiple devices can be used for larger wounds (Figures 3 & 4)

Figure 1. How DermaClips come packaged.

Figure 2. Closure of DermaClip.

Figure 3. Closure of wound using multiple DermaClips.

Figure 4. Wound healing process that used multiple DermaClips.

Conclusions/action items:

DermaClip utilizes similar concepts as the Top Closure S3 System: both consist of elements made of polypropylene and adhesive "plates" that are pulled together by a strap(s). Between the two designs, I am more partial to the DermaClip due to its two strap design that looks to allow more control over the amount of tension placed on the wound edges during approximation. DermaClips angled faces that push up the wound edges to ensure approximation is certainly a design element to be noted and potentially implemented into our design. The dimensions given also provide a good reference point as to potential sizes of our device.

▪ ELIZABETH SCHMIDA ▪ Sep 11, 2019 @08:11 AM CDT

MILITARY MEDICINE

An Innovative Advance in Non-invasive Wound Closure: A New Paradigm

Jeffrey S. Freed, MD, MPH, FACS, FACS; John Ko, MD, PhD, FACS†*

ABSTRACT

INTRODUCTION

DermaClip.pdf(1.3 MB) - download

9/22/2019 Barrette Design

▪ ELIZABETH SCHMIDA ▪ Sep 22, 2019 @11:21 AM CDT

Title: Barrette Design Sketch

Date: 9/22/2019

Content by: Lizzy S.

Present: N/A

Goals: Brainstorm potential designs that will approximate the wound edges of a 7cm laceration.

Content:

The Barrette Design (Figure 1) is similar to that of a hair clip (Figure 2). This type of device would basically raise and pinch the skin containing the wound edges together. Potential drawbacks of a device like this are that the operator would have no control over how tight the skin is pulled together and it may be difficult to "gather" enough skin inside the device depending on the laceration location.

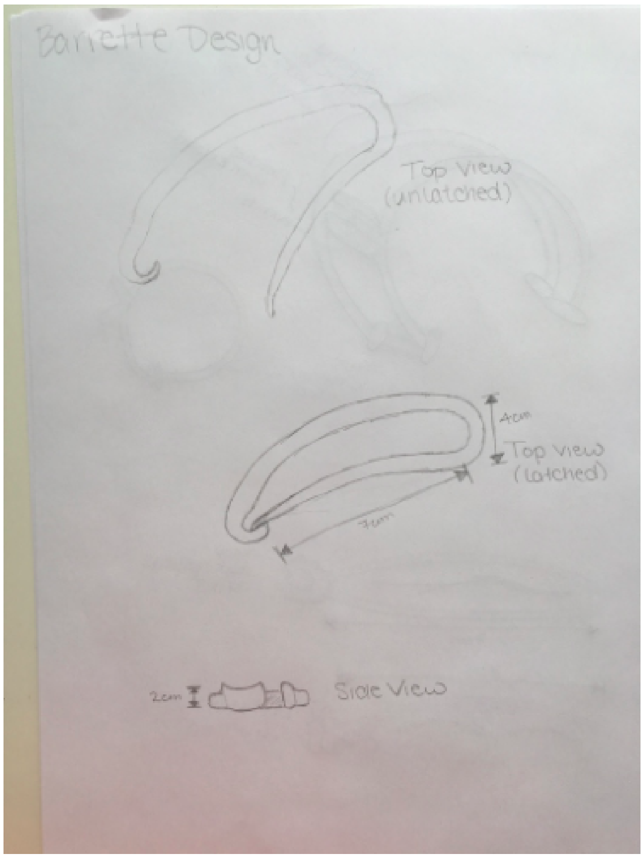


Figure 1. Sketch of the Barrette Design.

Figure 2. Image of the hair clip the design is based off of.

Conclusions/action items:

The team will be meeting at the beginning of this week to discuss design options and compile a design matrix. Will update this page based on feedback from the meeting.

9/22/2019 Butterfly Clip Design

▪ ELIZABETH SCHMIDA ▪ Sep 22, 2019 @11:31 AM CDT

Title: Butterfly Clip Design

Date: 9/22/2019

Content by: Lizzy Schmida

Present: N/A

Goals: Brainstorm potential designs that will approximate the wound edges of a 7cm laceration.

Content:

The Butterfly Clip design (Figure 1) is also based off of a hair clip. Instead of latching flush to the skin like the barrette clip, the device would have two circular rings with rubber feet that would pinch the skin together. There could potentially be a rubber bar running between the feet on each side of the device that would assist in holding the wound edges together. Depending on the exact mechanism used to open and close the "jaws," could possibly allow the device to extend and contract to accommodate wound size. This design however, does not allow much control over the amount on tension placed on the wound edges.

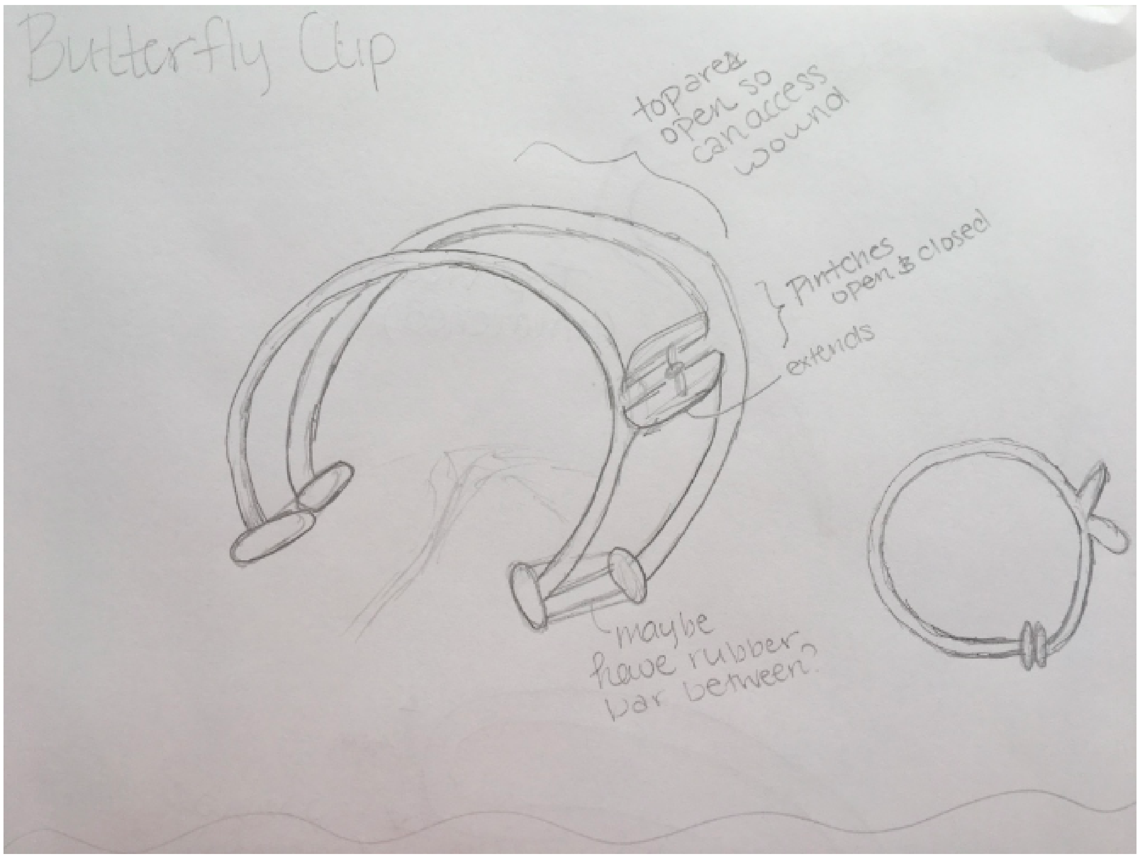


Figure 1. Sketch of Butterfly Clip Design

Conclusions/action items:

The team will be meeting at the beginning of this week to discuss design options and compile a design matrix. Will update this page based on feedback from the meeting.

9/22/2019 Arm Clip Designs

▪ ELIZABETH SCHMIDA ▪ Sep 29, 2019 @06:12 PM CDT

Title: Arm Clip Designs

Date: 9/22/2019

Content by: Lizzy S.

Present: N/A

Goals: Brainstorm potential designs that will approximate the wound edges of a 7cm laceration.

Content:

This design is similar to the Barrette design in that is would be flush to the skin, however, it would not have a latching mechanism. The Arm Clip design (Figure 1) has two different options for securing the wound edges together: there could be a knob system at one end of the device (similar to the knobs used to tighten biking shoes) or there could be a clip like structure seen on butterfly hair clips. A knob would be difficult to sterilize and has a higher chance of breaking due to wear than a butterfly clip end. The knob however, would give the operator more control over the forces induced on the wound edges.

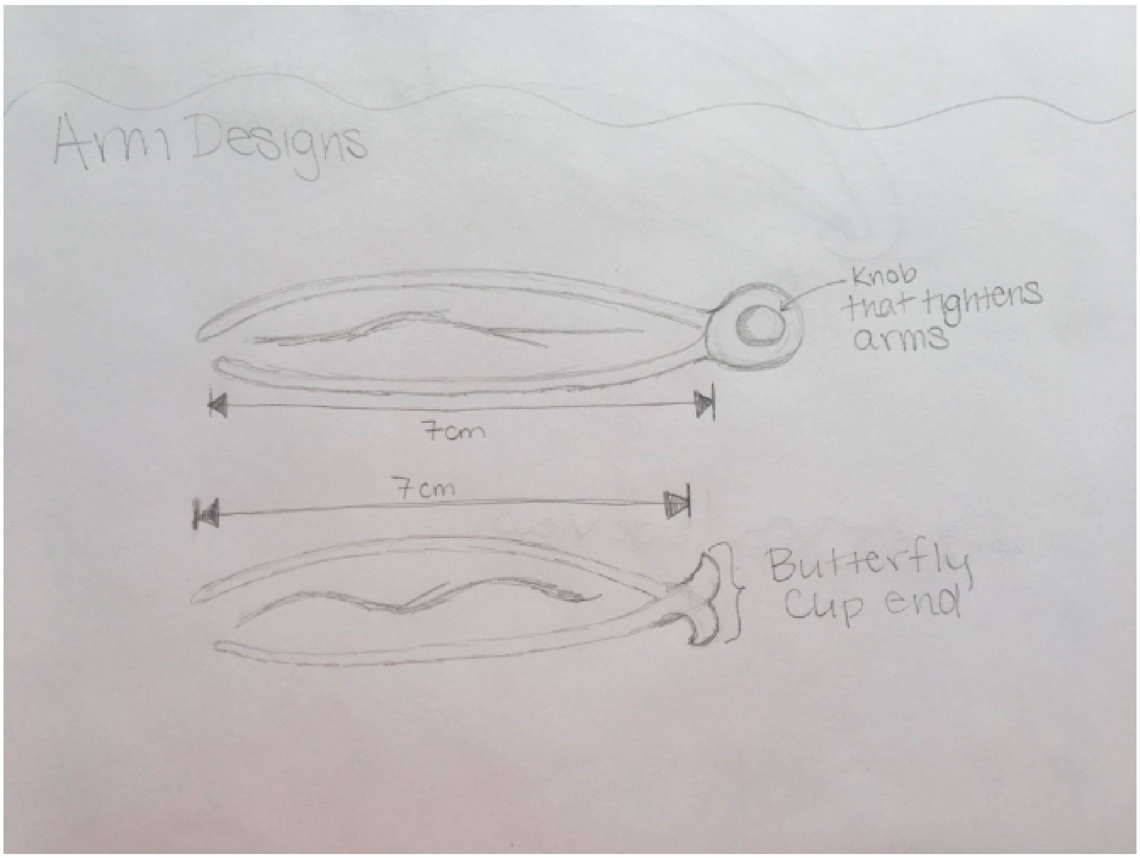


Figure 1. Arm Clip Sketches (knob and butterfly clip systems).

Update: 9/29/2019

While we have ultimately decided to go with a rectangle design, the arm clip design did make the matrix (was renamed the barrette design). A more detailed drawing was created for preliminary presentations (Figure 2).

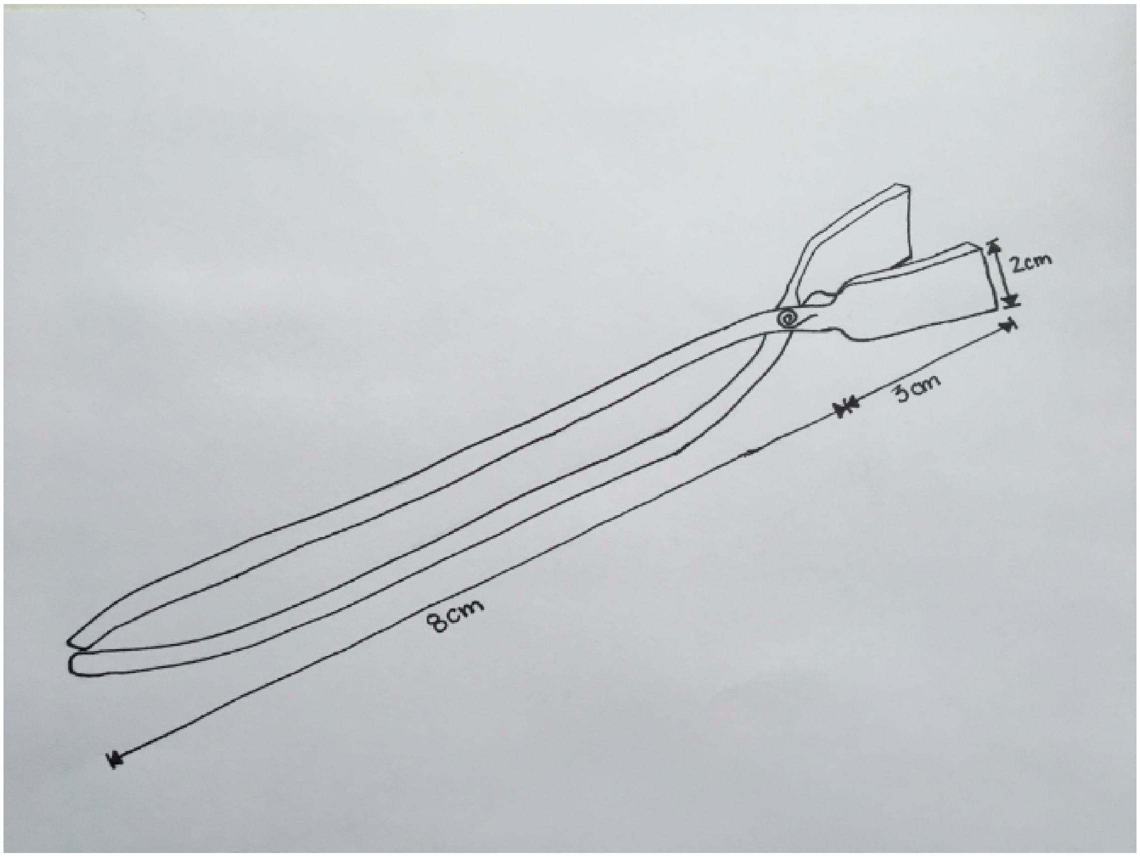


Figure 2. New and improved arm clip drawing that will be used in the prelim presentation. This version includes a spring hinge (like what find on a clothes pin).

Conclusions/action items:

The team will be meeting at the beginning of this week to discuss design options and compile a design matrix. Will update this page based on feedback from the meeting.

9/27/2019 Rectangle Design AutoDesk Files

▪ ELIZABETH SCHMIDA ▪ Oct 08, 2019 @11:56 AM CDT

Title: Rectangle Design AutoDesk Files

Date: 9/27/2019

Content by: Lizzy S.

Present: N/A

Goals: Create preliminary CAD models for the rectangle design

Content:

The rectangle design (Figure 1) was created in 3 different parts, wheels and a sheath and inner part that are each made up of 3 sides of a rectangle (1 long side, 2 short). The sheath is what will support the mechanism that will close and open the system. The inner part is what slips inside of the sheath during opening and closing of the device and has serrated-like outer edges on its two shorter sides. These serrated edges are used by the two wheels (could also be considered gear-like) to grip and more the inner piece.

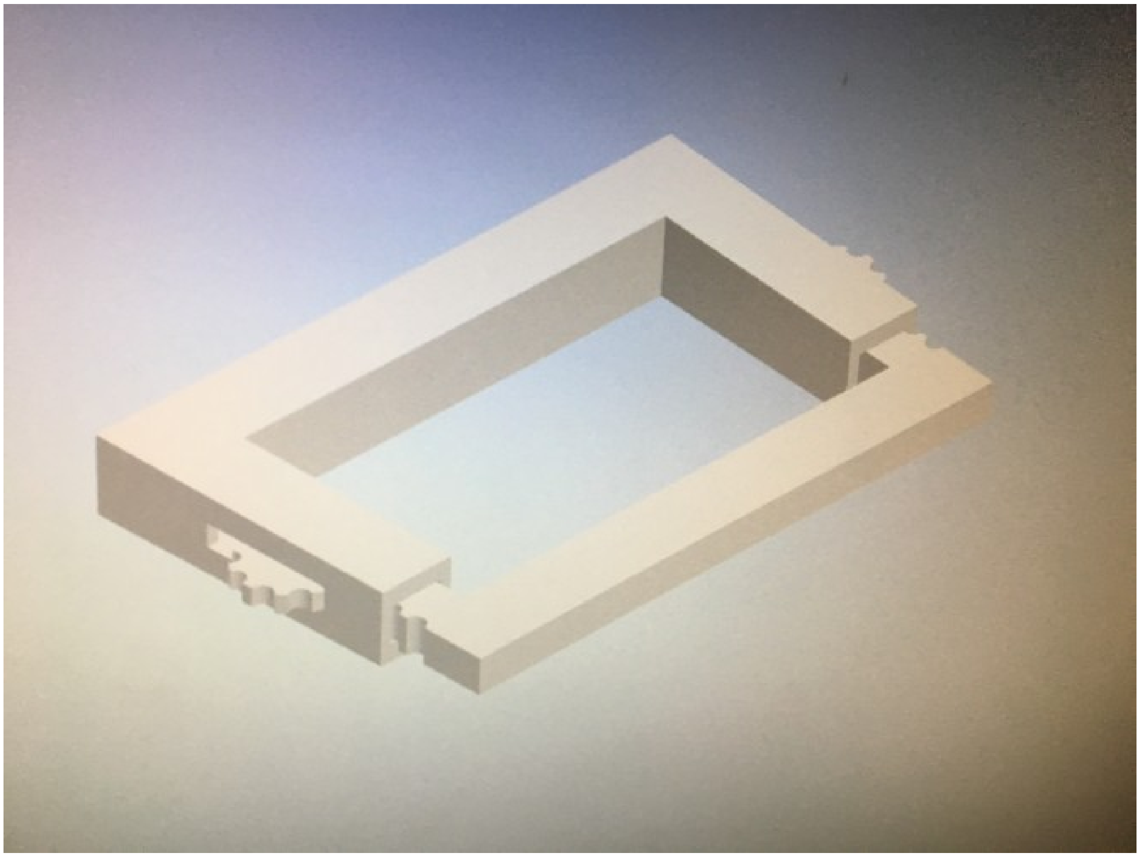


Figure 1. Image of rectangle assembly.

Once the 3 parts were created, and assembly of the device was made using 1 sheath, 1 inner part, and 2 wheels. A drawing of the assembly was also created (Figure 2).

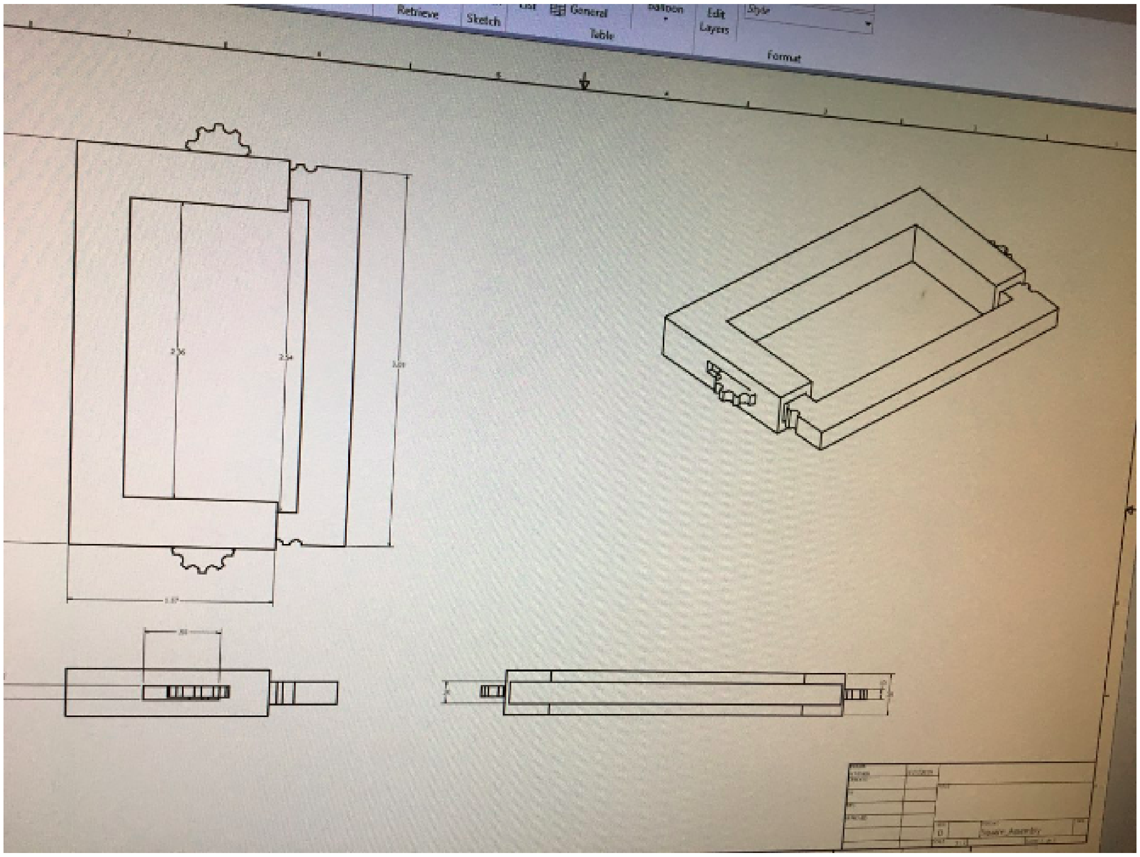


Figure 2. Image of preliminary drawing of the rectangle design (units needs to be converted from inches to cm).

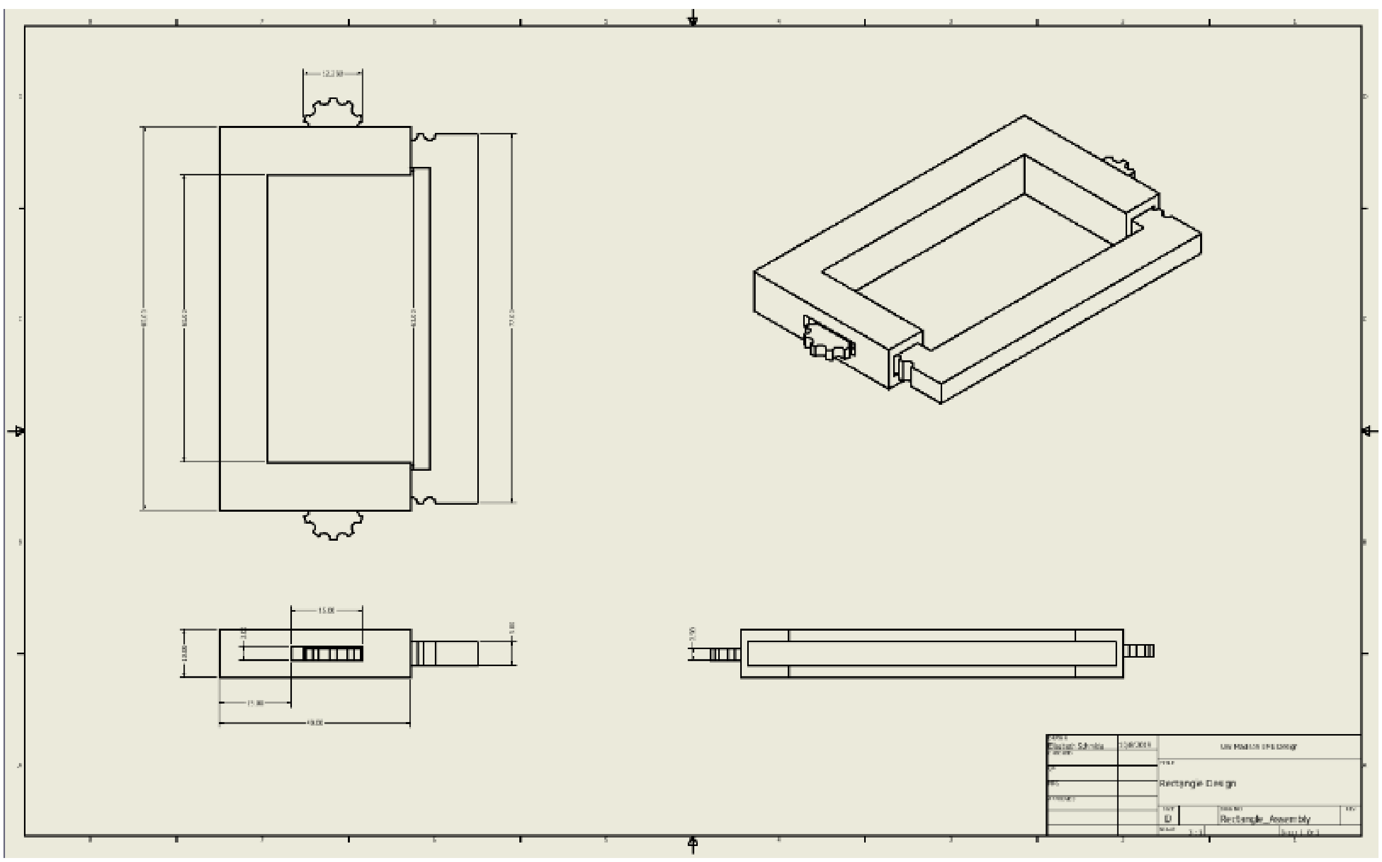


Figure 3. Updated drawing with dimensions in mm.

Conclusions/action items:

Thus far, these are just preliminary designs that will likely need to be updated during the semester. I was having difficulty within the assembly and drawing changing the units from inches to cm, so I will have to go play around with that a bit more. I will continue to update this page as revisions to the design and model are made.

Updated 10/8/2019: Had to re-create entire assembly and drawing in order to get units in metric. Could not figure out how to convert units over with assembly already created. Need to remember to do this right away in the future, will save LOTS of time...

▪ ELIZABETH SCHMIDA ▪ Sep 27, 2019 @01:57 PM CDT

Half_Roller.ipt(129.5 KB) - download

▪ ELIZABETH SCHMIDA ▪ Sep 27, 2019 @01:57 PM CDT

Inner.ipt(160.5 KB) - download

▪ ELIZABETH SCHMIDA ▪ Sep 27, 2019 @01:57 PM CDT

Roller.ipt(132.5 KB) - download

▪ ELIZABETH SCHMIDA ▪ Sep 27, 2019 @01:57 PM CDT

Sheath.ipt(157.5 KB) - download

▪ ELIZABETH SCHMIDA ▪ Sep 27, 2019 @01:57 PM CDT

Square_Assembly.dwg(247.4 KB) - download

▪ ELIZABETH SCHMIDA ▪ Sep 27, 2019 @01:57 PM CDT

Square_Assembly.iam(100.5 KB) - download

▪ ELIZABETH SCHMIDA ▪ Oct 08, 2019 @11:53 AM CDT

Rectangle_Assembly.iam(110 KB) - download

▪ ELIZABETH SCHMIDA ▪ Oct 08, 2019 @11:53 AM CDT

Rectangle_Assembly.idw(224 KB) - download

11/1/2019 Initial Fabrication Reflection

▪ ELIZABETH SCHMIDA ▪ Nov 01, 2019 @05:44 PM CDT

Title: Initial Fabrication Reflection

Date: 11/1/2019

Content by: Lizzy S.

Present: N/A

Goals: Reflect on some of the lessons learned from the team's initial fabrication attempts.

Content:

To test our fabrication ideas, we used thin sheets of Aluminum found in the scrap room off of the "blue room" in ECB. Snippers were first used to cut the aluminum, however, it became clear almost immediately that this was not a viable option as they caused significant bending of the metal. A bandsaw was then used to cut the Aluminum to the proper dimensions. A hole punch and jeweler's saw were used to cut slits into the length of four of the pieces that will hold the wingnut/fastener. Files were then used to smooth down the edges of the punched holes (see10/18/2019 Fabrication Meeting in the Team Activities folder for more details). The UW-TEAM LAB provided a strong adhesive glue that we used to attached the six pieces together. Due to the amount of time this method took and its inaccuracy (it was difficult creating straight, even slits), a new mode or material must be used.

Conclusions/action items:

One of the ideas I had after this initial fabrication is to attempt to make the two sides of the device out of two single pieces through bending. I am not sure how it would work on steel, but with the Aluminum we were using, we could bend it into shapes relatively easily. If we could make the "3 sides of the rectangle" out of a single piece of metal this would eliminate the need for welding.

Additionally, we need to determine another way to create the slits. Using a drill press may prove more efficient and accurate. Otherwise we could potentially use a mill in the TEAM LAB depending on the thickness of the steel we end up using.

Based on this first model, we can reduce the length of the wingnut sides of the rectangle by at least half.

Further brainstorming still needs to be done regarding additional "attachment accessories" for the device to help keep the device in place during approximation.

11/9/2019 Closing Mechanism

▪ ELIZABETH SCHMIDA ▪ Nov 09, 2019 @05:33 PM CST

Title: Closing Mechanism

Date: 11/9/2019

Content by: Lizzy

Present: NA

Goals: Reflect on an alternative method of closing/securing the device on the skin while in use.

Content:

Currently, the plan is to have wing nuts or knobs on both sides of the device that are tightened when the skin is pinched together. I have several reservations about this technique mainly due to potential difficulties tightening both sides of the device while holding it in place and the device providing enough force to continually pinch the skin.

One alternative option I have thought of is using a spring like those used on clothes pins (Figure 1). We could use the stainless steel we purchased to almost make a modified clothes pin with wide rods on the "pincher" ends to hold the skin together. This would in theory provide more force and be simpler for a doctor to use.

Figure 1. Clothes pin with spring mechanism.

Conclusions/action items:

I will discuss my concerns with the team on Monday and see if it is even realistic to incorporate a spring like this into the design.

11/20/2019 Testing Ideas

▪ ELIZABETH SCHMIDA ▪ Nov 27, 2019 @03:40 PM CST

Title: Testing Ideas

Date: 11/20/2019

Content by: Lizzy

Present: NA

Goals: Brainstorm potential tests the team can perform to qualify our device. The goal is to determine quantitative testing methods.

Content:

Testing Ideas

1. Ease of Use: We could have multiple individuals approximate a specific wound on the suture pad and rate on a scale of 0-5 how difficult it was to tighten the thumb screws while still holding the device in place.
2. Consistency: Approximate a wound edge multiple times with only being allowed to tighten the device in to place once each time. The percentage of how many times the device was successful could then be calculated.
3. Friction coefficient: Not entirely sure how this could be done, but could test for the friction coefficient before and after the silicone is applied to the two bottom faces.
4. Effective duration: Tighten device on arm for an extended period of time while filming it and determine how much it loosens/slips overtime.
5. Heat stability: We could do testing to ensure compatibility with the autoclave cycles it would experience while in service. If there is not obvious damage we could do MTS testing of some sort on the device to see if any mechanical properties had changed. As the device is in two pieces, one half would go in the autoclave and the other would not, then both would be tested and their results compared.
6. Solidworks testing: Simulations could be run to determine exact areas of stress concentration and the more likely points of failure.
7. Skin Tension: MTS testing will be done on samples of the suture pad to determine its modulus of elasticity. This can then be used to find the tensile skin force imposed by the device during wound edge approximation based on the displacement the device creates when used on the suture pad.

Conclusions/action items:

I have many different ideas as to how we can test our device, however, I am not sure how realistic they all our or how many we will be able to perform due to time constraints. It is likely that some of this testing will be done during the second semester of senior design.

11/30/2019 Tensile Force Analysis Using Mode I Fracture Mechanics Model

▪ ELIZABETH SCHMIDA ▪ Dec 06, 2019 @05:59 PM CST

Title: Tensile Force Analysis Using Mode I Fracture Mechanics Model

Date: 11/30/2019

Content by: Lizzy

Present: NA

Goals: Determine if this more complex model, typically used to analyze failure mechanics can be applied to determine the tensile forces imparted on the suture pad.

Content:

Source: D. Spain, “Fracture Toughness Measurements of Thin Film Silicone Polymers Using the Modified Edge Lift-off Test,” *MIT Department of Mechanical Engineering: Master's Thesis*, Sep. 2000.https://pdfs.semanticscholar.org/9e05/6ed8d28483f1cb90449682e641cf636f5f7f.pdf

My hope was to apply one of the fracture models I had explored in EMA 506 (Advanced Mechanics of Materials) to determine the tensile forces the device applied to the skin during wound edge approximation. The intent was to create a more complex and rigorous model that could be used instead of having to simplify everything to simply a formulation of Hooke's Law. Below is the worked out model and a check that the assumptions made for the below model are reasonable. The KIC value used for this model was found online in the above journal. The yield stress used to check the LEFM assumptions was taken from the stress strain curves I generated in Matlab from our MTS testing (Figure 1).

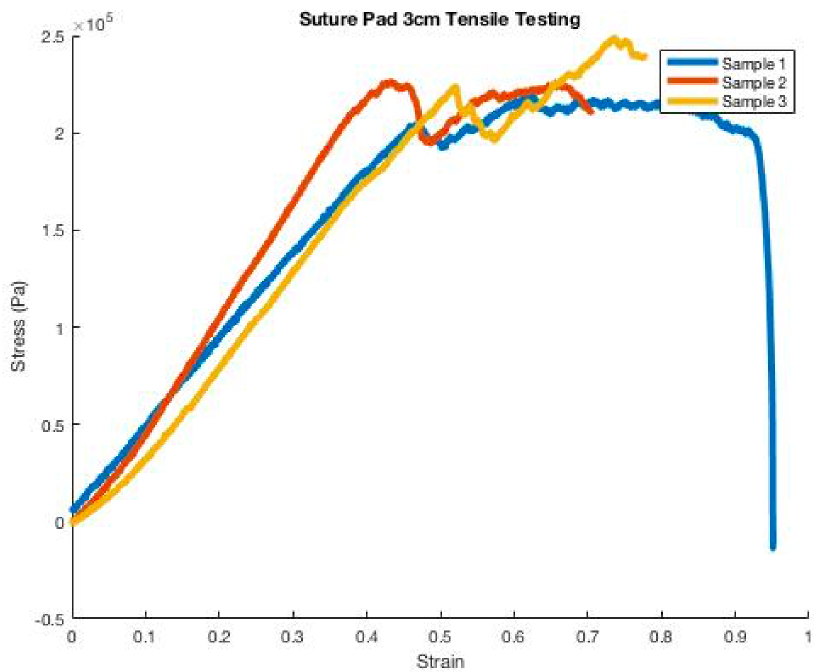
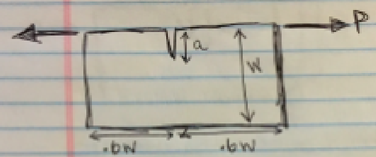


Figure 1. Stress strain curve with a yield strength at approximately 2.3x10^5 Pa.

MODE I FRACTURE MODEL

11/30/2019



~finite plate, edge crack, tensile force~

b = thickness of plate

$\alpha = \frac{a}{W}$

Stress intensity factor → $K_I = \left(\frac{P}{bW}\right) Y \sqrt{\pi a}$

$Y = \frac{5.23 + \alpha(516\alpha - 5.88)}{1 - 1.07\alpha}$

Linear Elastic fracture mechanics

~to use model must assume LEFM ∴ specimen must be sufficiently thick & crack length must exceed minimum length~

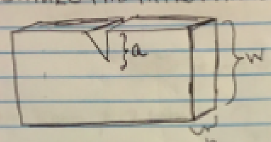
thickness → $t \geq 2.5\left(\frac{K_{IC}}{\sigma_y}\right)^2$

crack length → $a \geq 2.5\left(\frac{K_{IC}}{\sigma_y}\right)^2$ ← fracture toughness

* this is making the assumption that the material will fail in a brittle manner *

SUTURE PAD APPROX ANALYSIS

11/30/2019



a = 6.266 mm
W = 9.4 mm
b = 30 mm

~fracture occurs when $K_{IC} = K_I$ ∴
$K_{IC} = K_I = \left(\frac{P}{bW}\right) Y \sqrt{\pi a}$ ~

← must find P before can check if assumptions valid

$\alpha = \frac{a}{W} = \frac{6.266}{9.4} = .6666$

$Y = \frac{5.23 + (.6666)(516(.6666) - 5.88)}{(1 - 1.07(.6666))}$

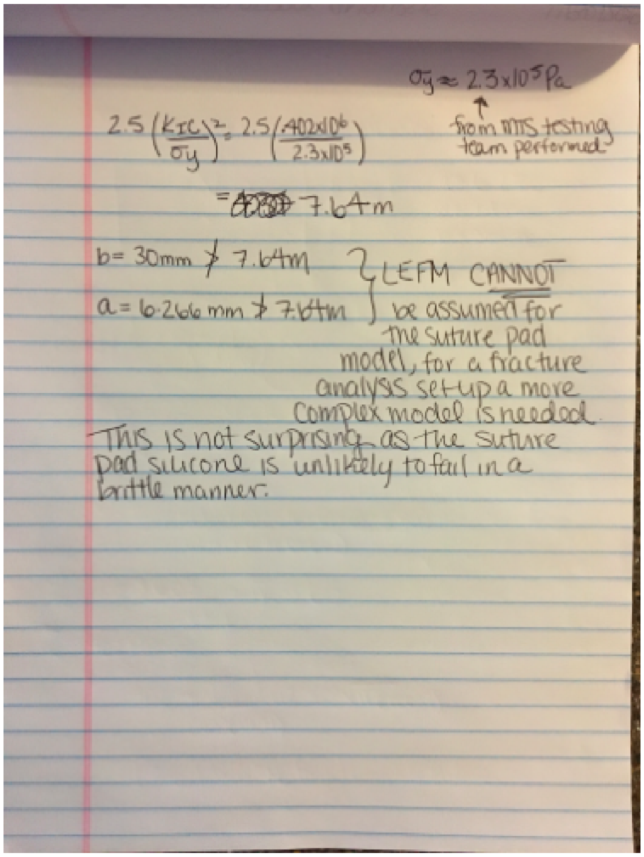
$= \frac{3.603}{.2867} = 12.565$

based on quick lit search

$K_{IC} = .402\ MPa\sqrt{m}$

$.402 = \frac{P}{(.03)(.0094)} (12.565)\sqrt{\pi(.00627)}$

$P = 6.43 \times 10^{-5}$ N to get complete failure



$\sigma_y \approx 2.3 \times 10^5$ Pa

↑ from MTS testing team performed

$2.5\left(\frac{K_{IC}}{\sigma_y}\right)^2 = 2.5\left(\frac{.402 \times 10^6}{2.3 \times 10^5}\right)$

$= 7.64$ m

$b = 30$ mm $\ngtr 7.64$ m

$a = 6.266$ mm $\ngtr 7.64$ m

} LEFM CANNOT be assumed for the suture pad model, for a fracture analysis set up a more complex model is needed.

This is not surprising as the suture pad silicone is unlikely to fail in a brittle manner.

Conclusions/action items:

As it can be seen, this model is not valid. This is not surprising as models such as this for mode I fractures (crack openings) are meant specifically for brittle materials. Upon further reflection, this method would have only given me the force at which the suture pad skin would break which isn't quite what the team is looking to calculate, however. if the assumptions had been proven valid, I could have found a way to manipulate the KIC value to find an estimated tensile force during approximation. For the poster and final report analysis, I will have to just simplify everything and just use Hooke's Law.

10/2/2019 Types of Wound Healing

▪ Jack Fahy ▪ Oct 02, 2019 @10:40 PM CDT

Title: Types of Wound Healing

Date: 10/2/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Describe the three main types of wound healing

Content:

There are three categories of wound healing. Which category a specific wound falls under depends on tissue type and method of closure. [1]

<u>Primary Intention</u>

- Most desired form of wound healing
- Heals in minimum amount of time, minimal scar tissue formation, no wound edge separation
- 3 phases:
    - Inflammatory - Occurs in first few days, increase in fibroblasts, cells, and blood supply to tissue at site of wound. Lasts 3 to 7 days. During acute phase, tensile strength of the skin does not increase significantly, so it is important that the wound closure method is strongly holding wound edges together.
    - Proliferative - Granulation tissue forms (fibroblasts form a collagen matrix). Occurs from day 3 onward. After a variable amount of time, enough collagen has formed where the tissue can withstand normal stress conditions. Natural wound contraction pulls the wound edges tighter together. This can be beneficial, but is very bad if the wound is on the hands, neck, or face, as it can cause disfigurement and excessive scarring. **Primary intention leads to minimal contraction response**.
    - Remodeling - Surface scar pales, initial volume of granulation tissue determines the final amount of collagen formed (the ultimate scar)

<u>Secondary Intention</u>

- Longer process than primary intention
- Caused by infection, excessive trauma, tissue loss, or **imprecise wound edge approximation**
- If this occurs, the wound is sometimes left open to heal from inner to outer surface.
- Granulation tissue with myofibroblasts close wound by contraction, greatly increasing chance of large scar formation. Excessive granulation tissue can protrude above wound surface and prevent epithelialization.

<u>Delayed Primary Closure</u>

- Surgical method for managing contaminated, dirty, or infected traumatic wounds, or if the wound has a great deal of tissue loss and high risk of infection. Common in military medical practices, or for dealing with traumatic shooting or knife wounds.
- Debridement of nonviable tissue, wound left open and packed with gauze. Gauze changed twice per day. Within 3-5 days, wound edge approximation can occur using adhesive strips, previously placed but untied sutures, or staples as long as there is no evidence of infection and red granulation tissue. Otherwise, the wound is allowed to heal through secondary intention.

Conclusions/action items:

The Ethicon Inc. Wound Closure Manual contains a great deal of relevant background information on wound edge approximation and the underlying processes of wound healing. It also contains information on wound closure through the use of DERMABOND, our client's primary method of wound closure. This should be further explored in the near future.

References:

[1] Ethicon Inc, D. Dunn, "Wound Closure Manual", *uphs.upenn.edu*, 2019. [Online]. Available: http://www.uphs.upenn.edu/surgery/Education/facilities/measey/Wound_Closure_Manual.pdf. [Accessed: 02- Oct- 2019].

10/4/2019 Dermabond and wound closure

▪ Jack Fahy ▪ Oct 06, 2019 @03:48 PM CDT

Title: Dermabond and Wound Closure

Date: 10/4/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Learn about the use of Dermabond

Content:

Skin adhesives are generally used for wounds with low tension, meaning the wound edges are fairly close together. 2-octyl cyanoacrylate, commercially known as Dermabond, is a very popular skin adhesive in today's medical world [1].

- Unlike it's predecessor, butylcyanoacrylate, Dermabond creates an adhesive layer on the skin that is flexible and transparent.
    - Its flexibility allows it to be applied on uneven surfaces and aids in reducing the effects of shear forces on the skin's surface.
- Dermabond is used on lacerations and surgical incisions alike
    - It does not leave "track marks" like sutures, enhancing the overall appearance of the final scar.
    - Patients are able to shower right after receiving treatment with Dermabond, as the adhesive will not degrade
- Best suited for wounds on the face, torso, and limbs
- High Viscosity Dermabond is also available
    - 6x thicker than normal Dermabond
    - Utilized on areas of the body prone to runoff of the adhesive during application (around eyes and nose)
- In 3 minutes, the sealing strength of Dermabond is equivalent to the strength of healed tissue at 7 days
- Dermabond prevents bacteria and microbes from penetrating the wound, greatly reducing the risk of infection.
- Dermabond keeps the wound area moist, increasing the rate of epithelialization
- Cosmetic results of Dermabond are equivalent to that of sutures
- Overall, Dermabond is faster and easier to apply than sutures, and is more gentle on the skin than sutures.

Conclusions/action items:

Dermabond is rapidly becoming a more and more popular method of wound closure. According to our client, nurses have told her that 80% of the wounds they close are done so using Dermabond, with the other 20% being sutures. With this is mind, it is important that our device will be suitable for use with Dermabond and leaves adequate space for the user to apply the adhesive to the wound edges.

References:

[1] Ethicon Inc, D. Dunn, "Wound Closure Manual", *uphs.upenn.edu*, 2019. [Online]. Available: http://www.uphs.upenn.edu/surgery/Education/facilities/measey/Wound_Closure_Manual.pdf. [Accessed: 04- Oct- 2019].

10/20/2019 Using tissue adhesive for wound closure on children

▪ Jack Fahy ▪ Dec 10, 2019 @01:24 PM CST

Title: Tissue adhesives for wound closure on children

Date: 10/20/2019

Content by: Jack

Present: Jack

Goals: Discuss the use of tissue adhesives on children

Content:

- Several factors of wound closure that are ideal with children
    - A method that is painless and safe
    - Relatively fast process
    - Produces minimal scarring
- Before gluing, the wound edges are held together with forceps or someone's fingers.
    - The glue is then applied to the wound and the edges are held together for ~ 1 minute.
        - This allows for a sufficient amount of bonding to take place on the skin
        - If the glue enters into the wound orifice, it can prevent proper healing
- As tissue adhesives are painless and fast, they are popular for use on children. However, they do have their limitations and cannot be used in all situations.

Conclusions/action items:

Conduct further research on Dermabond vs. sutures

References:

https://emj.bmj.com/content/19/5/382

10/21/2019 Cosmetic Results of Dermabond vs. Sutures

▪ Jack Fahy ▪ Dec 10, 2019 @01:42 PM CST

Title:Cosmetic Results of Dermabond vs. Sutures

Date: 10/21/2019

Content by: Jack

Present: Jack

Goals: Discuss the pros and cons of Dermabond vs. sutures in terms of final cosmesis.

Content:

In L. Bernard et al.'s *A Prospective Comparison of Octyl Cyanoacrylate Tissue Adhesive (Dermabond) and Suture for the Closure of Excisional Wounds in Children and Adolescents*, they investigated the effectiveness of Dermabond in comparison to traditional sutures [1].

- 42 patients undergoing excisional procedures at the San Diego Children's Hospital
    - 52 wounds total
- Cosmetic appearance of wounds were compared using two metrics:
    - Hollander Wound Evaluation Scale
    - visual analog scale
- 2 months after operation, the patients wound's were observed for cosmetic analysis.
- A statistically significant difference was found for the visual analog scale when comparing sutured wounds to glued wounds.
    - The suture group had a higher median score for the Hollander Wound Evaluation Scale, though it was not significant.
- It was concluded that Dermabond does not provide as optimal cosmetic results for excisional wounds or wounds that are under greater tension, "particularly those that would normally be closed with a 3-0 or 4-0 suture" [1].

Conclusions/action items:

This was a small scale study, so other larger scale studies should be reviewed to determine its accuracy.

References:

[1] https://jamanetwork.com/journals/jamadermatology/article-abstract/478502

9/9/2019 Zipline Medical

▪ Jack Fahy ▪ Sep 09, 2019 @03:53 PM CDT

Title: ZipLine Medical surgical wound closure device

Date: 9/9/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Describe the Zip Surgical device for wound closure

Content:

ZipLine Medical produces a few different wound closure devices, most notably the Zip Surgical skin closure device shown in Figure 1. The device consists of two hydrocolloid adhesive strips that sit on opposite sides of the wound [1]. Down the length of the strips are tightening mechanisms, essentially consisting of a plastic pull-tab that can be pulled to tighten/decrease the gap between the adhesive strips, thus pulling the edges of the wound together (similar to a zip tie mechanism). However, once pulled, it cannot be loosened. The device remains on for up to 2 weeks, or up to the doctor's discretion. It can easily be removed at home by the patient, eliminating a return visit to the hospital.

Figure 1: Zip Surgical skin closure device

The Zip device possesses a patented force distribution system, creating a so-called "isolation zone" around the wound and protecting it from the forces applied to it by the patient's movement. In a study, it showed to significantly decrease wound closure times vs. sutures, without increasing risk of infection. [2]

Conclusions/action items:

A hydrocolloid dressing could be a possible method of attaching our device to the skin of the patient. However, the device should be reusable and sterilizable, and a hydrocolloid dressing would likely be a one-time use product.

We likely won't have to account for the patient's movements affecting the wound, as our device is simply there to approximate the wound edges during suturing or glueing.

The Zip Surgical device could prove to be a good source of inspiration for our device when it comes to the wound tightening mechanism, though we obviously must make some adjustments as to not infringe on this products patents. Our tightening mechanism should also have the ability to be tightened and loosened repeatedly with ease.

References:

[1] https://www.ziplinemedical.com/zip/

[2] Noninvasive tissue adhesive for cardiac implantable electronic device pocket closure: the TAPE pilot study, S. M. Koerber & T. Loethen & M. Turagam & J. Payne & R. Weachter & G. Flaker & M. R. Gold & S. Gautam, https://link-springer-com.ezproxy.library.wisc.edu/content/pdf/10.1007%2Fs10840-018-0457-5.pdf

10/4/2019 Packaging of Medical Devices

▪ Jack Fahy ▪ Oct 06, 2019 @04:29 PM CDT

Title: Packaging of Medical Devices

Date: 10/4/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Learn about how medical devices are packaged

Content:

As medical technology advances, an integral part of the process advances as well. This integral part is device packaging.

- Due to increasing diversity of medical devices, packaging of these devices must keep evolving to fit health regulations
- Sterility of devices is of the utmost importance in order to avoid infection
- Criteria for packaging of wound closure devices is a follows [1]:
    - Packaging must ensure the preservation of product stability and sterility. Factors that can contaminate or degrade medical products include oxygen, temperature, moisture, light, and dust
    - Packaging must be strong and sturdy enough to prevent damage to the product and keep out microbes while the products are in transit or in storage
    - Product information must be readily displayed on the packaging
    - Packaging must allow for simple and safe transfer of the device from its packaging into a sterile work environment
- Medical devices are most commonly packaged in either a pouch or tray [2]
    - Pouches are the cheapest and fastest option. Two-four week manufacturing lead times, cost less than a dollar per pouch
    -  Figure 1: Pouch packaging of medical devices
    - Trays are more protective and provide a better appearance
        - Trays are commonly made of polyethylene terephthalate glycol (PETG), polyvinyl chloride (PVC), polycarbonate (PC), polypropylene (PP) and high impact polystyrene (HIPS) [2].
        - PETG is the most commonly used as it has adequate mechanical properties and is compatible with most styles of sterilization
        -  Figure 2: Tray packaging for a medical device
- **Package validation testing requirements are shown in ISO 11607**

Conclusions/action items:

Packaging of our device will be an important subject in the long-term if the product makes it to the market. Medical device packaging regulations should be further researched later in order to plan for how the device could be packaged.

References:

[1] Ethicon Inc, D. Dunn, "Wound Closure Manual", *uphs.upenn.edu*, 2019. [Online]. Available: http://www.uphs.upenn.edu/surgery/Education/facilities/measey/Wound_Closure_Manual.pdf. [Accessed: 04- Oct- 2019].

[2] N. Thompson, "Medical packaging 101: Basics medical device companies need to know", *Packaging Digest*, 2019. [Online]. Available: https://www.packagingdigest.com/medical-packaging/pmp-medical-packaging-101-basics-medical-device-companies-need-to-know-2018-06-28. [Accessed: 04- Oct- 2019].

10/24/2019 Effectiveness of Dermabond vs. Sutures

▪ Jack Fahy ▪ Dec 10, 2019 @02:45 PM CST

Title: Effectiveness of Dermabond vs. Sutures

Date: 10/24/2019

Content by: Jack

Present: Jack

Goals: Discuss cost of Dermabond vs. sutures

Content:

A study by EML Wong et al, titled *Cost-effectiveness of Dermabond versus sutures for lacerated wound closure: a randomised controlled trial*, examined the cost of Dermabond vs. Sutures and how that impacts its frequency of use in hospitals, as well as factors like infection frequency and cosmetic results.

- 205 patients, 105 treated with Dermabond, 96 treated wtih sutures.
- After 2 weeks, a Wound Evaluation Score (WES) as given to each wound based on ". . .absence of step off, contour irregularities, wound margin separation, edge inversion, excessive distortion, and overall cosmetic appearance" [1].
- After 2 weeks, a significantly greater number of Dermabond-treated patients scored the optimal WES compared to the suture group.
- The Dermabond grouped displayed a significantly lower infection score (the suture group displayed a higher rate of swelling).
- The Dermabond group reported overall greater satisfaction than the suture group.
- Wound closure time was shorter in the Dermabond group
- Overall cost for Dermabond group and Suture group was $30.88 and $26.07 respectively.
    - Although Dermabond material cost is higher, sutures require more follow-up visits and the need for stitch removal. This drains the hospital of worker resources.

Conclusions/action items:

Overall, Dermabond worked extremely well, often better than sutures.

References:

[1] https://www.hkmj.org/system/files/hkm1106sp6p4.pdf

9/22/2019 Silicone tips for Bow-Shaped device

▪ Jack Fahy ▪ Sep 22, 2019 @05:03 PM CDT

Title: Silicone tips for Bow-Shaped Device

Date: 9/22/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Document the benefits of silicone tips for a bow device

Content:

If a bow-shaped device is made, the tips of the bow that come into contact with the skin must be made of a material that is soft (to minimize patient discomfort) and able to firmly grip the skin. For this application, silicone could be an excellent choice for the following reasons:

1. Silicone is a flexible rubber that is commonly used in products designed form human usage. It is commonly used in certain clothing products, often strapless ones, to provide a strong grip between the fabric and the wearer's skin so that the item of clothing does not fall off. This is because silicone can have a relatively high coefficient of friction, usually between 0.25-0.75 but sometimes reaching 1.0 [1,2]. This is important, as the tips of the bow device must be able to grip the patient's skin without slipping when pushing/pulling the wound edges together.
2. Silicone is often used for o-rings and gaskets due to its excellent temperature resistance. It can operate normally under temperatures as high as 600 °F (315.6 °C) and as low as -150 °F (-101.1 °C) without losing its mechanical properties [2]. This means it can be easily sterilized in an emergency room or clinic through steam autoclaving, which reaches temperatures of 250 °F (121°C), without losing its functionality [3].
3. Silicone is pliable and won't be uncomfortable when pushed onto the skin of a patient.

Conclusions/action items:

Silicone would make an excellent choice for the bow-shaped device. Further research on where to purchase the appropriate kind of silicone must be done.

References:

[1] "The Coefficient of Friction of Silicone | Article | Jehbco Silicones", *Jehbco*, 2019. [Online]. Available: https://jehbco.com.au/coefficient-friction-changes/. [Accessed: 22- Sep- 2019].

[2] "Types and Properties of Moldable Silicone Rubber - Albright Technologies", *Albright Technologies | Silicone Molding, Medical Silicone Prototyping, Injection Molding & More*, 2019. [Online]. Available: https://albrightsilicone.com/types-and-properties/. [Accessed: 22- Sep- 2019].

[3] "Sterilizing Silicone", *Electronic Component News*, 2008. [Online]. Available: https://www.ecnmag.com/article/2008/08/sterilizing-silicone. [Accessed: 22- Sep- 2019].

10/1/2019 Stainless Steel for Medical Devices

▪ Jack Fahy ▪ Oct 02, 2019 @09:01 PM CDT

Title: Stainless Steel for Medical Device use

Date: 10/1/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Describe Stainless Steel's properties that make it suitable for medical device usage

Content:

Stainless Steel 304 is the most popular grade of stainless steel and is used in a variety of applications beyond just the medical world [1].

- Two key factors make Stainless Steel 304 highly suitable for medical devices:
  - High corrosion resistance
  - Low carbon content
- SS 304 will not react with bodily tissue, making it safe to use around open wounds and within the body
- SS 304 can also be autoclaved (autoclavability is a very important aspect of our device, as this is how tools and other repeated[use items are sterilized in clinics)
- SS 304 is a very workable metal, meaning it can easily be drawn into shape with no need for annealing
- Raw material cost of SS 304 is fairly cheap at around $1.55/lb [2]
- Corrosion resistance means SS 304 will not rust, reducing infection risk for patient

Mechanical properties of Stainless Steel 304 [3]

- Ultimate Tensile Strength = 505 MPa
- Yield Tensile Strength = 215 MPa
- Young's Modulus = 193-200 GPa
- Poisson's Ratio = 0.29
- Density = 8 g/cc

Conclusions/action items:

Stainless Steel 304 could be a great material choice for the bow, rectangle, or barrette design. More research on how to obtain this metal and how the team could fabricate the device from it will have to be done

References:

[1] "Medical Applications of Stainless Steel 304 (UNS S30400)", *AZoM.com*, 2019. [Online]. Available: https://www.azom.com/article.aspx?ArticleID=6641. [Accessed: 01- Oct- 2019].

[2] B. Fuller, F. Egbaria and I. Canorea, "MetalMiner Prices: Stainless Steel Prices", *Steel, Aluminum, Copper, Stainless, Rare Earth, Metal Prices, Forecasting | MetalMiner*, 2019. [Online]. Available: https://agmetalminer.com/metal-prices/stainless-steel/. [Accessed: 01- Oct- 2019].

[3] "ASM Material Data Sheet", *Asm.matweb.com*, 2019. [Online]. Available: http://asm.matweb.com/search/SpecificMaterial.asp?bassnum=mq304a. [Accessed: 01- Oct- 2019]

10/15/2019 Source for Stainless Steel

▪ Jack Fahy ▪ Nov 05, 2019 @02:50 PM CST

Title: Source for buying stainless steel

Date: 10/15/2019

Content by: Jack Fahy

Present: Jack

Goals: List sources to buy stainless steel from

Content:

McMaster-Carr (https://www.mcmaster.com/standard-stainless-steel-sheets) appears to be the best option for buying a sheet of stainless steel. Small quantities can be purchased for cheap (~$20 for the amount we need). Many other websites, such as Metal Depot (https://www.metalsdepot.com/stainless-steel-products/stainless-steel-sheet-plate), sell in bulk which makes it very expensive. MSCDirect (https://www.mscdirect.com/browse/tn/Raw-Materials/Metals/Stainless-Steel/Stainless-Steel-Sheets?navid=12102014) is relatively similar to McMaster-Carr in terms of price. However, Mcmaster-Carr usually delivers next day, so we will likely purchase materials from them.

Conclusions/action items:

McMaster-Carr will be our source for metals this semester. If problems arise, we may switch to MSCDirect.

11/2/2019 Purchase of stainless steel 304 from McMaster Carr

▪ Jack Fahy ▪ Nov 05, 2019 @03:09 PM CST

Title: Stainless Steel 304 purchase

Date: 11/2/2019

Content by: Jack Fahy

Present: Jack

Goals: Document purchase of SS304

Content:

McMaster-Carr offers a wide array of shapes and sizes for stainless steel 304. For our purposes, and based off of the aluminum prototype we constructed, a thin strip will likely suffice. In accordance with the dimensions we desire, a 1" x 36" strip of multipurpose stainless steel 304 with a 0.09" thickness will be purchased. The thickness of the aluminum pieces we used for our model was 0.036", and we experienced a great deal of difficulty in terms of the pieces easily bending. The higher amount of carbon in stainless steel gives it more strength [1]. This fact, combined with a greater thickness than the aluminum we used, should eliminate any issues we had with accidentally bending the pieces during fabrication.

Conclusions/action items:

The 1" x 36" x 0.09" strip of stainless steel 304 will be purchased form McMaster-Carr. Fabrication will occur once we receive the metal.

References:

[1] E. Aluminum, "The Difference Between Steel vs Aluminum | Eagle Mouldings", *Eagle Mouldings*, 2019. [Online]. Available: https://eagle-aluminum.com/steel-vs-aluminum/.

11/10/2019 Silicone as an Adhesive

▪ Jack Fahy ▪ Dec 10, 2019 @03:54 PM CST

Title: Liquid Silicone Rubber as an Adhesive

Date: 11/10/2019

Content by: Jack

Present: Jack

Goals: Discuss the possibility of using silicone as an adhesive for our device

Content:

Silicone Adhesives [1]

- 1 or 2 part system
  - 1 part: only one component that cures through either moisture in air or heating by UV radiation.
  - 2 part: mixing two components together, requires addition of curing agent
- Siloxane bonds are very high energy
  - provides high temperature resistance
  - cure to soft thermoset elastomers
- Categories of silicone by by-product
  - acetoxy silicones - good adhesion but promote corrosion. Likely not a good choice to apply to metal
  - oxime silicone - lower adhesion, slow cure time
  - alcoxy silicone - rapid curing, good adhesion. likely the best option for our purposes

Conclusions/action items:

The team should look into alcoxy silicone adhesives for use with our device

References:

[1] https://www.simtec-silicone.com/use-liquid-silicone-rubber-adhesive/

9/24/2019 Wishbone Design

▪ Jack Fahy ▪ Sep 24, 2019 @04:39 PM CDT

Title: Wishbone Design

Date: 9/24/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Describe a potential preliminary design for a bow-shaped device

Content:

*Drawing of design at bottom of page

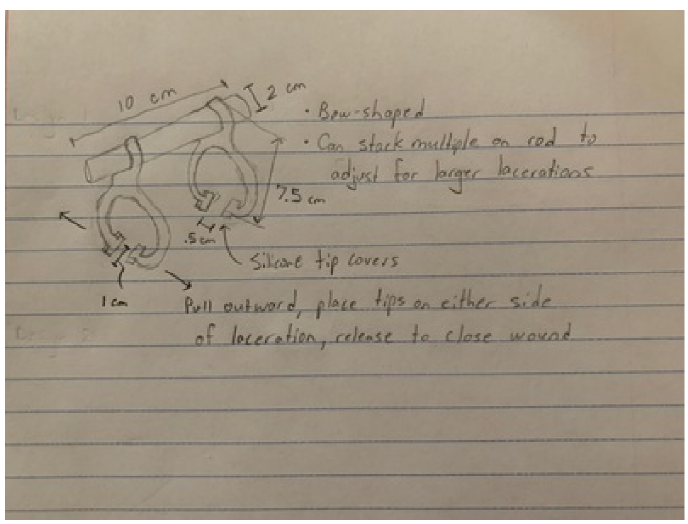
This design consists of "wishbone" shaped wound closers with two tips that are ~0.5-1.0 cm apart at rest. Silicone covers would be placed on the tips to provide added grip on skin. The closers themselves would be 7.5 cm in total length and the tips themselves would be ~1 cm in width. To close the wound, the tips are manually pulled outward, placed on either side of the laceration, and released so they spring back to their resting position, closing the wound. The material of the closers would have to be ductile enough that the tips could be pulled outward to increase the gap to approximately 2.5 cm, but stiff enough that the tips spring back to a 0.5-1.0 cm gap. If lacerations exceed a length that can be closed by one closer, a 10 cm rod made of a lightweight material could be threaded through holes on the top of the closers, allowing for multiple closers to be used for a single laceration.

The issue with this design is finding a material that will be able to bend and retain its original shape after repeated use. This problem could be eliminated by implementing a mechanism that allows for incremental opening and closing of the tip gap.

Conclusions/action items:

With this design in mind, the team can combine elements from all proposed bow-shaped devices to narrow our options down to a single design

▪ Jack Fahy ▪ Sep 24, 2019 @05:01 PM CDT



26DF660A-5AFB-4565-91EB-8E3DF4C93EF3.jpg(162.2 KB) - download

9/24/2019 Hook-Loop Design

▪ Jack Fahy ▪ Sep 24, 2019 @05:04 PM CDT

Title: Hook-Loop Design

Date: 9/24/2019

Content by: Jack Fahy

Present: Jack Fahy

Goals: Describe the hook-loop preliminary design

Content:

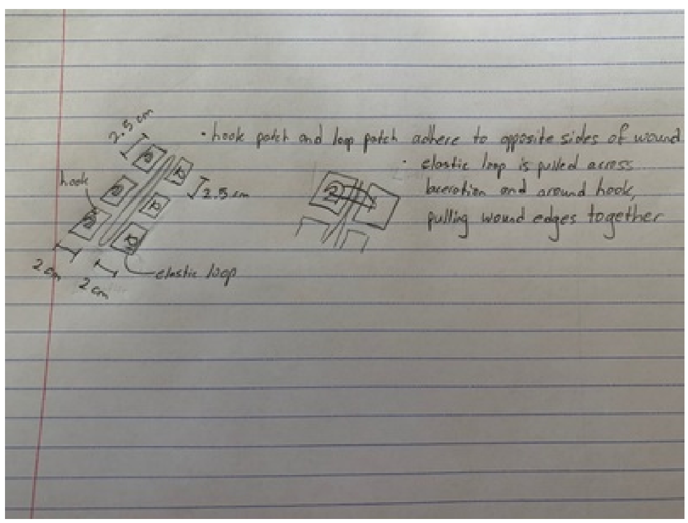
*Drawing of design at bottom of page

The hook-loop design consists of two adhesive patches. One patch has a hook and the other has a loop. These patches are adhered to the skin on opposing sides of a laceration. To close the wound, the loop is pulled across the laceration and is secured around the hook, pulling the wound edges together. This would likely be a one-use only device, unless the patches could be sterilizable and an adhesive could be reapplied to the bottom of the patches after each use.

Conclusions/action items:

This design will be discussed by the team to determine it's feasibility and effectiveness

▪ Jack Fahy ▪ Sep 24, 2019 @04:58 PM CDT



43AE4B0E-8F65-47FB-8C9A-99E9000127F6.jpg(186.9 KB) - download

11/11/2019 Fabrication Ideas

▪ Jack Fahy ▪ Dec 10, 2019 @12:45 PM CST

Title: Fabrication ideas

Date: 11/11/2019

Content by: Jack

Present: Jack

Goals: Discuss possible methods of fabrication

Content:

We currently have a long strip of stainless steel 304. To cut this down to the size we need, we will likely need to utilize either a band saw or drop saw in the TEAM Lab. However, my experience cutting thin aluminum with a band saw gives me concerns on the accuracy and stability with which I will be able to cut stainless steel, a thicker and stronger metal than aluminum. The drop saw will likely be our best option available to us. The Whitney punch we used for the aluminum prototype earlier this year was very inaccurate and our strip of stainless steel is likely too thick to use a punch on. The mill will likely be our best option in terms of precision and ease of use. After the slots are milled, laser cutting or water jet cutting will likely be our next course of action. More research must be done on these two options to decide which, if any, are possible for our material and size.

Conclusions/action items:

I will write up a procedure for using the mill to cut out the appropriate slots on our device. I will also talk to the TEAM Lab about using a laser cutter or water jet cutter to cut our stainless steel pieces.

11/20/2019 SolidWorks parts for final prototype design

▪ Jack Fahy ▪ Dec 10, 2019 @01:00 PM CST

Title: SolidWorks Parts for final design

Date: 11/20/2019

Content by: Jack

Present: Jack

Goals: Document the parts and assembly of final design in SolidWorks

Content:

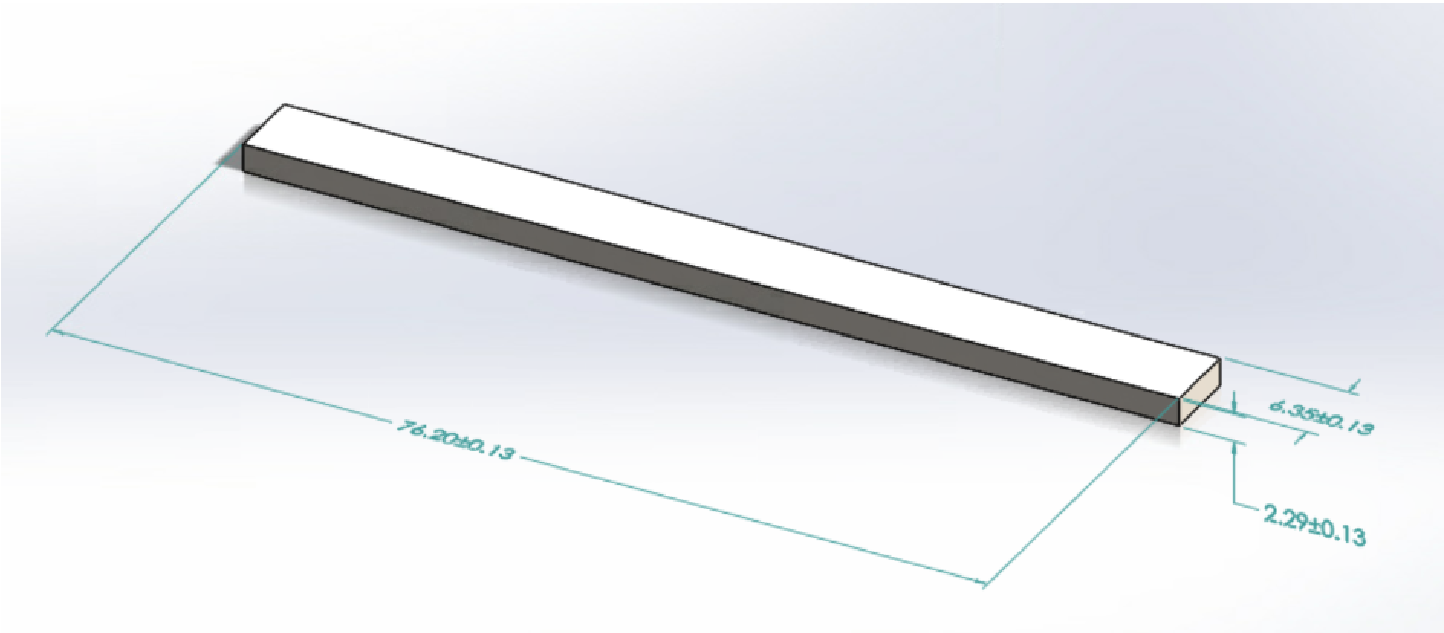


Figure 1. Model of long side of device. This is the part that contacts the patient's skin. Dimensions in mm

Figure 2. Model of slotted pieces. In accordance with our fabrication plan, one corner of the slotted pieces are sanded down to the width of the long piece so that they rest on the long pieces at a 45 degree angle. The angle at which the slotted pieces sit will not change how the device operates, so the team chose a 45 degree angle as it seemed the most natural.

Conclusions/action items:

A full assembly of these pieces is listed under the Design Process folder under Team Activities. A SolidWorks Drawing file will also be made to clearly layout the device's dimensions.

12/8/2019 SolidWorks Drawing of Assembly

• Jack Fahy • Dec 10, 2019 @01:04 PM CST

Title: SolidWorks Drawing of Assembly

Date: 12/8/2019

Content by: Jack

Present: Jack

Goals: Create a Drawing of our SolidWorks Assembly to clearly layout the product's dimensions

Content:

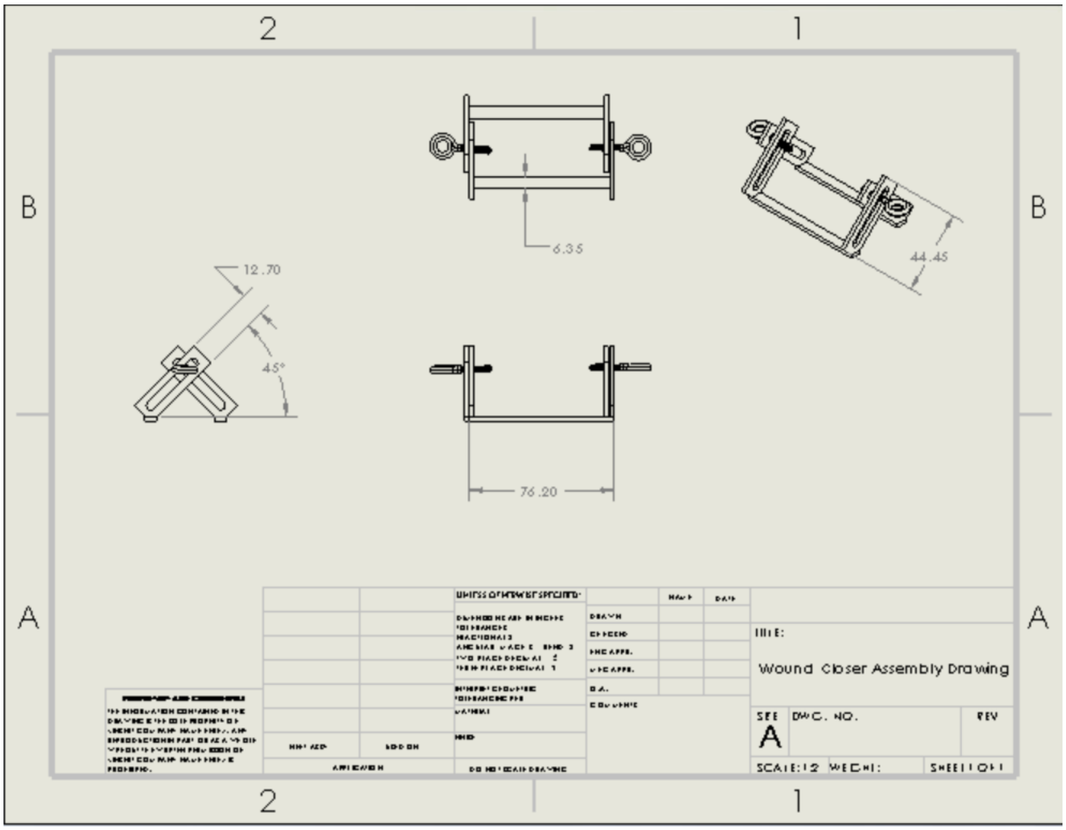


Figure 1. This Drawing defines important dimensions of the design and displays the assembly from a front view (middle), top view (top middle), side view (left), and isometric view (top right). All dimensions are in mm.

Conclusions/action items:

This Drawing will be included in the appendix of our final report

2014/11/03-Entry guidelines

▪ John Puccinelli ▪ Sep 05, 2016 @01:18 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 @03:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: