BME Design-Spring 2020 - Jurnee Beilke
Complete Notebook

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Kavya Vasan

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Team contact Information

Jurnee Beilke - Mar 14, 2020, 11:29 AM CDT

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
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Project description

Jurnee Beilke - Mar 14, 2020, 11:29 AM CDT

Course Number: BME 402

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 consists of two identical metal sides attached by two hinges and two springs. The hinges allow the device sides to pivot relative to one another, and the spring allows the sides of the device to be pulled apart by the physician and brought together once placed around the wound. 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.

02/24/2020 Client Meeting

KELLY STARYKOWICZ - Feb 25, 2020, 11:47 AM CST

Title: Client Meeting

Date: 02/24/2020

Content by: Jurnee

Present: All team members

Goals: Discuss the plans for the semester with the client and ask her some questions about the design.

Content:

Client thinks a device that is interspersed along the wound may work. Think of the spring from a clothes pin attached to the silicone bumpers. The skin edges should come up a tad during closure (wound eversion). Device could be scaled up or down for various wound sizes and separations. Client likes the t-shaped design along the skin. Personally adjust as needed per wound dimensions (each providers choice).

- During wound approximation, is the skin in tension or compression?

The wound will be closed in tension according to the client. The under layer of the skin is interconnected. The wound edges are being pulled in tension to close a wound - the skin would not be placed in tension.

- Estimation of the number of uses of our device in one year?

The number varies based on how many the hospital purchases. Each hospital varies for sterilization timeframe (once/week). The device could be used 10 times a day (10 lacerations per day).

- Most common wound locations on the body?

Hands/fingers are the most common

- How often is DermaBond used over sutures?

The client says that DermaBond is used over sutures. Small lacerations that need quick repairs are the majority of lacerations. DermaBond is the most common for pediatrics.

Conclusions/action items:

The team now needs to consider what design to pursue for the semester.

01/24/20 Advisor Meeting, First

KELLY STARYKOWICZ - Jan 24, 2020, 12:27 PM CST

Title: First Advisor Meeting

Date: 01/24/20

Content by: Kelly

Present: All team members

Goals: Go over the plan for the semester

Content:

- This semester is focused on testing
    - goal is to develop a journal article with our data
    - have to include last semester's report in appendix of journal article
    - different formatting
    - only publish journal article if we feel comfortable with it
        - publishing is not required for the course; only writing the article
    - Need to make it clear with the client that testing and the journal article is the priority for the semester
- Still need to think about some changes to the device
    - change silicone bumpers regardless
    - ask client about redoing the device so it has a hinge
- IRB- contact Mitch Tyler to see if it is necessary for our testing
    - copy Dr. Suarez-Gonzalez in email
    - have client as PI in case she wants to test with her patients
        - need to make sure her affiliation will allow her to be the PI
        - mention to Mitch Tyler that we would like client as PI
    - if not, Dr. Suarez-Gonzalez will be the PI
- Journal publications
    - check with client first- she may have ideas or preferences
    - Journal of Biomedical Devices is popular
        - their website will have the guidelines for that specific journal
        - peer reviewed- the journal takes care of this
    - Some journals are more difficult to get into- take that into account
- LabArchives
    - small design matrix about changes to device may be necessary
    - research on improvements to device
    - testing should be the focus
- Preliminary Presentations- 2 weeks from today
    - different format than usual
    - reiterate testing we have already done
    - guideline for the semester
        - finalizing prototype, testing, etc.

Conclusions/action items:

- BWIG email Dr. P about advisor not being listed on website
- Take team picture and upload to website
- Isabel and Kavya need to do Outreach
- Email Mitch Tyler about IRB
- Look into journals
- Preliminary Presentations: 2 weeks from today
- Set up client meeting

01/31/20 Advisor Meeting

Jurnee Beilke - Jan 31, 2020, 12:33 PM CST

Title: Advisor Meeting

Date: 01/31/20

Content by: Jurnee Beilke

Present: All

Goals: To establish the need for an IRB and discuss ways to improve the current prototype.

Content:

- Observations from Mitch
  - Approximation needs to be more clearly defined - literally define as bringing the edges together without gaps
  - Equation 1 is missing a symbol - changing a format (be careful)
  - Discussion - clarification between 3 and 5 p-value increasing
- Do we need an IRB now?
  - No, premature to pursue an IRB
  - If we started the protocol now, we would not be able to test until summer
  - The project is in a gray area
  - Testing on ourselves - academic advisors opinion that the device does not present any real harm
  - Not penetrating tissue or cutting
  - Theoretically, test on classmate within BME program
  - If we leave the program, we definitely need an IRB
  - The progress is very long and difficult and we likely will not make it through the protocol the first time through
  - There are a lot of steps the project needs to go through before we are ready to test on humans
- Steps to be taken
  - Model assumptions - skin is non-linear viscoelastic (Kelvin-Voigt or standard linear)
    - Solidworks model to examine mechanical properties (creep and relaxation)
  - Migrate to skin analog without fibrous matrix
  - Address real world concerns - anticipate how to test the device in non-ideal situation (jagged cut, iodine on skin, blood)
    - Not clean/intact skin
  - Re-design the device to be easier and/or incorporation of other functions
    - Wishbone design that comes from the backside of the arm is an idea to consider
    - Ask "is this still the best design?"
    - No one design fits all - wound size and limb size

Conclusions/action items:

The team now has a better idea of what to work on this semester.

02/21/20 Advisor Meeting

Jurnee Beilke - Feb 21, 2020, 12:50 PM CST

Title: Advisor Meeting

Date: 02/21/20

Content by: Jurnee

Present: All

Goals: To discuss the journal draft with our advisor.

Content:

- What is the appended document supposed to contain (breath, length)?

One page of current design and changes to be made (include sketches), and append the final report from last semester.

- How much of the draft needs to be completed by next week (testing, results)?

Include data from last semester only if the data is still applicable (make a note that we will update results and discussion as we go). We can begin drafting sections for discussion (we expect similar pain results as last semester...)

- Should we include existing devices?

Not necessary

- Include the results from last semester?

Only if they are relevant and may stay consistent with the new design

- Citations IEEE or Chicago?

IEEE is fine for the journal

- Fabrication plan and ideas?

Discussed spring idea

Conclusions/action items:

The team now has a better understanding of the requirements for the journal draft and the appended document with the design process description.

02/28/20 Advisor Meeting

Jurnee Beilke - Feb 28, 2020, 12:18 PM CST

Title: Advisor Meeting

Date: 02/28/20

Content by: Jurnee Beilke

Present: All

Goals: To receive feedback from Suarez on our design ideas.

Content:

- Ultimately, we need to consider the client's opinion on the design
    - Try to find a way to make both designs work or convince the client to pick one design
    - If she wants to move forward with the clothes pin design than the other updates, we will have to work with her on a design
    - Suarez is okay if we focus on fabrication this semester rather than testing
    - Try creating the proof of concept with the spring design
    - Once we create the proof of concept, we should talk to the client about her opinion of the device
    - Consider the timeframe left for fabrication and testing
- To strengthen the executive summary:
    - Market potential - settings the device can be used (wound approx or IV placement)

Conclusions/action items:

The team now has a better understanding of how to move forward with fabrication of the device.

03/06/20 Advisor Meeting

KELLY STARYKOWICZ - Mar 06, 2020, 12:26 PM CST

Title: Advisor Meeting

Date: 03/06/20

Content by: Kelly

Present: Jurnee, Jack, Kavya, Kelly

Goals: Go over report grades and update Dr. Suarez on our fabrication progress.

Content:

- Journal:
  - use past tense, not future tense!
  - don't need to say TEAM Lab or Makerspace in abstract
  - Design specifications: Not formatted correctly- don't explicitly state "design specifications"
    - rename it to wound approximation device and combine with prototype section
    - Say it <u>does</u> withstand autoclave temperatures, etc.
    - Don't need to list the original criteria
  - Introduction: don't need fabrication section in intro, include this in methods
    - Viscoelastic methods should not be in introduction, should be in results to support analysis
    - Work on the transitions between one section to another between subheadings
      - jump from dermabond into design specs- need a concluding statement that will transition into next section
    - Expand the intro sentence and each of the effects of poor healing/scarring
      - find statistics on wound reopening, etc.
      - be more convincing of why we need this device in clinics!
        - expand on this, it is too general!
- Notebook:
  - We need a project description!
  - Some entries don't fill all aspects of the template.
  - In conclusion items after research, state what you learned from the research (which materials may be better than others, etc.)
- Next week, instead of progress report, think of an outline of figures that we will have in our journal article
  - What figures we want to include and in what order to tell a complete story

Conclusions/action items:

- Add a problem description to the notebook!
- Make changes to the journal based off of Dr. Suarez-Gonzalez's feedback
  - Also review the paper on how to write a paper that Dr. Suarez emailed us.

03/27/20 Advisor Meeting

Jurnee Beilke - Mar 27, 2020, 12:29 PM CDT

Title: Advisor Meeting

Date: 03/27/20

Content by: Jurnee Beilke

Present: All

Goals: To discuss design plans for the rest of the semester.

Content:

- Dr. Suarez wanted to get a sense of how the online transition was going
- Current plan to have a final presentation - welcome to use BB collaborate or pre-recording the presentation
- Presentations should be done around April 24th (not a hard deadline)
- Add protocol on MTS testing - specific plans for testing (explain purpose and protocol)
- Test what I can on my parents (Jurnee)
- Kavya may be able to test/model with SolidWorks on her computer
- Need to create a poster still (maybe a powerpoint, Suarez will check)
- Need to write a report still with fabrication progress and testing plan
- Jack can do SolidWorks modeling as well
- Get in touch with the client about online classes and the course format
- The appended document should include the changes we made to the device this semester and any future changes we plan or need to make on the design

Conclusions/action items:

The team can get started on creating the final presentation and editing the final journal article based on the testing we can complete at home.

04/03/20 Advisor Meeting

KELLY STARYKOWICZ - Apr 03, 2020, 12:35 PM CDT

Title: Advisor Meeting

Date: 04/03/20

Content by: Kelly

Present: All team members

Goals: Discuss new edits to the journal article, the testing that has been performed, and plans for the rest of the semester.

Content:

- Final Presentations:
    - In our same presentation rooms as usual.
    - Dr. P still wants us to make a poster.
        - We can crop the poster and make it into powerpoint slides for the presentation.
        - Or zoom into the poster and present it that way.
    - They are encouraging us to pre-record the presentations and have live Q & A session.
        - Can do this on the other BBC session.
    - Need to test out how we would present and how we would zoom in and out of certain sections.
- Dr. Suarez-Gonzalez sent us additional comments about the Methods section for the journal article.
    - As we work on sections, we can send drafts to Dr. Suarez-Gonzalez to get feedback.
    - Methods should describe the fabrication section in detail.
    - We should send the Methods section to Dr. Suarez-Gonzalez when we have revised it.
    - Include Model numbers for the machines that we use and describe everything so that someone reading the paper could recreate what we did to fabricate.
- BBC Recordings
    - Need to play around with how we are going to present.
    - Need to try zooming in and out of poster on BBC and see how it records.
    - Need to figure out how to access recorded sessions without Canvas.
    - Consider using another website: screencast-o-matic.com or a different one to record the presentation
    - Right now, Dr. Suarez-Gonzalez needs to send us the links for each recorded session.
- Dr. Suarez-Gonzalez's personal number: 787-299-3681

Conclusions/action items:

- As a team we should try to create goals for when we want to complete certain sections of the report.
- We need to figure out the best way to record our presentation.
- We need to work on the Solidworks testing.
- Update the fabrication section to make it detailed enough for someone to replicate what we did by following this section.
- When we finish the Methods section, we should send it to Dr. Suarez-Gonzalez for feedback.

04/10/20 Advisor Meeting

Jurnee Beilke - Apr 10, 2020, 12:25 PM CDT

Title: Advisor Meeting

Date: 04/10/20

Content by: Jurnee

Present: All

Goals: To talk with Dr. Suarez about the final journal article (testing/results) and the final poster/poster session.

Content:

- The link from the email allows guests to be moderators but Canvas entry will not (need moderator status to record)
    - Join the link from the email
- Sharing the poster seems to work when you open files on the computer screen rather than through BB Collaborate (share screen)
- We will have to share the link of the recording for the poster session in April
- Content on final poster
    - Present previous design and changes made to the final design
    - Include only relevant testing from previous semester (tensile testing)
- Next week is the final Friday meeting unless we need to update her another day or have questions
- The team can send Suarez sections of the report as need for review

Conclusions/action items:

The team should continue working on the final journal article and the final poster.

04/17/20 Advisor Meeting

Jurnee Beilke - Apr 17, 2020, 12:31 PM CDT

Title: Advisor Meeting

Date: 04/17/20

Content by: Jurnee

Present: All

Goals: To ask any final questions about the poster session and journal.

Content:

- Questions for Suarez:
- Do we need to dress nice/have our faces in the recording of the poster?
    - Voiceover is okay - do not need to show video during recording
    - Make sure to specify who is speaking during the presentation since we cannot see faces
- Ask about how to phrase testing - like do we write what we wanted to do or what we actually did (sample size and such)?
    - Testing should look like a specific testing plan but also say "we did some preliminary testing on two individuals" in the journal
    - Additional testing can be placed in the future work section of the poster
- Problem statement - explicitly stated on poster?
    - Combine with motivation
- Market potential?
    - Can research with the library for market potential
    - Talk about the potential use in clinics for wound approximation
- Isabel wants to know what time she needs to be online since she has work?
    - Suarez will contact Isabel directly about missing the presentations
- Rubric will be left up to the advisor - no one size fits all for this semester (no general rubric)
    - All projects are at various in the design process
- Solidworks
    - Link animation in appendix of journal

Conclusions/action items:

The team should pre-record their presentation. The presentation is scheduled at 12:50 pm next Friday. The team will send the final poster to Suarez for edits, and hopefully record the presentation early-mid next week.

01/29/2020 Semester Timeline

KELLY STARYKOWICZ - Feb 14, 2020, 1:15 PM CST

Title: Semester Timeline

Date: 01/29/2020

Content by: Kelly

Present: All team members

Goals: Plan out our goals for the semester

Content:

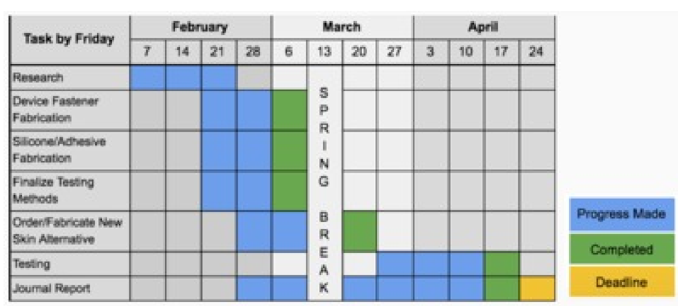
Goals for the semester:

- Research:
  - hinge options- to replace the thumbscrews
  - silicone bumpers
  - testing options
- Fabricate a new fastener/hinge
  - One that is easier to use and can be adjusted quickly
- Fabricate a new silicone/adhesive
  - To replace the cabinet bumpers and the silicone layer on the bottom of the device
- Finalize testing methods
- Order or create a new synthetic skin model
- Test the device
- Work on the journal report

Conclusions/action items:

We plan to complete these tasks according to the attached schedule.

KELLY STARYKOWICZ - Jan 29, 2020, 10:00 PM CST



BME402_Semester_Timeline.PNG(43.8 KB) - download

02/14/2020 Meeting with Makerspace

KELLY STARYKOWICZ - Feb 14, 2020, 1:15 PM CST

Title: Meeting with Makerspace

Date: 02/14/20

Content by: Kelly

Present: Kelly, Jack, Kavya

Goals: Meet with Kurt in the Makerspace to discuss how we would incorporate a torsion spring into our device

Content:

We first introduced Kurt to the problem, our device, and the changes we would like to make.

Kurt's ideas:

- Could 3D print something to fill the slot and have a center point to pass the axle of the torsion spring through
    - Don't use the Ultimakers (not accurate enough)
    - Suggests Form2 printers with "Tough" material
    - Fit accurately in slot (like a key) so it cannot rotate when torsion force is applied
- Would attach the 3D printed piece with the thumbscrew on the outside and a nut on the inside
- Have the torsion spring on the outside of the device
    - Would one torsion spring be enough?
        - Would probably need two
- Need to clamp something else on the side of the torsion spring to give it something to push against
- Torsion spring needs to have a positive stop on it so it is fixed
    - Something rigid to prevent the arms of the spring from moving when it is under force
    - Could just be a flat surface that is 3D printed; only needs to prevent it from moving in one direction
- Need to get torsion spring soon so we can base dimensions off of that
- 3D printed parts are small and would not take long

Alternative:

- Could 3D print the entire device for proof of functionality
    - In future work, we would mention that for clinical use, the device should be metal
- Fabrication: focus on 3D printing right now
- Functionality: we still may want the expertise of someone from the Team Lab to make sure that our idea will work

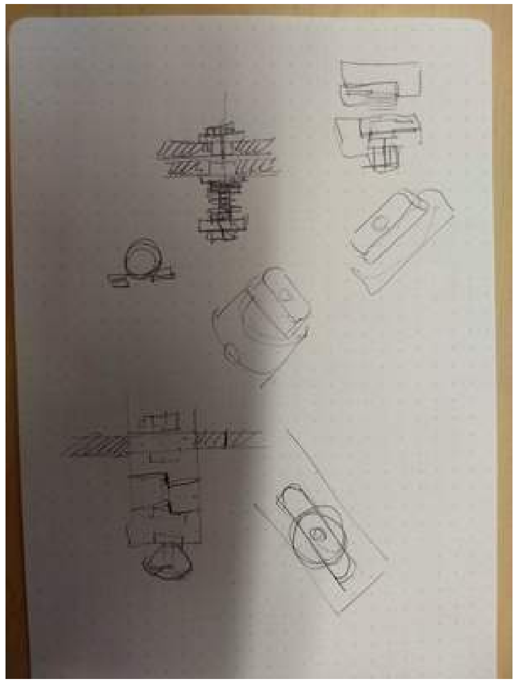
Look at a chip clip and look at how the ends of the spring are attached. Use this same idea to design our device but with the springs on the sides.

Conclusions/action items:

We need to discuss these options as a team and start drafting pieces that could be 3D printed.

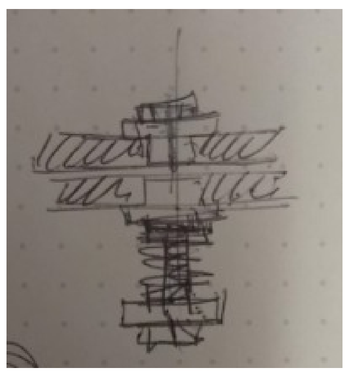
Kurt did a lot of sketching throughout the meeting. An image of these sketches is attached.

KELLY STARYKOWICZ - Feb 14, 2020, 1:05 PM CST



IMG_20200214_130333294.jpg(426.9 KB) - download

KELLY STARYKOWICZ - Feb 14, 2020, 1:14 PM CST



BME402_Sketch.PNG(59.2 KB) - download Here Karl drew his suggestion for how to implement a torsion spring into our current design. The two long horizontal bars are the bars on the device that have slots in them (side view). Above that is a 3D printed plastic piece held onto the thumbscrew with a nut. This would be the inside of the device, closer to the wound. The two slotted pieces would be filled with 3D printed pieces. Below the two slotted pieces are another 3D printed piece, then a torsion spring, then another 3D printed piece. The purpose of the 3D printed pieces are to give the spring something to push against when force is applied.

02/18/2020 Journal Guidelines

KELLY STARYKOWICZ - Feb 18, 2020, 9:07 PM CST

Title: Journal Guidelines

Date: 02/18/2020

Content by: Kelly

Present: Kelly

Goals: Learn about the guidelines for the Journal of Medical Devices.

Content:

See attached document.

Conclusions/action items:

The team needs to stick to these guidelines while writing our journal article.

KELLY STARYKOWICZ - Feb 18, 2020, 9:06 PM CST

Journal of Medical Devices

The Journal of Medical Devices is part of the American Society of Mechanical Engineers (ASME). The journal type we are writing is a Design Innovation Paper. The paper must be submitted to journaltool.asme.org as a PDF.

Basic Criteria:

- 7000 words
- 9 or 10pt Times Roman font
- Justified
- Single line spacing

Basic Elements of the Paper:

- Title
  - Should be concise and definitive.
- Author names and affiliations
  - Anyone who has contributed should be recognized as a co-author or in the acknowledgements.
  - Author name should consist of first name (or initial), middle initial, and last name.
  - Author affiliation should consist of University or company, mailing address, city/state/zip code, country name (not necessary if US), and e-mail, in that order.
- Abstract
  - 250 words maximum.
  - Clearly describe the objective, scope, and results.
- Body of paper
  - Should be organized into logical sections.
  - The purpose should be described at the beginning, then a description of the problem, the means of a solution, and any other information necessary to qualify the results and conclusions, then results and conclusions.
  - Headings and subheadings:
    - Should appear throughout the paper to divide it into logical parts and emphasize major points.
    - Paragraphs should not be numbered, but sections can be.
  - Equations:

Guidelines_for_Journal_Article.pdf(65 KB) - download

02/25/2020 TEAM Lab Meeting

KELLY STARYKOWICZ - Feb 25, 2020, 1:53 PM CST

Title: TEAM Lab Meeting

Date: 02/25/2020

Content by: Kelly

Present: Jurnee, Kelly, Jack, Kavya

Goals: Talk to Mike Hughes about our design ideas

Content:

Mike had a variety of ideas:

- Putting a small tension spring along the bottom of the slotted pieces to pull them together. There would be one spring on each side.
- Doing what Karl at the Makerspace suggested, but using bolts and straw pieces for proof of concept. (Figure 1)
- Putting additional bolts through the slotted pieces and hooking a torsion spring onto those.
- Redesign the entire device with pivoting arms. (Figure 2)
- Have a frame that hovers above the wound area with "feet" that rest on the wound area and pull it together. (Figure 3)
    - A tension spring would be used to pull the feet towards each other and approximate the wound edges.

Other ideas:

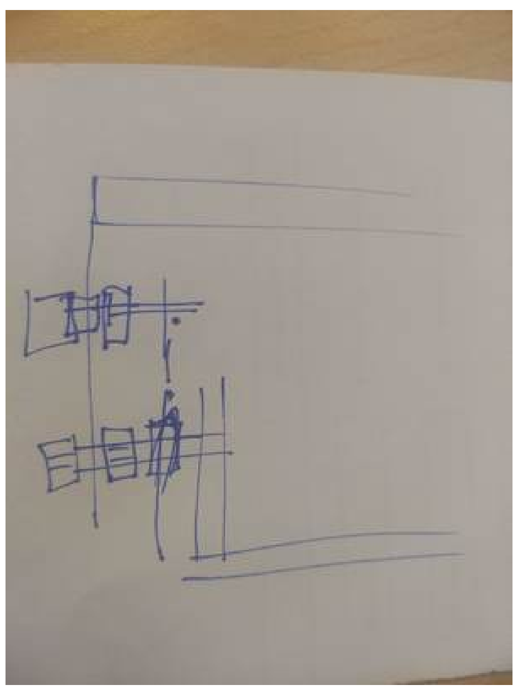
- Any of these designs could be 3D printed or made with acrylic. Acrylic cuts well with the laser cutter and glues well.

See the attached drawings from Mike to demonstrate the possible designs.

Conclusions/action items:

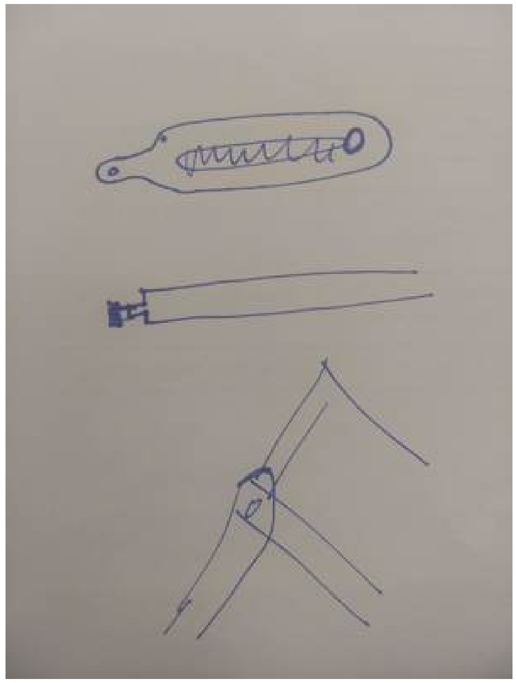
We need to discuss these ideas with Dr. Suarez-Gonzalez in our meeting on Friday to settle on one design to proceed with.

KELLY STARYKOWICZ - Feb 25, 2020, 1:50 PM CST



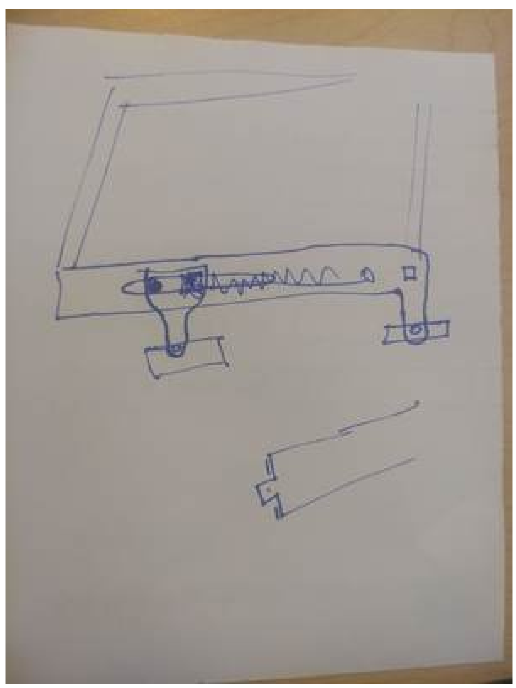
IMG_20200225_134727580.jpg(350.3 KB) - download Figure 1: Following the plan we made with the Makerspace staff, but making it out of bolts and rough materials simply for a proof of concept.

KELLY STARYKOWICZ - Feb 25, 2020, 1:49 PM CST



IMG_20200225_134715383.jpg(304.7 KB) - download Figure 2: Redesigning the device with pivoting arms.

KELLY STARYKOWICZ - Feb 25, 2020, 1:51 PM CST



IMG_20200225_134657545.jpg(335.4 KB) - download Figure 3: Having a frame that hovers above the wound area with "feet" that rest on the wound area and are pulled together with a tension spring.

02/29/2020 Springs

Jurnee Beilke - Mar 14, 2020, 11:44 AM CDT

Title: Springs

Date: 02/29/20

Content by: Jurnee Beilke

Present: All

Goals: To explore springs and determine which one will fit the device in terms of size and tension.

Content:

I went to ACE Hardware and purchased a variety of springs for the team to try out. I purchased 3 compression springs, 2 torsion springs, and 6 tension springs. When I showed the team, we explored how to incorporate each spring type into the device. The best match was a tension spring, which allowed the device sides to be pulled apart a reasonable distance to be placed around a wound and pulled the edges together to approximate the wound. The springs each have one loop on each end allowing us to attach the springs to screws secured on each half of the device (see images below).

Conclusions/action items:

We cleared this design with the client, who said she loved the idea. The spring allows for easier use than the clunky thumb screws the team used last semester. However, the device only has one resting position, but can be opened to different widths depending on wound size.

Jurnee Beilke - Mar 14, 2020, 11:43 AM CDT

IMG_5231.JPG(3.9 MB) - download Figure 1: Springs purchased from Ace Hardware.

04/08/2020 Individual Tasks for Remainder of Semester

KELLY STARYKOWICZ - Apr 08, 2020, 10:45 PM CDT

Title: Individual Tasks for Remainder of Semester

Date: 04/08/2020

Content by: Kelly

Present: Kelly and Jurnee

Goals: Divide up tasks for the remainder of the semester.

Content:

In order to make sure that the work distribution is equal and that everyone is contributing, we assigned specific tasks to everyone in the group.

- Kelly
    - Update image #'s and source #'s in journal article
    - Read through the methods and discussion/conclusion sections of journal article
    - Read through the design summary in Appendix A of journal article
    - Update the future work section of the poster
- Jurnee
    - Read through journal and design appendix
    - Add citations for added information (elastomer)
    - Add tape model #
    - Update abstract on journal
    - Update “final prototype and operation” section on final poster
    - Update testing and results on final poster with my testing
- Jack
    - Add updated images of Solidworks model to journal article where I commented
    - Fabrication section update in journal (make more detailed and include all details - part numbers and 3D printing steps…)
    - Description of Solidworks modeling and testing in Methods and Results sections of journal
    - Add model number for Ecoflex to the journal article where highlighted
    - Update “materials and fabrication” section on final poster
    - Add Solidworks testing and results to final poster
    - Update final cost of device in journal (under Wound Approximation Functionality) and on poster
- Isabel
    - Read through the methods and discussion/conclusion sections of the journal article - make sure the testing section is detailed enough for you to do it/recreate based off these sections
    - Read through the Design Summary in Appendix A of the journal article
    - Update the Abstract on the final poster
- Kavya

    - Solidworks Testing/Modeling- Keep us updated on the progress please!
    - Description of Solidworks Modeling and Testing in Methods and Results sections of journal
    - Add Solidworks testing and results to final poster

Conclusions/action items:

We need to complete these tasks within the next week and a half to be on time and prepared for poster presentations.

04/08/2020 Team Deadlines

KELLY STARYKOWICZ - Apr 08, 2020, 10:47 PM CDT

Title: Team Deadlines

Date: 04/08/2020

Content by: Kelly

Present: Kelly and Jurnee

Goals: Set deadlines for the team for the remainder of the semester

Content:

- Deadline: **April 17th**
    - Solidworks testing/modeling
- Deadline: **April 22nd** (poster session April 24th)
    - Poster
    - Record presentation
- Deadline: **April 29th**
    - Journal article (with design appendix)
    - Notebook
    - Peer Evaluations

Conclusions/action items:

We created these deadlines on our own to keep the team on track and ready for poster presentations.

04/13/2020 Future Work Ideas

KELLY STARYKOWICZ - Apr 13, 2020, 8:02 PM CDT

Title: Future Work Ideas

Date: 04/13/2020

Content by: Kelly

Present: Kelly

Goals: List ideas for the future work section of the poster

Content:

- Replace the double-sided adhesive with a surgical grade adhesive that is easier to use.
- Refabricate the device with holes rather than the long slots and pegs connected to the frame to hold the springs.
    - This will eliminate the 3D printed pieces and make the whole device able to be sterilized.
- Acquire human testing clearance from the IRB
- Testing:
    - Better synthetic model
    - Real skin wounds (animal skin)
    - Repeat Ease of Use and Displacement testing with a larger sample size
    - Redo tensile testing with a more accurate synthetic model

Conclusions/action items:

Need to talk this through with the team and see if this list is missing anything.

Then, need to consolidate this to fit on the poster.

04/25/20 Design Impact

Jurnee Beilke - Apr 25, 2020, 4:15 PM CDT

Title: Design Impact

Date: 04/25/20

Content by: Jurnee

Present: All

Goals: To discuss the impact the design will have in society and the medical field.

Content:

More than 10% of all emergency room visits involve the repair of a cut or laceration. During such repairs, skin tension pulls the wound apart while the clinician attempts to cleanly close the wound. It is important to keep the edges of the wound close together without gaps while suturing or gluing in order to prevent heavy scarring, poor healing, and other complications. Aesthetically, patients do not want permanent scarring from wounds, especially on highly visible areas of skin, such as the arms or legs. Additionally, poor healing can increase a patient's risk for infection and extend the time required for healing. Small laceration closure often requires two physicians, one using forceps to bring together the edges of the wound, also known as approximation, and the other to complete closure. There are already shortages of physicians in emergency rooms, urgent care clinics, and office settings where these repairs often occur and requiring two physicians for a small wound repair is not an efficient use of time. Currently, there is a lack of devices on the market that function solely for wound edge approximation. Surgical tools such as forceps are not designed to approximate wound edges, for they require at least one of the clinician's hands to function during the wound approximation, leaving only one free hand to partake in the wound closure. Forceps and other surgical tools may also pinch the skin and be uncomfortable to the patient. Therefore, there is a gap in the market for a device that allows accurate and quick wound approximation while functioning autonomously once placed on the skin to provide the clinician with the use of both hands to participate in wound closure.

Conclusions/action items:

Overall, this device will reduce the number of clinicians needed for repair, and fill a gap in the market for a device that approximates wounds.

Expenses Sheet

Jack Fahy - Apr 25, 2020, 3:24 PM CDT

Title: Expenses and Materials Sheet

Date: 02/22/2020

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	6	$0.39	$0	$2.34	N/A
Zinc Plated Wingnuts	Size 6-32	Menards	11/20/2019	6	$0.98	$0	$0.98	N/A
Ecoflex 00-30 Super Soft Platinum Silicone	Silicone Rubber curing mix - used for creating synthetic skin	Smooth-On	3/10/2020	1	$38.50	$2.12	$40.62	https://www.smooth-on.com/products/ecoflex-00-30/
3D-printed slot filler	PLA printed pieces to fill slots of device	N/A	3/12/2020	1	$0.15	N/A	$0.15	N/A
Reprint of slot filler	PLA printed pieces to fill slots of device (resized to better fit device)	N/A	3/13/2020	1	$0.31	N/A	$0.31	N/A
Tension Springs	Springs to convert device to hinging mechanism	Fleet Farm	3/13/2020	2	$0.89	N/A	$1.78	N/A
						TOTAL:	$87.49	

02/29/20 Spring Addition

Jurnee Beilke - Apr 06, 2020, 11:41 AM CDT

Title: Spring Addition

Date: 02/29/20

Content by: Jurnee Beilke

Present: All

Goals: To attach/fabricate an attachment for the spring to the device.

Content:

- After the correct size spring was chosen from the lot I purchased, the team decided that the best way to attach the springs was to place a thumb screw through the slots on the sides of the device using hex nuts to secure the screws in place. The loops of the spring were then placed around the screw as shown in the image below.
- This process was repeated on the other side of the device as well.
- The springs allow for much easier use of the device since the clinician can simply pull the edges apart and place the device around the wound and allow the sides to be drawn together from the force of the springs.
- Additionally, the team placed a screw through both slotted segments and secured it in place using hex nuts to act as a hinge for the device and a mechanism to hold the sides of the device together.

Conclusions/action items:

The springs work very well with the device, and provide a much easier to use mechanism than the thumb screw design we used last semester.

Jurnee Beilke - Apr 06, 2020, 11:41 AM CDT

IMG_5232.JPG(2.1 MB) - download Figure 1: Tension spring attached to the device.

03/12/20 3D Printing

Jurnee Beilke - Apr 06, 2020, 11:45 AM CDT

Title: 3D Printing

Date: 03/12/20

Content by: Jack Fahy

Present: All

Goals: To 3D print pieces to fill the hollow slots on each side of the device, so the screws acting as hinges do not slide around as the device pivots.

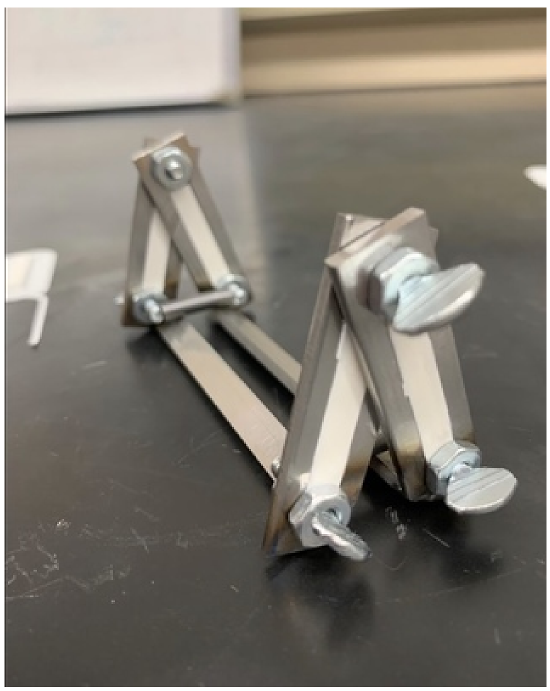
Content:

- Plastic pieces to fill the slots of the device were designed in SolidWorks
- These pieces were designed to prevent the hinge screw from sliding down the slotted segments
- Two semi-circle shaped regions were designed at the ends of each piece to leave room for the screws that attach to the springs and the hinge screw
- The pieces were 3D printed at the MakerSpace out of PLA

Conclusions/action items:

The pieces fit perfectly into the slots of the device, and function as designed to keep the hinge screw in place.

Jurnee Beilke - Mar 14, 2020, 12:03 PM CDT



IMG_5362.jpg(126.5 KB) - download Figure 1: 3D pieces within the hollow slots of the device.

4/12/2020 Final SolidWorks Model

Jack Fahy - Apr 25, 2020, 4:05 PM CDT

Title: Final Solidworks Model

Date: 4/12/2020

Content by: Jack

Present: Jack

Goals: Document final Solidworks model of device

Content:

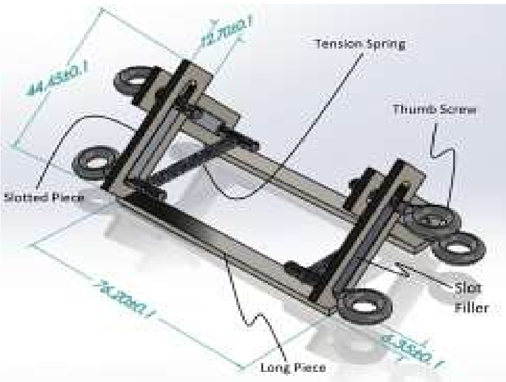


Figure 1. Solidworks model device. Dimensions in mm

Figure 1 shows the final model of the device designed in SolidWorks. Relevant parts and dimensions are labeled.The long sides, slotted sides, and slot fillers were created in separate part files and assembled in SolidWorks Assembly. The thumb screws were pulled from GrabCad (Micro Plastics-0100632EYEB075) and added to the assembly.

Conclusions/action items:

This model will be used for conducting motion study testing in SolidWorks

Solidworks Device Motion Studies

Kavya Vasan - Apr 28, 2020, 9:46 AM CDT

Title: Wound Edge Device Motion Studies in Solidworks

Date: April 21, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To create a visual representation of the intended motion of the device

Content:

- I played around with the motion study animation tools in Solidworks.
- First, I tried adding a linear motor to the right edge of one of the long edge parts to move left, and a linear motor to the left edge of the other long edge part to move right.
    - The speed of the motors was 0.1 in/sec. This didn't represent the hinging motion that the team wanted with the iteration of the prototype with the spring.
- The motion study that successfully show the hinging motion of the bottom long edges is Wound_Edge_Rotation_Motion_Long.mp4 (attached below).
    - I added a Rotary motion of 0.2 revolutions per minute (RPM) on the bottom edge of the right plane on the right slotted part. This motor is in the clockwise direction.
    - I added another Rotary motion of 0.2 revolutions per minute (RPM) on the bottom edge of the right plane on the left slotted part. This motor is in the counterclockwise direction.
    - This motion study was for 8 seconds with a frame rate of 15 frames/sec.
- The second motion study is a fully assembled version of the previous motion study. This is the Wound_Edge_Rotation_Motion_Long.mp4 (attached below).
    - This includes 3 thumb screws on each side of the device (1 on top and 2 on the bottom), a slotted piece within each slot (4), and and a spring attached to thumb screws on each side of the device.
    - This animation was 6 seconds.
    - This shows the hinging motion when the device is used with the springs.

Conclusions/action items: The final two animations helped visualize the device's new motion with the addition of the spring. I think each motion study showed a different view and had different advantages. The first motion study showed the motion of the device in its entirety in a trimetric view. This gave our viewers a view of the device as a whole. The second motion study showed the motion in the front view of the device, where the bottom hinging motion could be clearly seen without any obstruction.

Kavya Vasan - Apr 28, 2020, 9:46 AM CDT

Final_Wound_Edge_Rotation_Assembled_Motion.mp4(388.4 KB) - download This is an animation of the fully assembled device

Kavya Vasan - Apr 28, 2020, 9:46 AM CDT

Wound_Edge_Rotation_Motion_Long.mp4(182.7 KB) - download This is a motion study of the slotted parts attached to the long edges

04/25/20 Tensile Testing Protocol

Jurnee Beilke - Apr 25, 2020, 3:44 PM CDT

Title: Tensile Testing Protocol

Date: 04/25/20

Content by: Jurnee

Present: All

Goals: To detail the protocol for tensile testing to determine the force required for approximation.

Content:

- A silicone model suture kit was used (ARTAGIA 2nd Generation Suture Practice Kit)
- The silicone model was cut into 10 samples, 3 cm long strips (1 cm wide and 1 cm thick)
- The strips were tested in tension using an MTS machine - the load frame used to perform the testing was an MTS Criterion Model C43.104
- A 1 kN load cell was used for testing - the testing system was interfaced with TW Elite
- The data program was manually triggered to start, and the crosshead movement of the MTS machine began to apply tension forces to the sample strips (extension rate of 100 mm/min)
- The test ran until the silicone began to slide out the textured grips
- The program recorded the time (s), load (N), and displacement (mm)
- The tensile testing data was analyzed using MATLAB to create stress-strain curves from the output data consisting of load and deformation values
- To convert from load to stress (σ), the force (F) can be divided by the cross-sectional area (A) (Eqn. 1)
- To obtain strain (ε), the change in length of the specimen (ΔL) is divided by the original length (L) (Eqn. 2)

$$\sigma = \frac{F}{A} \qquad \text{Eqn. 1}$$

$$\varepsilon = \frac{\Delta L}{L} \qquad \text{Eqn. 2}$$

-
- An incision was made in the silicone skin approximately 3 cm in length
- The silicone was then draped over an individual's lateral forearm until the wound edges splayed to mimic a real wound
- Two markings were made on opposite sides of the wound, and the original distance between the two markings was measured using calipers
- The final device was then used to approximate the laceration edges of the silicone skin
- Once the skin edges were approximated, the final distance between the markings was measured
- The change in length of the silicone from elongating the material to close the wound could then be computed - with the change in length and the original length measured, the strain of the silicone could be calculated using the strain equation
- With the strain value, the team used the graphs generated from MATLAB to find the stress applied to the silicone skin
- The force applied was also determined by multiplying the stress value by the area normal to the force

Conclusions/action items:

This test method was able to provide information about the forces applied by the device to the skin and the ability of the silicone suture kit to model human skin.

04/25/20 Device Functionality Protocols

KELLY STARYKOWICZ - Apr 26, 2020, 9:28 AM CDT

Title: Device Functionality Protocols

Date: 04/25/20

Content by: Kelly

Present: All

Goals: Explain protocols for device functionality testing

Content:

- Device Displacement Testing
    - The device was placed on an individual and the sides of the device were released until the skin was raised to stimulate wound approximation.
    - Lateral forearms, lateral upper arms, ventral torso, ventral thighs, and dorsal calves were included during testing.
    - Markings were placed on the skin on either side of the device to denote the starting position.
    - After the five minute interval was completed, new markings were made to denote the final position of the device.
    - The distance between the original and final markings were recorded to determine how much the device moved and slipped while in use.
    - This procedure was then repeated with ten individuals.
- Discomfort Testing
    - This test was conducted simultaneously with the device displacement test.
    - A zero to five point scale was developed to quantify the comfort of the device and can be seen below in Table 1.
    - The prototype was tested for discomfort on the lateral forearm of 10 individuals.
    - While in place, the individual was asked to rank their pain level according to the scale. These scores were recorded and averaged to determine the overall comfort of the device during use.

Table 1: Discomfort Scale

Pain Rating	Description
0	Aware of the device, but no pain experienced
1	Uncomfortable
2	Slight pain
3	Mild pain or pinching
4	Moderate pain
5	Severe pain

- Ease of Use Testing
    - Ten individuals operated the device on another person’s skin and rated it on a scale from one to ten based on how intuitive it was.
    - A rating of one implies the device is simple and easy to use with minimal instruction, and a rating of ten implies the device is extremely difficult or impossible to use without assistance.

Conclusions/action items:

The device displacement testing determined how much the device moved while in service, and if the device remained on the skin while in use.

The discomfort testing was conducted during the device displacement test to ensure that the device was not causing patients harm.

The ease of use testing allowed for assessment of device operation in terms of how intuitive device setup was and if there were any major complications with the design.

The results from these three tests can be used to evaluate the device and determine what improvements, if any, need to be made to the design.

03/29/20 Device Testing Summary

Jurnee Beilke - Apr 06, 2020, 11:32 AM CDT

Title: Device Testing

Date: 03/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To test the device using as many of the protocols as I can during this COVID self-isolation.

Content:

- I am currently at home with my parents, and they will serve as my subjects for testing
- The first test I ran with them was the device displacement during use/service
  - I placed the device on multiple areas of my parents' bodies (forearm, upper arm, calf, thigh, and torso/stomach)
  - I marked the skin in the location of the device at the start and then again after a 5 minute interval
  - I measured the distance using calipers and recorded the distance moved
- The second test I ran with my parents was device discomfort
  - I placed the device on their forearms as this is a sensitive area of skin that allows for accurate pain reception
  - I had my parents rank the pain from the device on the scale provided (0-5)
- The last test I ran was ease of use
  - I had my parents use the device on my arm and rank the ease of use on a scale of 1-10 (1 being easy and intuitive and 10 being impossible to use without help)

Data: See the attached file for data.

Conclusions/action items:

Overall, the device had minimal displacement over the 5 minute interval. However, we would have liked to see zero displacement on a perfect device. Additionally, the device imparted minimal pain on the subjects, and the device was ranked relatively easy to use by both subjects.

Jurnee Beilke - Apr 06, 2020, 11:33 AM CDT

Table 1. Device displacement data for bare skin

Location	Subject 1	Subject 2
Lateral forearm	0.5 mm	0.3 mm
Upper Arm	1.1 mm	1.0 mm
Thighs	0.1 mm	0.3 mm
Calves	0.6 mm	0.4 mm
Torso	0.4 mm	0.1 mm

Table 2. Discomfort level scores during approximation

Subject	Pain Rating
1	1
2	1

Subject 1 notes: slight discomfort during use
Subject 2 notes: slight discomfort during removal

Table 3. Ease of use scores

Subject	Ease of Use
1	2
2	1

Subject 1 notes: The double sided tape was tricky to figure out - why is it needed, how to place it? After exploring she could see that the tape was used to adhere to skin and the device itself was easy to understand and use with the addition of springs, but the tape was a challenge.
Subject 2 notes: It was self-explanatory what the device needed to do, but the tape was problematic.

Device_Testing_Data.pdf(51.6 KB) - download

04/25/20 Tensile Testing Results

Jurnee Beilke - Apr 25, 2020, 3:54 PM CDT

Title: Tensile Testing Results

Date: 04/25/20

Content by: Jurnee

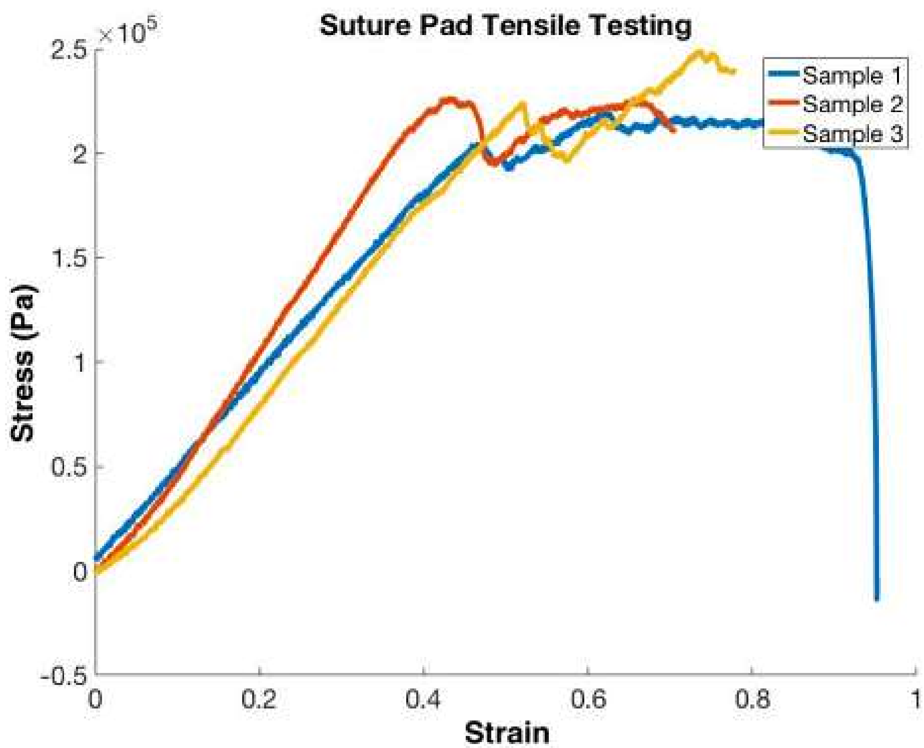
Present: All

Goals: To present and discuss tensile testing results.

Content:

- The average modulus of elasticity for the 3 cm length suture pad specimens were found to be 0.4358 ± 0.0738 MPa
- A linear model was developed for estimating the tensile forces that the wound edges of the suture pad experience during approximation (Eqn. 10)
- Using the stress-strain plot generated in MATLAB, the developed linear model is applicable for measured strains between 0.00 and 0.35 (the MATLAB code is presented in the appendix of the final report from last semester and last semesters notebook)

$$F = 0.4358 * \varepsilon * A \qquad \text{Eqn. 10}$$

- 

- Using the above model (Eqn. 10) and the measured displacements of the suture pad during approximation, induced tensile forces ranging from 27.68 to 38.95 N were observed

Conclusions/action items:

Based on the MTS testing, an average modulus of 0.436 MPa was found. Using this value and the measured areas and strains of the suture pad during wound edge approximation, tensile forces ranging between 27.68 and 38.95 N were calculated. These tensile forces induced by the device in the suture pad were far greater than the target range of 6.5 to 7.8 N for human skin. This drastic difference in tensile forces is due to the high modulus of elasticity found for the suture pad samples. Upon further investigation, it was found that suture pads have an embedded mesh to enhance durability. While this mesh allows for an optimal lifespan of the device with respect to suturing practice, it ultimately makes its use as a skin model for mechanical testing invalid. Moving forward, the MTS testing will be re-conducted using a more accurate, synthetic model of skin in order to determine the tensile forces induced during wound edge approximation. One such model is an elastomer like silicone or polyurethane.

04/25/20 Device Functionality Results

KELLY STARYKOWICZ - Apr 25, 2020, 4:10 PM CDT

Title: Device Functionality Results

Date: 04/25/20

Content by: Kelly

Present: All

Goals: Discuss results of the device functionality testing.

Content:

- Device displacement testing:
  - Upon analyzing the total displacement of the device on skin after a five minute period, an average displacement of 0.48 ± 0.34 mm was measured for bare skin.
  - The average displacement for the forearm was 0.4 mm, the upper arm was 1.05 mm, the thigh was 0.2 mm, the calf was 0.5 mm, and the torso was 0.25 mm.
  - The raw data from this test is attached in Table 1.
- Discomfort testing:
  - An average pain score of 1.0 out of 5.0 during device use was found.
  - Subjects noted that there was only slight discomfort during use and removal.
  - Upon removal, shallow indentations were observable in the individual's skin for up to two minutes after use.
  - The discomfort level scores and images of the indentations can be found in Table 2 and Figure 1, respectively.
- Ease of Use testing:
  - An average ease of use score of 1.5 out of 10.0 during device use was found.
  - Subjects noted that the double-sided tape was the trickiest part of the device to understand and use. The removal of the peel paper on the tape was difficult.
  - The ease of use scores can be found in Table 3.

Conclusions/action items:

- Device Displacement Testing:
  - The device will be used to approximate wounds 2 cm to 5 cm in length so an average displacement of 0.48 mm from the initial position was inconsequential.
  - This indicates that the device displaced a small yet detectable amount during approximation, and this issue of displacement must be addressed in the future.
  - Ideally, the device would remain in the initial position throughout its entire time in use to maintain approximation without any gaps.
- Discomfort testing:
  - The device only caused slight discomfort to the users and did not harm the skin, which was an important design criterion that had been established.
- Ease of use testing:
  - The device was rather intuitive to use, but the skin adhesive will need to be replaced with a medical grade tape with easy-to-remove peel paper, so clinicians can easily apply the adhesive to the device and attach the device to the patient's skin.

KELLY STARYKOWICZ - Apr 25, 2020, 4:00 PM CDT

Table 1: Device displacement for bare skin

Location	Subject 1	Subject 2
Lateral forearm	0.5 mm	0.3 mm
Upper arm	1.1 mm	1.0 mm
Thighs	0.1 mm	0.3 mm
Calves	0.6 mm	0.4 mm
Torso	0.4 mm	0.1 mm

Table 2: Discomfort level scores during approximation.

Subject	Pain Rating
1	1
2	1

Table 3: Ease of use scores as rated by multiple individuals using the device.

Subject	Ease of Use Score
1	2
2	1

KELLY STARYKOWICZ - Apr 25, 2020, 4:13 PM CDT

Device_Markings.jpg(346.2 KB) - download Figure 1: Image of the red markings left on the subject's skin after device use

04/25/20 Conclusions

Jurnee Beilke - Apr 25, 2020, 4:03 PM CDT

Title: Project Conclusions

Date: 04/25/20

Content by: Jurnee

Present: All

Goals: To discuss the overall conclusions of the testing we completed for this design project.

Content:

The goal was to design a device to approximate wound edges while suturing or gluing. This will reduce the number of clinicians needed to repair lacerations. The resulting prototype consists of two identical metal structures that are connected via a hinge mechanism and tension springs. To aid in wound closure, double sided adhesive is used to maintain device contact with the skin.

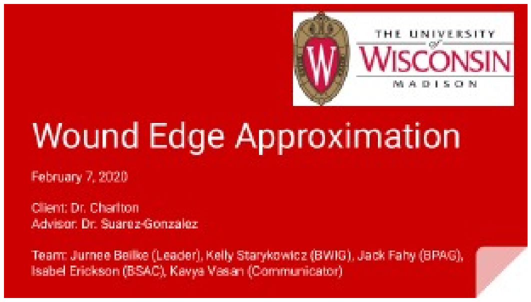
As a result of testing and evaluation, the force required for approximation on the silicone suture pad was higher than reported values of human skin. This was due to the durable mesh layer within the silicone; the elastic modulus of the suture pad was significantly higher than both the values for pure silicone and human skin. The silicone suture pad is therefore not an accurate model for skin, and a different model should be utilized in future experiments. In terms of device functionality, the displacement of the device from its initial position was detectable, yet relatively small. Additionally, the device caused the patient minimal discomfort, and only left light markings on the skin. Multiple subjects rated the current design as easy to use, which is important for the device will be used by a variety of clinicians.

Conclusions/action items:

Despite the Coronavirus pandemic, the team was able to complete preliminary testing of the current, updated prototype. We were not able to redo tensile testing with an improved skin model due to lack of access to labs and resources. However, I was able to perform several tests at home with my parents. In future semesters, the sample sizes should be increased and an improved skin model should be tested and explored.

02/20/20 Preliminary Presentation

KELLY STARYKOWICZ - Feb 20, 2020, 5:37 PM CST



Preliminary_Presentation_4_.pdf(1.9 MB) - download

02/26/20 Journal Article Draft

KELLY STARYKOWICZ - Apr 08, 2020, 10:39 PM CDT

Approximation Device Designed to Free Both Hands for Wound Repair

Kelly Starykowicz, Jack Fahy, James Bellke, Isabel Erickson, Karyn Vance
Affiliation: Students in the Biomedical Engineering Design Program at the University of Wisconsin - Madison

Abstract

Each year, 6 million laceration cases are treated in emergency departments. With lacerations larger than 2 cm, skin tensions pull the wound edges apart, making repair difficult. Clinicians often require a second individual to approximate skin edges while the wound is closed. Currently, no device exists designed solely to approximate wounds. The team designed a prototype to accurately and repeatedly approximate wound edges, allowing the clinician use of both hands during repair. The designed solution is a metal frame consisting of two identical stainless steel sides, which are connected via torsional springs. The device is assisted by double-sided adhesives, which are placed on the skin-contacting edges. The opening of the device is placed around the wound, and the long edges are pulled together by the springs to approximate the wound. The team utilized the Makerspace and TEAM Lab for fabrication. Further modifications and testing are required prior to device use in clinical settings.

Introduction

More than 10% of all emergency room visits involve the repair of a cut or laceration. During such repairs, skin tension pulls the wound apart while the clinician attempts to cleanly close the wound with stitches or tissue adhesives such as Dermabond [1]. It is important to keep the edges of the wound close together without gaps while suturing or gluing in order to prevent heavy scarring, poor healing, and other complications. For large wounds, this problem is often solved within operating rooms with wound closure systems. However, small laceration closure often requires two physicians, one using forceps to bring together the edges of the wound, also known as approximation, and the other to complete closure. There are already shortages of physicians in emergency rooms, urgent care clinics, and office settings where these repairs often occur and requiring two physicians for a small wound repair is not an efficient use of time. Currently, there is a lack of devices on the market that function solely for wound edge approximation. Surgical tools such as forceps are not designed to approximate wound edges, for they require at least one of the clinician's hands to function during the wound approximation, leaving only one free hand to partake in the wound closure. Forceps and other surgical tools may also pinch the skin and be uncomfortable to the patient. Therefore, there is a gap in the market for a device that allows accurate and quick wound approximation while functioning autonomously once placed on the skin to provide the clinician with the use of both hands to participate in wound closure.

Skin Properties

Journal_of_Medical_Devices_Draft.pdf(902 KB) - download

04/25/20 Final Poster

KELLY STARYKOWICZ - Apr 25, 2020, 3:24 PM CDT

Final_Poster_-_BME_402.pdf(3 MB) - download

01/30/20 Skin Alternatives

Jurnee Beilke - Jan 30, 2020, 11:45 AM CST

Title: Skin Alternatives

Date: 01/30/20

Content by: Jurnee Beilke

Present: NA

Goals: To understand the physical properties of skin in order to choose an alternative for mechanical testing of our device.

Content:

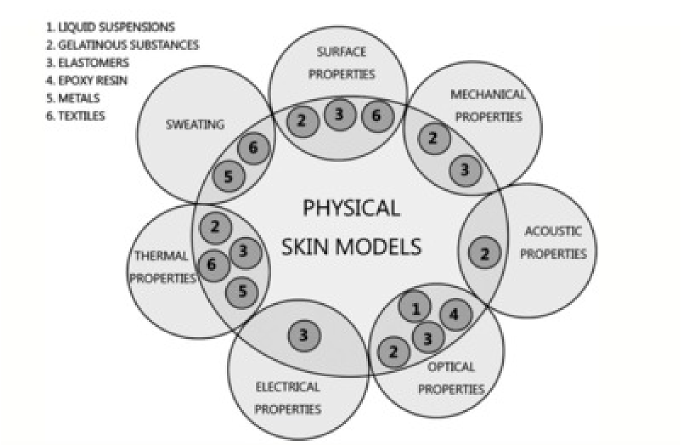
- Introduction
  - Tests on animals, humans, cadavers, and explants have been used to study material-skin interactions
  - Studies were useful to establish safety margins and improved the characterization of skin
  - Experiments on human and animal skin raise ethical issues and are highly variable
  - Cell cultures simulating skin are commercially available and used for research and testing - however physical properties do not yet mimic that of real skin
  - Models based on biologically inactive materials, called physical skin models are preferable
  - Physical skin models allow obtaining long term stability, lower costs, easy storage and manipulation
- Basic Properties and Functions of Human Skin
  - Human skin has complex properties and functions
  - Generally, skin properties are anisotropic - time, site, temperature, method dependent
  - Skin structure is organized into three main layers: epidermis, dermis, and hypodermis
  - The epidermis is thin, consists of keratinocytes
  - The dermis is thicker and is built up of collagen and keratin fibers (strength of the skin)
  - The hypodermis is the fat layer which protects the body from heat and cold
  - Main functions of skin are: protection, repair and adaptation, sensation, and temperature regulation
- Phases in the Development of Skin Models
  - First, the main requirements such as skin characteristics, properties, and functions needs to be established
  - Second, material and processing methods have to be chosen
  - Third, effective manufacturing of the model
  - Fourth, testing and feedback
  - Fifth, validation of the skin model
- Materials to Simulate Human Skin
  - Physical skin models can be produced based on numerous combinations of materials, structures, and morphologies
  - Liquid suspensions
    - Liquid suspensions have been used to simulated optical properties of tissues - scattering and absorption properties
    - Suspensions of lipid, polymeric, and inorganic particles can be added in liquids such as water, milk, and oil
  - Gelatinous substances
    - Creation of gels
    - Model allows for the control of physical, mechanical, and chemical properties
    - Representatives include gelatin, agar, agarose, collagen, PVA
    - Gelatin - simulate the density and viscosity of skin and the deformation and kinetic dissipation/deformation
    - Agar - not as stable and possess a limited lifetime, yet gels are versatile
    - PVA - mechanical properties are tunable with the range of soft tissues
  - Elastomers
    - Polymers exhibiting rubber-like viscoelastic properties
    - Silicones, polyurethane, as well as other polymers
    - Silicones - cross linked polydimethylsiloxanes are widely used, fillers can be added to strengthen the properties
    - Polyurethanes - varying soft to hard phase ratio, use as mechanical skin models
  - Epoxy resin
    - Thermal skin models as well as instrument calibration
    - Cross lined or thermoset plastics
  - Metals

    - Models are mainly used in systems to probe thermal properties
    - High thermal responsiveness
  - Textiles
    - Based on natural and synthetic materials
    - Simulating sweat distribution of humans
- Nano- and Micro-fillers
  - To obtain tailored models, fillers are added to a liquid of solid matrix
  - Influences various properties
- Conclusion
  - There is a large variety of materials used to simulate physical properties of human skin
  - The role of skin models is to mimic the chosen properties of human skin
  - Future skin models might be based on investigations in which improvements are achieved

Conclusions/action items:

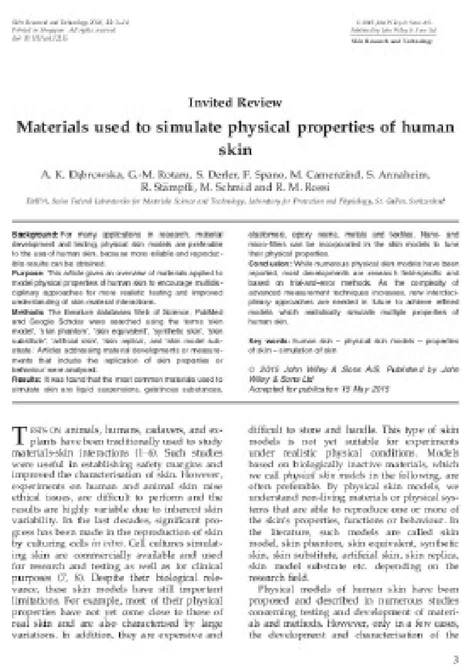
Based on this literature review, I think the team should explore skin alternative models with gelatinous substances and elastomers. After reading the section about polyurethanes mimicking skin mechanics, I believe the team could utilize polyurethane or silicones for our skin model.

Jurnee Beilke - Jan 30, 2020, 11:45 AM CST



Screen_Shot_2020-01-30_at_11.42.12_AM.png(373.9 KB) - download Figure 1: Diagram of skin properties and corresponding skin models.

Jurnee Beilke - Jan 30, 2020, 11:46 AM CST



Invited Review

Materials used to simulate physical properties of human skin

A. K. Dąbrowska, G.-M. Rotaru, S. Derler, F. Spano, M. Camenzind, S. Annaheim, R. Stämpfli, M. Schmid and R. M. Rossi

Background: For many applications in research, material development and testing physical skin models are preferable to the use of human skin, because more reliable and reproducible results can be obtained.

Purpose: This article gives an overview of materials applied to model physical properties of human skin to encourage multidisciplinary approaches for more realistic testing and improved understanding of skin-material interactions.

Methods: The literature databases Web of Science, PubMed and Google Scholar were searched using the terms 'skin model', 'skin phantom', 'skin equivalent', 'synthetic skin', 'skin substitute', 'artificial skin', 'skin replica', and 'skin model substrate.' Articles addressing material developments or measurements that include the replication of skin properties or behaviour were analysed.

Results: It was found that the most common materials used to simulate skin are liquid suspensions, gelatinous substances, elastomers, epoxy resins, metals and textiles. Nano- and micro-fillers can be incorporated in the skin models to tune their physical properties.

Conclusion: While numerous physical skin models have been reported, most developments are research field-specific and based on trial-and-error methods. As the complexity of advanced measurement techniques increases, new interdisciplinary approaches are needed in future to achieve refined models which realistically simulate multiple properties of human skin.

Key words: human skin – physical skin models – properties of skin – simulation of skin

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Accepted for publication 15 May 2015

Tests on animals, humans, cadavers, and explants have been traditionally used to study materials-skin interactions (1–6). Such studies were useful in establishing safety margins and improved the characterisation of skin. However, experiments on human and animal skin raise ethical issues, are difficult to perform and the results are highly variable due to inherent skin variability. In the last decades, significant progress has been made in the reproduction of skin by culturing cells in vitro. Cell cultures simulating skin are commercially available and used for research and testing as well as for clinical purposes (7, 8). Despite their biological relevance, these skin models have still important limitations. For example, most of their physical properties have not yet come close to those of real skin and are also characterised by large variations. In addition, they are expensive and difficult to store and handle. This type of skin models is not yet suitable for experiments under realistic physical conditions. Models based on biologically inactive materials, which we call physical skin models in the following, are often preferable. By physical skin models, we understand non-living materials or physical systems that are able to reproduce one or more of the skin's properties, functions or behaviour. In the literature, such models are called skin model, skin phantom, skin equivalent, synthetic skin, skin substitute, artificial skin, skin replica, skin model substrate etc. depending on the research field.

Physical models of human skin have been proposed and described in numerous studies concerning testing and development of materials and methods. However, only in a few cases, the development and characterisation of the

3

D-browska_et_al-2016-Skin_Research_and_Technology.pdf(305.8 KB) - download

Jurnee Beilke - Feb 01, 2020, 1:46 PM CST

Citation:

Dąbrowska, A., Rotaru, G., Derler, S., Spano, F., Camenzind, M., Annaheim, S., Stämpfli, R., Schmid, M. and Rossi, R. (2015). Materials used to simulate physical properties of human skin. *Skin Research and Technology*, 22(1), pp.3-14.

02/02/20 Skin Properties and Models

Jurnee Beilke - Feb 02, 2020, 9:07 AM CST

Title: Skin Properties and Models

Date: 02/02/20

Content by: Jurnee Beilke

Present: NA

Goals: To understand the biological/physiological properties of skin and explore what models exist.

Content:

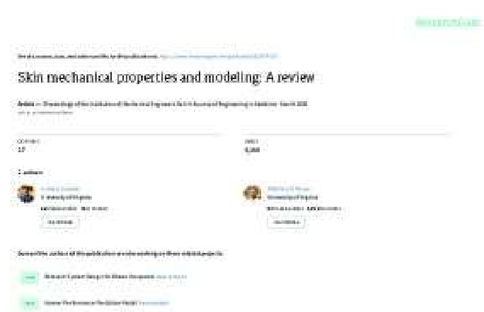
- Skin is the largest organ in surface area
- Functions
  - Protection from the environments, temperature regulation, adaptation of contours of the body during movement
- The skin is made of several layers, each of which is different - making the skin mechanically complex
- Clinicians use the mechanical properties of skin to understand the laceration process
- Skin layers
  - Epidermis
  - Dermis - dense ECM
  - Hypodermis - adipose
- Typical components
  - Collagen - strength and volume
  - Elastin - recoiling and deformation
  - Reticulin
- In vivo experiments provide data on tissue in its natural state
  - Often difficult to assess the contribution of each isolated layer of skin
  - Methods for testing skin
    - Indentation - rigid indenter is used to apply deformation to the skin
    - Torsion - constant rotation applied to the skin
    - Tension - skin is loaded parallel to surface
    - Suction - skin is elevated by applying a partial vacuum
- Skin is viscoelastic and does not always possess Hookean behavior
- In vitro testing has advantages over in vivo
  - Sample can be tested over various loading conditions - stress strain relationship can be obtained
  - Methods for testing skin
    - Biaxial tension - stretch skin in multiple directions
    - Uniaxial tension - stretch skin in one direction
  - Skin is anisotropic
- Mechanical behavior of skin
  - Non-linear stress-strain relationship
  - When skin is stretched, the stiffness of the material increases with higher strain levels
  - Collagen is the main support in the linear region of the curve
  - Skin is strain rate dependent - viscoelastic
  - Skin exhibits the relaxation behavior of VE materials (stress in the skin will decay over time)
  - Mechanical properties depend on orientation - anisotropy
    - Langer's lines
  - Skin shows load history-dependent behavior
  - Strain rate is among the predominant factors which affect the soft tissue failure properties
  - Age is another factor that impacts the stiffness of skin
    - Stiffness decreases with age
- Skin Modeling
  - Linear-elastic modeling
    - Represent the skin as a linear-elastic material that follows Hooke's law
    - Rough estimation of the response of tissue to mechanical loading with representing viscoelasticity
  - Whole skin models
    - Models that look at the effective properties of skin without differentiating the layers
    - Elastic modulus values around 0.001 MPa
  - Models of skin layers
    - Isolating and modeling one of the three layers of skin

        - Considering epidermal and dermal components
    - Bi-linear elastic modeling
        - Model skin as a bi-linear elastic material
        - Assume homogeneous material without viscoelastic and anisotropic properties
    - Hyper-elastic modeling
        - Mooney-Rivlin and neo-Hookean Model
        - Ogden Model
        - Polynomial Model
        - Exponential Models
        - Gasser-Ogden-Holzapfel Model
    - Viscoelastic model
        - Skin shows non-linear instantaneous elastic response, quasi-linear viscoelastic (QLV)
    - Aging and micro-structural modeling
        - Model skin aging and study of various factors of wrinkle formation
- Discussion
    - Human skin is anisotropic, non-linear, viscoelastic, and loading history-dependent
    - QLV model compared to elastic is able to characterize the mechanical behavior of skin

Conclusions/action items:

I think the team should consider exploring a viscoelastic model for skin when considering skin alternatives to test our device instead of elastic/Hookean behavior, which only provides rough estimates of mechanical properties.

Jurnee Beilke - Feb 02, 2020, 9:08 AM CST


Skin mechanical properties and modeling: A review

Joodaki2015SkinMechanicalPropertiesandModelingAReview.pdf(1.2 MB) - download

Jurnee Beilke - Feb 02, 2020, 9:09 AM CST

Citation:

Joodaki, H. and Panzer, M. (2018). Skin mechanical properties and modeling: A review. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, 232(4), pp.323-343.

02/02/20 Synthetic Skin

Jurnee Beilke - Feb 02, 2020, 10:20 AM CST

Title: Synthetic Skin

Date: 02/20/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore skin alternatives for the mechanical and functional testing of our device.

Content:

- Physical skin models have the advantage of obtaining long-term stability, lower costs, easy storage/manipulation, control over mechanical properties
    - Skin models can be used for the design and experimental testing of skin features
- Structure and mechanical property of skin
    - Skin is complex multi-layer tissue
        - Epidermis
        - Dermis - strength and flexibility
        - Hypodermis - supportive structure
    - Skin is a protective barrier for the inner tissues of the body
    - Skin is highly non-linear, anisotropic, heterogeneous, and viscoelastic
    - Elastic modulus values
        - 3.5-1000 MPa dry stratum corneum
        - 10-50 MPa wet stratum corneum
        - 1.5 MPa viable epidermis
        - 8-35 kPa dermis
- Physical skin models
    - Gelatinous substances
        - Gelatin - hydrolyzed form of collagen with mechanical and surface properties similar to skin
        - PVA - mechanical properties are tunable with soft tissue but mainly used for imaging techniques
    - Elastomers
        - Silicone - models are durable and tunable to skin properties
        - Silicone rubbers are an approximate substitute for human skin in terms of mechanical properties (Dragon Skin)
        - Polyurethane - viscoelastic properties make this material an excellent mechanical model (Lorica artificial leather)
    - Combinations
        - Silicone and polyurethane - reproduce mechanical behavior of human skin
        - PVA and silicone - mimic mechanical properties of skin
        - Polyvinylidene fluoride and silicone - represent skin and soft tissue
- Conclusion
    - Development of skin models is essential
    - Skin models can typically only mimic human skin in one or a few aspects

Conclusions/action items:

I think the team should consider silicone or polyurethane skin models or a combination of the elastomers because this article highlights these materials as the best for mimicking the mechanical properties of skin.

Jurnee Beilke - Feb 02, 2020, 10:21 AM CST

41_129.pdf(776.1 KB) - download

Jurnee Beilke - Feb 02, 2020, 10:22 AM CST

Citation:

LIN, L., LI, J. and ZENG, X. (2017). The Development of Physical Skin Model for Biomechanical Applications. *Journal of the Society of Biomechanisms*, 41(3), pp.129-136.

02/09/20 Viscoelastic Properties of Skin

Jurnee Beilke - Feb 09, 2020, 9:53 PM CST

Title: Viscoelastic Properties of Skin

Date: 02/09/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore the properties of human skin in order for the team to find a suitable alternative to human skin for testing.

Content:

- Introduction
  - Skin displays viscoelastic, anisotropic mechanical behavior in vivo
  - Langer lines exist and demonstrate the anisotropy of skin
- Methods
  - The device fixes two jaws to the skin that are moved in opposite directions by motors
  - The force and displacement information is then recorded and processed
  - Device is characterized as simple, painless and non-invasive and connects clamps to the skin
  - Possibility of taking measurements on different parts of the body in different directions
  - Maximum force: 4 N
  - Traction tests were followed by creep and relaxation tests
  - Results curve can be divided into three parts
    - The first is purely elastic deformation
    - The second is viscoelastic phase
    - The third is constant creep
  - The model is composed of three parts
    - Spring to represent the elastic part of skin
    - Spring and dashpot system that accounts for viscous part for the short term
    - Spectrum that comes into play for long-term effects
  - The anisotropy of skin is due to the elastic fibers not being distributed evenly
- Results
  - Comparison of model and experimental results demonstrate the validity of the model
  - For 80% of patients, the experimental values and model correlate
- Discussion
  - Results show that the viscoelastic model can account for the behavior of the skin
  - The model enables the simulation of anisotropy in 80% of patients

Conclusions/action items:

This paper is useful due to the viscoelastic model equations the paper contains. The team can likely use these equations when testing and modeling our skin alternative used for testing. The Kelvin-Voigt model or Standard-Linear models may also be useful.

Khatyr, F., Imberdis, C., Vescovo, P., Varchon, D. and Lagarde, J. (2004). Model of the viscoelastic behaviour of skin in vivo and study of anisotropy. *Skin Research and Technology*, 10(2), pp.96-103.

Jurnee Beilke - Feb 09, 2020, 9:51 PM CST

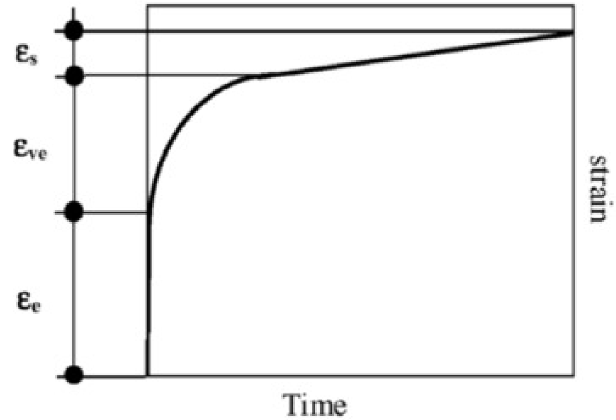


Fig. 2. Displacement of the skin under constant stress.

Screen_Shot_2020-02-09_at_9.50.07_PM.png(78.3 KB) - download

Jurnee Beilke - Feb 09, 2020, 9:52 PM CST

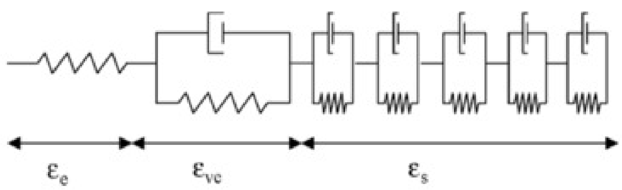


Fig. 4. Analogical model.

Screen_Shot_2020-02-09_at_9.50.21_PM.png(53.6 KB) - download

Jurnee Beilke - Feb 09, 2020, 9:52 PM CST

$$\varepsilon = \varepsilon_{\mathrm{e}} + \varepsilon_{\mathrm{ve}} + \varepsilon_{\mathrm{s}}$$

Screen_Shot_2020-02-09_at_9.50.37_PM.png(7.9 KB) - download

Jurnee Beilke - Feb 09, 2020, 9:52 PM CST

$$\sigma = E_{\mathrm{ve}} * \varepsilon_{\mathrm{ve}} + \eta * \dot{\varepsilon}_{\mathrm{ve}} \Rightarrow \varepsilon_{\mathrm{ve}} = \frac{\sigma}{E_{\mathrm{ve}}} * (1 - \exp(-t/\tau))$$

Screen_Shot_2020-02-09_at_9.50.42_PM.png(24.4 KB) - download

Jurnee Beilke - Feb 09, 2020, 9:52 PM CST

$$\varepsilon_s = A * \sigma * \left[1 - \sum_{i=1}^{5} a_i * \exp\left(-\frac{t}{b_i}\right)\right]$$

$$\text{with } \sum_{i=1}^{i=5} a_i = 1$$

Screen_Shot_2020-02-09_at_9.50.49_PM.png(39.6 KB) - download

Jurnee Beilke - Feb 09, 2020, 9:53 PM CST

Model of the viscoelastic behaviour of skin *in vivo* and study of anisotropy

Fouad Khatyr[1], Claude Imberdis[1], Paul Vescovo[1], Daniel Varchon[1], and Jean-Michel Lagarde[2]

j.1600-0846.2004.00057.x.pdf(217.4 KB) - download

04/14/20 Pain Receptors of Body

Jurnee Beilke - Apr 14, 2020, 9:09 PM CDT

Title: Pain Receptors of Body

Date: 04/14/20

Content by: Jurnee Beilke

Present: NA

Goals: To understand what parts of the body are the most sensitive to pain.

Content:

- Thermal and pain sensations in humans depend on impulses produced by receptors and conveyed to central nervous system
- The Marstock method - thermostimulator in contact with the skin allows for pain and temperature perception
- Thermode was placed into contact with skin by an elastic band at nine sites
    - face, thenar, forearm, upper arm, thorax, abdomen, thigh, leg, and dorsum of foot
- 150 volunteers (67 women and 83 men) were examined
- Temperature sensation was determined as the warm-cold difference
- Pain sensation was determined by cold pain and heat pain thresholds
- No sensation differences between the right and left side were found
- Females showed greater sensitivity than males
- Sensitivity to temperature was found to be age dependent but pain threshold was not affected by age
- Results demonstrated that the face area had the greatest sensitivity and the leg and foot had the least sensitivity
- Variation was considerable for sensation is a matter of interpretation of stimuli

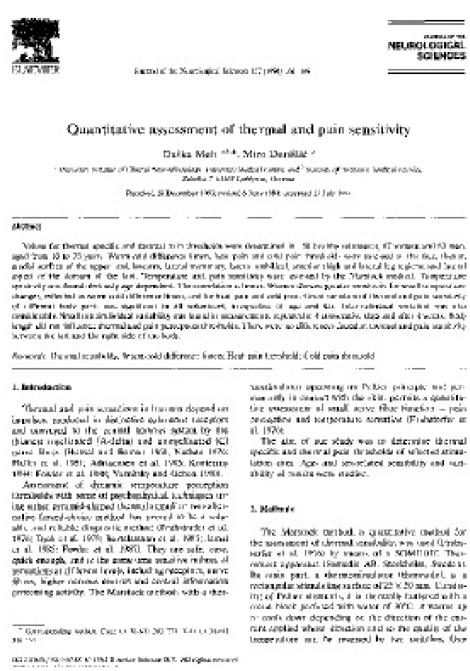
Conclusions/action items:

According to this paper, the face is the most sensitive to pain and temperature while the arms, legs, and torso hold intermediate sensitivity thresholds. I found it interesting that females are more sensitive than males, and age plays a role in sensitivity of skin.

Citation:

Meh, D. and Denišlič, M., 1994. Quantitative assessment of thermal and pain sensitivity. *Journal of the Neurological Sciences*, 127(2), pp.164-169.

Jurnee Beilke - Apr 14, 2020, 9:09 PM CDT


NEUROLOGICAL SCIENCES

Quantitative assessment of thermal and pain sensitivity

1. Introduction

2. Methods

1-s2.0-0022510X94900698-main.pdf(496.1 KB) - download

02/09/20 Device for Skin Approximation of Wounds

Jurnee Beilke - Feb 09, 2020, 9:27 PM CST

Title: Device for Skin Approximation of Wounds

Date: 02/09/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore any new existing devices on the market since last semester to make sure our device remains novel.

Content:

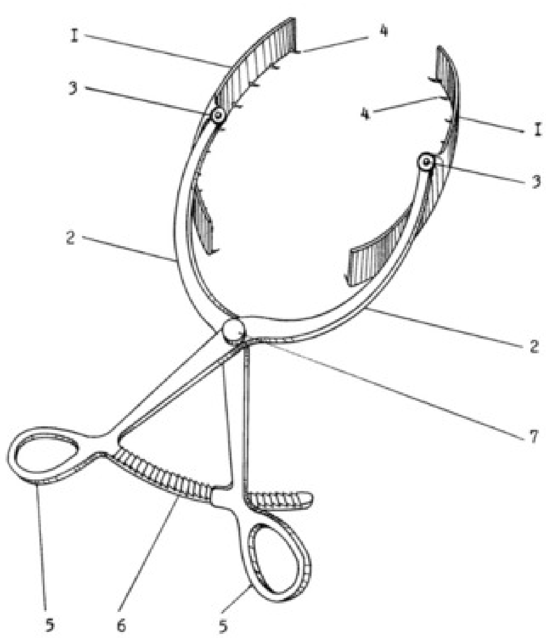
- Device comprises two branches, each with hooks facing towards the hooks of the opposite side
- The working parts are pivotally mounted and exist as interconnected crossed branches
- Device consists of curved elastic plates arranged with their surfaces perpendicular to the plane
- Hooks are equipped with the lower edge of the plate
    - Hooks are sharpened at the ends but are bent upwards

Conclusions/action items:

I am not sure if this device is commercially available. The patent is Russian. However, the team had an idea similar to this device (the hairpin design). This design has a much more threatening appearance than our design, especially with the hooks. The hooks might help the design grip the skin better, but they seem painful.

https://russianpatents.com/patent/219/2195203.html

Jurnee Beilke - Feb 09, 2020, 9:27 PM CST



Screen_Shot_2020-02-09_at_9.26.48_PM.png(190.8 KB) - download Figure 1: Image of the Russian design.

02/09/20 Codes and Standards

Jurnee Beilke - Feb 09, 2020, 9:32 PM CST

Title: Codes and Standards

Date: 02/09/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore the codes and standards the device needs to follow as outlined by the FDA.

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
- 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

02/16/20 Torsional Spring with Clip

Jurnee Beilke - Feb 16, 2020, 10:29 PM CST

Title: Clip using Torsional Spring

Date: 02/16/20

Content by: Jurnee Beilke

Present: NA

Goals: To examine how other devices use hinge mechanisms for variable widths.

Content:

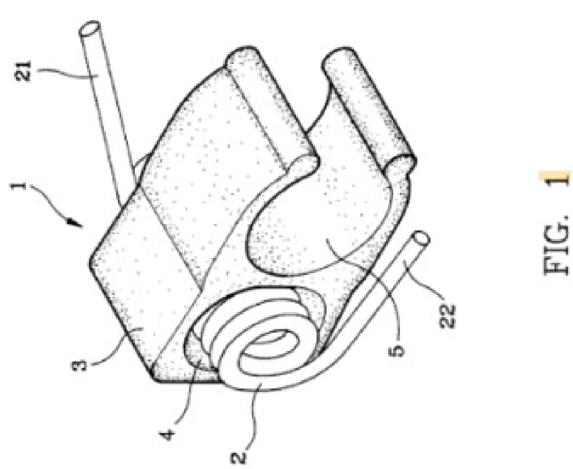
- US5666702A Patent
- Device contains a torsional spring with an attached clip
- The spring has a helical portion as well as a non-coiled portion (for attachment to the clip)
- The design is mainly to be used as a clamping apparatus
- Clip is designed to clamp and hold slim objects such as pens, screwdrivers, and pencils - our torsion spring can be adjusted for width to clamp wound edges together

Conclusions/action items:

I think the use of a torsion spring would simplify the fastening/hinge mechanism of our device. The current thumbscrews are clumsy and need to be redesigned. Attaching a torsional spring to the edges of the device may allow for improved ease of use.

https://patents.google.com/patent/US5666702A/en

Jurnee Beilke - Feb 16, 2020, 10:30 PM CST



Screen_Shot_2020-02-16_at_10.29.53_PM.png(44.5 KB) - download Figure 1: Example of the torsion spring.

Jurnee Beilke - Feb 16, 2020, 10:31 PM CST

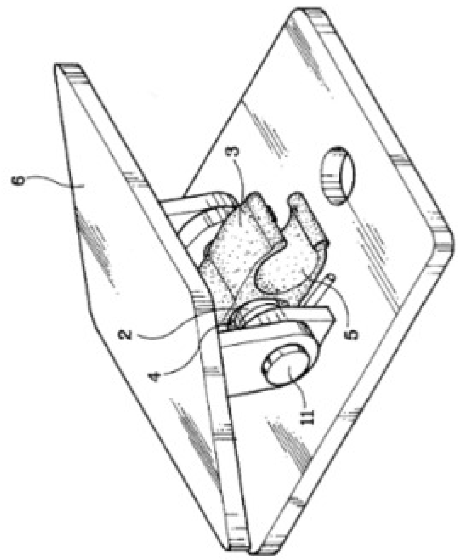


FIG. 2

Screen_Shot_2020-02-16_at_10.30.02_PM.png(56.2 KB) - download Figure 2: Example of the torsional spring in the clip.

Jurnee Beilke - Feb 16, 2020, 10:31 PM CST

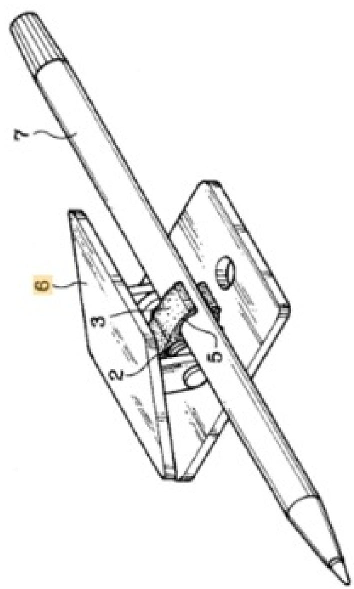


FIG. 3

Screen_Shot_2020-02-16_at_10.30.15_PM.png(50.2 KB) - download Figure 3: Example of clamping of slim object.

02/02/20 GeckSkin

Jurnee Beilke - Feb 02, 2020, 10:40 AM CST

Title: GeckSkin

Date: 02/02/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore GeckSkin as a possible skin adhesive for our device.

Content:

- A new super adhesive based on the mechanics of gecko feet
- An index card sized portion of GeckSkin can hold 700 pounds on a smooth surface
- Strong adhesion, yet easy and residue-free release
- The science
    - GeckSkin relies on draping adhesion - created with materials that can drape to create conformal contact with a surface while still maintaining high, elastic stiffness
    - Design enables adhesive loads to be evenly distributed across the pad surface
    - Rapid and low energy transition between attachment and detachment
- Composition
    - Stiff fabrics such as carbon fiber and Kevlar with soft elastomers such as polyurethane or PDMS
    - Combination of the soft elastomer with stiff fabric allows the pad to drape over a surface to maximize contact
    - The skin is woven into a synthetic tendon

Conclusions/action items:

While this material seems like an excellent candidate for our device adhesive, I am not sure the material is widely available to purchase or can be used with human skin. I cannot seem to find if this invention has been used on humans in the medical field. Overall, this material is quite inspiring!

https://geckskin.umass.edu/#zone-content

02/02/20 Silicone Gel for Skin Adhesion

Jurnee Beilke - Feb 02, 2020, 10:47 AM CST

Title: Skin Silicone Gel

Date: 02/02/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore skin adhesive options.

Content:

- When exploring GeckSkin products, I came across this silicone gel
- The design appears to be a sort of tape/bandage made of silicone that is removed from release paper and applied to the skin
- This product is commercially available
- The silicone gel is medical grade and gentle on skin
    - Grip and peel repeatedly
- Sheet size is 8.5 x 11"
- The price is $20

Conclusions/action items:

I think this is an interesting option to allow our device to adhere to skin. The silicone gel could be cut and applied to the edges of the wound, and the device edges could be placed on the gel and drawn together. I think the team should order some and test it out considering the cost is reasonable.

https://www.buygeckskin.com/geckskin-products/silicone-gel-to-grip-amp-peel-human-skin

Jurnee Beilke - Feb 02, 2020, 10:48 AM CST

geckpeel.jpg(98.9 KB) - download

Jurnee Beilke - Feb 02, 2020, 10:48 AM CST

geckpeel1.jpg(123.3 KB) - download

02/05/20 How to Pick a Journal to Publish

Jurnee Beilke - Feb 05, 2020, 6:55 PM CST

Title: How to Pick a Journal to Publish

Date: 02/05/20

Content by: Jurnee Beilke

Present: NA

Goals: To understand the steps to pick a journal to submit our paper/device to by the end of the semester.

Content:

1. Create a list of available journals in your subject area and the types of articles published in them

2. Consider the quality of your article and the typical articles published in those journals

3. Establish what journal impact factor you are trying to achieve

4. Make sure the aims and values of the article match that of your paper

5. Research and explore the articles previously published by that journal

6. Explore aspects of the journal such as the peer review process, instructions to authors, open access options, audience of the journal, and acceptance rates

7. Prepare a final list of journals that meet all requirements

Conclusions/action items:

I now have a better idea of how to approach the task of picking a journal to publish our article.

https://www.editage.com/insights/how-do-i-choose-a-proper-journal-to-publish-my-research-paper

02/05/20 Journal Options

Jurnee Beilke - Feb 05, 2020, 7:43 PM CST

Title: Journal Options

Date: 02/05/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore what journals we can submit our paper to at the end of the semester.

Content:

Journal of Biomedical Engineering and Medical Devices

- Academic journal providing the opportunity to researchers to explore the latest research developments
- Journal is of high standards in terms of quality
- The journal publishes articles with a variety of subjects including:
    - Bio-instrumentation, biomaterials, nano-materials, biomechanics, cellular tissue engineering, medical electronics, clinical engineering, as well as many more
- Open access and peer-reviewed international journal
- The journal is dedicated to providing the advancements of scientific knowledge concerning biomedical sciences
- Online review and editorial tracking systems are used for quality review process

https://www.longdom.org/biomedical-engineering-medical-devices.html

The Journal of Medical Devices

- Presents papers on medical devices that improve diagnostic and therapeutic treatments
- The focus of the journal is on applied research and the development of new medical devices
- Journal provides coverage of novel devices that allow new surgical strategies, new drug delivery, reductions in complexity/cost, or adverse results of healthcare
- Design innovation category features papers focusing on novel devices
- The scope of the journal includes:
    - Orthopedic, cardiovascular, rehab, neurological, and other medical devices

https://asmedigitalcollection.asme.org/medicaldevices/pages/about

Nature Biomedical Engineering

- Integrating the life sciences, physical sciences, and engineering
- The journal covers materials, therapies, devices, technology, systems, methods, and processes that facilitate the understanding of human disease prevention, diagnosis, and treatment
- Focus is to disseminate biological, medical, and engineering advances that inspire improvements in human healthcare
- Emphasis is placed on advances that draw on both the biomedical sciences and the physical sciences, engineering, and informatics
- The journal is highly regarded and articles will be excluded whose relevance for healthcare is judged to be insufficient

https://www.nature.com/natbiomedeng/

Biomedical Research

- Journal focus is on understanding and accelerating the medical research and associated subjects
- Biomedical Research is a unique platform to collect and disseminate scientific understanding on biomedicine and related disciplines
- The journal is open access which renders a global platform for academicians, researchers, and students
- The scope of the journal is to provide a scientific communication medium to discuss and share advancements in the biomedical sciences
- Aim to assemble precise, specific, and detailed data on this subject
- The journal is an interdisciplinary research journal for publication of original research work in biomedical sciences

http://www.biomedres.info/

Conclusions/action items:

After researching several of the more popular journals for biomedical engineering, I think the team should work to publish within the Journal of Medical Devices or the Journal of Biomedical Engineering and Medical Devices. Both journals have values and scope that match the team's project and goals this semester. Additionally, these journals encourage the publication of novel devices such as our wound approximating device.

02/05/20 Skin Adhesivses

Jurnee Beilke - Feb 05, 2020, 8:13 PM CST

Title: Skin Adhesives

Date: 02/05/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore/brainstorm ideas for device adhesion to skin.

Content:

- After exploring the internet, I stumbled upon double-sided fashion tape
- Essentially, one side of the tape sticks to skin while the other side sticks to the fabric of clothes
- There are multiple brands available, but I think the team could consider using this design for our device to adhere more easily to skin

- Fearless Tape (Amazon)
    - Holds to clothing steady
    - Strip size 1/2" wide x 3" long
    - Safe on skin - adhesive is designed to be safe on skin and not cause irritation or residue
    - Extra strength formula is designed to keep clothes in place all day
    - The double-sided tape adheres to clothes and skin

https://www.amazon.com/Fearless-Tape-Double-Sided-Fashion/dp/B01K2CMFVM

- Hollywood Fashion Tape (Joann)
    - Easy-to-use
    - Clear, double stick tape
    - Special formula is gentle on skin and hypoallergenic
    - Strips are 3" long

https://www.joann.com/hollywood-fashion-tape-the-original-36-dbl-stick-strips/7689474.html

- After a bit more research, I found medical grade double sided tapes that could work for the design
- The clinician can simply peel the release paper off and place one side of the tape on the device and the other side on the patient's skin to assist the device in gripping the skin
- The tape could then be easily removed before sterilizations and further use

- Medical Grade Adhesive Tape (Amazon)
    - Medical grade double clear tape roll
    - 1" width but can be cut down to the correct sizing
    - Tape is designed for sensitive skin

https://www.amazon.com/Vapon-Topstick-Double-Medical-Adhesive/dp/B017Q19UHY

- Double Sided Medical Tape (Parafix)
    - Double sided tape offers reliable adhesion to skin as well as to films, plastics, and metals
    - Tape strengths offer permanent or temporary attachment of two substrates and are ideal for stick to skin and device assembly applications
    - The tape is hypoallergenic, breathable, and conformable
    - Adhesive can be gentle or aggressive depending on the length of wear
    - Rubber, acrylic, and silicone adhesives
    - Clinically tested
    - Sterilized by gamma radiation and steam
    - Fluid resistant

- Clean removal

https://parafix.com/product-groups/medical-grade-materials/double-sided-medical-tape/

Conclusions/action items:

After exploring several options, I think the team could experiment with double-sided skin tape with the cheaper fashion tapes before ordering a custom medical grade tape from Parafix for use with our device.

02/24/20 Viscoelastic Models

Jurnee Beilke - Feb 24, 2020, 1:32 PM CST

Title: Viscoelastic Models

Date: 02/24/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore viscoelastic models for skin, which incorporate both elastic solid and viscous fluid.

Content:

Viscoelastic models incorporate the properties of two components; one of which is the spring representing the elastic solid and the second is the dashpot which represents the viscous liquid . The first model is the Maxwell model that contains a spring and a dashpot in series. This model is good at predicting stress relaxation behavior but poor at predicting creep behavior of viscoelastic materials. The second model is Kelvin Voigt which contains a spring and a dashpot in series. This model is good at predicting creep behavior but poor at stress relaxation predictions. Finally, there is the Standard Linear model which contains a spring in series with a dashpot that are both in parallel to another spring. The Standard Linear model is good at predicting both stress relaxation as well as creep.

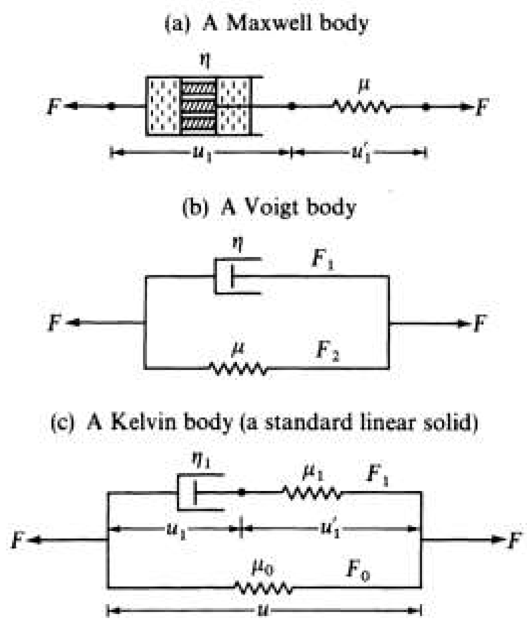


Figure 1: Viscoelastic models with springs and dashpots.

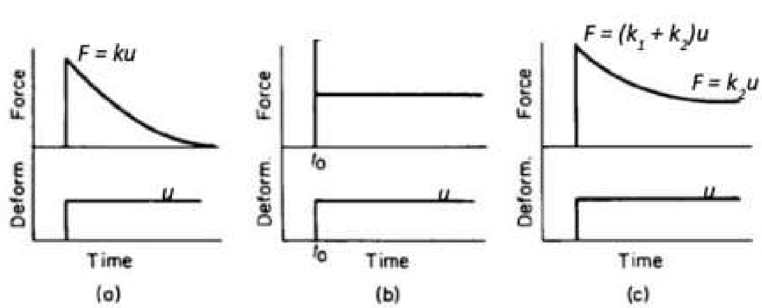


Figure 2: Mechanical responses of viscoelastic models.

Please view the attached pictures for the derivation of the viscoelastic model equations below.

Conclusions/action items:

I think the viscoelastic models above should be used during the testing portion of our design project because skin is viscoelastic instead of HILE (homogeneous, isotropic, linear, elastic).

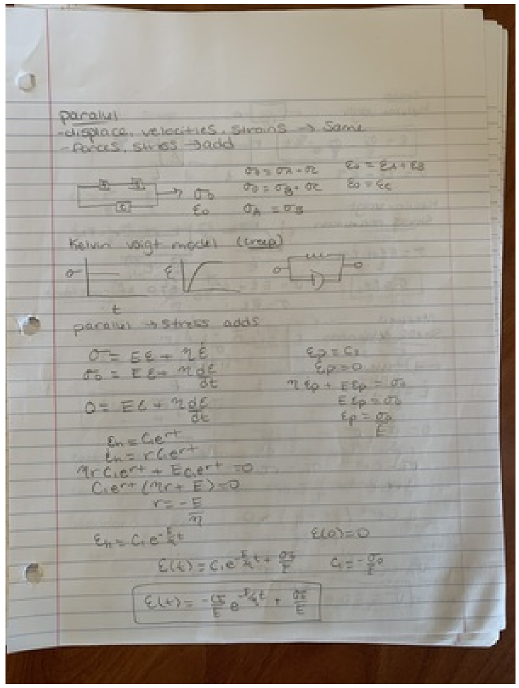
Citations:

Özkaya, N., Nordin, M. and Leger, D. (1999). *Fundamentals of Biomechanics*. New York, N.Y.: Springer-Verlag.

Fung, Y.C. (1993). *Biomechanics: Mechanicals Properties of Living Tissues.* New York: Springer-Verlag New York, Inc.

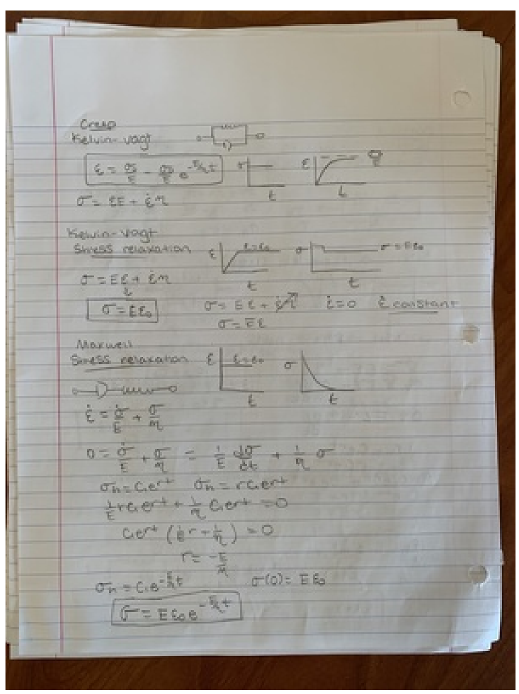
En.wikipedia.org. (2020). *Standard linear solid model*. [online] Available at: https://en.wikipedia.org/wiki/Standard_linear_solid_model [Accessed 24 Feb. 2020].

Jurnee Beilke - Feb 24, 2020, 1:20 PM CST



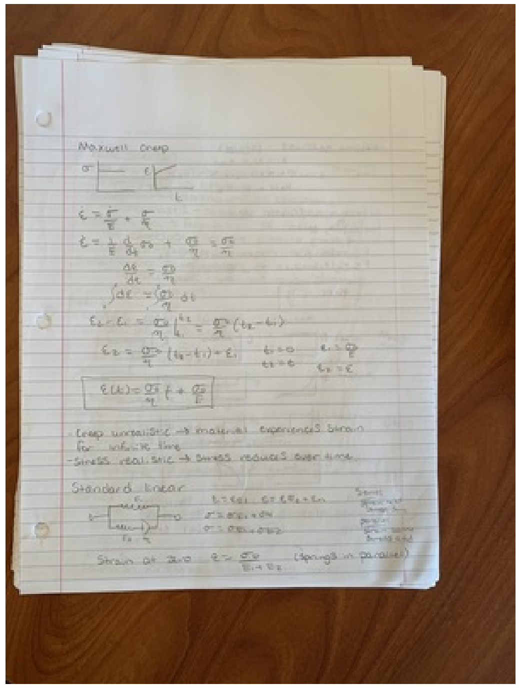
IMG_5175.jpg(2.4 MB) - download Viscoelastic models: Kelvin Voigt creep response

Jurnee Beilke - Feb 24, 2020, 1:20 PM CST



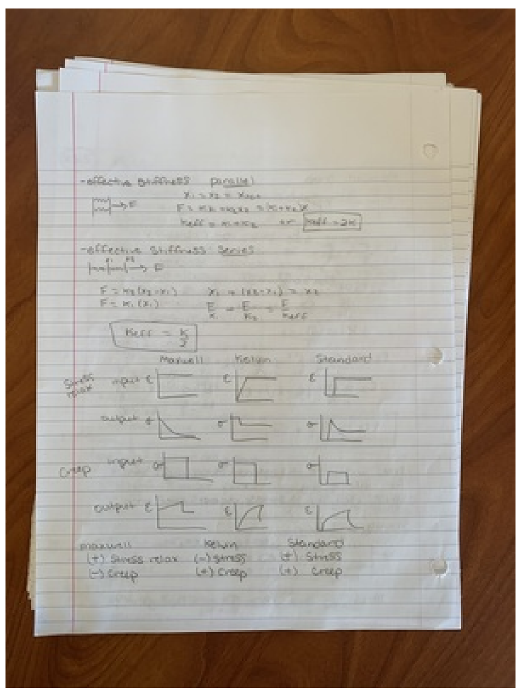
IMG_5176.jpg(2.2 MB) - download Viscoelastic models: Kelvin-Voigt stress relaxation and Maxwell stress relaxation

Jurnee Beilke - Feb 24, 2020, 1:21 PM CST



IMG_5177.jpg(2.3 MB) - download Viscoelastic models: Maxwell creep response

Jurnee Beilke - Feb 24, 2020, 1:22 PM CST



IMG_5178.jpg(2.3 MB) - download Viscoelastic model responses to creep and stress relaxation

02/24/20 Silicone Skin

Jurnee Beilke - Feb 24, 2020, 2:39 PM CST

Title: Silicone Skin Model

Date: 02/24/20

Content by: Jurnee Beilke

Present: NA

Goals: To find commercially available silicone models to use for testing.

Content:

https://www.smooth-on.com/products/ecoflex-gel/

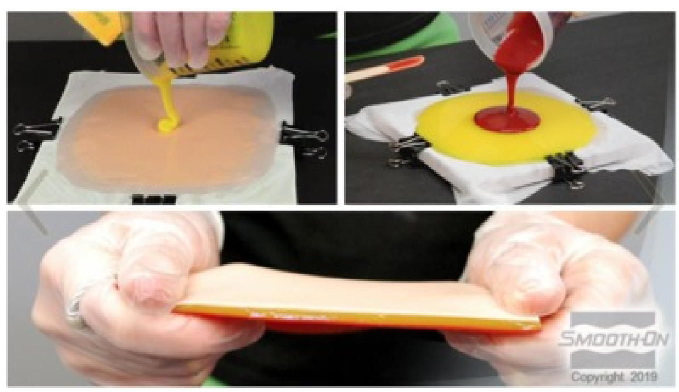
Ecoflex

- Soft, platinum silicone rubber gel
- Skin safe
- Shore hardness 000-35
- Silicone gel for filling encapsulated makeup appliances and prosthetics
- Ecoflex can be tacky when cured
- Preparation
    - Materials should be stored/used at room temp (23 C)
    - Limited shelf life
    - Pre-mix part B then mix required amount of Parts A and B into mixing container
    - Allow to cure for 2 hours at room temp before demolding

Conclusions/action items:

I think Ecoflex could be a functional option for our design testing.

Jurnee Beilke - Feb 24, 2020, 2:16 PM CST



Screen_Shot_2020-02-24_at_2.15.59_PM.png(1.2 MB) - download Image of Ecoflex being used to simulate skin.

02/29/20 Spring Exploration

Jurnee Beilke - Mar 02, 2020, 4:44 PM CST

Title: Spring Exploration

Date: 02/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To buy some springs that could possibly be used in our device.

Content:

- This weekend, I went to Ace Hardware and purchased a variety of springs
    - Extension, torsion, and compression
- I searched around and purchased all of the small size springs I could find in the store (see image below)
    - 6 extension springs
    - 3 compression springs
    - 2 torsion springs
- I next attempted to incorporate the springs into our design to allow the design to be easily opened and placed around the wound
    - I was able to incorporate 2 extension springs in the device as a proof of concept (see image below)
    - I am hoping to meet with the team this week to play around more with the springs and see which if any will work for our design and decide what parts need to be fabricated for the device to function

Conclusions/action items:

I feel more at easy about the device knowing that we have springs to try and that I was able to incorporate 2 springs relatively easily. Hopefully, the team will have some interesting ideas as well!

Jurnee Beilke - Mar 02, 2020, 4:44 PM CST

IMG_5231.JPG(3.9 MB) - download Figure 1: The springs I purchased from Ace Hardware.

Jurnee Beilke - Mar 02, 2020, 4:45 PM CST

IMG_5232.JPG(2.1 MB) - download Figure 2: My idea of incorporating a tension spring into the device.

03/14/20 Adhesive Ideas

Jurnee Beilke - Mar 14, 2020, 11:58 AM CDT

Title: Adhesive Ideas

Date: 03/14/20

Content by: Jurnee Beilke

Present: NA

Goals: To explore new adhesive ideas for attaching the device to skin.

Content:

Instead of the large adhesive bumpers we used last year, I think the team could use a double sided tape to secure the device to the patient's skin. This morning I experimented with Scotch double-sided tape. First, I placed the tape on each skin-contacting side of the device. Then I placed the device on my own skin (with the help of my parents) and moved my arm around to test how well the device could remain in place. The tape seemed to effectively hold the device in contact with my skin. Also, the tape only takes seconds to put into place and is easy to remove.

Conclusions/action items:

I think a medical-grade double sided tape could be an alternative adhesive to the silicone bumpers from the last prototype.

Jurnee Beilke - Mar 14, 2020, 11:56 AM CDT

IMG_5361.JPG(2.4 MB) - download Figure 1: Device in place on my arm using double-sided tape.

03/29/20 Adhesive Tape

Jurnee Beilke - Apr 06, 2020, 11:20 AM CDT

Title: Adhesive Tape

Date: 03/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To determine which tape works the best to adhere to skin based on the supplies I have at home during safer at home in Wisconsin.

Content:

- My dad and I found some double sided tapes to try in order to determine what works best to adhere to skin to maintain the device in place
- There were 4 types of tape used
- Type 1: Scotch mounting tape
    - This tape was clear, flexible, and squishy/gelatin-like in texture
    - The tape almost felt like silicone gel
    - This tape stuck the best during my experimental trials
    - https://www.fleetfarm.com/detail/scotch-clear-mounting-tape/0000000276277?Ntt=scotch%20mounting%20taoe
- Type 2: Trimbrite molding repair tape
    - This tape was dark in color and not clear
    - The tape was not as flexible as the first tape and did not stick to skin as well
    - https://www.fleetfarm.com/detail/trimbrite-molding-repair-tape/0000000050783?Ntt=tape
- Type 3: Duck mountain tape
    - This tape was foamy in texture and white in color
    - The tape was soft, but did not adhere well to skin
    - https://www.fleetfarm.com/detail/duck-white-removable-mounting-tape/0000000294142?Ntt=duck%20mounting%20tape
- Type 4: Scotch double-sided tape
    - This tape was the easiest to use
    - The tape was thin and adhere decently well to the skin
    - https://www.fleetfarm.com/detail/scotch-0-5-in-x-250-in-double-sided-tape-dispensered-roll/0000000205447?Ntt=tape

Conclusions/action items:

The best working tape was the Scotch double-sided mounting tape since it adhered the best to skin and the device, so I used this adhesive for testing the device.

03/29/20 Testing Summary

Jurnee Beilke - Apr 06, 2020, 10:59 AM CDT

Title: Device Testing

Date: 03/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To test the device in as many way as the team planned to gather data.

Content:

- Since there is a pandemic, I am isolating at home with both my parents, so they were my subjects for testing
- The first test I ran was the device displacement during use
    - Since I do not have the SkinPrep at home with me (still in Madison), I was only able to test the bare skin condition
    - I placed the device on several locations of my parents bodies and marked the start and end locations of the device over a 5 min interval and measured the distance with a calipers
- The second test I ran was the discomfort scale
    - I placed the device on the forearm of my parents and asked them to rank their pain on the provided scale
    - I chose the forearm because it is a more sensitive area of the body
- The last test I ran was the ease of use
    - I had my parents use the device on my arm and rank how intuitive the device was to use and how easy it was to apply to my skin/wound

Data: See the attached file for data and notes.

Conclusions/action items:

Overall, the device did not move a major distance during use, but the device still moved slightly which is not optimal. The device also did not cause major pain/harm, and was found to be relatively easy to use by both my parents.

Jurnee Beilke - Apr 06, 2020, 11:02 AM CDT

Table 1. Device displacement data for bare skin

Location	Subject 1	Subject 2
Lateral forearm	0.5 mm	0.3 mm
Upper Arm	1.1 mm	1.0 mm
Thighs	0.1 mm	0.3 mm
Calves	0.6 mm	0.4 mm
Torso	0.4 mm	0.1 mm

Table 2. Discomfort level scores during approximation

Subject	Pain Rating
1	1
2	1

Subject 1 notes: slight discomfort during use

Subject 2 notes: slight discomfort during removal

Table 3. Ease of use scores

Subject	Ease of Use
1	2
2	1

Subject 1 notes: The double sided tape was tricky to figure out - why is it needed, how to place it? After exploring she could see that the tape was used to adhere to skin and the device itself was easy to understand and use with the addition of springs, but the tape was a challenge.

Subject 2 notes: It was self-explanatory what the device needed to do, but the tape was problematic.

Device_Testing_Data.pdf(51.6 KB) - download

Jurnee Beilke - Apr 06, 2020, 11:05 AM CDT

IMG_5540.jpg(2.1 MB) - download Device markings on skin.

Jurnee Beilke - Apr 06, 2020, 11:05 AM CDT

IMG_5541.jpg(1.8 MB) - download Device markings on skin.

Jurnee Beilke - Apr 06, 2020, 11:06 AM CDT

IMG_5542.jpg(1.8 MB) - download Device markings on skin.

Jurnee Beilke - Apr 06, 2020, 11:07 AM CDT

IMG_5547.jpg(2.1 MB) - download Device markings on skin.

03/29/20 Protocols

Jurnee Beilke - Apr 24, 2020, 4:42 PM CDT

Title: Testing Protocols

Date: 03/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To detail the testing protocols used for device displacement, discomfort scale, and ease of use.

Content:

Device Displacement

Device displacement during life in service was quantified. One condition with bare skin was tested for displacement. To test on bare skin, the prototype was placed on an individual and the sides of the device were released until the skin was raised to simulate wound approximation. Lateral forearms, lateral upper arms, ventral torso, ventral thighs, and dorsal calves were included during testing. Markings were placed on the skin on either side of the device to denote the starting position. After the five minute interval was completed, new markings were made to denote the final position of the device. The distance between the original and final markings were recorded to determine how much the device moved and slipped while in use. This procedure was then repeated two times. This test determined how much the device moved while in service, and if the device remained on the skin while in use.

Discomfort Scale

Pain level was measured during skin approximation to ensure that the device was not causing patients harm. The team developed a zero to five point scale to quantify the comfort of the device. The device was tested for discomfort on the lateral forearm of two individuals, for the arm has comparable if not more sensitivity to pain than the torso and legs. While in place, the individual was asked to rank their pain level according to the scale. These scores were recorded and averaged to determine the overall comfort of the device during use.

Ease of Use

The team had two individuals operate the device on another person's skin and rate it on a scale from one to ten based on how intuitive the design is. A rating of one implies the device is simple and easy to use alone, and a rating of ten implies the device is extremely difficult or impossible to use without assistance. This testing allowed the team to see if the operation of the device is intuitive and if there are any major complications with the design.

Conclusions/action items:

These testing protocols should provide the team with preliminary feedback on the effectiveness of the device, which can be analyzed and interpreted in the results.

03/29/20 Results

Jurnee Beilke - Apr 24, 2020, 4:47 PM CDT

Title: Testing Results

Date: 03/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To provide the results from the testing I completed at home with my parents.

Content:

Device Displacement

Upon analyzing the total displacement of the device on skin after a five minute period, an average displacement of 0.48 ± 0.34 mm was measured for bare skin. The average displacement for the forearm was 0.4 mm, the upper arm was 1.05 mm, the thigh was 0.2 mm, the calf was 0.5 mm, and the torso was 0.25 mm.

Discomfort Scale

An average pain score of 1.0 out of 5.0 during device use was found. Subjects noted that there was only slight discomfort during use and removal. Upon removal, shallow indentations were observable in the individual's skin for up to two minutes after use.

Ease of Use

An average ease of use score of 1.5 out of 10.0 during device use was found. Subjects noted that the double-sided tape was the trickiest part of the device to understand and use. The removal of the peel paper on the tape was difficult.

Conclusions/action items:

The results indicate that the device remained in place during use, the device did not cause pain to patients, only mild discomfort, and the device was relative easy to use, but the double-sided tape posed a challenge for use of the design.

03/29/20 Conclusions

Jurnee Beilke - Apr 24, 2020, 5:02 PM CDT

Title: Testing Conclusions

Date: 03/29/20

Content by: Jurnee Beilke

Present: NA

Goals: To discuss the implications of the results from my testing.

Content:

Since the device will be used to approximate wounds 2 cm to 5 cm in length and utilizes an improved adhesive compared to previous prototypes, the average displacement of 0.48 mm from the initial position seems relatively insignificant. This indicates that the device displaced a small yet detectable amount during approximation, and this issue of displacement must be addressed in the future. A goal for improvement in function would be to achieve maximum displacement of zero during the 5 minutes of service. Ideally, the device would remain in the initial position throughout its entire time in use to maintain approximation without any gaps. Additionally, the device only caused slight discomfort to the users and did not harm the skin, which was an important design criterion that the team had established. For ease of use, the skin adhesive will need to be replaced with a medical grade tape that is easy to remove the peel paper. This will allow clinicians to easily apply the adhesive to the device and attach the device to the patient's skin.

Conclusions/action items:

In terms of device functionality, the displacement of the device from its initial position was detectable, yet relatively small. However, the device caused the patient minimal discomfort, and only left light markings on the skin. The device was also rated as easy to use by multiple subjects, which is important for the device will be used by a variety of clinicians.

04/24/20 Project Summary

Jurnee Beilke - Apr 24, 2020, 7:23 PM CDT

Title: Project Summary

Date: 04/24/20

Content by: Jurnee Beilke

Present: NA

Goals: To summarize the main aspects of this project including the problem, design criteria, motivation, and proposed solution.

Content:

Problem: Each year, six million laceration cases are treated in emergency departments. With lacerations larger than two centimeters, skin tension pulls the wound apart, making repair difficult without assistance. Clinicians often require a second individual to pull the edges of the wound together, also known as wound approximation, while repairing the wound. Precise wound approximation is imperative to ensure proper wound healing with minimal scarring. Currently, there are no devices on the market designed solely to approximate wounds, for competing designs complete wound closure as well as wound approximation.

Motivation: More than 10% of all emergency room visits involve the repair of a cut or laceration. During such repairs, skin tension pulls the wound apart while the clinician attempts to cleanly close the wound with sutures or tissue adhesives such as Dermabond. It is important to keep the edges of the wound close together without gaps while suturing or gluing in order to prevent heavy scarring, poor healing, and other complications. Aesthetically, patients do not want permanent scarring from wounds, especially on highly visible areas of skin, such as the arms or legs. Additionally, poor healing can increase a patient's risk for infection and extend the time required for healing.

Design Criteria: The overall goal of the design is to hold the wound edges together while a clinician is suturing or gluing. While doing this, the device must stay in place and not harm the skin or inflict pain on the patient. It needs to function for wounds between 2-5 centimeters for at least 350 uses- the estimated number of uses for one device in one year. Additionally, it must be reusable and therefore sterilizable. Thus, it should withstand standard autoclave sterilization: at least 30 minutes at 121°C. The final device must not weigh more than 0.23 kilograms (0.5 pounds) and should be fabricated within the $300 budget. Since the device will be used in a variety of settings with many populations, it should have a simple, clean, and non-threatening appearance. The design should also be easy to use by a variety of clinicians with varying backgrounds.

Proposed Solution: The proposed solution is a metal frame consisting of two identical stainless steel sides, which are connected via tension springs and thumb screws secured by hex nuts. The device works by having the user pull the sides of the device apart, place them around the wound, and the springs then pull the long sides together to approximate the edges of the wound. The device attaches to the skin via double-sided adhesives in order to prevent dislocation during use. Ideal locations for use of the device include the arms, legs, and torso. Preliminary testing demonstrated that the device was able to maintain approximation during a five minute interval, caused minimal discomfort to patients, and was easy to use as rated by multiple individuals. Further modifications and testing are required prior to device use in clinical settings.

Conclusions/action items:

I think this write-up provides a decent summary of our design project this semester, from the motivation to the proposed solution. This summary should help any readers of this notebook understand the basic principles of this project.

04/24/20 Design Impact

Jurnee Beilke - Apr 24, 2020, 7:33 PM CDT

Title: Design Impact

Date: 04/24/20

Content by: Jurnee Beilke

Present: NA

Goals: To explain the impact our design will have on the consumer market.

Content:

The main impact this device will serve is in clinical settings within the medical field. Small laceration closure often requires two physicians, one using forceps to bring together the edges of the wound, also known as approximation, and the other to complete closure. There are already shortages of physicians in emergency rooms, urgent care clinics, and office settings where these repairs often occur and requiring two physicians for a small wound repair is not an efficient use of time. Currently, there is a lack of devices on the market that function solely for wound edge approximation. Surgical tools such as forceps are not designed to approximate wound edges, for they require at least one of the clinician's hands to function during the wound approximation, leaving only one free hand to partake in the wound closure. Forceps and other surgical tools may also pinch the skin and be uncomfortable to the patient. Therefore, there is a gap in the market for a device that allows accurate and quick wound approximation while functioning autonomously once placed on the skin to provide the clinician with the use of both hands to participate in wound closure.

Conclusions/action items:

Overall, this device will allow clinicians the use of both hands during a laceration repair, which will free up the resources of additional clinicians who can in turn assist more patients. This device also has the potential of improving the outcomes of laceration repairs, both biologically and aesthetically.

Green Pass - Copy

Jurnee Beilke - Feb 10, 2020, 10:30 PM CST

Image.png(1.7 MB) - download

02/01/2020 Spring Research

KELLY STARYKOWICZ - Feb 01, 2020, 6:00 PM CST

Title: Spring Research

Date: 02/01/2020

Content by: Kelly

Present: Kelly

Goals: Research types of springs to learn more about them and see what kind we may want to use

Content:

- Torsion Springs: [1]
  - These are the types found in clothespins and mousetraps
  - They should be used in the direction in which the coils are wound
    - Left-hand wound: wind clockwise toward you
    - Right-hand wound: wind counter-clockwise toward you
  - Deflection angle: the angle between the legs of the torsion spring
    - Also represents the maximum rotation of the spring
    - This is because springs rotate until the legs of the spring are parallel
- Tension springs [2]
  - These are also known as extension springs and are used to lift heavy loads.
  - When a load is applied, the springs extend but resist the extension
  - Have different types of hooks on the ends
- Compression springs [3]
  - These are often used in medical devices, valves, and electronics.
  - They can be used to resist force or store mechanical energy.
  - They are the opposite of tension springs; their length is shortened so that the spring is compressed
  - They look very similar to tension springs

[1] "Carr," *McMaster*. [Online]. Available: https://www.mcmaster.com/torsion-springs. [Accessed: 01-Feb-2020].

[2] "What Are Tension Springs?," *The Spring Store*. [Online]. Available: https://www.thespringstore.com/what-are-tension-springs.html. [Accessed: 01-Feb-2020].

[3] "Conical Spring Manufacturer," *Stanley Spring and Stamping Corporation*. [Online]. Available: https://www.stanleyspring.com/compression-springs/. [Accessed: 01-Feb-2020].

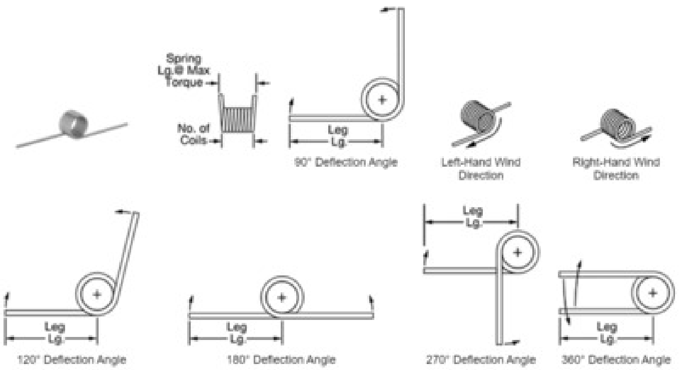
[4] "Extension Springs - Carbon & Stainless Steel Extension Spring Manufacturer: Century Spring Corp.," *Century Spring*, 13-May-2019. [Online]. Available: https://www.centuryspring.com/products/extension-springs/. [Accessed: 01-Feb-2020]

[5] "Compression Springs," *Compression Springs | Standard Compression Springs | Custom Compression Springs - Murphy & Read Spring Manufacturing Co.* [Online]. Available: https://www.mrspring.com/compression-springs.html. [Accessed: 01-Feb-2020].

Conclusions/action items:

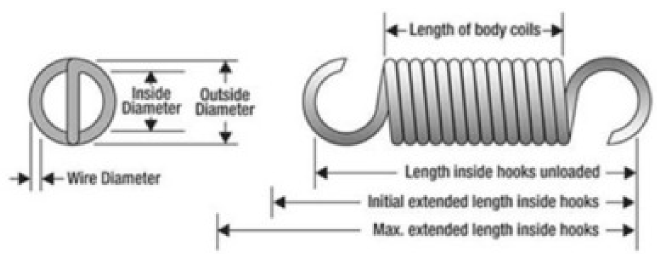
Based on my research, it looks like the Torsion Spring is the ideal spring for our device.

KELLY STARYKOWICZ - Feb 01, 2020, 5:29 PM CST



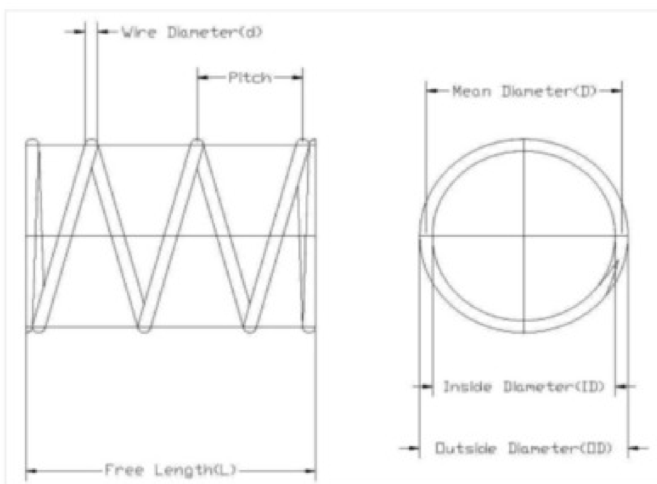
Torsion_Springs.PNG(96.3 KB) - download This image shows different types of torsion springs that vary in wind direction and direction angle [1].

KELLY STARYKOWICZ - Feb 01, 2020, 5:58 PM CST



Tension_Springs.PNG(111.4 KB) - download This image shows a torsion/extension spring and its general dimensions that can be changed [4].

KELLY STARYKOWICZ - Feb 01, 2020, 5:59 PM CST



Compression_Spring.PNG(122.1 KB) - download This image shows a compression spring and its general dimensions that can be changed [5].

02/01/2020 Torsion Springs Research

KELLY STARYKOWICZ - Feb 01, 2020, 10:39 PM CST

Title: Torsion Springs Research

Date: 02/01/2020

Content by: Kelly

Present: Kelly

Goals: Learn about torsion springs and their applications

Content:

- The free ends (or legs) of the torsion springs need to be attached to the device
    - When the legs are moved, the spring tries to push them back to their original position
        - We do not want the put any unnecessary strain on the device, so the resting position should be the position the device is in when the wound edges are approximated
- Can work in the clockwise or counter-clockwise direction
    - It is recommended that the force is applied in the direction of the wind
- When torsion springs wind up, their diameter decreases and and their overall length increases
- Common applications: clothespins, garage doors, clipboards, hinges
- Various configurations:
    - Leg angle
        - 0 degree leg angle = straight/parallel springs
            - Angle increases during unwinding
    - Leg length
        - Length of the free ends of the spring
    - Inside diameter
        - More important for when the spring needs to fit over a certain area (must fit within a minimum diameter)
    - Outside diameter
        - More important for when a spring needs to fit into a certain space (must fit within a maximum diameter)
    - Wire diameter
    - Body length
        - Length of the spring while at rest
- Spring properties:
    - Spring Rate- "the angular return torque provided per unit of angular displacements" (ex: in-lbs per degree)
    - Maximum Deflection- "max. angular deflection of spring to overstress"
    - Maximum Load- "the rated load at the rated maximum deflection"

Source: “Torsion Springs - Learn About: Lee Spring,” *Learn About | Lee Spring*. [Online]. Available: https://www.leespring.com/learn-about-torsion-springs. [Accessed: 02-Feb-2020].

Conclusions/action items:

We know that we want the resting position of the spring should be the position that the device is in when wound edges are approximated.

However, we need to learn more about spring constants and the spring dimensions and their effects to determine which configuration will be the most appropriate for our device.

02/01/2020 Torsion Spring Spring Constant

KELLY STARYKOWICZ - Feb 01, 2020, 11:01 PM CST

Title: Torsion Spring Spring Constant

Date: 02/01/2020

Content by: Kelly

Present: Kelly

Goals: Find the equation to calculate the spring constant of a torsion spring

Content:

Equation: **k = P*M/D**

k = spring constant (in-lbs/degree)

P = force exerted on spring (lbs)

M = moment arm (inch)

D = deflection (degrees)

See attached image for a better idea of what these variables represent.

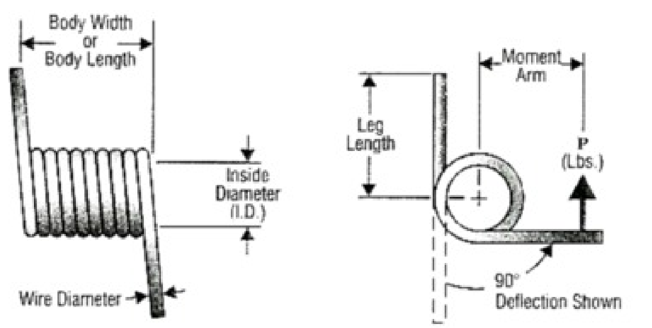
Source: Llc, "Torsion Spring Force Calculator and Formula," *Engineers Edge*. [Online]. Available: https://www.engineersedge.com/spring_torsion_calc.htm. [Accessed: 02-Feb-2020].

Conclusions/action items:

This equation should help us determine the necessary dimensions for the spring once we decide on the proper spring constant for our device.

The spring constant is critical to the function of the spring and therefore the device. We need to research and experiment to determine a suitable spring constant (k).

KELLY STARYKOWICZ - Feb 01, 2020, 10:58 PM CST



Torsion_Spring1.PNG(85.5 KB) - download Different views of a torsion spring to show its various dimensions.

02/05/2020 Journal Possibilities

KELLY STARYKOWICZ - Feb 05, 2020, 9:05 PM CST

Title: Journal Possibilities

Date: 02/05/20

Content by: Kelly

Present: Kelly

Goals: Learn about possible journals to have our article in

Content:

- Journal of Biomedical Engineering and Medical Devices
    - Open access and peer-reviewed
        - Editorial Tracking
        - 21 days rapid peer review process
    - Part of Longdom
- Journal of Medical Devices
    - Medical devices- specializes in novel devices that reduce complexity or cost or allow new strategies in surgery or drug delivery
    - It may be difficult to publish an article here as it is part of ASME (American Society of Mechanical Engineers)
- Journal of Medical Engineering and Technology
    - Open access journal
    - Looks like it might be more difficult to publish an article in this journal as it is part of Taylor & Francis
- Journal of Biomedical Science
    - Open access, peer reviewed
    - Part of BMC

Conclusions/action items:

From my research, it looks like the Journal of Biomedical Engineering and Medical Devices will be the easiest to get into and it still fulfills all of our requirements (rapid peer review, open access).

02/12/2020 Skin Properties

KELLY STARYKOWICZ - Feb 12, 2020, 4:52 PM CST

Title: Skin Properties

Date: 02/12/2020

Content by: Kelly

Present: Kelly

Goals: Find possible skin models that would work for testing our device

Content:

- The role of skin is to protect the body and receive stimuli from the surroundings
- 3 layers of skin tissue:
  - Epidermis: outer layer, major role is protection
    - The epidermis is thickest on the palms of the hands and the soles of the feet.
  - Dermis: major role is to support and strengthen the epidermis
  - Subcutis: a fat layer beneath the dermis that supplies nutrients to the other layers and insulates the body

Our device will be in contact with the epidermis. It should be able to function on limbs and the torso, regardless of the thickness of the epidermis layer.

- Skin changes throughout life:
  - In babies and young children, the skin is very smooth and soft. They do not sweat much. This is because there is very little sebaceous gland function.
  - During adolescence, hair growth begins/increases and the skin becomes more pigmented. This is when acne and sweating become more common. This is due to an increase in sebaceous gland function.
  - As people age, their lifestyles, as well as sun and wind exposure, cause the skin to become more dry and wrinkled.
- Skin differences based on location:
  - Skin varies based on its location.
  - The skin of the eyebrows is very thick, while the skin of the eyelids is very thin.
  - The skin of the soles of feet differ greatly from the skin of the arm.

Ideally, our device should be able to function on all of the above types of skin. It should function on everyone from young children to elderly adults, as well as on the skin of the arm to the skin on the foot.

- Skin surface:
  - The surface of the skin has an abundance of sweat glands, hair follicles, and skin lines.

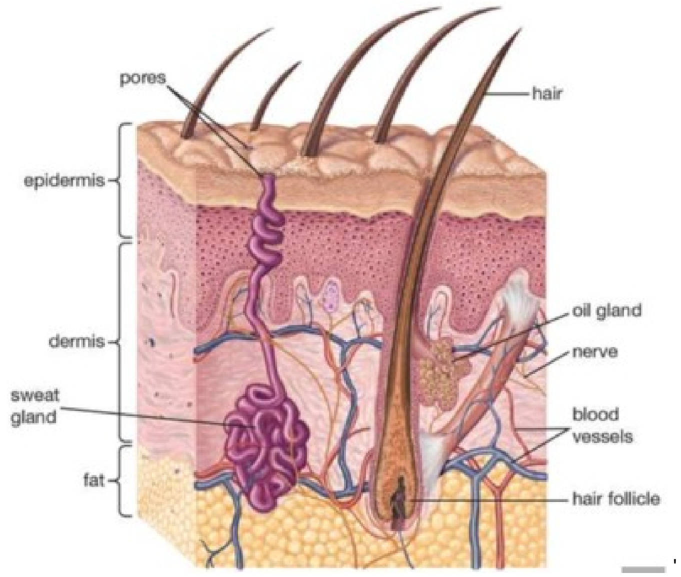
Our device should function on individuals with more or less sweat glands, hair follicles, and skin lines than the average person.

Source: W. Montagna and F. J. G. Ebling, “Human skin,” *Encyclopædia Britannica*, 11-Apr-2016. [Online]. Available: https://www.britannica.com/science/human-skin. [Accessed: 12-Feb-2020].

Conclusions/action items:

- Our device should be able to function on:
  - Limbs and the torso, regardless of the thickness of the epidermis layer.
  - All types of skin, from young children to elderly adults, as well as on the skin of the arm to the skin of the foot.
  - Individuals with more or less sweat glands, hair follicles, and skin lines than the average person.

KELLY STARYKOWICZ - Feb 12, 2020, 4:55 PM CST



Skin_Cross_Section.PNG(758.2 KB) - download An image of a skin cross section. This image shows the different layers and what they typically contain. SOURCE: W. Montagna and F. J. G. Ebling, “Human skin,” Encyclopædia Britannica, 11-Apr-2016. [Online]. Available: https://www.britannica.com/science/human-skin. [Accessed: 12-Feb-2020].

02/16/2020 Geckskin Research

KELLY STARYKOWICZ - Feb 16, 2020, 3:30 PM CST

Title: Geckskin Research

Date: 02/16/2020

Content by: Kelly

Present: Kelly

Goals: Learn about Geckskin and how it could be used for our device

Content:

- Geckskin is a powerful adhesive.
- It was designed based on the mechanics of gecko feet.
  - Geckos can climb vertically.
- A 4" x 6" piece of Geckskin attached to a smooth surface can hold 700 lbs and then be removed easily without leaving behind residue.
- It relies on draping adhesion, which is created with materials that drape so they can conform to the surface while maintaining high elastic stiffness in directions where forces are applied.
  - This allows loads to be evenly distributed across the adhesive, as well as a rapid and low-energy transition when the adhesive is attached and detached.
- Geckskin is made of an integration between stiff fabrics (Kevlar, carbon fiber, etc) and soft elastomers (polyurethane or PDMS).

Source: https://geckskin.umass.edu/

- Geckskin is reusable.
- It has high shear strength and low peel strength.
- It can be made from a variety of materials depending on the application.
- Geckskin's structure is key to its ability to hold large loads.
- Its design utilizes van der Waals forces and is based on the anatomy of Geckos combined with mathematics.
- Limitations of Geckskin:
  - It will wear out over time. The specific time depends on its exact materials and what it is being used for.
  - Dirt interferes with its function and cleaning can reduce its lifespan.
  - It functions better on smooth surfaces than porous surfaces (increased surface area).
  - Water may interfere with functionality.
  - It will not "grip and peel human skin or hair."
    - **Note:** This may not work well for our device if this is the case.

Conclusions/action items:

While Geckskin is a great product, it may not work well for our device due to its limitations on human skin.

02/18/2020 Journal Guidelines

KELLY STARYKOWICZ - Feb 18, 2020, 8:55 PM CST

Title: Journal Guidelines

Date: 02/18/2020

Content by: Kelly

Present: Kelly

Goals: Learn about the guidelines for the Journal of Medical Devices.

Content:

The Journal of Medical Devices is one journal within the American Society of Mechanical Engineers (ASME).

There is an ASME guide for all journal entries to follow.

Of the types of journals that ASME accepts, our journal would classify as a Design Innovation Paper. The recommended length for Design Innovation Papers is **7000 words**.

The paper must be in PDF format and submitted at journaltool.asme.org.

Font: 9 or 10 pt. Times Roman, justified, single line spacing

- Basic Elements of a Paper:
  - Title
    - Should be concise and definitive.
  - Author names and affiliations
    - Anyone who has contributed should be recognized as a co-author or in the acknowledgements.
    - Author name should consist of first name, middle initial, and last name.
    - Author affiliation should consist of University or company, mailing address, city/state/zip code, country name (not necessary if US), e-mail.
  - Abstract
    - 250 words maximum
    - Clearly describe the objective, scope, and results.
  - Body of paper
    - Should be organized into logical sections.
    - The purpose should be described at the beginning, then a description of the problem, the means of a solution, and any other information necessary to qualify the results and conclusions, then results and conclusions.
    - Headings and subheadings:
      - Should appear throughout paper to divide it into logical parts and emphasize major points.
      - Paragraphs should not be numbered, but sections can be.
    - Equations:
      - Should be numbered consecutively, beginning with (1) and including any appendices.
      - The number should be within parentheses and be in the right column on the same line as the equation.
      - Within the text, the equation should be referenced as "Eq. (x)"
        - However, if the reference is what begins a sentence, the word should be spelled out: "Equation (x)..."
      - All symbols should be defined, with units.
  - Acknowledgements
    - Individuals who have made an important contribution and have not been mentioned elsewhere should be recognized here.
  - Nomenclature
    - List should be in alphabetical order (capital letters before lowercase letters), followed by Greek letters, and subscripts and superscripts last.
  - Appendices
  - References
    - References should be cited in numerical order according to their order of appearance.

        - The numbered reference should appear in brackets: [1]
        - For two citations, the numbers should be separated by a comma: [2,3]
        - For more than two citations, the numbers should be separated by a dash: [5-7]
        - All references must include a DOI.
        - ASME primarily uses the Chicago Manual of Style for reference format.
        - References should be listed at the end of the paper; not in the footnotes.
    - Figures and tables
        - Figures:
            - Figures should be numbered consecutively and have a caption that states the figure number and a brief title or description.
            - Within the text, figures should be referenced as "Fig. 1".
                - However, if the reference is what begins a sentence, the word should be spelled out: "Figure 1..."
            - A separate list of figure numbers and their captions should be included at the end of the paper for production purposes.
            - ASME only accepts .tif and .eps files for images.
        - Tables:
            - Should be numbered consecutively and have a caption that states the table number and a brief title.
            - A separate list of table numbers and their captions should be included at the end of the paper for production purposes.
- Other elements:
    - SI units should be included.
        - If US units are given preference, the SI unit should be provided in parentheses or in a supplementary table.
    - Pages should be numbered.
    - Technical terms or phrases should be defined.
    - If first person is used, bias should be avoided.
    - Only mention company names in the acknowledgements.
    - The paper should be concise.
    - Avoid long quotations- refer to sources instead.
    - Omit lengthy data and calculations that are not crucial to understanding the subject.
    - Spell out acronyms on first use. Put the acronym in parentheses after the spelled-out term.

Sources:

https://www.asme.org/publications-submissions/journals/information-for-authors/journal-guidelines/writing-a-research-paper

https://www.asme.org/wwwasmeorg/media/resourcefiles/shop/journals/asme_guide_for_journal_authors_final.pdf

Conclusions/action items:

We need to be sure to stick to these guidelines when writing our paper.

03/11/2020 Skin Adhesive Research

KELLY STARYKOWICZ - Mar 11, 2020, 7:12 PM CDT

Title: Skin Adhesive Research

Date: 03/11/2020

Content by: Kelly

Present: Kelly

Goals: Research types of skin adhesives

Content:

We want an adhesive that can be used to attach the device to the skin during the time that it is in use. Therefore, the adhesive must:

- Be easily removable
- Not harm the skin
- Stick to both skin and stainless steel
- Be inexpensive, as it will not be reused

From my research, I found the following possible adhesives:

- It Stays- Body Adhesive
    - This adhesive is meant for skin and is used for holding up stockings and holding straps or hairpieces in place.
    - It is said to move with the skin and be pliable.
    - It washes off with water.
    - It has a roll-on application method.
    - It is non-toxic and hypo-allergenic.
    - Ingredients: Glycerin USP, Isopropyl alcohol, potassium sorbate, vinyl acetate
    - Costs $8.50 for 2 ounces.
    - https://www.brightlifedirect.com/products/it-stays-body-adhesive?variant=1949359669307&gclid=CjwKCAjwmKLzBRBeEiwACCVihs0PG_W_FQVxlj9bMlpPfo6WynbALtBkrOjfiZBPZEsbn7NpSEhCgxoCJCIQAvD_BwE
- Ben Nye Prosthetic Adhesive
    - This adhesive is meant to attach prosthetics to limbs.
    - It is advertised for prolonged wear of prosthetics and is sweat resistant.
    - It removes easily, but Ben Nye's Remove-It All is needed to do so.
    - Comes in a jar- would need a spatula or similar tool to apply it.
    - Ingredients: Acylic/Acrylates, Copolymer, Residual Monomers, Ammonium Hydroxide, Polyacrylate Thickener
    - Costs $8.00 for 1 fluid ounce.
    - https://camerareadycosmetics.com/products/ben-nye-prosthetic-adhesive?variant=22324444551&gclid=CjwKCAjwmKLzBRBeEiwACCVihsrcwelyetUvO7GeForHjoBFM58KI1feB1p-v8_DVbQT3nZMhOhMlhoCHFYQAvD_BwE
- Osto-Bond Skin Bond Latex Adhesive
    - This is a skin bond that is used to create a strong adhesion between skin and an appliance.
    - It is supposed to be sturdy and durable, while gentle on skin.
    - It is applied with a brush.
    - I cannot find information on how easy it is to remove, but it is described as being waterproof. Therefore, I imagine it may be more difficult to remove than other products.
    - Contains latex and zinc oxide.
        - NOTE: Ideally, we should not incorporate anything containing latex into our design, as allergies are common.
    - Costs $13.99 for 4 ounces.
    - https://www.medicalsupplydepot.com/Ostomy-Supplies-1/Bonding-Adhesive/Montreal-Ostomy-Osto-Bond-Skin-Bond-Adhesive.html

Conclusions/action items:

Of these three skin adhesives, I think that the It Stays Body Adhesive is the best one. It is easy to apply and remove, inexpensive, non-toxic, strong, and does not harm the skin, according to the website and many reviews of the product. My two main concerns for this product are (1) its application method- the roll on application is not ideal for our situation and (2) whether or not it would stick to stainless steel. Since stainless steel is very smooth and not textured like skin or a typical fabric, I fear that this adhesive- or any of the three adhesives above- would not stick to our device. I plan to show these websites to the team and see what their thoughts are.

04/26/2020 Types of Medical Adhesives

KELLY STARYKOWICZ - Apr 26, 2020, 10:18 AM CDT

Title: Types of Medical Adhesives

Date: 04/26/2020

Content by: Kelly

Present: Kelly

Goals: Learn about the different types of medical adhesives available.

Content:

The main improvement needed for our device right now is an improved adhesive. During the ease of use testing, the main complaint from our subjects was that the adhesive was difficult to use.

- Pressure Sensitive Adhesives (PSAs)
    - can be made up of many different materials
    - forms a bond by being pressed onto a surface (rather than requiring heat or water)
    - often used as bandages- can be woven or unwoven
    - there are double-sided PSAs as well
- Electrical Conductive Adhesives
    - these are compatible with electrodes and medical sensors
    - these often come as a gel or film
    - these adhesives are not necessary for our design, but could be tested with the device to compare to PSAs
- Synthetic Adhesives
    - Acrylics/cyanocrylates (CAs)
        - these are common adhesives for suturing wounds because they reduce scarring and infections
        - acrylic adhesives, like pressure sensitive tapes, are used for various disposable applications, like bandages
        - some acrylics are only to be used under dry conditions and others are for wet conditions
    - Silicones
        - commonly used for medical bonding
        - this material is popular because it is biocompatible
    - Polyurethanes
        - commonly used for bandaging
        - are resistant to water
- Biological Adhesives
    - these are used in surgical applications- often for suturing wounds and for skin grafting
    - these are made from a variety of proteins, such as fibrin, which is a common clotting material used for wound applications

Conclusions/action items:

For our current design, Pressure Sensitive Adhesives would probably be the most effective and efficient. We would want these to be made out of some type of synthetic adhesive; any of the three listed above would work. I would not recommend biological adhesives because they would make the process more expensive and would introduce a whole new set of FDA Codes that would need to be implemented.

04/26/2020 Codes and Standards

KELLY STARYKOWICZ - Apr 26, 2020, 9:33 AM CDT

Title: Codes and Standards

Date: 04/26/2020

Content by: Kelly

Present: Kelly

Goals: Learn about the codes and standards that apply to noninvasive medical devices like 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.

04/26/2020 Codes and Standards

KELLY STARYKOWICZ - Apr 26, 2020, 9:52 AM CDT

Title: Codes and Standards

Date: 04/26/2020

Content by: Kelly

Present: Kelly

Goals: Learn about the FDA's Codes and Standards for medical devices.

Content:

Everything involving our device is under Title 21 (Food and Drugs) of the Code of Federal Regulations.

- Part 800 provides general information for medical devices, including their requirements and the administrative procedures that surround them.
- Part 803 is about medical device reporting and the requirements that are needed for reporting.
- Part 806 is about reporting corrections and removals for medical devices
  - This would only be used if a correction needed to be made.
- Part 808 is about exemptions from Federal preemption of state and local medical device requirements
  - This could be helpful for launching the market for the device in the short-term, but overall would not be needed since the goal of the device is to be used in a variety of states and countries.
- Part 814 is about premarket approval for medical devices
  - This is one of the most important codes for our device! We would definitely need to learn a lot about this part when finalizing the design for use in clinics.
- Part 860 is about medical device classification procedures and how to correctly classify our medical device
- Part 880 is about general hospital and personal use devices
  - I believe our device could fall under this section, so we would need to be sure to follow these limitations and specifications.

Conclusions/action items:

Our design is not yet finalized, but if this project continues, the next team should take the above codes and standards into consideration when completing the design.

Of the standards listed above, the most important ones to consider are Parts 800, 803, 814, and 860. These four standards cover the general requirements for medical devices, the requirements for reporting on medical devices, premarket approval, and classification for medical devices.

01/25/20- Improvements to Design

KELLY STARYKOWICZ - Jan 25, 2020, 9:07 AM CST

Title: Improvements to Design

Date: 01/25/20

Content by: Kelly

Present: Kelly

Goals: List improvements that can be made to the design as we discussed at the end of last semester

Content:

- Research different types of fake skin to find one that more accurately represents human skin
    - We can use this to redo the MTS testing from last semester
- Research sterile adhesives that could replace the silicone bumpers
    - Need to be smaller than the cabinet bumpers we currently use
    - Need to either be (1) inexpensive and sterile when purchased, or (2) able to be sterilized in an autoclave
    - Consider making them in the Makerspace with a mold
        - This was Dr. Puccinelli's suggestion at poster presentations.
- Brainstorm how a hinge mechanism would work and decide if we are able to re-fabricate this semester

Conclusions/action items:

- Research the following:
    - fake skin models
    - sterile adhesives
    - hinge mechanism
- Need to get IRB clearance

01/29/2020 Semester Goals

KELLY STARYKOWICZ - Jan 29, 2020, 10:15 PM CST

Title: Semester Goals

Date: 01/29/2020

Content by: Kelly

Present: All

Goals: Set goals for the semester and lay out a timeline

Content:

- Research- will be done throughout the semester, but the team hopes to complete the majority of it by February 28th
    - Hinge/fastener options
    - Silicone bumper/adhesive alternatives
    - Possible synthetic skin models
    - Testing ideas
- Fabrication of new fasteners- complete before spring break
- Fabrication of new silicone/adhesive- complete before spring break
- Finalize testing methods- complete before spring break
- Order or fabricate a synthetic skin model- complete by March 27th
- Testing- complete by April 24th
- Journal article- complete by April 24th

Conclusions/action items:

The team will follow the above timeline throughout the course of the semester. By sticking to this timeline, we should be able to devote enough time to testing and writing the journal article.

02/22/2020 Clothespin Torsion Springs

KELLY STARYKOWICZ - Feb 22, 2020, 8:54 PM CST

Title: Clothespin Torsion Springs

Date: 2/22/2020

Content by: Kelly

Present: Kelly

Goals: Take apart some clothespins to observe the torsion spring.

Content:

When we explain our torsion spring idea to someone, it is almost always compared to a chip clip. Chip clips use torsion springs and are closed at resting position. Then a force is applied to open the ends of the chip clip and then released to close them again, usually to grasp onto an object. Clothespins are very similar to chip clips, so I bought a package at the grocery store to observe and take apart. I am listing my observations below and attaching images.

- The torsion spring itself is rather stiff; it is the length of the "legs" of the clothespin that makes it easier to operate.
    - We thought our side slotted pieces on our prototype were too long, but this may prove to be helpful for the ease of use. They would just function as a longer moment arm.
- The legs of the torsion spring point in the same direction (a 360 degree deflection angle) and are simply bent to fold into the clothespin and fit better into the design.
- This torsion spring has only 3 coils.
    - The torsion spring for our project should be about the same size, so 3 coils is a good starting point.

Conclusions/action items:

Based on my observations of the torsion spring within the clothespin, we should be able to use a torsion spring with a 360 degree deflection angle, 3 coils, and a stiffness no greater than that of the clothespin.

KELLY STARYKOWICZ - Feb 22, 2020, 8:45 PM CST

Snapchat-644441303.jpg(23.5 KB) - download Images of the torsion spring when assembled and unassembled from the clothespin.

KELLY STARYKOWICZ - Feb 22, 2020, 8:45 PM CST

Snapchat-1523405303.jpg(22.8 KB) - download Images of the torsion spring when assembled and unassembled from the clothespin.

KELLY STARYKOWICZ - Feb 22, 2020, 8:45 PM CST

Snapchat-1996034171.jpg(40.8 KB) - download Images of the torsion spring when assembled and unassembled from the clothespin.

KELLY STARYKOWICZ - Feb 22, 2020, 8:45 PM CST

Snapchat-1759040113.jpg(139.9 KB) - download Images of the torsion spring when assembled and unassembled from the clothespin.

02/22/2020 Clothespin Torsion Spring Stiffness

KELLY STARYKOWICZ - Feb 22, 2020, 9:32 PM CST

Title: Clothespin Torsion Spring Stiffness

Date: 02/22/2020

Content by: Kelly

Present: Kelly

Goals: Calculate the stiffness of the torsion spring within a clothespin.

Content:

I have found many different equations to calculate the spring constant of a torsion spring. I plan to use several of them and see what range of spring constants I calculate as a result. For the approximate force applied, I am going to use 8 Newtons, based on prior research that shows 6.5-7.8 Newtons would need to be applied to approximate wound edges.

Option 1:

Source: https://www.engineersedge.com/spring_torsion_calc.htm

k = P*M/Deg

where k = spring constant (in-lbs/degree), P = force exerted on spring (lbs), M = moment arm (inches), Deg = deflection angle (degrees)

1 Newton = 0.224809 lb-force

k = (0.224809 lb-force)*(0.75 in)/(360 deg) = <u>4.68 x 10^-4 in-lbs/deg</u>

Option 2:

Source: https://www.acxesspring.com/torsion-spring-rate-force-constant.html

R = Ed^4/10.8 DN

where R = spring rate per 360 degrees, E = modulus of elasticity for the wire (psi), d = wire size (in), D = mean diameter (in), N = number of active coils

<u>NOTE:</u> I could not find what type of metal is used for the torsion springs in the clothespins I bought. The packaging states they are "sturdy, galvanized, no rust wire springs." I am going to assume stainless steel, which has an elastic modulus of 28 x 10^6 psi.

R = (28 x 10^6 psi)(0.0625 in)^4/(10.8)(0.21875 in)(3 coils) = <u>60.282 pounds/degrees</u>

Conclusions/action items:

Based on my results, it is clear that I need to do more research to find a reliable equation to determine the spring constant of a torsion spring.

03/03/2020 Hinge Research

KELLY STARYKOWICZ - Mar 03, 2020, 7:02 PM CST

Title: Hinge Research

Date: 03/03/2020

Content by: Kelly

Present: Kelly

Goals: Learn about different types of hinges and which ones may work for our device.

Content:

Ideally, we want the top of our device to pivot on each side, rather than slide and pivot. We can accomplish this by simply filling the slot with a 3D printed piece, but we also want to look into different types of hinges to see if we could incorporate a hinge.

- Butt Hinge
  - These are the hinges typically used for doors.
  - Multiple butt hinges are typically used at once.
  - Has two rectangular metal plates joined by a pin or a rod
  - Case Hinges are very similar to butt hinges. They are just more decorative and visually appealing.
- Hospital Hinge
  - These are shorter than typical hinges and made out of stainless steel.
  - They function similar to butt hinges, but are more compact and have rounded edges.
- Knife Hinge
  - These are shaped like scissors.
  - They are commonly used as side support in the lids of toolboxes.
- Latch Hinge
  - These consist of a latch and a hinge combined.
  - They typically consist of a spring release or a spring-loaded handle that releases the body from the application.

There are a large amount of hinges on this website, but the above four are the ones that could work for our design.

Source: https://monroeengineering.com/info-hinges-types-of-hinges.php

Conclusions/action items:

From my research, it appears that a basic butt hinge or a knife hinge could be used in our design. I have attached images of these two hinges and will show them to the team to get their opinions.

KELLY STARYKOWICZ - Mar 03, 2020, 7:03 PM CST

Butt_Hinge.PNG(45.6 KB) - download Image of a butt hinge.

KELLY STARYKOWICZ - Mar 03, 2020, 7:04 PM CST

Knife_Hinge.PNG(49.6 KB) - download Image of a knife hinge.

03/26/2020 Project Background

KELLY STARYKOWICZ - Mar 26, 2020, 9:07 PM CDT

Title: Project Background

Date: 03/26/2020

Content by: Kelly

Present: Kelly

Goals: Provide background on the project

Content:

Wound approximation = when the edges of a wound are pulled together so that there are no gaps

Wounds over 1-2 centimeters in length splay because of skin tension. This is why wound edge approximation is necessary. If wound edges are not approximated properly, the wound will heal poorly and scarring may result.

In clinics and emergency rooms, wounds are commonly closed with sutures (stitches) or Dermabond. Dermabond is a liquid tissue adhesive that seals the wound and polymerizes about 30 seconds after application. Dermabond is becoming increasingly popular, especially with children, as it is less threatening and does not require any anesthesia. Both suturing and gluing with Dermabond requires the wound edges to be approximated first.

Conclusions/action items:

Our client, Dr. Charlton, came to us hoping that we would design a device that could be placed on/around a wound to approximate the wound edges while a clinician sutures or glues the wound.

03/26/2020 Design Criteria

KELLY STARYKOWICZ - Mar 26, 2020, 9:14 PM CDT

Title: Design Criteria

Date: 03/26/2020

Content by: Kelly

Present: Kelly

Goals: Discuss the design criteria for the project.

Content:

Our client, Dr. Charlton, came to us hoping that we would design a device that could be placed on/around a wound to approximate the wound edges while a clinician sutures or glues the wound.

She originally specified that she would like the device to function on wounds on the limbs and torso that are 2-5 centimeters in length.

From the client's specifications and our own research, we came up the following design criteria:

- Use on limbs and torso
- Wounds 2-5 cm long
- Withstand sterilization in an autoclave: at least 30 minutes at 121 degrees Celsius.
- Stay in place during wound approximation.
- Not inflict pain or harm the patient's skin.
- Function for approximately 180 uses- the estimated number of uses for a single device in one year (due to sterilization times)
- Be relatively lightweight- less than 230 grams.
- Fabricated within a budget of $300.

Conclusions/action items:

We need to design our testing plan around these criteria to ensure that our device is meeting the above specifications.

03/26/2020 Project Motivation

KELLY STARYKOWICZ - Mar 26, 2020, 9:24 PM CDT

Title: Project Motivation

Date: 03/26/2020

Content by: Kelly

Present: Kelly

Goals: Summarize the motivation for this project.

Content:

Various lacerations are common occurrences in emergency rooms and clinics. In order to suture or glue such a wound, clinicians must first approximate wound edges. This typically requires two physicians: one to approximate wound edges while another closes the wound. Clinicians have developed various ways to do this with one person, but these methods can be quite complicated and may not always be successful.

Reserving two clinicians to close one wound is not feasible in modern emergency rooms or clinics. These physicians are often very busy and understaffed. Our client, Dr. Charlton, came to us hoping that we would design a device that could be placed on/around a wound to approximate the wound edges while a clinician sutures or glues the wound. Therefore, with this device, only one physician would be needed to close a wound and it can be done rather easily.

Conclusions/action items:

Reducing the number of clinicians needed for each wound repair would be very helpful for clinics and emergency departments across the world. This would allow many physicians to direct their attention to a larger variety of patients and other pressing emergency cases.

2/12/2020 Gelatine-based skin substitute

Jack Fahy - Feb 25, 2020, 8:52 PM CST

Title: Gelatin-based skin alternative

Date: 2/12/2020

Content by: Jack

Present: Jack

Goals: Learn about a possible skin substitute for testing

Content:

The water content of human skin heavily impacts its properties. Many skin models neglect this aspect

Gelatin-based skin models can solve this problem. The Swiss Federal Laboratories for Materials Science and Technology have developed such a model. [1]

- The intent of this model was to replace the need for humans in textile testing
    - Normally, textile companies test the comfort and properties of their fabric by having human subjects rub it on their skin and studying how the subject's skin reacts.
    - As textile's react differently on skin depending on how wet the skin is, the moisture content of human skin is highly important in these tests.
    - A gelatin-based model that can simulate varying degrees of moisture in skin would eliminate the need for human subjects.
- The important aspect of this model for our team's purpose is that it mimics the frictional behavior of human skin against various materials.
- The model is made by embedding gelatin on a layer of cotton. To prevent the gelatin from dissolving when it contacts water, the gelatin is cross-linked.

Conclusions/action items:

Further research will be conducted on how to cross-link gelatin to make a suitable skin model.

References:

[1] https://medicalxpress.com/news/2017-04-artificial-gelatine-based-skin-simulates-human.html

2/15/2020 Cross-linking Gelatin to create a human skin model

Jack Fahy - Feb 25, 2020, 9:05 PM CST

Title: Cross-linking Gelatin

Date: 2/15/2020

Content by: Jack

Present: Jack

Goals: Learn how to cross-link gelatin

Content:

To create a gelatin-based skin model, we will have to cross-link the gelatin to prevent it from dissolving in water.

In *A water-responsive, gelatine-based human skin model*, by A. Dabrowski et al., the researchers developed a gelatin-based skin model [1].

First, a 10 wt% of gelatin in distilled water was spread over a knitted cotton fabric in 3 layers. Each layer was 300 micrometers. After each layer was applied, the fabric was allowed to dry for 24 hours at room temp. The cotton-gelatin fabric was then placed in a 1 wt% solution of gluteraldehyde in DPBS (Dulbecco's Phosphate-Buffered Saline). This sat for 24 hours at room temp with continuous stirring of 130 rpm to allow the gelatin to cross-link. The skin model was then rinsed with distilled water and dried by evenly pressing between paper towels. The paper towels were swapped out every day for 6 days. Drying was complete after the 6th day.

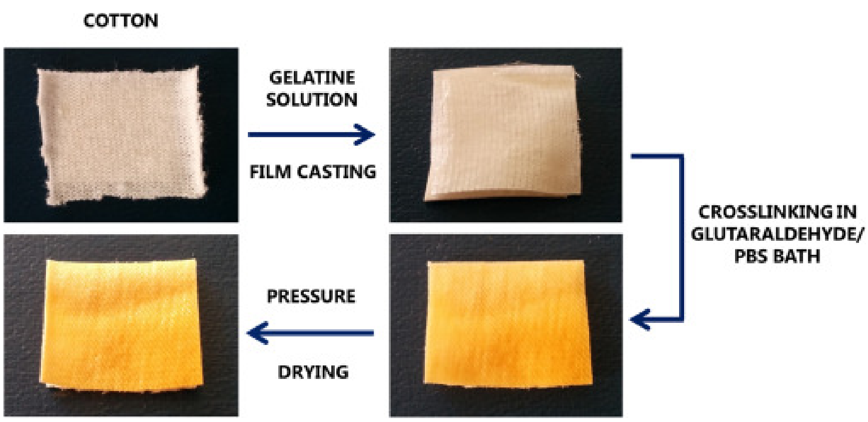


Figure 1. Progress of skin model creation from A. Dabrowksi et al.

Conclusions/action items:

The team must decide if it is feasible to attempt creating this skin model with the team and resources remaining this semester.

References:

[1] https://www.sciencedirect.com/science/article/pii/S0301679X17300361

2/02/2020 Double sided adhesive tapes

Jack Fahy - Feb 25, 2020, 9:36 PM CST

Title: Double-sided adhesive tapes

Date: 2/02/2020

Content by: Jack

Present: Jack

Goals: Find possible double sided tapes the can be used for our prototype

Content:

There are a variety of double-sided tapes that could be useful for our application

3M™ Medical Tape 1509, Double Sided Transparent Polyethylene, 80# Liner, Configurable [1]

- Tackified acrylic adhesive. Acrylic adhesives are safe for use on skin and also bond well to metal.
- Fluid resistant. This is important, as sweat or blood from the patient's skin could interfere with the adhesive's bonding ability.
- One suggested usage is "Attach devices to the body or skin and a variety of substrate materials"

3M™ Medical Tape 1510, Double Sided High Tack Conformable Polyethylene, 54# Liner, Configurable [2]

- Synthetic rubber adhesive. Good for use on skin but does not stick to metal as well as acrylic adhesives
- Fluid resistant
- Likely less effective than adhesive Medical Tape 1509 for our purpose

Vancive MED 6503SI [3]

- Soft silicone adhesive on one side, tacky acrylic adhesive on other side.
- Silicone side is repositionable
- Perforation pattern that adds breathability and moisture resistance

Conclusions/action items:

The team should decide on the best adhesive for our purpose and purchase it for testing.

References:

[1] https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Medical-Tape-1509-Double-Sided-Transparent-Polyethylene-80-Liner-Configurable/?N=5002385+8710676+3294739714&rt=rud

[2] https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Medical-Tape-1510-Double-Sided-High-Tack-Conformable-Polyethylene-54-Liner-Configurable/?N=5002385+8710676+3294739675&rt=rud

[3] https://parafix.com/product/vancive-med-6503si/

4/1/2020 Mechanical properties of Human Skin

Jack Fahy - Apr 28, 2020, 1:07 PM CDT

Title: Young's Modulus of Human Skin

Date: 4/1/2020

Content by: Jack

Present: Jack

Goals: Document the researched values of Young's Modulus of skin to use as a reference against our skin models

Content:

In *Mechanical Behavior of Skin: A Review*, by Kalra et al., a literature review of skin properties was conducted to obtain general ranges of values of its mechanical properties. The portion of their review that is most relevant to our problem is the collection of values from tensile testing. Skin is viscoelastic, and its stress-strain response is generally as follows:

1. For strains up to 0.3%, elastin is contributing to a majority of the stress response, as collagen fibers are still crimped. Elastin exhibits a highly linear response, so the response of skin at these low strain values is isotropic, and the stress strain response is linear with a low Young's Modulus [1].
2. Between 0.3% and 0.6% strain, collagen begins resisting as the fibers become more and more uncrimped. The stress strain response is now non linear (the toe region).
3. Above 0.6% strain, collagen is completely uncrimped and the stress strain response becomes linear. At 0.7% strain (the ultimate tensile strain), collagen fibers fail.

For tension tests of human skin, the Young's Modulus can vary greatly depending on the orientation of collagen fibers to the direction of pull, as well as the strain rate. At quasistatic strain rates, or rates slow enough to appear static, E of skin ranges from 4-15 MPa, or 580-2175 psi. At dynamic strain rates, the E value for skin can range greatly, from 14 to 100 MPa, or 2030 to 14,504 psi. This wide variation comes from the direction the sample is tested in tension, with testing in the transverse direction providing far higher E values than the longitudinal direction [1]. Direction of the sample's Langer lines also affects E. However, for all tests, Kalra et al. found that the Young's Modulus increases with strain rate.

Conclusions/action items:

Though the Elastic Modulus of skin shows great variability, we can utilize the direction of Langer lines at different parts of the body to estimate an approximate Young's Modulus when testing at specific sites on the body.

References:

[1] https://www.hilarispublisher.com/open-access/mechanical-behaviour-of-skin-a-review-2169-0022-1000254.pdf

1/28/2020 Geckskin

Jack Fahy - Feb 21, 2020, 2:48 PM CST

Title: Geckskin Research

Date: 1/28/2020

Content by: Jack

Present: Jack

Goals: Learn about the capabilites of Geckskin

Content:

Geckskin is a synthetic adhesive material made up of common material components [1].

- It is modeled after Geckos' feet. Their feet have millions of tiny hairs called setae. These hairs are soft and conform very tightly to the surface the Gecko is walking on. This causes Van der Waals interactions to become strong, allowing them to easily cling to a surface and remove their foot with ease.
- Geckskin is made of a soft elastomer, like polyurethane or polydimethylsiloxane (PDMS) woven into a stiff fabric, like Kevlar or carbon fiber.
    - This results in what is known as draping adhesion, where the material creates conformal contact with a surface. The stiff fabric allows the material to maintain a high, elastic stiffness in the directions of force.
    - Adhesive loading is evenly distributed across the material surface
- Geckskin can be easily applied and removed from surfaces without leaving any residue
    - This is important, as we want to avoid leaving markings and residue on the patient's skin

Conclusions/action items:

Geckskin shows a lot of promise as an adhesive material for our device, but we are unsure as to how well it will stick to skin. This will have to be tested before moving forward with the adhesive.

References

[1] geckskin.umass.edu

1/31/2020 Geckskin purchasing options

Jack Fahy - Feb 21, 2020, 3:04 PM CST

Title: Where to purchase Geckskin

Date: 1/31/2020

Content by: Jack

Present: Jack

Goals: Note possible websites to buy geckskin from

Content:

https://www.buygeckskin.com/geckskin-products

- Offer 3 kinds of small geckskin pads
- However each says it is designed to hold paper
- $6-8 for ten pads
- Fairly cheap so it is worth buying some to test it out

From the Geckskin UMass website, where the material was created, they do not link any places to buy geckskin.

Conclusions/action items:

The lack of availability for Geckskin reduces the promise that the material has, however it is still worth trying out.

3/12/2020 Making synthetic skin with Ecoflex

Jack Fahy - Apr 26, 2020, 3:42 PM CDT

Title: Synthetic skin from Ecoflex

Date: 3/12/2020

Content by: Jack

Present: Jack

Goals: Lay out plan of fabricating fake skin using Ecoflex 00-30

Content:

Safety:

- Wear vinyl gloves when handling the silicone mixing solutions. Latex gloves will inhibit the curing of the silicone rubber.
- Conduct work in properly ventilated room to avoid inhaling fumes

Procedure

- Thoroughly stir solution B prior to mixing.
- Mix a 1:1 ratio of solution A to solution B in a container. Mix for 3 minutes.
- Vacuum degassing for 2-3 minutes is recommended to remove air trapped within the rubber mixture.
- Pour the mixture into curing container. A 5" x 5" x 0.5" (length x width x thickness) overall size should be sufficient for testing purposes. Pour at a single spot and allow the liquid to spread naturally throughout the container.
- Cure for 4 hours at room temp.
- Post-curing is recommended to quickly acquire maximum physical properties from the rubber. Expose to 176 degrees F for 2 hours, then 212 degrees F for 1 hour, then cool to room temp before removing from curing container.

Conclusions/action items:

With this procedure in place, the team can move forward with creating the synthetic skin needed for testing.

3/21/2020 EcoFlex 00-30 material properties

Jack Fahy - Apr 28, 2020, 12:18 PM CDT

Title: Ecoflex 00-30 material properties

Date: 3/21/2020

Content by: Jack

Present: Jack

Goals: Document the properties of Ecoflex 00-30

Content:

From the document provided by Smooth-On with the Ecoflex 00-30 we purchased, the material properties are as follows:

- Specific gravity: 1.07 g/cc
- Specific volume: 26.0 cu. in./lb.
- Shore Hardness: 00-30
- Tensile Strength: 200 psi
- 100% Modulus: 10 psi
- Elongation at Break %: 900%
- Die B Tear Strength: 38 pli (pounds per lineal inch)

Conclusions/action items:

The material properties of the Ecoflex 00-30 will later be compared to those of actual skin.

1/30/2020 SolidWorks Drawing of Assembly

Jack Fahy - Dec 10, 2019, 1:04 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:

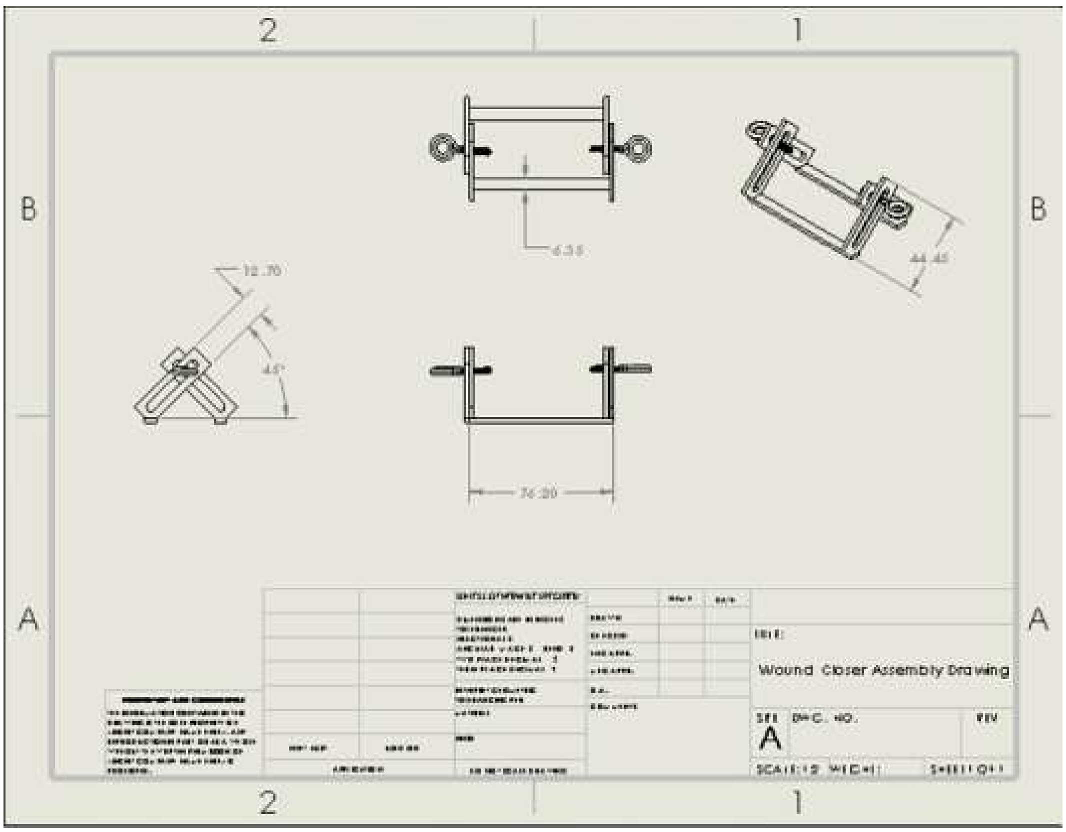


Figure 1. This Drawing defines important dimensions of the design and displays the assembly from a front view (middle), top view (top middle), side view (left), and isometric view (top right). All dimensions are in mm.

Conclusions/action items:

This Drawing will be included in the appendix of our final report

1/30/2020 SolidWorks Parts for First Prototype

Jack Fahy - Dec 10, 2019, 1:00 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:

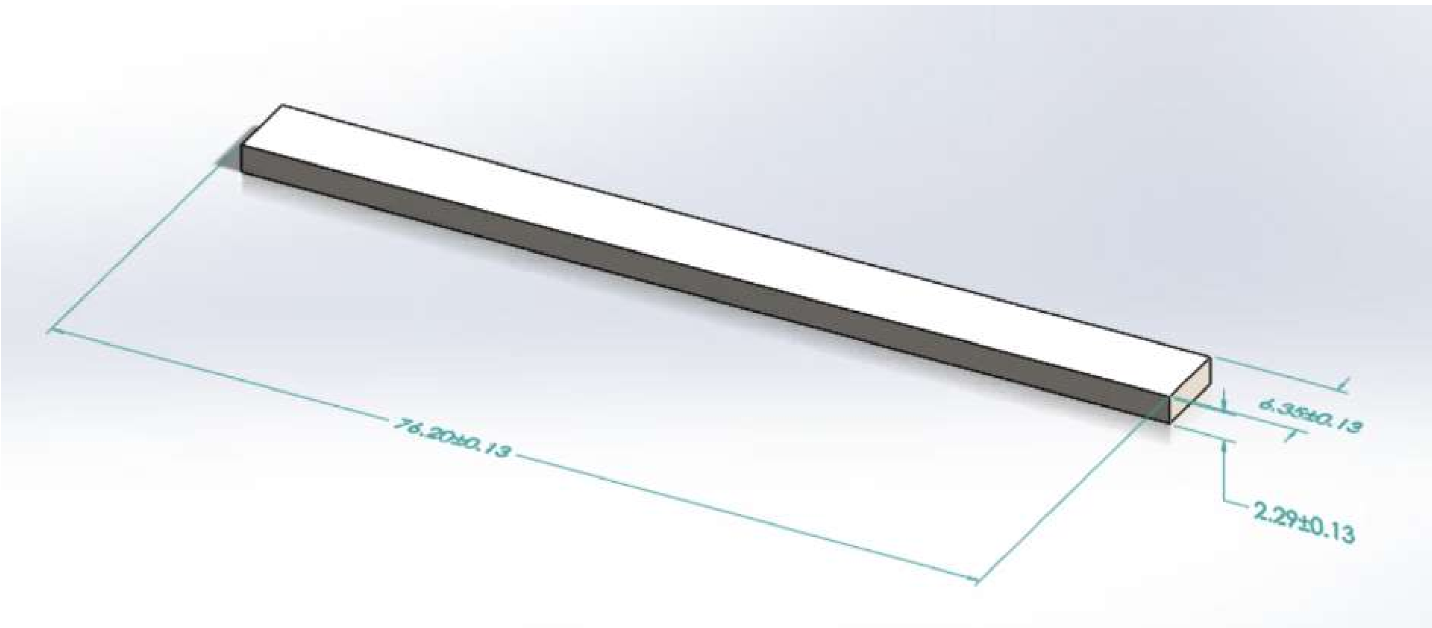


Figure 1. Model of long side of device. This is the part that contacts the patient's skin. Dimensions in mm

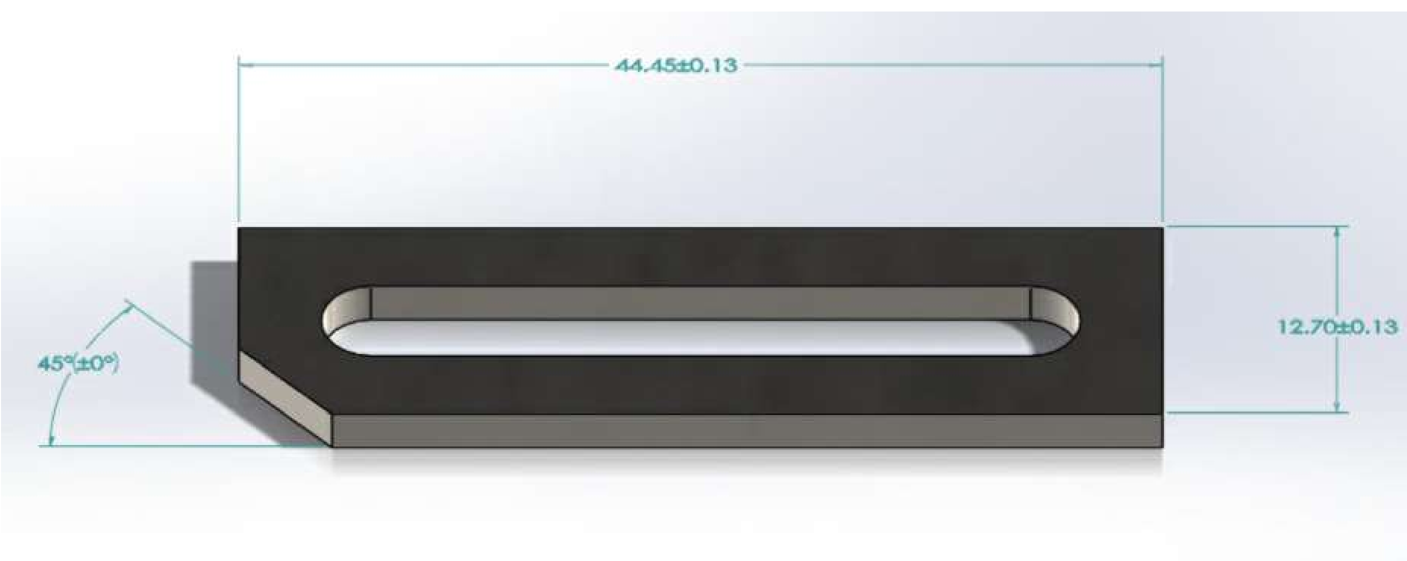


Figure 2. Model of slotted pieces. In accordance with our fabrication plan, one corner of the slotted pieces are sanded down to the width of the long piece so that they rest on the long pieces at a 45 degree angle. The angle at which the slotted pieces sit will not change how the device operates, so 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.

3/2/2020 SolidWorks Slot Filler 1st Iteration

Jack Fahy - Apr 09, 2020, 12:56 PM CDT

Title: Slot Filler first iteration

Date: 3/2/2020

Content by: Jack

Present: Jack

Goals: Present first attempt at printing a slot filler

Content:

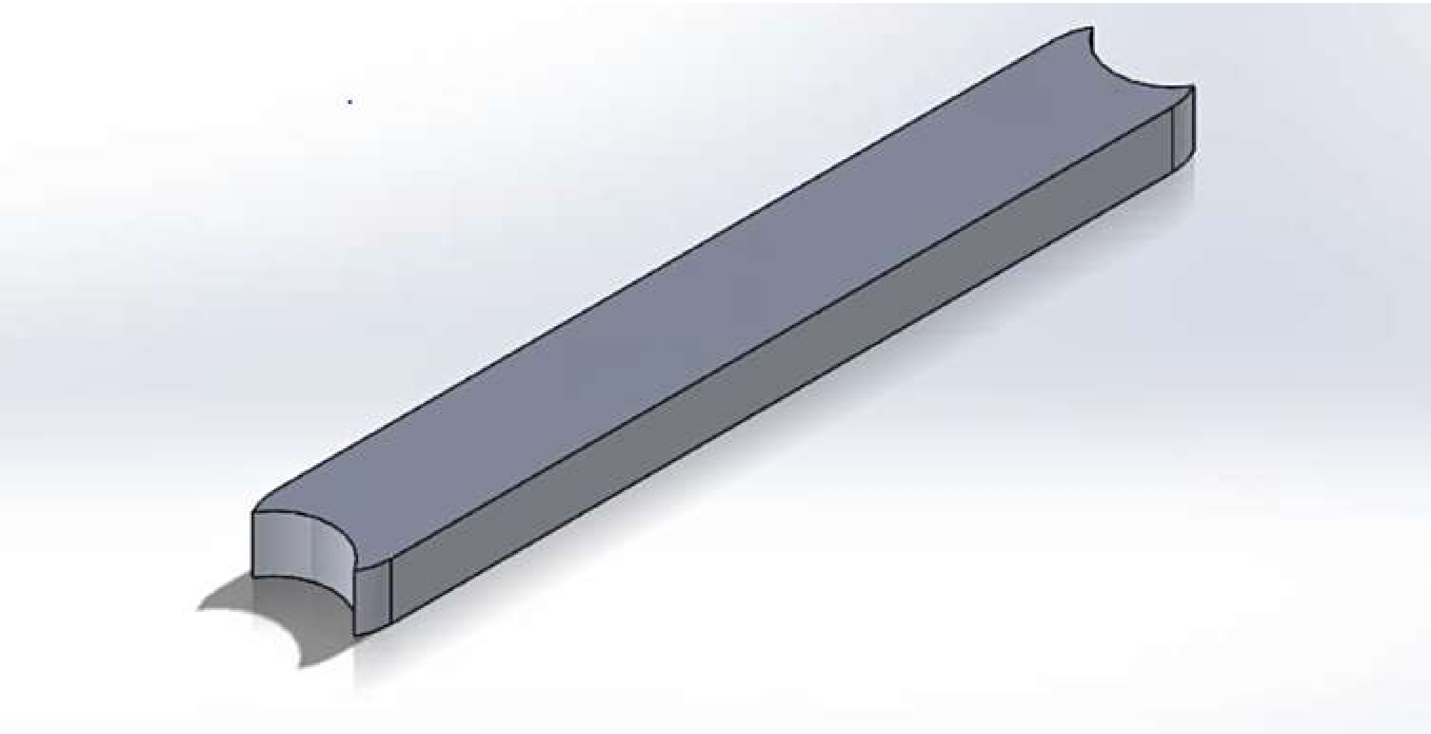


Figure 1. First iteration of slot filler design. Length = 1.25", Width = 0.19", Height = 0.09", Radius of curvature = 0.09"

Figure 1 shows the SolidWorks model of the slot filler. Dimensions are listed in the caption. The slot filler was successfully printed at the MakerSpace using PLA. However, it was slightly too long and too wide for the slots in our device. A second and possibly third iteration of this model will have to be constructed.

Conclusions/action items:

The slot filler will be re-dimensioned in SolidWorks and reprinted to better fit the slots of our device.

3/7/2020 SolidWorks Slot Filler Iteration 2 and 3

Jack Fahy - Apr 09, 2020, 1:06 PM CDT

Title: Slot Filler iterations 2 and 3

Date: 3/7/2020

Content by: Jack

Present: Jack

Goals: Present the second and third iterations of the slot filler model

Content:

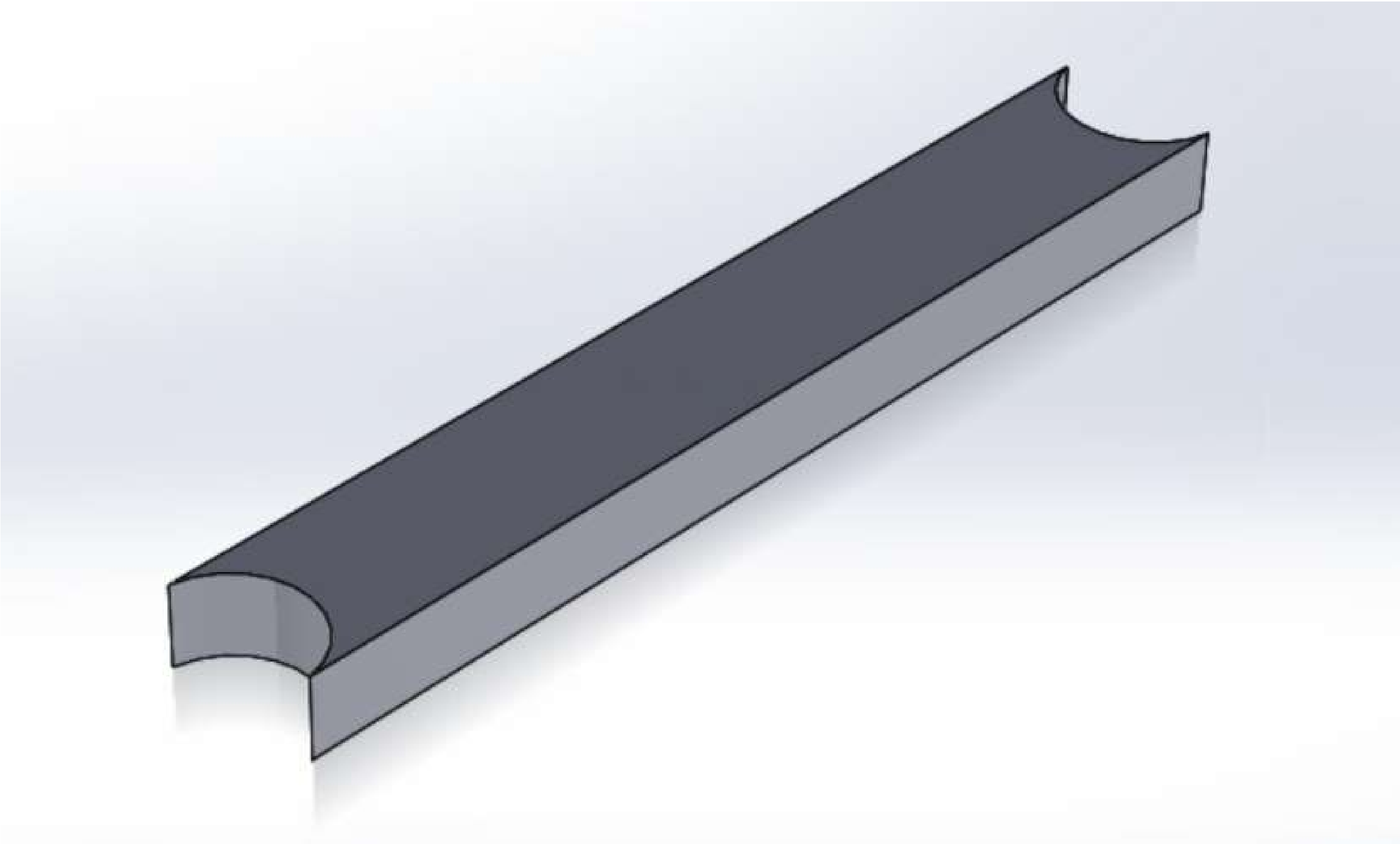


Figure 1. SolidWorks model of slot filler iteration 2. Length = 1.20", Width = 0.18", Height = 0.09", Radius of Curvature = 0.09"

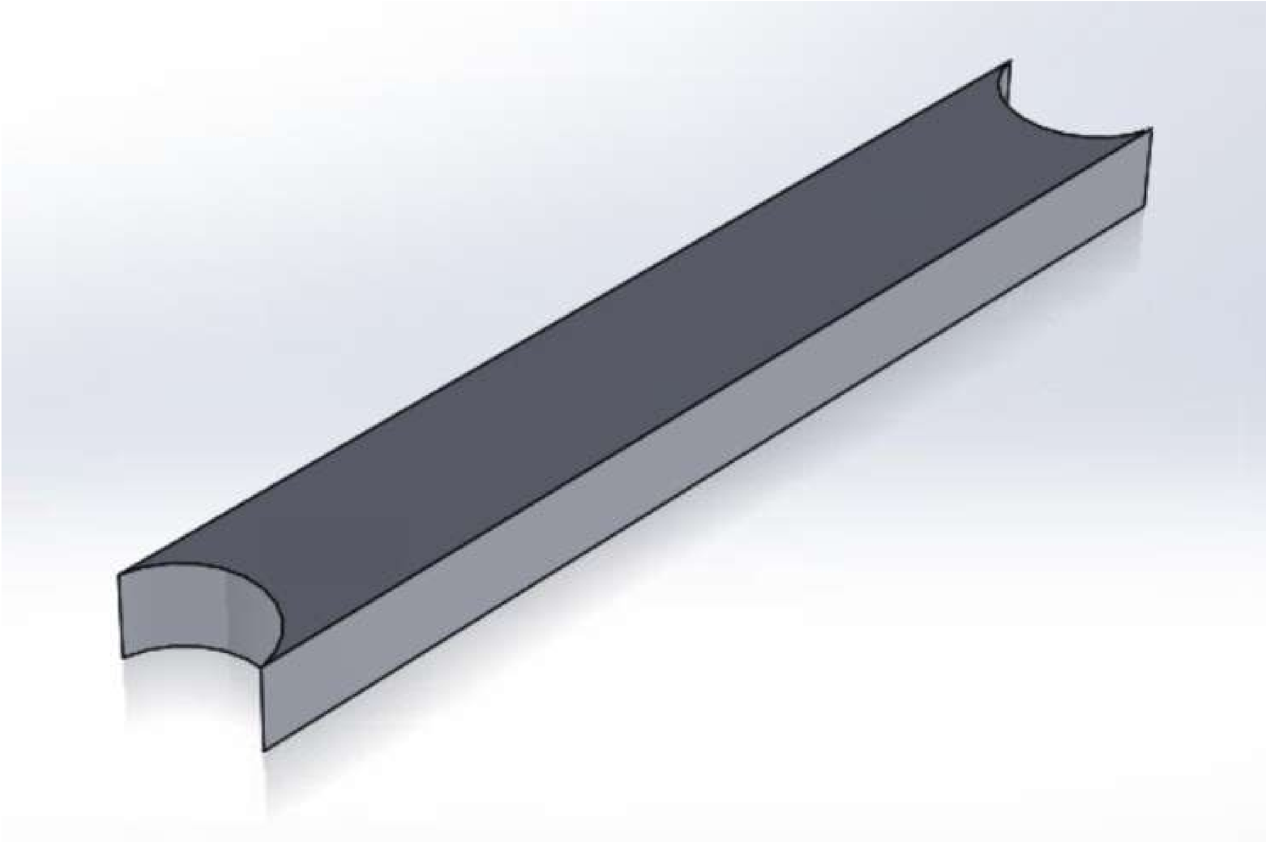


Figure 2. SolidWorks model of slot filler third iteration. Length = 1.18", Width = 0.18", Height = 0.09", Radius of Curvature = 0.09"

Figures 1 and 2 show the second and third iteration of the slot filler. They were printed simultaneously in the MakerSpace so that both could be tested immediately. The only difference between the second and third iteration is the lengths; the third iteration is 0.02" shorter than the second iteration. The second iteration (1.20" in length) was a perfect fit for the slots, so we will be moving forward with that slot filler.

Conclusions/action items:

Now that we have functional slot fillers, our device can be assembled and prepared for testing.

2/15/2020 Prototype Redesign Ideas

Jack Fahy - Feb 21, 2020, 3:28 PM CST

Title: Prototype Redesign Ideas

Date: 2/15/2020

Content by: Jack

Present: Jack

Goals: List ideas for prototype redesign

Content:

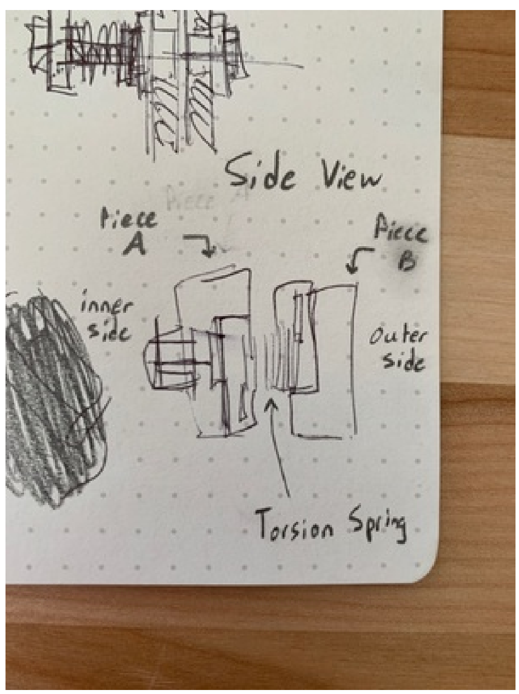
After meeting with the Makerspace staff, we have a good idea of how to move forward with our prototype redesign in order to implement torsion springs.

- With the addition of torsion springs, the slots become effectively useless, so a piece that fits into the slot to fill it can be 3D-printed. This piece must have a small hole that a rod, or axle, can be fit through. Shown in Bottom picture below
- A nut will be placed on the inner side of the axle to secure it on that side.
- Two more pieces must be 3D-printed that will secure the torsion spring. The axle will be threaded through the first piece (Piece A) on the outer side of the device. The axle is then threaded through the torsion spring's middle hole, followed by the second 3D-printed piece (Piece B). Pieces A and B have cut out sections where the arms of the torsion spring will rest against. Shown in Top picture below.
- A nut will be placed on the outer side of the axle to secure the torsion spring between pieces A and B.

Conclusions/action items:

A fabrication plan should be written up before moving forward with fabrication

Jack Fahy - Feb 21, 2020, 3:26 PM CST



3E516548-B736-4B33-B9ED-F1373B946055.jpg(131.7 KB) - download Pieces A and B secure torsion spring

Jack Fahy - Feb 21, 2020, 3:27 PM CST

4D537181-7629-4641-B6C5-CAF4B0C2F7CD.jpg(126.2 KB) - download Slot filler will be 3D-printed to the slot's specifications

2/24/2020 Sketch of Torsion Spring Implementation

Jack Fahy - Feb 25, 2020, 8:30 PM CST

Title: Sketch of Torsion Spring Implementation

Date: 2/24/2020

Content by: Jack

Present: Jack

Goals: Record sketch of how the team plans on using torsion springs with our device

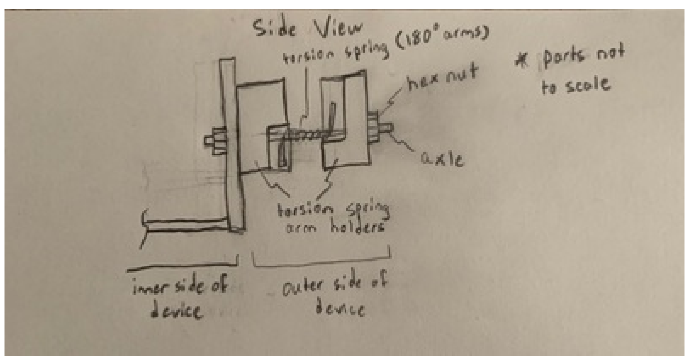
Content:

The sketch below depicts how we intend to add a torsion spring to one side of our current prototype. The same would be done to the other side of the prototype. The torsion spring arm holders and axle would be 3D-printed. Another piece not shown in the sketch, will be printed to fill the slot in the prototype.

Conclusions/action items:

With this idea in mind, we should start working on the Solidworks models of the 3D printable parts.

Jack Fahy - Feb 25, 2020, 8:28 PM CST



63E6A011-2712-4D79-A74D-F5A7E22EFBAC.jpg(37.4 KB) - download

2/9/2020 Torsion springs from McMaster-Carr

Jack Fahy - Feb 25, 2020, 10:02 PM CST

Title: Torsion springs from McMaster-Carr

Date: 2/9/2020

Content by: Jack

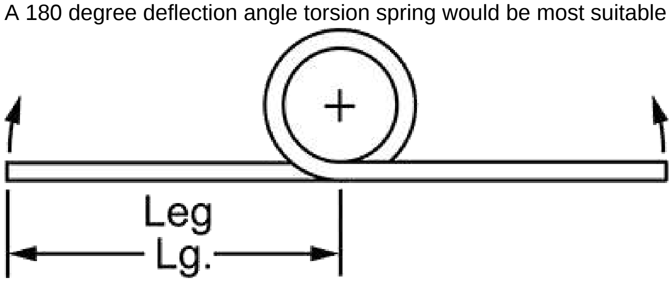
Present: Jack

Goals: Find available torsion springs on McMaster-Carr

Content:

McMaster-Carr carries a variety of torsion springs, including corrosion-resistant and custom-made springs. [1]

- Left hand springs wind clockwise toward you.
- Right hand springs wind counterclockwise towards you.
- The type of wind we need depends on how we decide to model the torsion spring leg holders.
- A 180 degree deflection angle torsion spring would be most suitable



- An outside diameter (OD) of 3 to 5 mm (0.118" to 0.197") is needed. The hole in the slot filler, and thus the axle, will need to be within that size range. We want the torsion spring to rest fairly snug on the axle, so we want the outer diameter to be as close to the axle diameter as possible
  - The smallest spring available has an OD of 0.109", so we should be able to find one that fits our size requirements.
- Max Torque (in-lbs) is measure as the torque required to bring the legs of the spring parallel to each other. We need a fairly light max torque to avoid difficulty with operating the device.
  - Of the springs within our size range, the max torque ranges from 0.05 in.-lbs. to 0.075 in.-lbs. This should be low enough to make operation easy.
- The springs are sold in packs of 6 and are ~$6 for a pack

Conclusions/action items:

The team must decide on a desired outer diameter for the spring, and then move forward with purchasing a pack.

References:

[1] https://www.mcmaster.com/torsion-springs%2ftorsion-springs-5

3/27/2020 Implementation of Slot Fillers

Jack Fahy - Apr 28, 2020, 12:36 PM CDT

Title: Slot Filler Implementation

Date: 3/27/2020

Content by: Jack

Present: Jack

Goals: Show how the slot fillers will be used with our device

Content:

After the first iteration of slot fillers failed, as they were too large, I resized the SolidWorks model to create two possible fillers, Option 1 with dimensions 1.20" x .08" x .09" and Option 2 with dimensions 1.18" x .08" x .09" (length x width x thickness). Option 1 provided the best fit in the device’s slots and are shown in Figure 1. Note that the fillers were printed with White PLA

Figure 2 shows the fit of the slot fillers in the device. Once press fit into the slots, the fillers do not move around and provide just enough room for the thumb screws to be placed through the slots at both ends.

Conclusions/action items:

Device revisions are now complete and the team can move on to testing.

Jack Fahy - Apr 28, 2020, 12:34 PM CDT

Figure_1.jpg(80.4 KB) - download Figure 1. Option 1 slot fillers right after 3D-printing.

Jack Fahy - Apr 28, 2020, 12:35 PM CDT

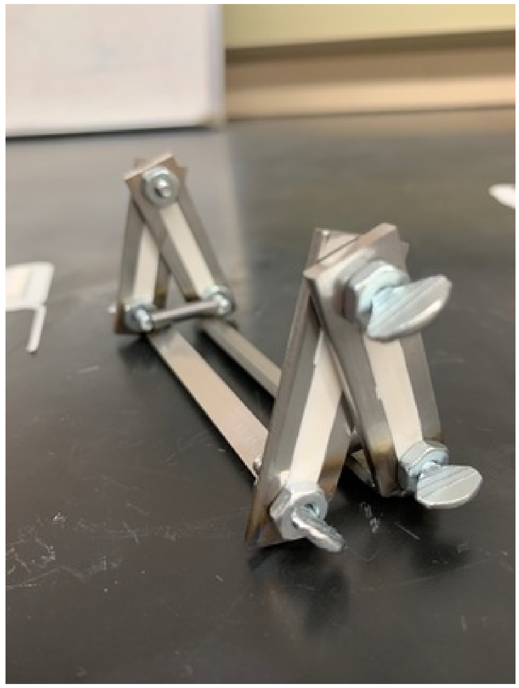


Figure_2.jpg(69.4 KB) - download Figure 2. The slot fillers were press-fit into the slots, securing the thumb screws in place at the ends of the slots.

4/20/2020 Future Design Work

Jack Fahy - Apr 28, 2020, 1:25 PM CDT

Title: Future Design Work

Date: 4/20/2020

Content by: Jack

Present: Jack

Goals: Lay out what changes must be made to the device in future iterations

Content:

The team was able to create a functioning prototype that has great potential. In the future, a few design changes need to be made that will improve the overall quality of the prototype.

1. Eliminate slot fillers
    - Now that we have converted the device into a hinging mechanism using the tension springs, the slots no longer serve a purpose, and the slotted sides should be remade into simple rectangular pieces.
2. Eliminate Thumb Screws
    - At the top of either end of the device, where the pieces overlap, a simple hole could be drilled large enough for a simple axle to pass through to allow the device to hinge more smoothly. The thumb screws towards the bottom of the device, which function as connection points for the ends of the tension springs. could also be redesigned in favor of small hooks that extend from the metal side pieces. The tension spring could then be secured around the hooks, eliminating the potential for the springs to slip off of the screws and improving the overall aesthetic and functionality of the device.
3. Better adhesive application
    - Arguably the most important aspect that must be changed is the adhesive application to the bottom of the device. Proper adhesion to the skin is essential for the wound closer to function optimally, so either a reusable adhesive or a medical grade skin tape that is easy to apply and remove must be implemented.
4. Rounding of inner sides of long edges
    - To improve patient comfort, the inner edges of the device's long sides (the sides that contact the skin and push the wound edges together) could be rounded to provide more comfortable contact against the skin, as the edges of the long sides could potentially be rough or sharp and inflict pain to the patient.

Conclusions/action items:

If this project continues, these design changes could result in a highly marketable device with the potential to greatly impact the way wound closure is performed.

Ideas for Skin Model to Test - 31 Jan 2020

ISABEL ERICKSON - Feb 21, 2020, 1:54 PM CST

Title: Ideas for Skin Model

Date: 21 Feb 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Come up with Ideas for possible skin models

Content:

Team needs a skin model that has a similar friction coefficient, experiences the viscous properties of skin tension, is able to be cut and is small enough to place our device onto.

Important Consideration for Skin Models:

- Skin is dual-layered including the Epidermis (nonvascular) and the Dermis (vascular).
- Skin Friction
- Elasticity
- Roughness
- Hydration - Affects most other properties

An article by Swiss National Laboratory Engineers, describes a new bio-mimicking gelatine-based physical skin model.

- Broad Range of Applied Normal Load (0.5-5 N)
- Amount of Water (0-100 micro-liters per cm squared

Important Info from Introduction:

Good Candidates with similar Frictional Properties: Lorica, polyurethanes, silicones - However, do not interact with water

Factors on frictional behavior of human skin:

- Age
- Gender
- Health Conditions
- Anatomical Region
- Hydration Level

Top layer of skin is the Stratum Corneum - rough and stiff layer under normal conditions , however hydration = softening = increase in contact area

Gelatine as Skin Model - derived from collagen (important in Dermis layer of skin) Similar Properties

- Physical
  - density, stiffness (used in ballistic performance), (energy dissipation)
- Can absorb water

New model - Gelatine as base with cotton-based textile used as the extracellular matrix

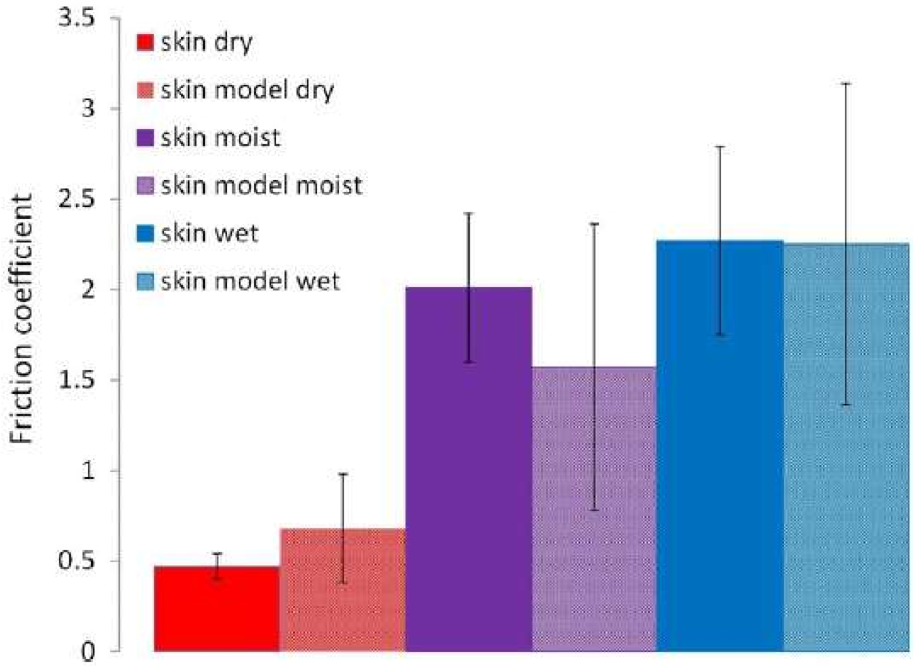


Fig. 4. Average friction coefficients for human skin and the skin model rubbed against Martindale fabric in dry, moist and wet conditions.

Figure 1. Friction Coefficient Testing with varying water levels.

Conclusions/action items:

Add water addition to the test of skin models, skin is not completely dry and requires some water to live and also has oils on it. Maybe having the cotton strips is not as bad of an idea as originally thought.

Journal Article on Skin Models:

[2] A. Dąbrowska *et al.*, “A water-responsive, gelatine-based human skin model,” *Tribol. Int.*, vol. 113, pp. 316–322, 2017, doi: 10.1016/j.triboint.2017.01.027.

Basic Laceration Care Information - 31 Jan 2020

ISABEL ERICKSON - Feb 24, 2020, 5:39 PM CST

Title: Understanding Basic Laceration Care

Date: 31 Jan 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Understand Basic Wound Care, Understand What Types of Wounds need Closure (How Deep etc.)

Content:

Laceration Repair

When do wounds need repair?

- exposed muscle, fat, tendon, bone
- dirt/debris in the wound
- feeling if something is inside the wound
- bleeding continues after applying direct pressure for 10-15 minutes
- Depth of cut more than 1/8 to 1/4 inches deep (Past the skin into the subcutaneous membrane)
- Location on area of high stress (joint/hands/feet/chest)
- Possible Intense Scarring

At Home Treatment

- Apply direct pressure to the wound. Use gauze, a clean cloth, plastic bags, or, as a last resort, a clean hand. If wound bleeds through the gauze or cloth, do not remove it. Add more gauze.
- If possible, elevate the wound above the heart. This will make it harder for blood to flow to the wound.
- Do not tie a tourniquet around an affected limb. This may cause more damage.
- If bleeding stops, let water run over the wound. Tap water is ok.
- If muscle, tendon, bone, or organs are exposed, do not try to push them back into place.
- If feeling faint, lie down or sit with head between the knees.

At Clinic Treatment

Dermabond

- Glue that holds wounds together

- Not for very deep cuts

- Will fall off in 5-10 days

Steristrips

Adhesive tape that closes wounds that are clean/shallow and easy to close

Stitches

Deep Bleeding Wounds with jagged edges or exposed fat/muscle

- can put internal stitches to repair tissues,

- stitch wound shut

- Clean with saline, apply antiseptic and cover with gauze

Staples

RISKS

Tetanus - bacterial infection, from dirt dust saliva or feces

RECOVERY

Avoid Strenuous Activities

Take Antibiotics if Needed

https://em.uw.edu/sites/em.uw.edu/files/Chapter%2035%20Wound%20Care.pdf

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

https://www.facs.org/~/media/files/education/patient%20ed/wound_lacerations.ashx

Conclusions/action items:

Understand which methods doctor's plan to use with our device.

Pertinent Skin Anatomy and Physiology - 21 Feb 2020

ISABEL ERICKSON - Feb 21, 2020, 1:17 PM CST

Title: Pertinent Skin Anatomy and Physiology

Date: 21 Feb 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Understand Skin Anatomy and Physiology for Design Considerations

Content:

Skin, is the body's largest organ. Skin and its Accessory Structures such as exocrine glands (sweat and sebaceous), sensory receptors, hair follicles etc. make up the integumentary system. This essential system has 8 major functions.

1. Protection

2. Water Regulation

3. Temperature Regulation

4. Vitamin D Synthesis

5. Sensory Perception

6. Excretion by Secretion

7. Storage

8. Non-verbal communication

Skin (cutaneous membrane) also has two major layers, the epidermis (outer layer), and the dermis (lower layer).

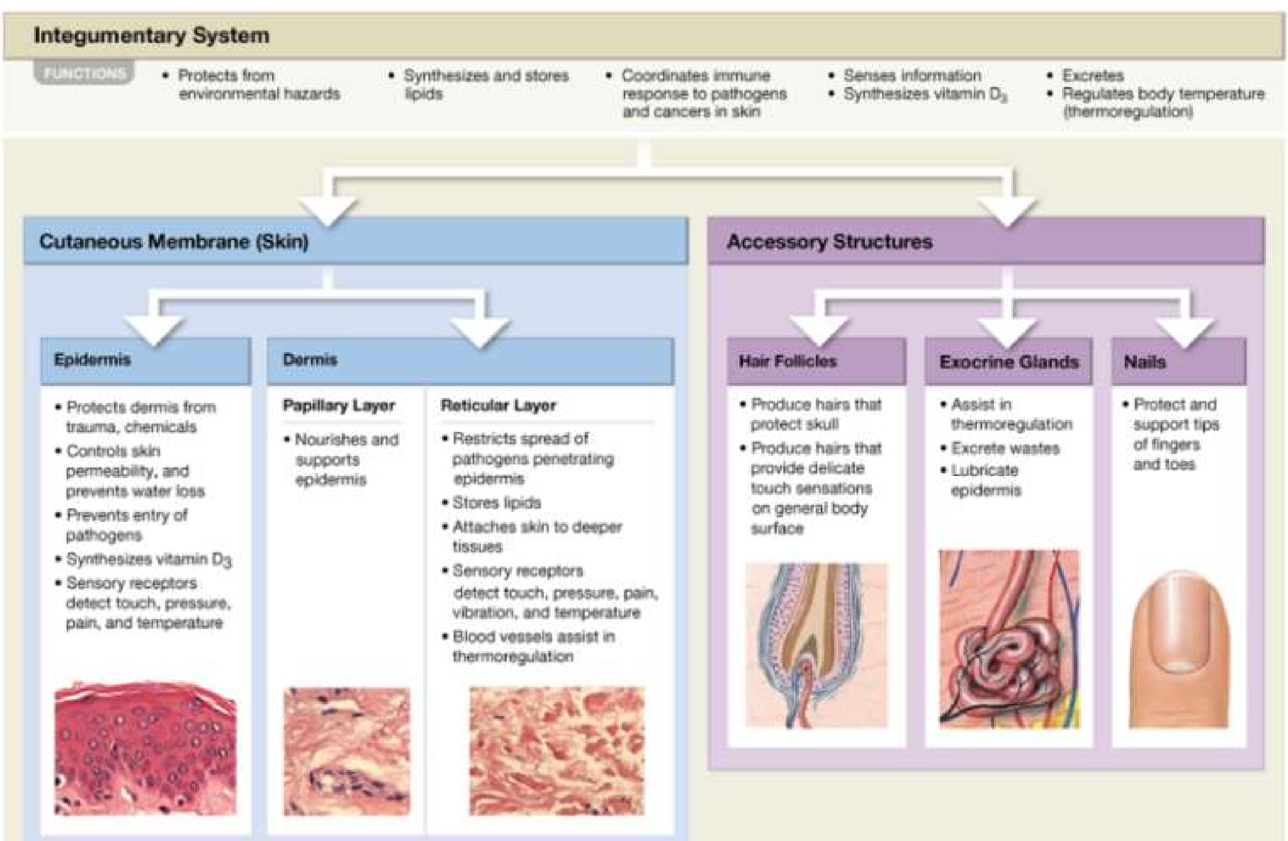


Figure 1. Explanation of Basic Anatomy of the Integumentary System

The epidermis is the outer layer of the skin (the layer the team will be contacting with the wound approximation device) It is mostly made up of layers of flattened keratinocytes which provide physical/mechanical protection, they also help to waterproof the skin. They also do vitamin D synthesis, produce antibiotics/enzymes to detoxify skin and are joined by desmosomes (allow the tight waterproof connection). Other cells in the epidermis include Melanocytes (produce melanin, absorb UV light), Tactile Epithelial Cells (Receptors for Touch), Dendritic Cells (part of the immune system, use endocytosis to transport foreign proteins to nearby lymph nodes to start an immune response). Free nerve endings are also in the deep epidermis which sense pain and temperature (some light touch as well)).

The epidermis contains 5 main layers. Epidermis is AVASCULAR.

1. Stratum corneum - Top layer, contains many layers of flattened, dead, interlocking keratinocytes. Layer is water resistant, but not waterproof (permits slow water loss by insensible perspiration).

2. Stratum lucidum - Glassy layer in thick skin only

3. Stratum granulosum - Keratin fibers develop here, Keratinoyctes begin to flatten, become thinner and flatter, organelles disintegrate and the cells die to form the stratum corneum at the upper layers.

4. Stratum spinosum - Some keratinocytes divide in this layer, Melanocytes and Dendritic Cells are also present in this layer, keratinocytes are bound together by adherens to the cytoskeleton in this layer.

5. Stratum basale - deepest layer, attached to the basal lamina, contains stem cells that create more keratinocytes and other epidermal cells. (Creates ridges that create more surface area for diffusion to the this layer to ensure the stem cells have enough nutrients).

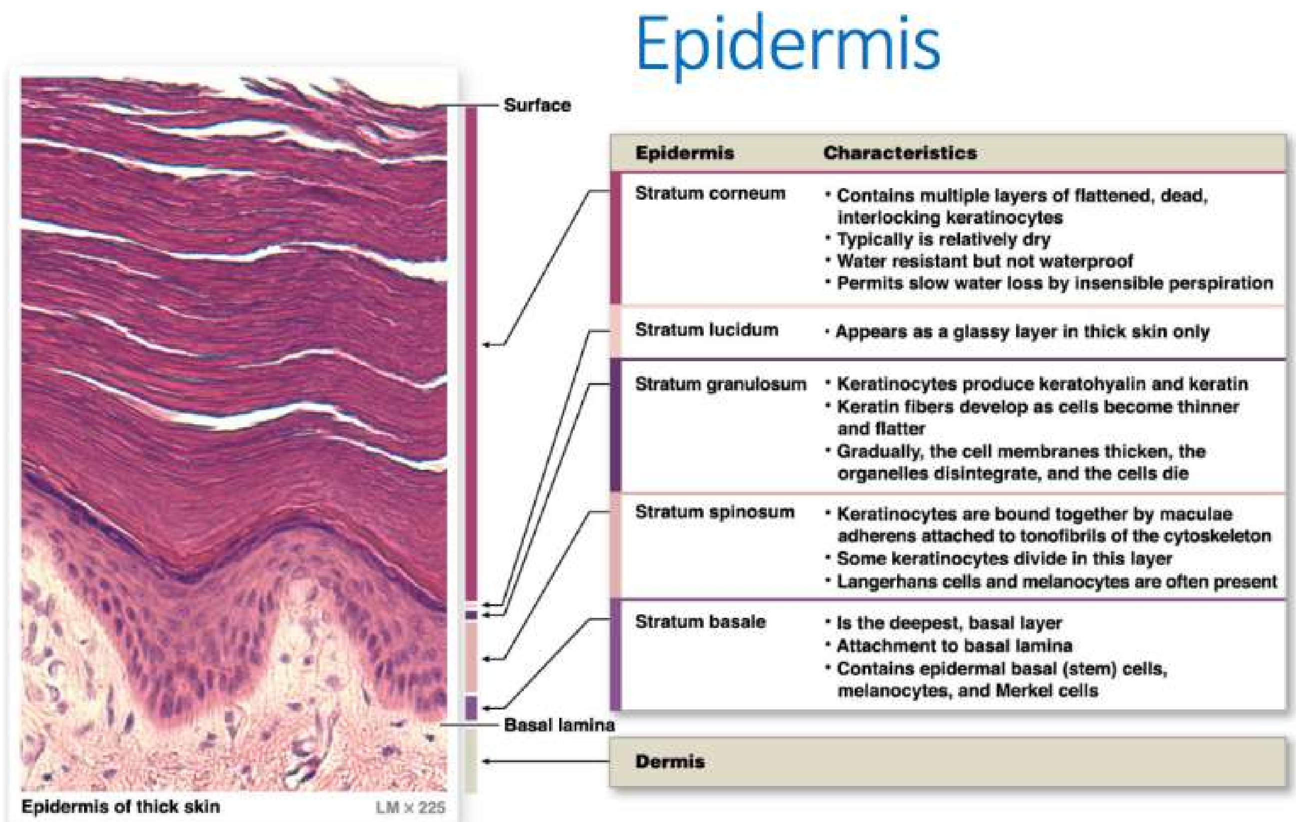


Figure 2. Depiction of the layers of the epidermis

The other layer of the skin is the Dermis. This layer is highly vascularized and provides nutrients to the basal layer of the epidermis through diffusion. The vasculature in the Dermis is also important for controlling body temperature. Nerve fibers are also mostly in the dermis where there are tactile (touch) receptors, as well as pain receptors. These nerves control blood flow and glandular secretion in the skin. The dermis also houses most of the glands (sebaceous = oily matter that lubricates the skin and hair) (sweat).

There are two layers in the dermis.

1. Papillary (Upper)

This layer is mostly composed of areolar connective tissue (known for its airy appearance that gives space for blood vessels, nerve bundles and organs), it connects skin to underlying muscle.

The dermal papillae interlock with the epidermal ridges to allow for easy diffusion. (Creates fingerprints from Friction ridges)

2. Reticular (Lower)

This layer is mostly dense irregular connective tissue (strong in many different directions). There are also bundles of collagen fibers, blood vessels, glands, hair follicles and nerves.

Cleavage Lines: Organized collagen and elastin fibers (In thin parallel bundles to resist stress / forces).

Relevance to Project: When skin in cut perpendicular to the cleavage lines, the skin tends to splay out. If cut parallel, the skin wound tends to stay much closer together, not requiring much wound approximation.

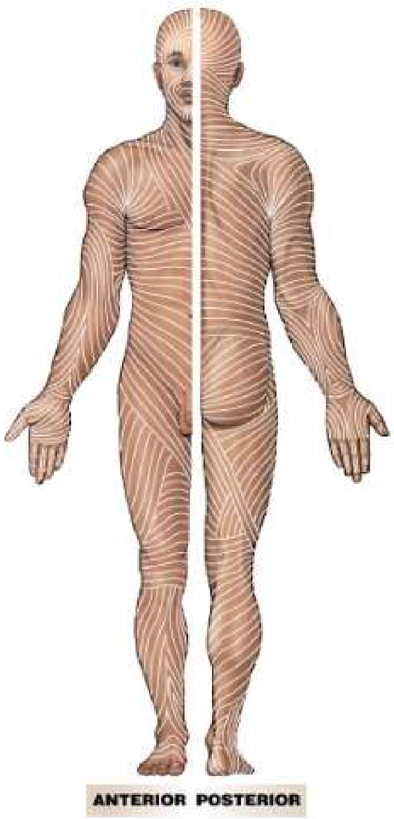


Figure 3. Cleavage lines on a Male.

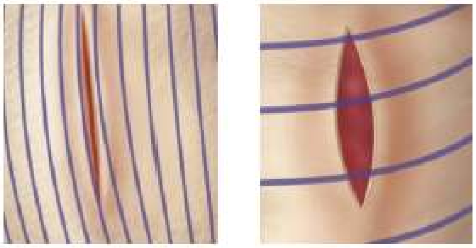


Figure 4. Cuts Parallel and Perpendicular to Cleavage Lines

Conclusions/action items:

The epidermis and dermis make up the two layers of the skin. Cuts that reach the reticular layer of the dermis and are cut perpendicularly to the cleavage lines (collagen and elastin fiber organizations) tend to splay out more and require wound approximation before wounds are able to be healed. I hope to look more into what force the cleavage lines give to keep the wound in place, this would help us choose a rotational spring to use in our redesign.

Source:

[1] F. (Ric) PH. D. Martini and Robert B. Tallitsch PH.D., *Human Anatomy Ninth Edition*, Ninth. Pearson, 2018.

Modelling Viscous Properties - 22 Feb 2020

ISABEL ERICKSON - Feb 22, 2020, 3:09 PM CST

Title: How to Model Viscous Properties in FEA Modeling

Date: 22 Feb 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Isabel Erickson

Content:

Modeling Viscous Materials

Elastic materials are able to dissipate the mechanical energy due to viscous effects are characterized as viscoelastic materials.

$$\underset{\sim}{\sigma}(t) = \int_0^t 2G(t-\tau)\frac{\partial \underset{\sim}{e}}{\partial \tau}\partial\tau + \underset{\sim}{I}\int_0^t K(t-\tau)\frac{\partial \phi}{\partial \tau}\partial\tau$$

Multi-Axial Stress Rate Equation

Then relaxation must be represented by using Maxwell's Model

$$G(t) = G_o\left[1 - \sum_{i=1}^{N_G} g_i\left(1 - e^{-t/\tau_i^G}\right)\right]$$

$$K(t) = K_o\left[1 - \sum_{i=1}^{N_K} k_i\left(1 - e^{-t/\tau_i^K}\right)\right]$$

Generalized Maxwell Model

The effect of temperature on material behavior also has to be taken into account which can be approximated using the WLF (Williams-Landel-Ferry) Equation.

$$\ln\gamma = \left(\frac{C_1\bar{T}}{C_2+\bar{T}}\right)\ln(10),\ \bar{T} = T - T_o$$

Conclusions/action items:

Decide what type of Viscoelastic Model to be used for Modelling.

Abbott Perclose Proglide

ISABEL ERICKSON - Apr 10, 2020, 9:11 PM CDT

Title: Abbot Perclose ProGlide Suture

Date: 10 March 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: ZipStitch

Content:

The idea for this product is to be able to repair wounds that would need stitches in areas that medical care is not readily available such as in the wilderness. ZipStitch works by using a zip-type like using a hyper-colloid pressure sensitive material to stick on to the skin and then use a zip-tie shaped design to pull the edges of the wound together, approximating it long enough to allow to allow sufficient healing to prevent scarring and infection. This also doesn't cause any pinched areas that prevent prolonged strong blood-flow and healing. The zip-tie design also allows the device to protect from foreign items getting into the wound and the ability to change the pressure on the wound as the wound begins to heal. The ZipStitch is also easy to pull off in the end.

Conclusions/action items: The ZipStitch is a great design that uses ZipTies to approximate the wound as well as close it for healing.

Dermabond

ISABEL ERICKSON - Apr 10, 2020, 9:28 PM CDT

Title: Dermabond

Date: 10 April 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Understand Devices that could be used with out product

Content:

Dermabond is an advanced Topical Skin Adhesive that can be used instead of stitches to close severe wounds. It not only gives strenght to wounds and maintains the barrier and wound closure but also has antibacterial properties that kill 99.99% of bacteria on direct contact.

The Instructions Include

1. Thorough Wound Cleansing

2. pat the wound dry with sterile gauze

3. Maintain the wound in a horizontal plane

4. Crush the ampule

5. Approximate the wound and maintain it while applying dermabond and 60 seconds after

6. Immediately and with pressure apply dermabond along the length of the wound

7. Keep the wound approximated

8. Make sure to not apply any liquids or ointments to the wound after

Conclusions/action items:

The design needs to hold the approximation for at least a few minutes and give the physician time to be able to do the approximation.

29Jan2020-Notes from Fall Semester Work

ISABEL ERICKSON - Jan 29, 2020, 10:21 AM CST

Title: Main Ideas from Fall 2019

Date: 28 Jan 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Gain a background of what the team accomplished last semester and start to generate ideas for improvements

Time Spent: 2 hours

Content:

Understanding of Problem: Clinicians have a hard time with repairing lacerations on their own. Often times another person is needed to approximate the edge of the wound to ensure proper repair. Additionally, poor wound approximation can lead to more scarring than necessary. Currently, doctors use forceps to hold small wounds together which are not designed for wound edge approximation due to the doctor needing to use one hand to use the forceps and not being able to suture/glue the wound together correctly. A device is needed that can quickly and accurately approximate the wound autonomously and allow the physician to fully participate in wound closure.

Existing Devices: No devices that only approximate wounds and do not also close them for healing

Problem Statement / Specifications: Designed for a wound 2 -5 cm in size. Design must overcome splaying tension from skin before locking into place. Main Goal: Hold wound edges together while a clinician is suturing or glueing. The device must stay in place, and not harm the skin/cause pain. At least 350 uses per year (last at least a year.) Must be sterilizable (autoclave). Not weight more than 0.5 pounds. Should be fabricated under $300. The device should also be simple, clean and have a non-threatening appearance.

Preliminary/Proposed Final Designs:

Bow-Shaped

Hook and Loop

Barrette

Rectangle

- revised design to include to angles slotted pieces on both sides of the device to allow the long edges to slide together without the need for a gear system. The sides in contact with the skin were also covered in a layer of silicone (protect against slip).

- Materials used were

- Stainless Steel 304 (sterilized via autoclave, relatively inexpensive, easy to fabricate with)
- Silicone (flexible rubber, to add friction on connection with skin, can also be sterilized in autoclaves)

- Fabricating using waterjet cutting, Eisen Mills, Band Saw, Sander and Welder

thumb screws/nuts in the slots at a 45 degree angle allow the differing area of the edge finder

Bumpers were added with the idea to place them at each corner of the wound area and the long sides of the device are fit around the bumpers. Next the sides are pushed together to approximate the wound edges.

The final cost was $43.07 and weighed 50.81g. (Well in tolerance)

Testing and Results

1. Determine Force applied by the user and the force applied by the device to the user's skin

(What is the point of testing the silicone strips alone?).

Displacement of the suture pad induced tensile forces from 27.68 N to 38.95 N.

Testing how well the device approximated the wound edges by finding the strain the device created on the silicon skin wound. The stress was also determined through the stress strain equation which was then used to determine the force.

- Did we ever determine the force applied by the user?

2. Device displacement in life of service. (SkinPrep and no SkinPrep) Skin Raised to stimulate skin approximation. Markers placed to simulate starting position. 3 minute length (how long it takes to fix wound). Distance between original and final markings determined hoe much the device moved.

Total displacement was between 0.7300 and 1.500 mm (no Significant difference between using SkinPrep and not using SkinPrep).

3. Patients ranked pain level, 0-5 point scale tested on the forearm of each team member.

Average pain score of 0.75 out of 5.

4. Qualitative Examination of Device Functionality. Device should not harm the skin, were there marks on the skin etc. after the 3 minute test?

Shallow Indentations were found.

Discussion

Suture Pads actually have an embedded mesh that makes them much stronger than real skin (might not de suitable for testing) - Team needs to find new "skin" for testing

Displacement of the device during treatment needs to be addressed (Max displacement less than 2.5% of the wound length - so about 0.5 mm displacement or less)

Silicone Bumpers are not reusable and would need to be replaced

Wounds are also not always linear - skin sample was not HILE

Having a real wound might cause the pain to be much higher when using the device

The device may displace more with a real wound as well with the tension pulling it apart (body fluids/ antisepctic creams)

Locking Hinge Screw would work better than the them screws to operate

Conclusion

Need to adhere the device better to the skin

Need a better way to test the device on more realistic skin. (Maybe pig or animal skin?)

Clinicans use the device and rate? - Need IRB

Fix the hinge system to make it easier to use

Conclusions/action items:

Research new types of skin to use for testing

Research better hinge systems

Research better ways to adhere the device to the skin

Prepare for the presentation on 2/7

14Feb2020 - Outreach Presentation

ISABEL ERICKSON - Feb 22, 2020, 3:17 PM CST

Title: Outreach Presentation

Date: 14Feb2020

Content by: Entire Outreach Team

Present: Entire Outreach Team

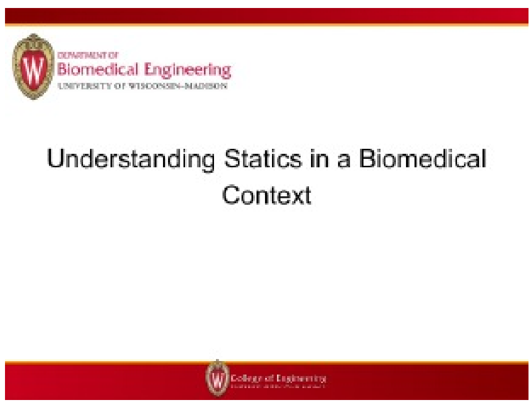
Goals: Complete Outreach

Content: Went to Baraboo to teach an AP Physics course with team.

Conclusions/action items:

Finish turning in all Outreach Items

ISABEL ERICKSON - Feb 24, 2020, 5:44 PM CST



Outreach_Presentation.pdf(3 MB) - download

Standard Information

ISABEL ERICKSON - Apr 10, 2020, 9:55 PM CDT

Title: Standards for Wound Closure Devices

Date: 1o April 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Understand Standard for Devices Similar to our design

Content:

There are Standards for sale such as Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants (ASTM F2458).

4.1 Materials and devices that function at least in part by adhering to living tissues are finding increasing use in surgical procedures either as adjuncts to sutures and staples, or as frank replacements for those devices in a wide variety of medical procedures. While the nature and magnitude of the forces involved varies greatly with indication and with patient specific circumstances, all uses involve to some extent the ability of the material to resist imposed mechanical forces. Therefore, the mechanical properties of the materials, and in particular the adhesive properties, are important parameters in evaluating their fitness for use. In addition, the mechanical properties of a given adhesive composition can provide a useful means of determining product consistency for quality control or as a means for determining the effects of various surface treatments on the substrate prior to use of the device.

4.2 The complexity and variety of individual applications for tissue adhesive devices, even within a single indicated use (surgical procedure, which itself may vary depending on physical site and clinical intention) is such that the results of a single tensile strength test is not suitable for determining allowable design stresses without thorough analysis and understanding of the application, adhesive behaviors, and clinical indications.

4.3 This test method may be used for comparing adhesives or bonding processes for susceptibility to fatigue, mode of failure, and environmental changes, but such comparisons must be made with great caution since different adhesives may respond differently to varying conditions.

4.4 A correlation of the test method results with actual adhesive performance in live human tissue has not been established.

Conclusions/action items:

This Standard could be useful in finding better tests to ensure the device is safe, however this device isn't an adhesive or sealant.

Ideas for better adhesive to skin - 31 Jan 2020

ISABEL ERICKSON - Feb 21, 2020, 2:02 PM CST

Title: Initial Ideas for better Skin Adhesive

Date: 29 Jan 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Understand options for basic temporary skin adhesives

Content:

My first though was to make a thicker strip of the silicone to attach to the device. However, the team told me that a thicker layer fell of easier due to the friction force being stronger than the adhesive force holding the silicone onto the model. Then I thought about cutting a hole through the middle of the silicone layer to make the connection a lot stronger and prevent the silicone from ripping off the device. The only issue is that the welded connection currently blocks the silicone from sliding in without making an extra cut. I am thinking to cut the silicone to slide it on and then sew it back together with suture material to simulate that there was no cut there.

Conclusions/action items:

Talk to group about ideas.

Overall Ideas for Improvements

ISABEL ERICKSON - Feb 21, 2020, 1:59 PM CST

Title: Overall Ideas for Improvements

Date: Starting 31 Jan 2020,

Content by: Isabel Erickson

Present: Entire Team

Goals: List Improvements as they are brought up

Content:

31 Jan 2020

Improve the definition of Wound Approximation

Better Define what we expected in the Results

IRB?

- gray area is testing on oneself

- academic advisors opinion, not actually penetrating any tissue

- can try it on classmates, fits into expectations of the classroom experience

(Clinical Environment or Anyone Outside the Classroom, we cannot do it without the IRB)

- Not make them happy the first time through, would need to wait until the summer

- Need to demonstrate benefit is much better than the damage

Could test on tissue samples from cadaver or porcine tissue sample

Skin does not behave due to Hooke's Law

- Could test in a solid works model, also includes time constant in the tissue behavior

Need to not have the fibers matrix (Appropriate Tissue)

Test the device in non-ideal situations

Go back to basic and think if this is the best rendition of the prototype

Maybe with a Spring? (Goes around the back side instead of over the front of the arm?)

Conclusions/action items:

Figure out how to get the torsional spring added to the design

Ensure that skin model is a good substitute for skin

Actually do testing with approximating a wound

24 Feb 2020 - Ideas for Skin Model for Testing

ISABEL ERICKSON - Feb 24, 2020, 5:49 PM CST

Title: Ideas for Skin Model for Testing

Date: 24 Feb 2020

Content by: Isabel Erickson

Present: Isabel Erickson

Goals: Generate Ideas on Skin Models

Content:

- Models with Gelatine
- Models that allow some water absoption

Conclusions/action items:

Design Ideas/Inspiration

ISABEL ERICKSON - Apr 10, 2020, 8:43 PM CDT

Title: Design Ideas / Inspiration

Date:

Content by: 1 March 2020

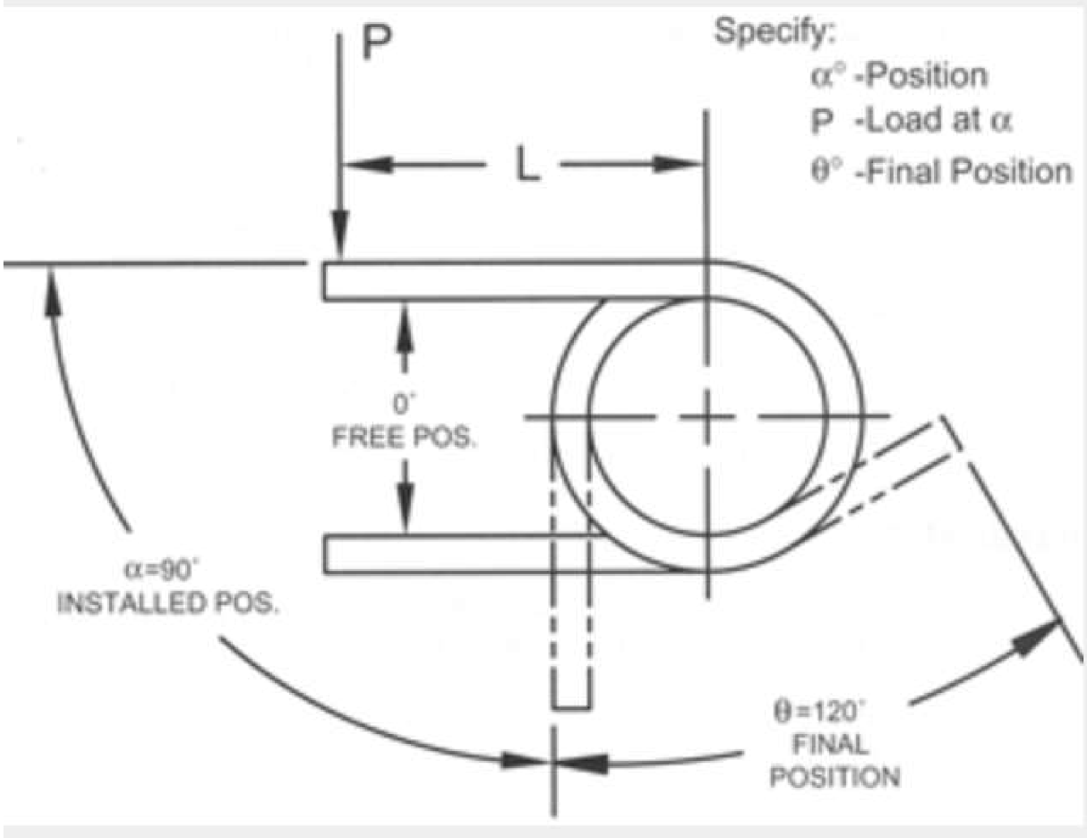
Present: Isabel Erickson

Goals: Come up with ideas for improvements

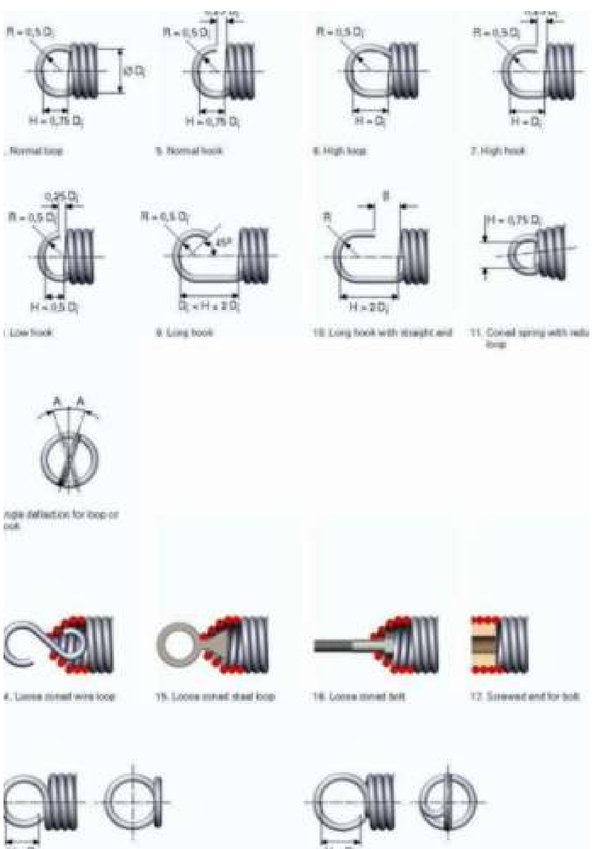
Content:

Our client talked to us about a clothes pin idea in order to easily close and open the device so that it can be placed on the skin very quickly and easily by one physician. I think this could be useful with our design and we could even put more than one along the wound to allow better access to the wound for the physician. However, this design would be easy to slip off the patient or possibly cause too much pinching and cause pain because the amount of pinching cannot be changed.

Another idea was to use a torsional spring. The idea of this is to just pull open the device and let it naturally pinch on to the skin similarly to the clothes pin idea. However, this design wold be difficult and would require a lot of testig to use because it is hard to determine what force of pinching is needed for all types of skin. It also would require extra fabrication and ideally a different setup that would prevent the extra slots cut out and just have a spot for the torsional spring. It would also require somewhere to push against and may not be as intuitive as as the very similar clothes pin idea.



Another idea was to use normal springs to connect the two sides of the device together and them similarly pull apart the design and allow it to load naturally on the skin. I think this idea would be a lot more intuitive for people to use and easier to interchange various springs depending on the elasticity of the skin. This would also be helpful for testing on the skin model with actually pulling together various types of cuts instead of just pulling the skin together.



Conclusions/action items:

Speak with team about the designs

FINAL DESIGN

ISABEL ERICKSON - Apr 10, 2020, 10:09 PM CDT

Title: Previous to Final Design

Date: 10 April 2020

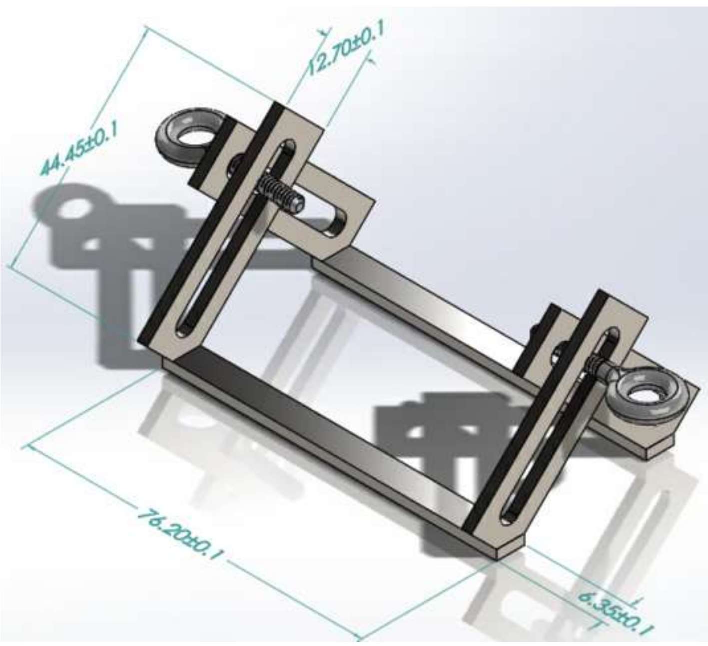
Content by: Team

Present: Isabel Erickson

Goals: Explain the Final Design

Content:

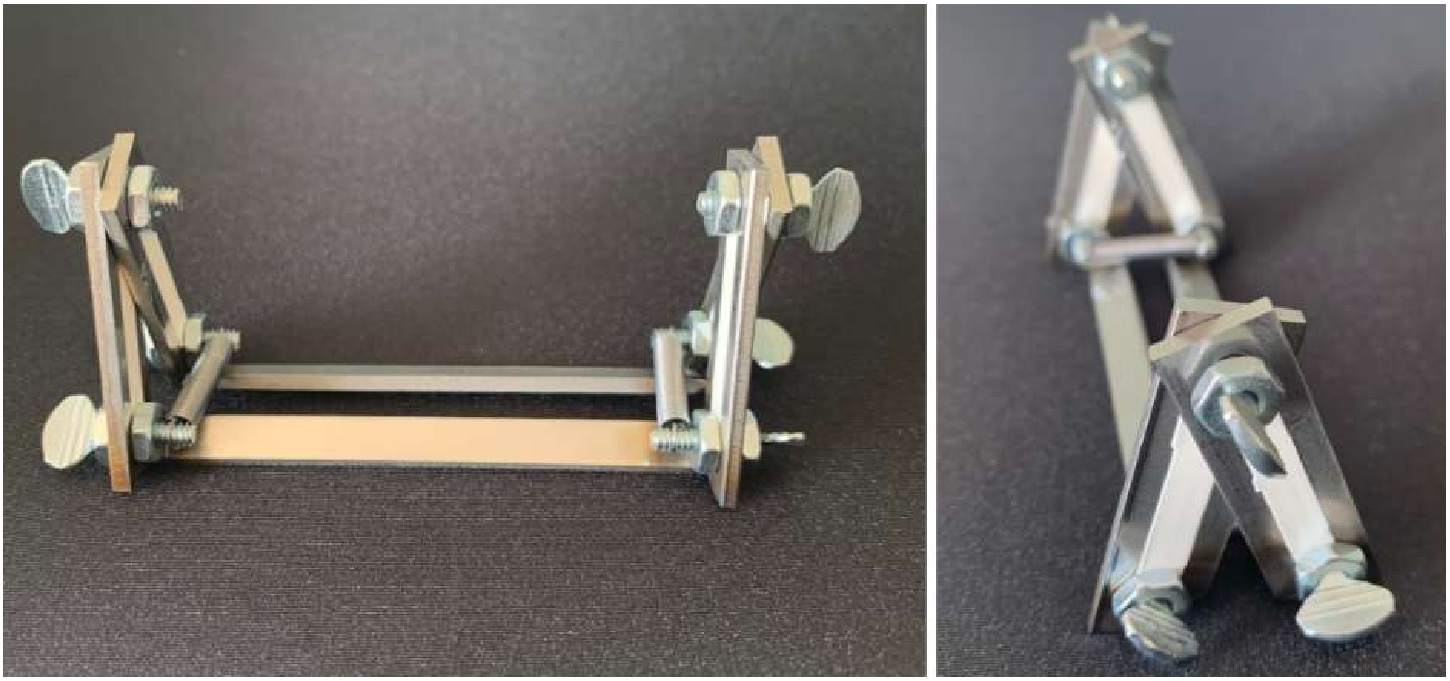
The final assembled prototype is depicted in Fig. 2, 3, and 4. Dimensions are consistent with those shown in Fig. 1. The prototype is a metal frame consisting of two identical stainless steel sides with three pieces: one long, thin segment with a thin layer of silicone along the bottom and two rectangular 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. To increase the effectiveness of the device, hard silicone bumpers are included in the device operation procedure. One bumper is placed at each corner of the designated wound area, and the long sides of the device are fit around the bumpers. Those sides are then pushed together to approximate the wound edges. The thumb screws can then be tightened to secure the device in place on the skin. The device weighed 50.81 g.



Improved Final Design

The improvement to the final desi

The silicone bumpers will be replaced with a double sided, medical grade adhesive tape, which is easier to apply. One side of the tape will be placed on the skin-contacting metal edges, and the other side will be placed on the skin when the device is positioned around the wound. This will allow the device to maintain contact with the skin and stay in place for the duration of its use.



New Final Prototype

The fabricated prototype is shown in Fig. 5. The prototype is a metal frame consisting of two identical stainless steel sides with three pieces: one long, thin segment 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 at the top and hex nuts through the slots. Additionally, the sides are connected with tension springs near the bottom to hold the device in resting position while also allowing the sides to be pulled apart during use. To increase the effectiveness of the device, double-sided adhesive tape was included in the device operation procedure. A piece of tape is placed on each skin-contacting side of the device. The device is then pulled open by the clinician and placed on either side of the wound while pressing the edges against the skin to secure the tape in place. Those sides are then pulled together to approximate the wound edges via the force from the tension springs.

Conclusions/action items:

Work on Final Paper

Device Displacement

ISABEL ERICKSON - Apr 10, 2020, 10:24 PM CDT

Title: Testing - Device DIsplacement

Date: 10 April 2020

Content by: TEam/me

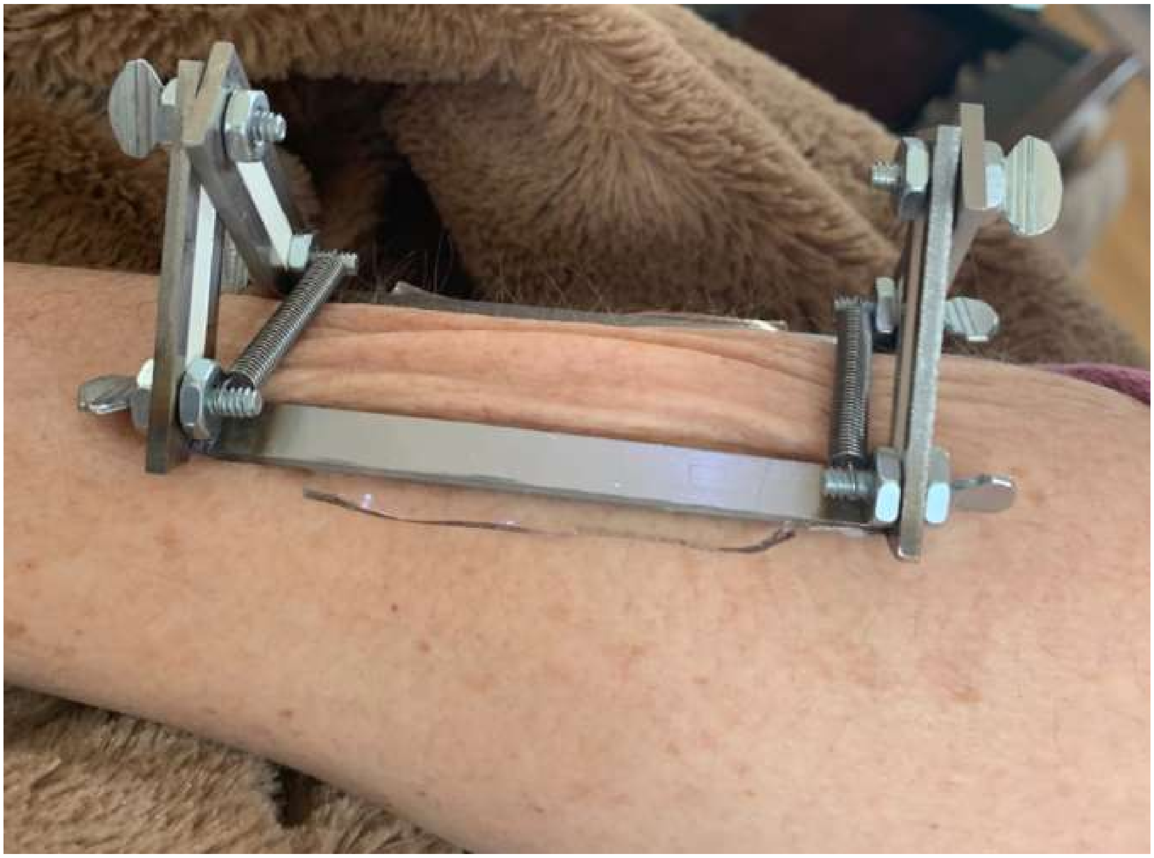
Present: Isabel Erickson

Goals: Understand Device Displacement Testing

Content:

Device Displacement was important according to standards for similar devices, so it should be important for testing our device. The team was having difficulties with too much displacement and was an important thing to test thoroughly. The team decided to use double sided tape in the end to remove the silicon bumpers and instead use reusable methods for ensuring strong adhesion each time.

To test on bare skin, the prototype was placed on an individual and the sides of the device were released until the skin was raised to simulate wound approximation. Lateral forearms, lateral upper arms, ventral torso, ventral thighs, and dorsal calves were included during testing. Markings were placed on the skin on either side of the device to denote the starting position. After the five minute interval was completed, new markings were made to denote the final position of the device. The distance between the original and final markings was recorded to determine how much the device moved and slipped while in use. This procedure was completed ten times for each condition. This method determined how much the device moved while in service, and if the device remained on the skin while in use.



Conclusions/action items:

Continue Testing

Other Testing

ISABEL ERICKSON - Apr 10, 2020, 10:24 PM CDT

Title: Testing

Date: 10 April 2020

Content by: Team

Present: Isabel Erickson

Goals: Share Completed Testing

Content:

(Very small patient size due to Corona Virus)

Ease of Use

An average ease of use score of 1.5 out of 10.0 during device use was found, (Subject 1 = 2) (Subject 2 = 1). Subjects noted that the double-sided tape was the trickiest part of the device to understand and use. The removal of the peel paper on the tape was difficult.

Discomfort Scale

An average pain score of 1.0 out of 5.0 during device use was found. Subjects noted that there was only slight discomfort during use and removal. Upon removal, shallow indentations were observable in the individual's skin for up to two minutes after use (Fig. 11).

Conclusions/action items:

Finish Paper

Wound Approximation

Kavya Vasan - Apr 29, 2020, 9:24 PM CDT

Title: Wound Approximation

Date: January 31, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To understand the process of wound approximation

Content:

- Wounds need to be approximated precisely to ensure that they heal and don't scar.
- Staples:
    - For linear lacerations on scalps and extremities, staples are used.
    - Can be put quickly
    - Good for when there is fast bleeding and when there are a lot of wounds.
    - They are cost-effective and don't need much training
- Sutures:
    - These are the most common method of wound repair.
    - Non-absorbable sutures have good tensile strength and are used for superficial wounds.
    - absorbable sutures are used for deeper wounds and decreases the tension. This has a lower risk of the wound gaping.
    - Choice of suture depends on tension degrees, type of wound, and desired cosmetic results.
    - simple interrupted sutures - good tensile strength and aesthetically pleasing.
    - rapid hemorrhage/long wounds - minimal tension wounds need running sutures. They're quick to apply and spread tension along the wound. Higher risk of gaping.
    - Mattress stitch - provide more strength, minimizes tension, and closes wound edges better.
- Adhesives:
    - For percutaneous wounds or simple pediatric cases, skin glues are quick and less painful.
    - Adhesive tapes and skin glues can be used for deeper wounds too.
    - They have minimal wound inflammation, lower infection rate than sutures and and can be removed easily.
- Primary intention healing: when wound edges are pulled together by staples/sutures.
    - Healing includes wound epithelization and connective tissue deposition for lower infection rates.
- Secondary intention wound healing - wounds heal by being left open for granulation tissue to form contraction.
    - more risk of infection because of the lack of epidermal barrier

A. Waheed and M. Council, “Wound Closure Techniques,” *Wound Closure Techniques*, May 2019.

Conclusions/action items: This gives good background information on the problem that we are trying to solve. This is used in urgent care, emergency rooms and surgeries. Need to research skin properties and tissue adhesives to gain more knowledge on how to test the device on skin models.

Skin properties

Kavya Vasan - Feb 26, 2020, 12:13 AM CST

Title: Skin Properties

Date: February 7, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To learn about the mechanical properties and physiological properties of skin

Content:

- Largest surface area on body
- It protects from environment agents, temperature fluctuation, and adapts to body contour.
- Skin is mechanically complex due to its layers
    - Epidermis - 75-150 micrometers
        - sublayers: stratum spinosum, stratum granulosum, stratum basale, stratum corneum
    - Dermis - dense fibrous tissue, 1.5-2.5 mm
    - Hypodermis/subcutaneous - adipose cells, insulating, 10% of body mass
- Skin is made up from: collagen that gives strength and volume , elastin (recoil and deform) gives mechanical behavior, and reticulin
- Methods used to test
    - indentation: rigid indenter is used to apply deformation to skin
        - Hertz Formulation: (1/Er) = (1-v^2)/E + (1-vi^2)/Ei
    - torsion - constant rotation/torque applied to skin with intermediary disk
    - tension - skin loaded parallel to surface
    - suction - skin is elevated by applying a partial vacuum with a circular aperture.
- Skin is viscoelastic and anisotropic.
- Skin testing to get stress strain graph: biaxial tension - stretches skin in multiple directions, uniaxial tension - stretches skin in one direction
- Mechanical properties of skin
    - Non-linear stress-strain relationship
    - When skin is stretched, at higher strain, the stiffness of the material increases
    - Collagen is the main support in linear region of stress-strain curve
    - Viscoelastic property - skin is strain rate dependent
    - Skin exhibits the relaxation behavior characteristics of viscoelastic materials
        - stress in skin material decays over time when held at constant strain
    - Mechanical properties depend on orientation which are called Langer's lines
    - Strain rate is a major variable that affects soft tissue failure properties
    - Age also changes skin stiffness as stiffness decreases with increase in age

H. Joodaki and M. B. Panzer, “Skin mechanical properties and modeling: A review,” *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, vol. 232, no. 4, pp. 323–343, Mar. 2018.

Conclusions/action items: Using the knowledge of these properties, we need to develop more testing methods for the existing device and research how materials like silicone will react to the skin. The device needs to be able to stay in place during the approximation, so conduct more research on adhesive materials.

Skin Anatomy and Tensile properties

Kavya Vasan - Apr 29, 2

Title: Skin Anatomy and Tensile properties

Date: February 7, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To learn about the different components of skin and the tensile properties to understand how the device would interact with skin

Content:

- Part of the integumentary system
- Layers:
    - Epidermis
        - Stratum Basale
        - Stratum Spinosum
        - Stratum granulosum
        - Stratum Lucidum
        - Stratum Corneum
    - Dermis
        - Papillary layer
        - Reticular layer
    - Hypodermis
        - Lipid storage

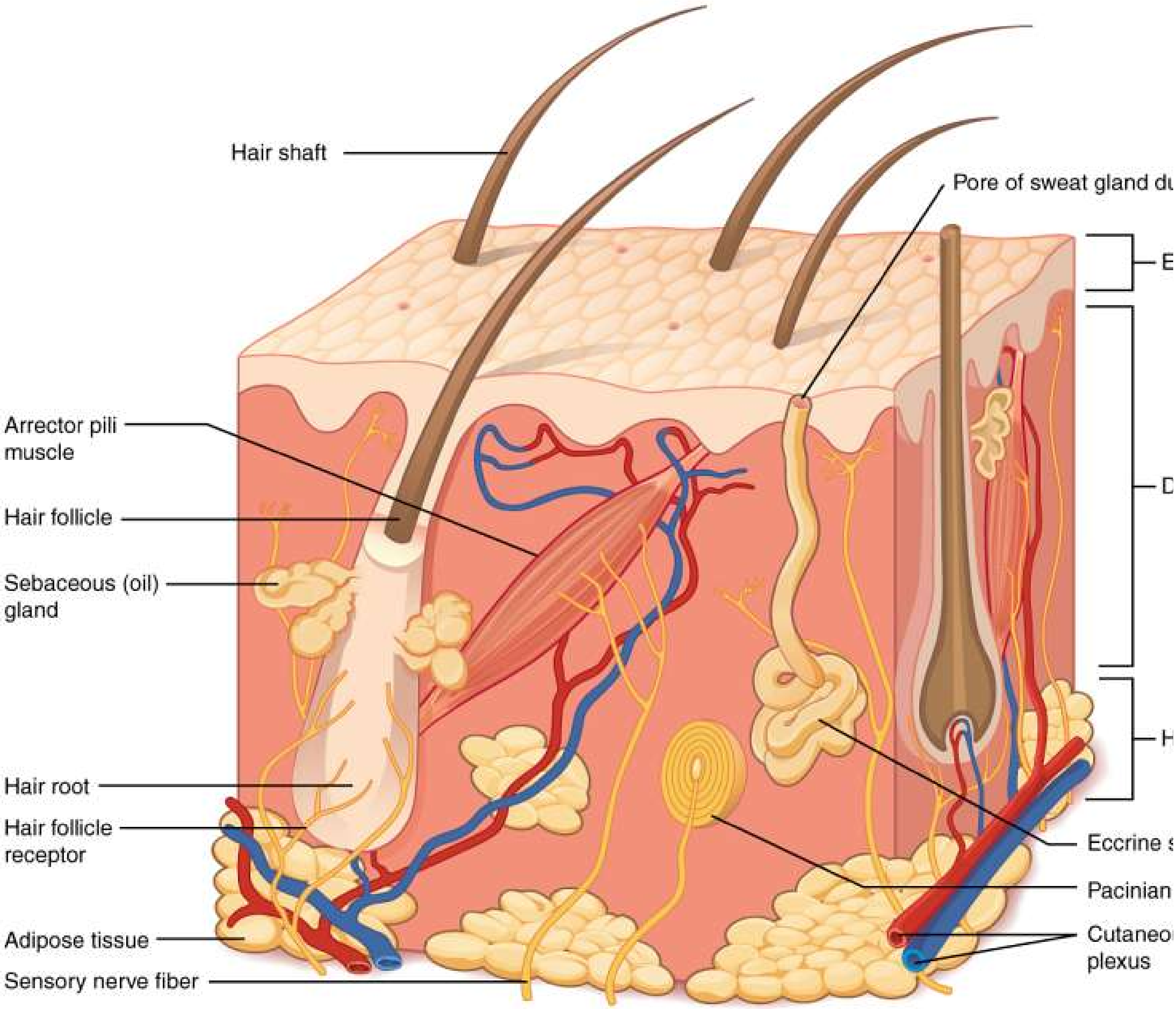


Figure 1. Layers of Human Skin

"5.1 Layers of the Skin," *Anatomy and Physiology*, 06-Mar-2013. [Online]. Available: https://opentextbc.ca/anatomyandphysiology/chapter/5-1-layers-of-the-skin/. [Accessed 2020].

Mechanical Behavior of Human Skin

- Elastin fibers have low resistance at 0.3% strain. Skin is isotropic here and collagen is crimped. Elastin has a linear response here.
- Collagen plays a big role in its mechanical properties. Aging leads to less collagen, with changes the skin's elasticity and strength.
- As more strain is applied (0.6%), the collagen crimps become straight. At 0.7% strain, ultimate tensile strength is attained.
- Young's Modulus of human skin varies with the orientation of collagen fibers and strain rate. It ranges from 4-15 MPa at static strain rates.
- E ranges from 14-100 MPa at dynamic strain rates. The variation is due to the direction in which the skin is held in tension.
- Transverse gives a higher Young's Modulus than longitudinal.
- Young's Modulus increases with strain rate.
- Langer's lines directions affect Young's modulus, due to different orientations.

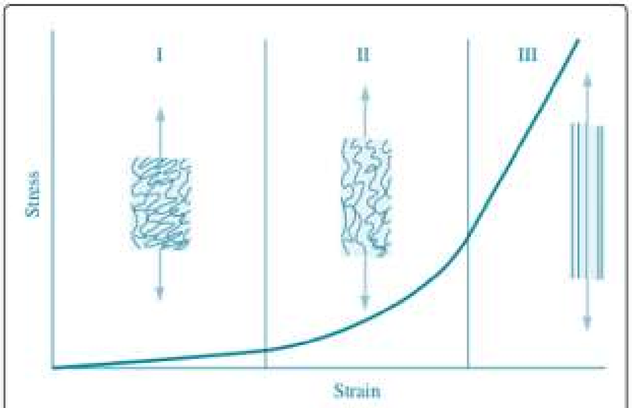


Figure 1: Structure of collagen fibre in different phases [5].

Figure 2. Stress-Strain curve of collagen fibers

K. A and L. A, "Mechanical Behaviour of Skin: A Review," *Journal of Material Science & Engineering*, vol. 5, no. 4, 2016.

Conclusions/action items: The basic anatomy of skin is to understand the different components contributing to its mechanical properties. The tensile strength data gives an indication of the r that we should expect to see while testing our skin model. The effects of collagen are really important because different skin types have different mechanical properties. Age is a big factor in c production. I think that we should have a range of test subjects so that we can see how our device works on people of different ages.

Ecoflex Silicone skin

Kavya Vasan - Feb 26, 2020, 1:30 PM CST

Title: Silicone skins

Date: February 17, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To find a viable silicone or other material pad that can mimic skin tension properties

Content:

- Ecoflex: Platinum-catalyzed silicones
- Negligible shrinkage
- Varsatile because when mixing, one can thin the silicone.
- Available in different hardness: Shore A-5, Shore 00-50, 00-35, 00-30, 00-20, 00-10, 000-35
- used for prosthetics, orthotics cushioning and special effects. It is Skin Safe
- It has low viscosity and is a soft, strong and stretchy rubber material.
- Can stretch to a large magnitude without tearing, will rebound to original form, and can be colored.
- Cure times can range from 5 mins to 4 hours, depending on the type of ecoflex.
- Epoxy adhesive cement is available but they don't work very well on metals like nickel and tin.

"Ecoflex™ Series, Super-Soft, Addition Cure Silicone Rubbers," *Smooth-On*. [Online]. Available: https://www.smooth-on.com/product-line/ecoflex/. [Accessed: 17-Feb-2020].

Conclusions/action items: This is one of the most versatile materials to play around with. Depending on the cost, we could order a little and see whether the one of the ecoflex silicones would have the desired skin properties to test. It needs to be non toxic to mix all the ingredients together. Do more research on synthetic skins and silicone based pads to test the prototype on.

Types of Synthetic Skin Models

Kavya Vasan - Apr 29, 2020, 5:10 PM CDT

Title: Synthetic Skin Models

Date: March 15, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To research existing skin models that simulate the properties of real skin

Content:

- Physical skin models have long-term stability, they are cheaper and are easy to store and manipulate.
  - Their physical properties can be reproduced. This is good for testing of mechanical properties of skin.
- They are more ethical than human/animal skin testing.
- The dermis controls strength and flexibility. It has collagen and elastin fibers.
- The hypodermis is viscous and connects muscle to skin.
- The skin protects from mechanical and UV damage.
- Elastic modulus of dry stratum corneum: 3.5-1000 MP, Elastic modulus of wet stratum corneum: 10-50 MPa.
- Elastic modulus of viable epidermis: 1.5 MPa, and Elastic modulus of dermis: 8-35 kPa. These values are affected by skin hydration, environment humidity, and test method.
- Skin models are made with synthetic polymers to mimic performance of human skin.
  - combinations of liquid suspensions, gelatinous substances, metals, textiles and elastomers.
- Gelatinous substances:
  - Gelatine: This is an irreversible hydrolyzed form of collagen.
  - It is a component of skin, bones and connective tissue.
  - Long shelf life.
  - Used as skin model for wound reconstruction.
  - The model has glycerol and lipids to mimic lipids in skin layer for hydrophobicity.
  - Mechanical and surface properties close to that of human skin.
- Polyvinyl alcohol gels:
  - PVA gives a crystalline structure. It is soluble in water and can crosslink to form hydrogels.
  - It is adhesive and emulsifying, high tensile strength and flexibility.
  - It is resistant to solvents and grease - which is good because we want to model's properties to last.
  - Biocompatible and easy to manufacture. It's used for imaging because its properties are similar to those of soft tissues.
  - Elastic modulus of PVA is 38 kPa and the Elastic modulus PVA gel is 50 kPa.
- Elastomers:
  - Silicone: Known as siloxane. It is inert and synthetic. Its properties can be simulated, is non toxic and has long-term stability. Can manipulate properties to be similar to human skin properties.
  - Dragon skin: silicone rubber that is used for prosthetics.
  - Friction and traction properties are similar to those of human skin.
- Polyurethane:
  - Copolymer of urethanes. They are viscoelastic, therefore they are used to study mechanical skin-like properties.
  - These models are used for medical training.
- Combinations:
  - Silicone and Polyurethane: Very promising. There is interfacial adhesion strength and similar subdermal stiffness to skin.
  - PVA and Silicone: these mimic the mechanical properties of human skin. There's a similar friction coefficient.
  - Silicone gel: This is used to represent skin and soft tissue, with different layers.

LIN, L., LI, J. and ZENG, X. (2017). The Development of Physical Skin Model for Biomechanical Applications. *Journal of the Society of Biomechanisms*, 41(3), pp.129-136.

Conclusions/action items: Our team should explore models that are being sold, to test the prototype. According to my research, we should look into models made of polyurethane and elastomers because they mimic human skin properties quite well. If there are combinations of silicone and polyurethane, then we should look into buying them since they have mechanical properties that are close to those of human skin.

Derma clips

Kavya Vasan - Apr 29, 2020, 5:45 PM CD

Title: DermaClip

Date: 2 February, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To get information on Dermaclips, an existing product for wound approximation

Content:

- Non-invasive skin closure that is quick and easy for surface wounds.
- It doesn't puncture or crush the skin
- Alternative to sutures and skin glues
- Has been used on thousands of patients for:
    - C-sections, abdominoplasty, masectomy, hip replacement, wound/laceration repair, pediatric wound closure.
- can be used in the ER or in a clinic.
- It reduces the time taken to close a wound.
- It is quick, single-use and made out of plastics.
- It makes a hinge in the middle, between 2 layers of acrylate adhesive to lift and evert the skin.
- The distance can be adjusted for larger wounds.
- Versatile for different types of wounds.
    - Large Dermaclip is good for long straight incision with a gap.
    - Regular DermaClip is for slender wounds with curvature, are smaller and need precision.
- Made from non-latex, strong and durable adhesive
- It can keep the wound closed for 7-10 days.
- Gentle for fragile skin - diabetic and geriatric, and reduces focal tension on skin edges to prevent skin tearing.
- Small amount of simple training can allow wound closure of 3 inch incisions to be closed in 2 minutes.

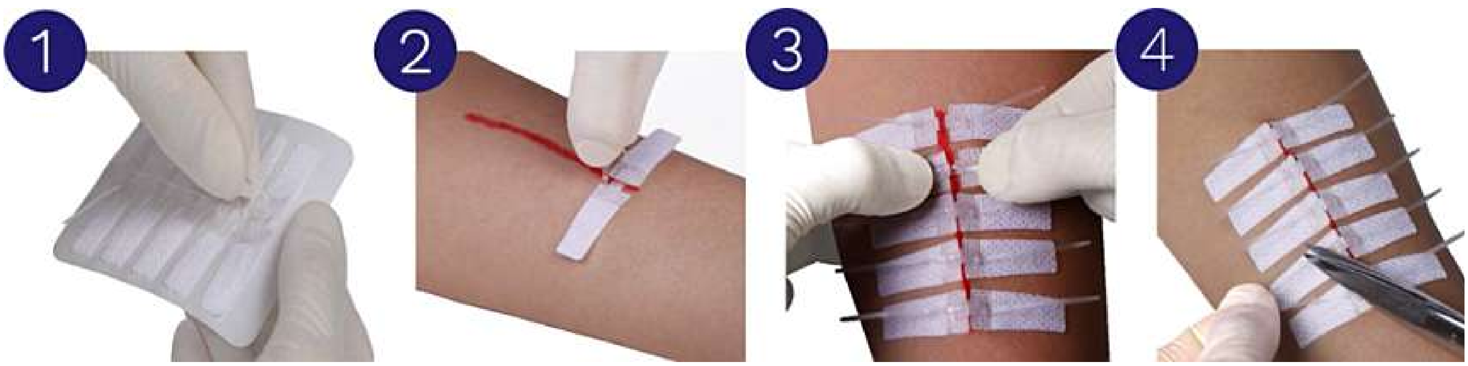


Figure 1. Steps on how to use Dermaclips

"DermaClip Non-Invasive Skin Closure Device, Revolutionizing Wound Care," *DermaClip US, LLC*. [Online]. Available: https://www.dermaclipus.com/. [Accessed: 02-Feb-2020].

Conclusions/action items: This has been used on patients and shows promising results. But this covers the wound and doesn't allow for suturing or the use of dermabond. The clients wants one device that is adjustable, will stay on skin to pull the wound edges together to use dermabond for closing the wound. To use Dermabond, the device needs to keep the wound edges accessible. Also, this device could have an intimidating appearance to children, so our device should not look intimidating.

Geckskin

Kavya Vasan - Apr 29, 2020, 5:47 PM CDT

Title: Geckskin

Date: 18 February, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To find out about the adhesive mechanisms used in Geckskin

Content:

- 3 x 5 " can hold 700 pounds on smooth surface, is easily removable and doesn't have residue.
- Doesn't depend on viscoelasticity, it uses draping adhesion
    - created with materials that drape to create conformal contact with a surface while maintaining high, elastic stiffness when forces are applied.
- Adhesive loads are distributed more evenly along the geckoskin surface
    - allows for fast and low energy transition when attaching or detaching
- It is made of stiff materials - carbon fiber and Kevlar, with soft elastomers - polyurethane or PDMS.
    - This allows to maximize contact.
- The skin is woven into synthetic tendon, like real gecko feet, which allows to maintain stiffness and rotational freedom.
- High shear strength and low peel strength
- Uses van der waals forces, but differently from tape
- Starting price is $7.50

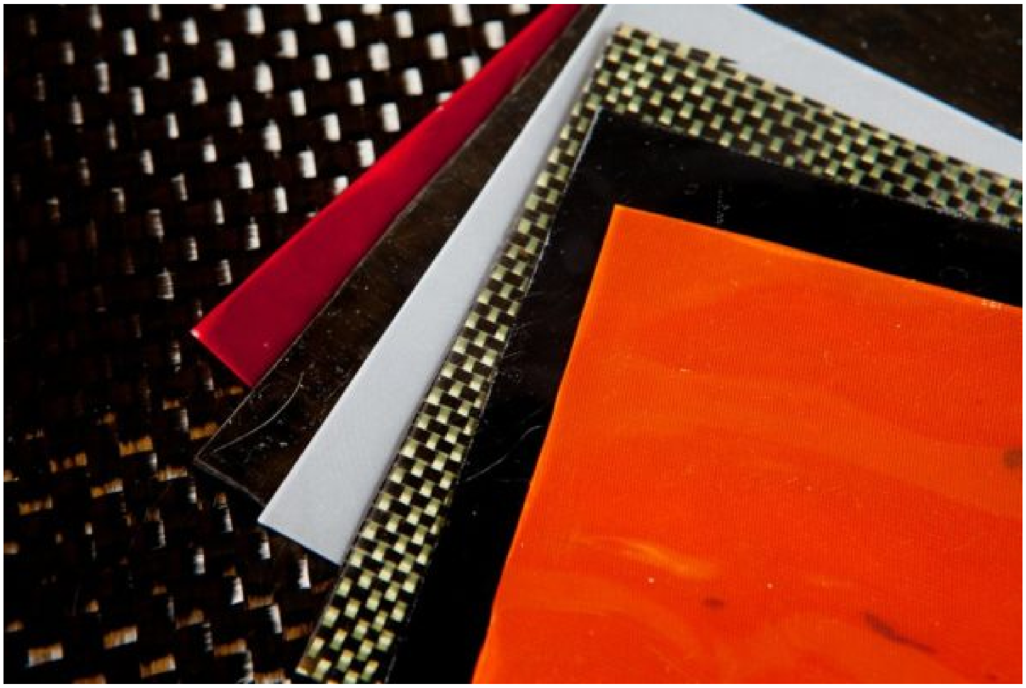


Figure 1. Geckskin sheets in the market

"GeckSkin," *UMassAmherst*. [Online]. Available: https://geckskin.umass.edu/. [Accessed: 18-Feb-2020].

"GeckSkin," *GECKSKIN®*. [Online]. Available: https://www.buygeckskin.com/. [Accessed: 18-Feb-2020].

Conclusions/action items: The combination of stiff fibers and soft elastomers has resulted in useful properties. This could be a viable option to see whether our device will stay in place on human skin with this material. It is also cheap, so we could try it out.

Top Closure S3

Kavya Vasan - Apr 29, 2020, 8:22 PM CDT

Title: Top Closure S3 device

Date: March 17, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To gain information on current devices in the market, and to see what works and what doesn't work in the design

Content:

- The Top Closure S3 product is not reusable.
- It is used when atrophic tissue is present at the wound edges, or a patient has received radiation and/or chemothereapy.
- It has 2 attachment plates and a strap for approximation.
- The device is made out of Polypropylene.
- There is double-sided tape on the bottom of the attachment plates, to stick to the skin.
    - It is hypoallergenic, non-toxic and medical grade.
- There are oval openings in the attachment plate to allow for suturing or stapling of the wound.
- This device can be used for low tension wounds as well as high tension wounds.
- It stretches the skin temporarily to close the wound and heal it.
- It can secure the wound with sutures/staples to make sure there is minimal scarring.

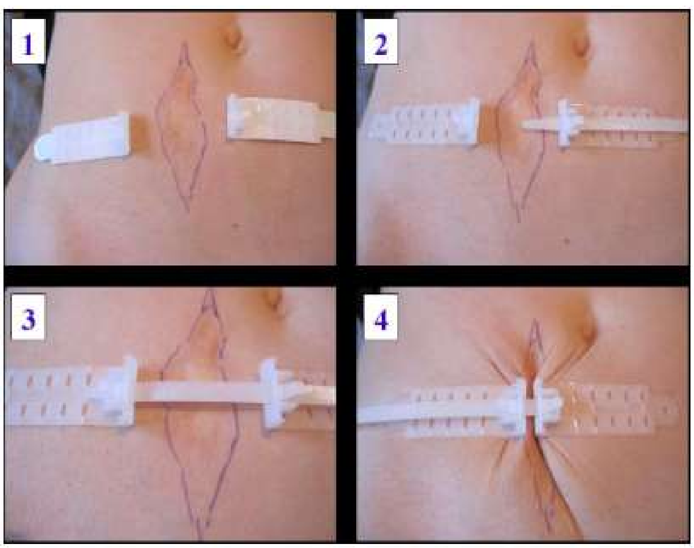


Figure 1. How to use the Top Closure S3 device

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

Conclusions/action items: This has the same problem as Dermaclips. This is secured over the wound edges. The client will use Dermabond to secure the wounds, so the device should be able to pinch the wound edges together, with out covering the wound. The medical grade adhesive that is used for this device could be useful, because we need a adhesive to secure our device onto the patient's skin. I need to look into the medical grade adhesives used in these devices.

Standards and Codes

Kavya Vasan - Apr 29, 2020, 9:10 PM CDT

Title: Standards and Codes

Date: April 1, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To gain knowledge about the codes needed for medical devices for wound approximation

Content:

- Center for Devices and Radiological Health (CDRH) of FDA is in charge of the medical device program.
- Medical Device Classification:
    - It is based on the risk posed on the patient and user, by the device.
    - Class I - devices with the lowest risk and Class III - devices with the most risk.
- Section 201(h) of the Federal Food, Drug and Cosmetic Act defines a medical device as any 'instrument, machines, contrivance, impact, or in vitro reagent intended to treat, cure, prevent, mitigate, or diagnose diseases in humans.
- Title 21, Volume 8, Part 878, subpart E: Surgical Devices, Sec. 878.4320: Removable Skin Clip
    - This is a Class 2 device
    - It connects skin briefly to assist in healing of wounds. It clips on to human skin.
    - It is similar to what our prototype intends to do

Source: https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device

Conclusions/action items: Our device needs to conform to Medical Device standards set forth by institutions such as the FDA. If this design is continued in future semesters, a patent will need to be obtained. This information is essential for our journal article and to get a device into the market.

Torsion Springs

Kavya Vasan - Feb 26, 2020, 12:21 PM CST

Title: Torsion Springs

Date: 14th February 2019

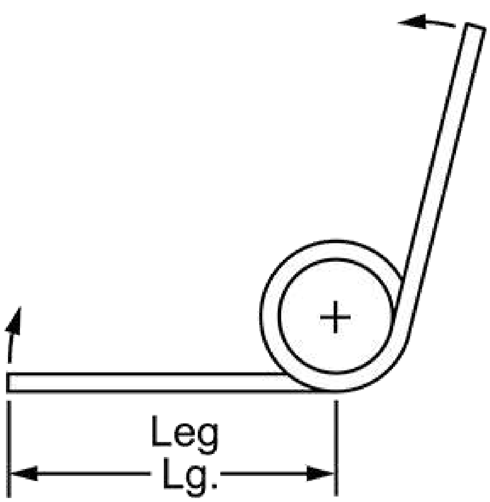
Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To understand how torsion springs work and its properties

Content:

- Torsion springs are found in clothespins, spring clamps, and mouse traps.
- They wrap around a shaft or rod to keep pressure on the items they rotate.
- They're used in the direction that the coils are wound.
    - Left wound - clockwise, right wound -counterclockwise
- Deflection angle = angle between legs and depicts max spring rotation
- Springs rotate until the legs are parallel. Max torque is the torque needed to get to this point.
- Wile rotating a torsion spring, it tightens around a shaft and increases spring length.
- Should not exceed max shaft diameter. This will interfere with spring motion.
- Torque = k*theta



120 deg deflection angle torsion spring

"Torsion Springs," *McMaster-Carr*. [Online]. Available: https://www.mcmaster.com/torsion-springs/torsion-springs-5/. [Accessed: 14-Feb-2020].

Conclusions/action items: Depending on the stiffness and size, we could implement torsion spring with bolts, into the current prototype. We should order different types of torsion springs and after calculating the moments and forces required, we can choose which type to use. One possibility is to buy some hanger clips and play with the spring mechanism in them.

Notes with Makerspace Expert

Kavya Vasan - Apr 29, 2020, 2:36 PM CDT

Title: Design Idea Notes with Karl from the Makerspace

Date: February 14, 2020

Content by: Kavya Vasan

Present: Kavya, Jack, Kelly

Goals: To get some insight on how to implement torsion springs into our device and get other ideas for improvement

Content:

- 3D print something to fill in the slot, so that the device acts like a hinge.
- A nut on the outside.
- No need to adjust on the inside.
- Want the torsion spring to be on the outside, near the screw, so that we don't need to re-fabricate.
- Can put a nut inside and a nut outside to keep the two parts in position.
- Need another clamp on the outside, so that the torsion spring can push against it.
- Can 3-D print this model to show functionality, if it doesn't need to be in steel to show that.
- Team lab can give expertise for the spring mechanism.
- We can get fast prototypes if we 3-D print the parts.
- Buy a chip clip and see the torsion mechanism.

Conclusions/action items: We don't want to re-fabricate the device so ideally we can attach the torsion spring to our existing prototype, and we can get more ideas from TeamLab experts on how to do that. We can also 3D print this design as a proof of concept and continue testing.

Advantages of 3-D Printing and Choosing materials

Kavya Vasan - Apr 29, 2020, 7:47 PM CDT

Title: Advantages of 3-D printing and criteria for choosing material

Date: February 15, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To find out the benefits of 3-D printing to fabricate

Content:

- Advantages of 3D printing
  - Advantages over traditional manufacturing techniques (CNC, lathe, mill).
  - Delivers design quickly and accurately
  - Much faster than traditional manufacturing. Can print a complex design within hours and more accurate than people measuring.
  - It is single-step manufacturing.
  - Fused deposition modeling (FDM) uses filament coils at $25/kg (ex: PLA). Stereolithography SLA printing of resin costs $150/L. 3-D printing is cheap, but more expensive for resin materials.
  - It gives design freedom for complex models that may not be able to be manufactured otherwise. Since components are constructed one layer at a time, design requirements such as draft angles, undercuts and tool access do not apply.
  - However, if it isn't adequately supported, the print will fail.
  - Sustainable - produces little waste.

B. Redwood, "The Advantages of 3D Printing," *3D Hubs*. [Online]. Available: https://www.3dhubs.com/knowledge-base/advantages-3d-printing/. [Accessed: 25-Nov-2019].

- Choose right material to 3-D print
  - Compare mechanical and thermal properties of different materials.
  - Tensile Strength: Resistance of a material to breaking under tension.
  - Young's Modulus: Resistance of a material to stretch under tension (stiffness).
  - Elongation: Resistance of a material to breaking when stretched.
  - Flexural Strength: Resistance of a material to breaking when bent.
  - Flexural Modulus: Resistance of a material to bending under load.
  - Impact Strength: Ability of a material to absorb shock and impact energy without breaking.
  - Indentation Hardness (shore): Resistance of a material to deformation.
  - Compression set: Permanent deformation remaining after material has been compressed.
  - Tear Strength: Resistance of a material to growth of cuts under tension.
  - Heat deflection temperature: Temperature at which a sample deforms under a specified load.
  - Thermal Expansion: Tendency of a material to expand (or shrink) in response to a change in temperature.

"How to Choose the Right 3D Printing Material," *Formlabs*. [Online]. Available: https://formlabs.com/blog/how-to-choose-the-right-3D-printing-material/. [Accessed: 25-Nov-2019].

Conclusions/action items: 3-D printing is an excellent option that is cheap for our budget. It can be used from a solidworks model. It is accurate, it can make a complex model, and it is fast. This can be used to show a proof of concept to avoid refabrication, or to print certain parts to attach to the existing design. The slot filler is an easy design to make in soldworks and can be printed out of PLA.

Skin Adhesives

Kavya Vasan - Feb 26, 2020, 1:13 PM CST

Title: Skin Adhesive Research

Date: February 20, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To research options for adhesives for the prototype to stick to patient skin

Content:

- Double sided Medical Tape
  - Rubber, acrylic and silicone adhesives
  - can stick to foams, metals, plastics and non-wovens
  - hypoallergenic, breathable and conformable
  - range of colors, clear available
  - fluid resistance
  - can be used on prosthetics and wound care dressings

https://parafix.com/product-groups/medical-grade-materials/double-sided-medical-tape/

- Fearless body tape
  - Cheap: $9.90
  - Safe on skin
  - used to stick clothes to skin
  - Can be used on different fabrics and on metal pins
  - Each strip is 1/2 in by 3 in long
  - Can wash off easily

https://www.amazon.com/Fearless-Tape-Double-Sided-Fashion/dp/B01K2CMFVM

- Dermabond
  - 'Surgical skin glue'
  - Medical skin adhesive that glues incisions and injuries.
  - It reduces infection chances and healing rates are improved.
  - Quick to reduce time taken for the procedure
  - Can be used with deep dermal stitches
  - There are different types for different wound sizes and types
  - Adds protection and strength

https://www.usamedicalsurgical.com/blog/dermabond-surgical-skin-glue/

Conclusions/action items: We should buy the medical tape to test how it works with the prototype and how easily it can be removed from the prototype. Since it also has different colors, that could be appealing to children when using the prototype on them.

Viscoelastic Models

Kavya Vasan - Apr 29, 2020, 10:47 PM CDT

Title: Viscoelastic models for skin

Date: March 10, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To use information on viscoelastic models to model skin's response to stress and strain

Content:

- Skin exhibits viscoelastic behavior, having both elastic solid and viscous liquid properties.
- It can be modeled using viscoelastic models.
- The models are combinations of springs and dashpots.
- The Maxwell model has a spring and a dashpot in series.
  - Accurate at predicting stress relaxation behavior but poor at predicting creep behavior.
- The Kelvin Voigt model has a spring and a dashpot in parallel.
  - This model is accurate at predicting creep behavior but not stress relaxation response.
- The Standard Linear model has a spring in series with a dashpot, that are in parallel with another spring.
  - Accurate at predicting both stress relaxation and creep behavior.
- Maxwell stress relaxation response: $\boldsymbol{\sigma} = E*\boldsymbol{\varepsilon}_0*e^{-E/\eta*t}$
- Maxwell creep response: $\boldsymbol{\varepsilon} = (\boldsymbol{\sigma}_0/\boldsymbol{\eta})*t + \boldsymbol{\sigma}_0/E$
- Kelvin Voigt stress relaxation response: $\boldsymbol{\sigma} = E*\boldsymbol{\varepsilon}_0$
- Kelvin Voigt creep response: $\boldsymbol{\varepsilon} = -(\boldsymbol{\sigma}_0/E)*e^{-E/\eta*t} + \boldsymbol{\sigma}_0/E$
- Standard Linear model equations:

$$\boldsymbol{\varepsilon} = \boldsymbol{\varepsilon}_{E1} = \boldsymbol{\varepsilon}_{E2} + \boldsymbol{\varepsilon}_{\eta}$$

$$\boldsymbol{\sigma} = \boldsymbol{\sigma}_{E1} + \boldsymbol{\sigma}_{E2} = \boldsymbol{\sigma}_{E1} + \boldsymbol{\sigma}_{\eta}$$

$$\boldsymbol{\varepsilon} = \boldsymbol{\sigma}/(E_1 + E_2)$$

- Skin doesn't exactly model each of these viscoelastic models because it has a mixture of different components.
- A synthetic skin model can be tested and a stress strain curve can be obtained to see which model the skin resembles.
- Unloading and loading of forces can be seen in Hysteresis.

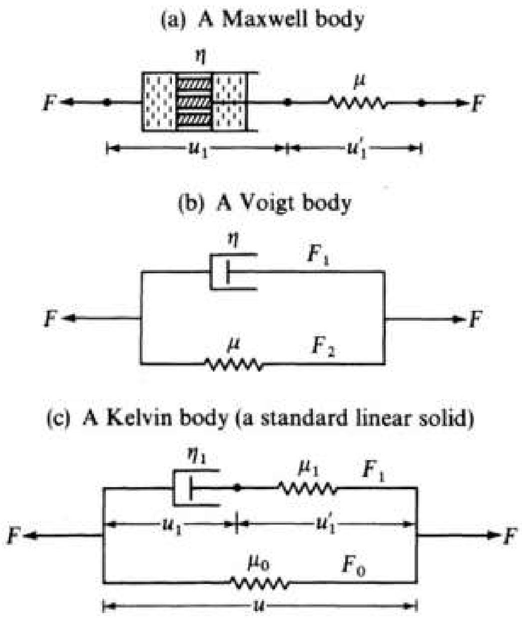


Figure 1. Maxwell, Kelvin-Voigt and Standard linear models

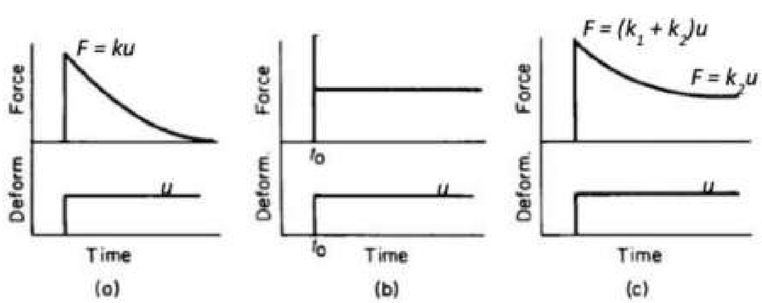


Figure 2. Response to stress relaxation and creep corresponding to the models in Fig. 1

Özkaya, N., Nordin, M. and Leger, D. (1999). *Fundamentals of Biomechanics*. New York, N.Y.: Springer-Verlag.

Fung, Y.C. (1993). *Biomechanics: Mechanicals Properties of Living Tissues.* New York: Springer-Verlag New York, Inc.

Conclusions/action items: These mathematical models can be used to understand the mechanical skin behavior of the synthetic skin model that is intended for testing. Skin is complex, so stress relaxation and creep responses can help us visualize how skin will respond to the forces applied from the device.

Spring Types and Equations

Kavya Vasan - Apr 29, 2020, 11:21 PM CDT

Title: Comparison between Springs

Date: April 5, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To choose a spring that can makes a hinging motion

Content:

- Clothespin Spring (Torsion Spring)
  - k = P*M/Dk
  - k is the spring constant (in*lb/deg)
  - P is the force exerted on the spring in lb
  - M is the moment arm in inches
  - D is the deflection in degrees

Figure 1. Clothespin with a torsion spring

- The clothespin has a torsion spring with 3 coils.
  - The mechanism acts like a chip clip, which is a design idea mentioned by the client.
  - This can be attached to the sides of the device to see if the motion will be resisted.
- Tension spring
  - Extension springs, extend when a load is applied.
  - If the spring is pulled from the sides, it will extend with resistance.
  - These springs have round ends that can attach to hooks or screws.
  - Instead of a sliding motion, we want the device to hinge around the wound.
  - The tension spring looks like a good candidate to fit with the width of the device.

Figure 2. Tension Spring

Llc, “Torsion Spring Force Calculator and Formula,” *Engineers Edge*. [Online]. Available: https://www.engineersedge.com/spring_torsion_calc.htm. [Accessed: 05-Apr-2020].

“What Are Tension Springs?,” *The Spring Store*. [Online]. Available: https://www.thespringstore.com/what-are-tension-springs.html. [Accessed: 05-Apr-2020].

Conclusions/action items: An improvement to our current device is to change the device from a sliding motion to a hinging motion when approximating the wound. This reduces the shear on the surface of the skin, which would be safer for the wound. We can experiment with the torsion spring from the clothespin and a tension spring to see if this motion is achieved. I think that the tension spring would work better because it resists motion when extended. So when it is released, it will resist and slow down the motion. Also the hooks can be attached to rods or screws inserted on the sides of the device.

Solidworks Spring Model

Kavya Vasan - Apr 28, 2020, 1:10 AM CDT

Title: Solidworks Spring Model

Date: March 13, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To create a spring that can be added to the model of the final device

Content:

- I made the model starting with a 2 inch diameter circle sketch.
- I inserted a helix/spiral curve feature. It has 8 revolutions and 135 degree start angle.
- A circle sketch of 0.25 in diameter was made at the end of the helix. With a boss extrude of this circle along the helix, the spring is 0.25 in thick.
- It represents that tension spring that is attached to the 2 thumb screws inserted at the bottom of 2 slotted parts of the device.

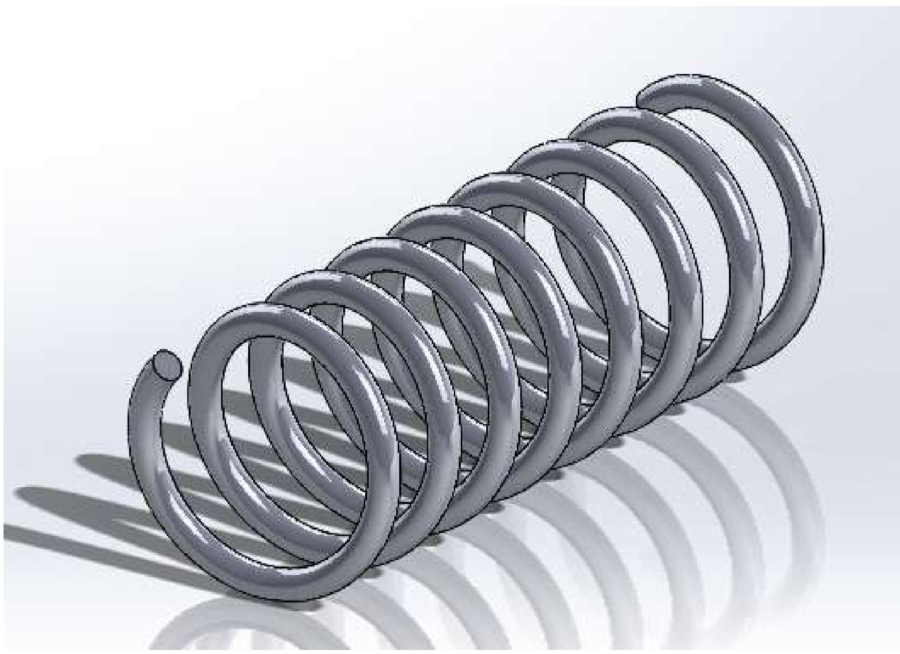


Figure 1. Solidworks model of tension spring

Conclusions/action items: This spring is to be added to the final solidworks assembly of the device, along with thumb screws and the slot fillers that Jack made. This model might need to be modified to fit onto the diameter of the thumb screws. Due to Covid-19, I wasn't able to test the motion of springs with different values of stiffness on the device. I will make a motion study of the device to show the hinging motion of the long edges with the addition of this spring.

Solidworks Device Motion Studies

Kavya Vasan - Apr 28, 2020, 9:45 AM CDT

Title: Wound Edge Device Motion Studies in Solidworks

Date: April 21, 2020

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To create a visual representation of the intended motion of the device

Content:

- I played around with the motion study animation tools in Solidworks.
- First, I tried adding a linear motor to the right edge of one of the long edge parts to move left, and a linear motor to the left edge of the other long edge part to move right.
  - The speed of the motors was 0.1 in/sec. This didn't represent the hinging motion that the team wanted with the iteration of the prototype with the spring.
- The motion study that successfully show the hinging motion of the bottom long edges is Wound_Edge_Rotation_Motion_Long.mp4 (attached below).
  - I added a Rotary motion of 0.2 revolutions per minute (RPM) on the bottom edge of the right plane on the right slotted part. This motor is in the clockwise direction.
  - I added another Rotary motion of 0.2 revolutions per minute (RPM) on the bottom edge of the right plane on the left slotted part. This motor is in the counterclockwise direction.
  - This motion study was for 8 seconds with a frame rate of 15 frames/sec.
- The second motion study is a fully assembled version of the previous motion study. This is the Wound_Edge_Rotation_Motion_Long.mp4 (attached below).
  - This includes 3 thumb screws on each side of the device (1 on top and 2 on the bottom), a slotted piece within each slot (4), and and a spring attached to thumb screws on each side of the device.
  - This animation was 6 seconds.
  - This shows the hinging motion when the device is used with the springs.

Conclusions/action items: The final two animations helped visualize the device's new motion with the addition of the spring. I think each motion study showed a different view and had different advantages. The first motion study showed the motion of the device in its entirety in a trimetric view. This gave our viewers a view of the device as a whole. The second motion study showed the motion in the front view of the device, where the bottom hinging motion could be clearly seen without any obstruction.

Kavya Vasan - Apr 28, 2020, 12:24 AM CDT

Final_Wound_Edge_Rotation_Assembled_Motion.mp4(388.4 KB) - download This is an animation of the fully assembled device

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Kavya Vasan - Apr 28, 2020, 12:25 AM CDT

Wound_Edge_Rotation_Motion_Long.mp4(182.7 KB) - download This is a motion study of the slotted parts attached to the long edges

Green Pass

Kavya Vasan - Oct 08, 2019, 11:16 PM CDT

Title: Green Pass

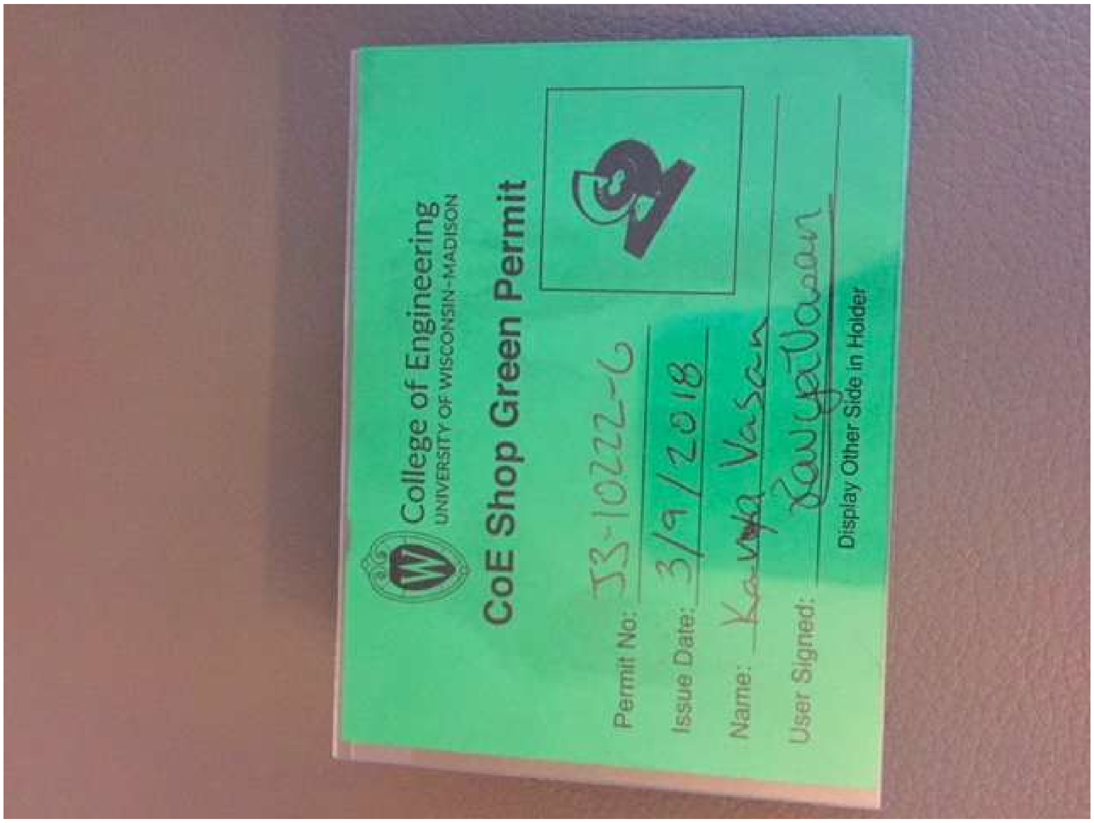
Date: March 2018

Content by: Kavya Vasan

Present: Kavya Vasan

Goals: To have access to the lathe and mill.

Content:



Conclusions/action items: I have shop access and can use the mill and the lathe. This will be a good tool for fabrication of some of our device components.

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

Team contact Information

Jack Fahy - Dec 03, 2019, 10:29 PM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
Suarez-Gonzalez	Darilis	Advisor	dsuarez@wisc.edu		
Charlton	Nicola	Client	nicola.charlton@aurora.org	414-630-6308	
Beilke	Jurnee	Leader	jbeilke2@wisc.edu	(715)-551-4188	
Schmida	Lizzy	Communicator	schmida@wisc.edu	(608)799-6484	
Fahy	Jack	BSAC/BPAG	jfahy@wisc.edu	(585) 732-3272	
Starykowicz	Kelly	BWIG	kstarykowicz@wisc.edu	847-989-9141	

Project description

Jurnee Beilke - Sep 24, 2019, 9:55 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, 5:19 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, 1:43 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, 6:41 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, 6:56 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, 6:58 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

12/17/19 Final Advisor Meeting

KELLY STARYKOWICZ - Dec 17, 2019, 12:53 PM CST

Title: Final Advisor Meeting

Date: 12/17/19

Content by: Kelly

Present: Kelly, Lizzy

Goals: Discuss presentation and report

Content:

- Did well on report- 94%
    - Incorporate more math throughout
    - Add more chemistry-related info (with dermabond)
    - Some redundancy- needed more proofreading
    - Incorporate more research about the market because of the potential this device has
    - Testing- sample size of 3 is too small
        - hard to draw strong, clear conclusions
    - Tensile testing should have been presented differently (data was good though)
        - because skin is being compressed, it was unclear and a bit confusing
    - Missing a transition in background research section
    - Don't present the solution in the abstract
- Presentation ~98% for each person
    - Problem Statement not on poster
    - Include date on poster
    - CAD Drawings were missing some labels
    - In results, state how long (actual amount of time) the red marks stayed on the arm
- Notebook- still grading

Conclusions/action items:

- Next Semester
    - not a final report
        - final report will go in appendix, so we need to fix errors
- Will be in contact about IRB

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 .

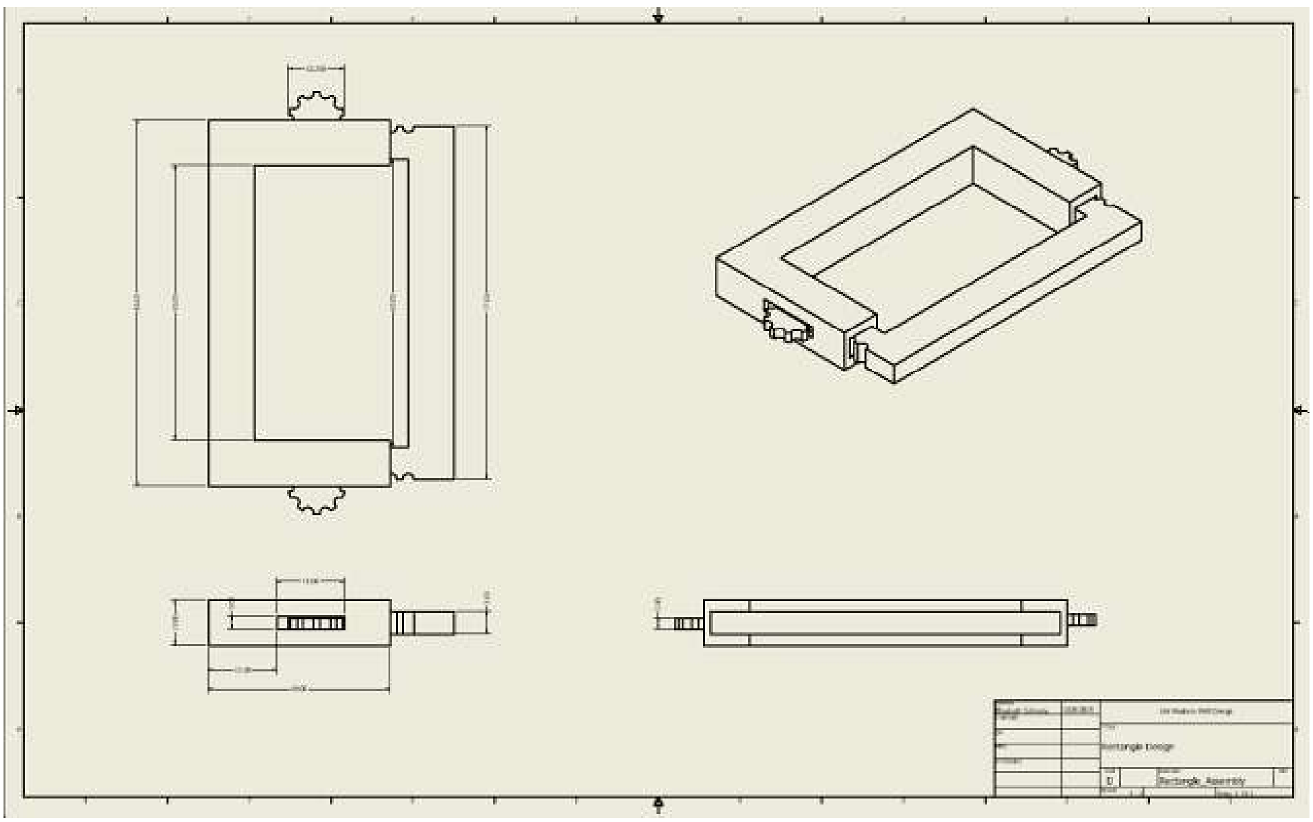


Figure 1. AutoDesk Inventor drawing of the rectangle design.

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, 7:32 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, 9:18 PM CST

Title: SolidWorks Model of Final Design

Date: 11/21/19

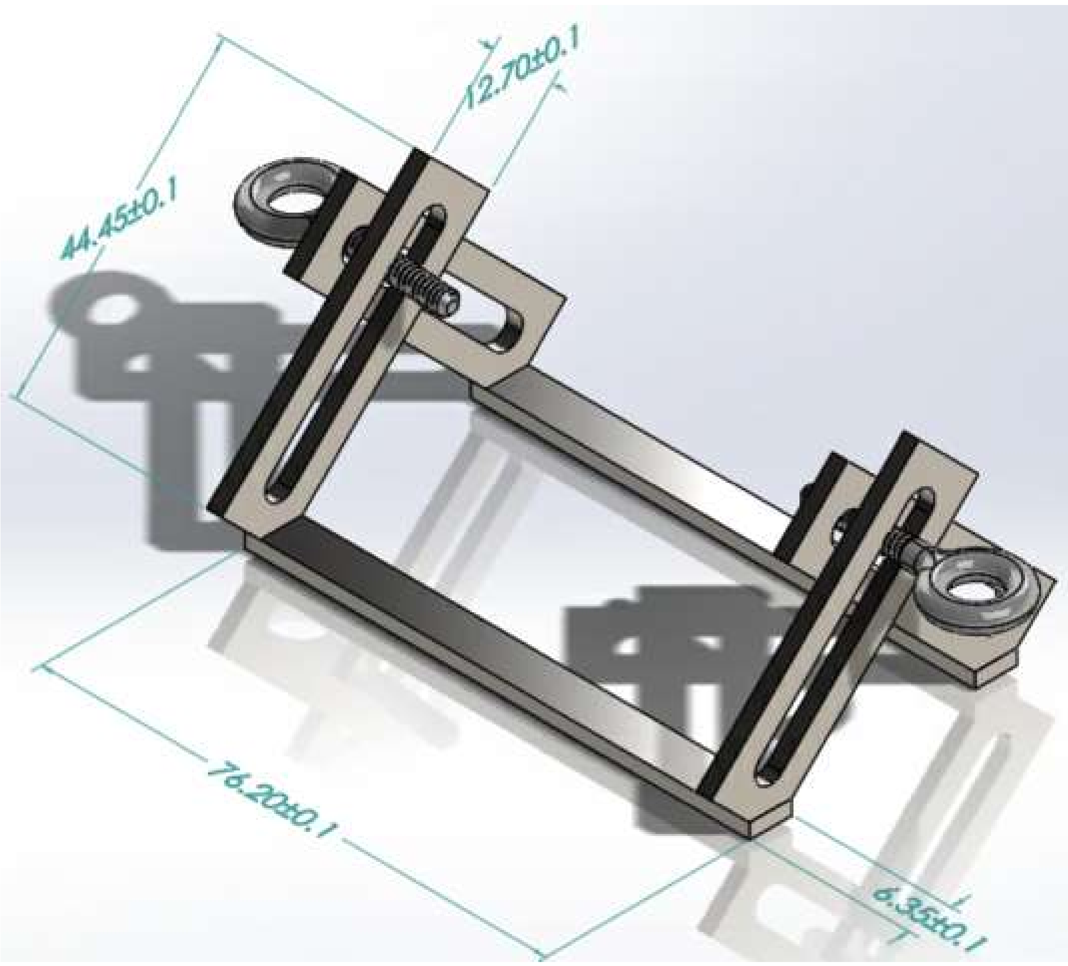
Content by: Jack

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, 9:23 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 P

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 mate 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&hvtarg 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 sc 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, 7:58 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, 9:56 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

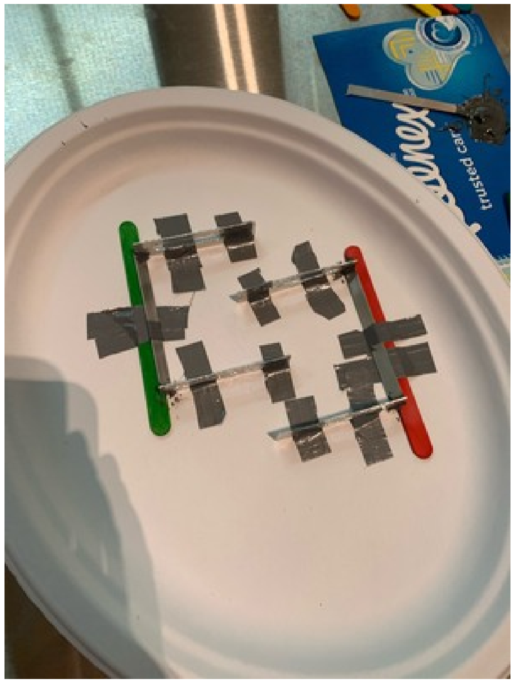
Figure 1: Whitney punch used to hollow out rectangles.

- 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:

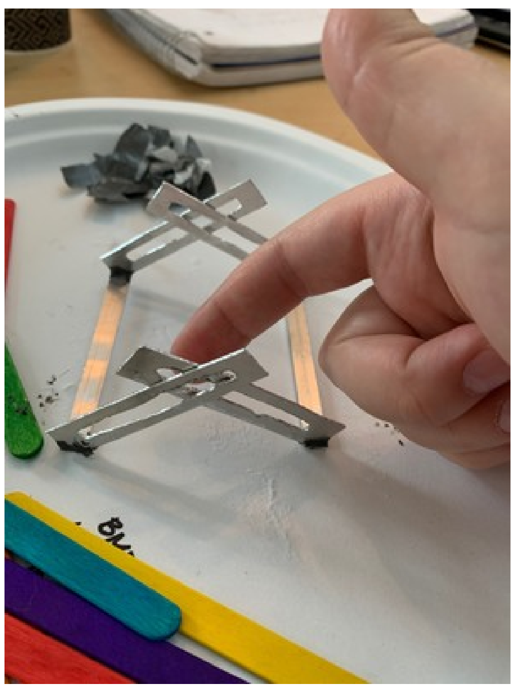
The team must wait for the epoxy to cure before we can handle and examine the design. Once cured, we can assemble the design using wing nuts and show the prototype to the client/advisor for feedback before we fabricate a final design for testing. We also might want to consider purchasing some steel instead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

Jurnee Beilke - Oct 28, 2019, 9:59 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, 9:09 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, 2:41 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.

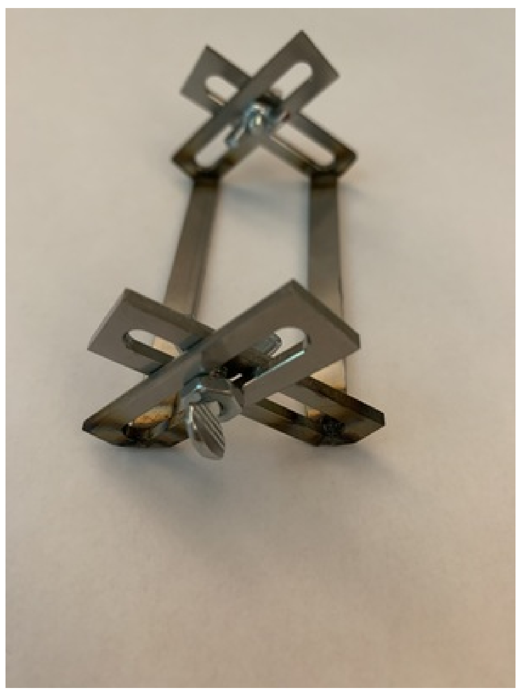
Content:

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, 4:59 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, 8:37 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:

$$\sigma = \varepsilon E$$

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

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

$$F = \frac{\Delta L}{L} EA$$

$$F = \varepsilon EA$$

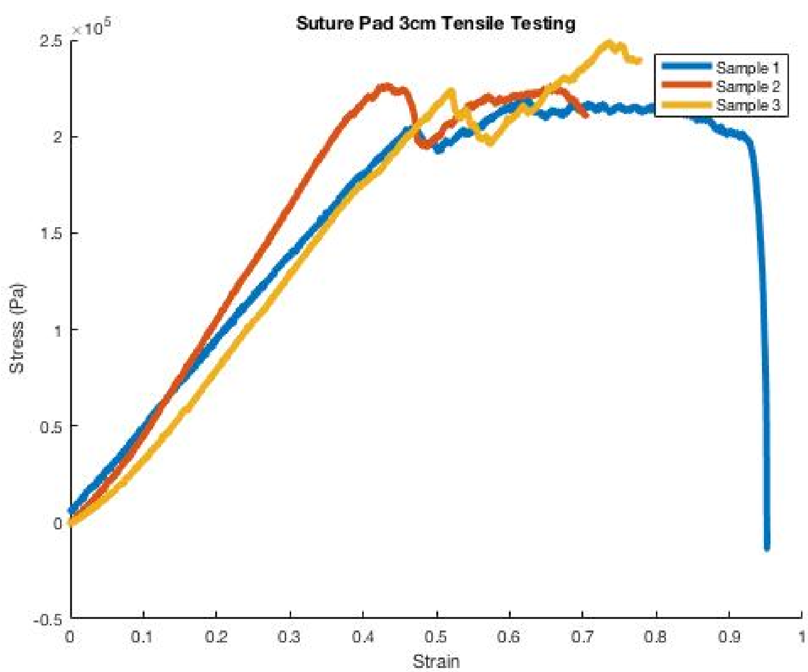


Figure 1. Stress-strain curves from MTS testing for the 3 cm samples.

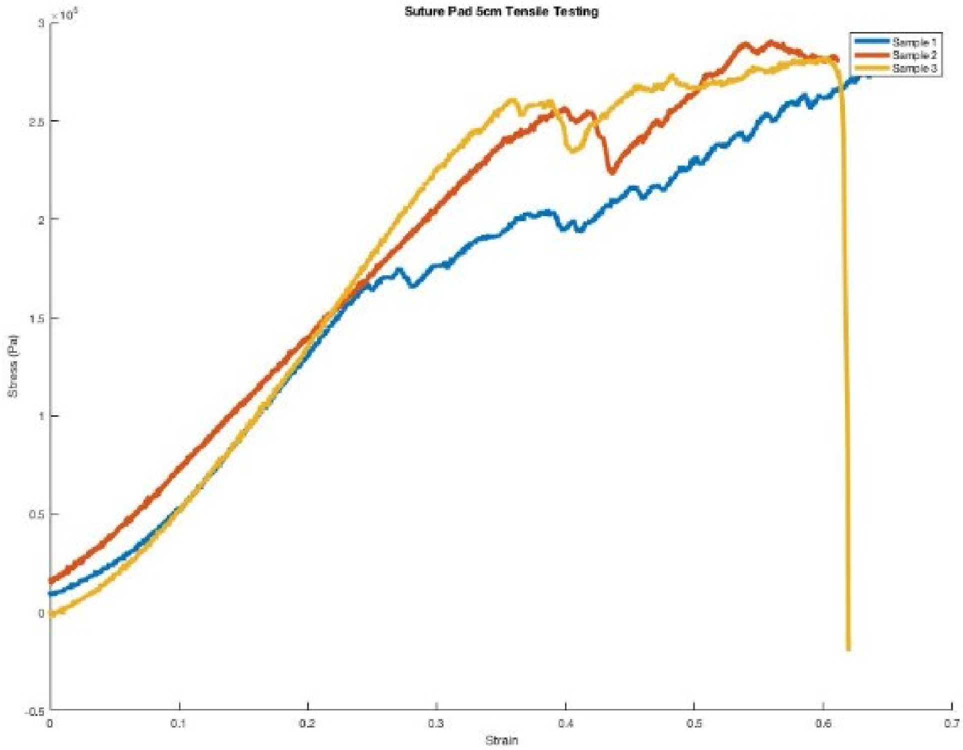


Figure 2. Stress-strain curves generated from MTS testing for the 5 cm test samples.

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

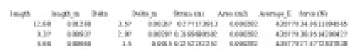
Conclusions/action items:

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, 1:42 PM CST



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

ELIZABETH SCHMIDA - Nov 27, 2019, 1:44 PM CST

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, 1:48 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, 1:32 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.

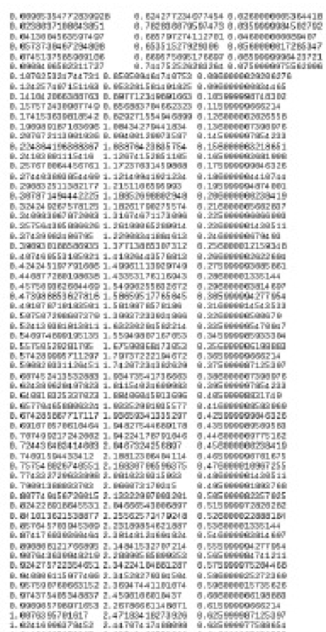
Content:

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:

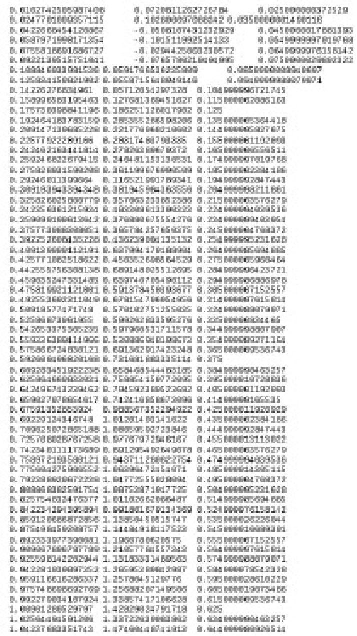
Some slippage was observed during testing. The TA assisting with the testing suggested analyzing the data for the elastic modulus after 1 mm of displacement had occurred. Attached are the text files for each run. The relevant data required for analysis are the first column and second columns as displacement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

ELIZABETH SCHMIDA - Nov 27, 2019, 1:34 PM CST



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

ELIZABETH SCHMIDA - Nov 27, 2019, 1:34 PM CST

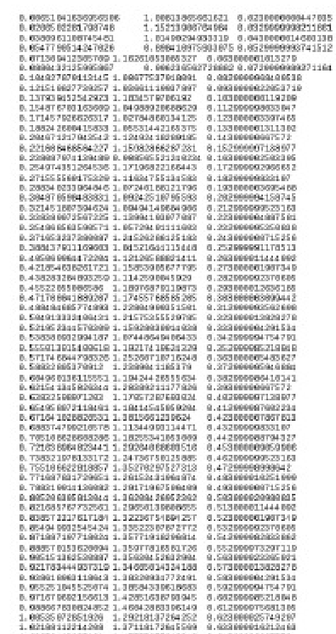


Sample2.txt(78.8 KB) - download MTS Raw Testing Data for the suture pad samples

ELIZABETH SCHMIDA - Nov 27, 2019, 1:34 PM CST

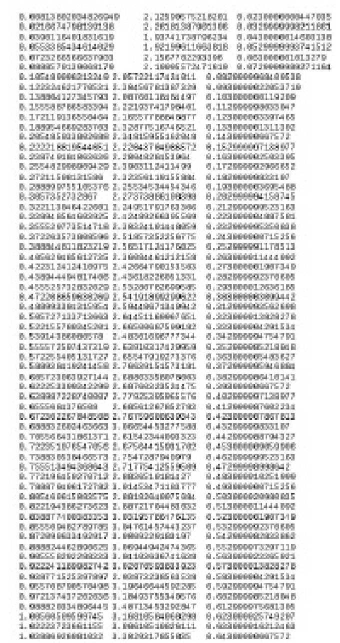
Sample3.txt(84 KB) - download MTS Raw Testing Data for the suture pad samples

ELIZABETH SCHMIDA - Nov 27, 2019, 1:34 PM CST



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

ELIZABETH SCHMIDA - Nov 27, 2019, 1:34 PM CST



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

ELIZABETH SCHMIDA - Nov 27, 2019, 1:34 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, 3:52 PM CST

Wound Edge Approximation

Preliminary Report

Biomedical Engineering Design 400

Department of Biomedical Engineering

University of Wisconsin

October 9th, 2019

Team Members:

Jamie Reilke (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, 3:53 PM CST

Preliminary_Presentation_2_.pdf(875.7 KB) - download

Revised PDS

KELLY STARYKOWICZ - Dec 04, 2019, 3:53 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:

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- 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(131.4 KB) - download

Final Poster

KELLY STARYKOWICZ - Dec 09, 2019, 8:35 PM CST

Final_Poster_1_.pdf(2.6 MB) - download

10/09/19 Outreach Meeting

Jurnee Beilke - Oct 09, 2019, 1:51 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, 1:58 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, 5:10 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, 3:00 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:

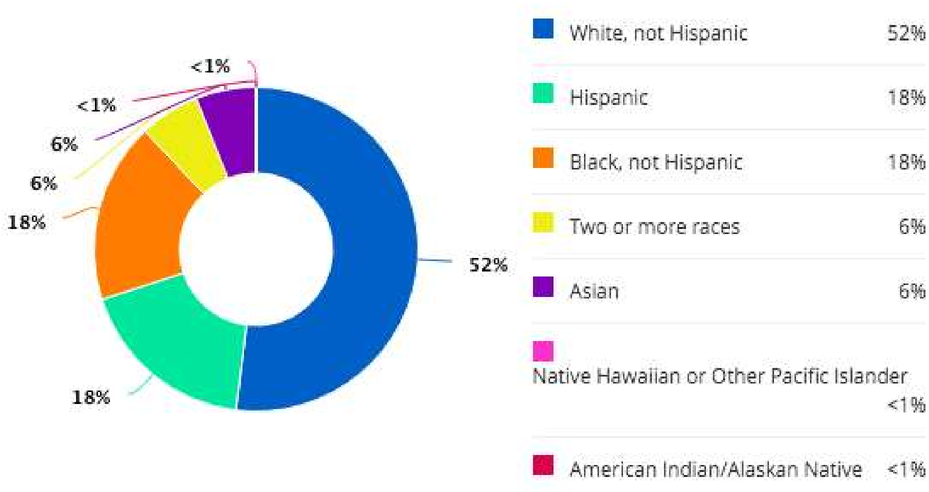
On Friday, November 22nd, we performed our senior outreach activity at Crestwood Elementary (5930 Old Sauk Rd, Madison, WI 53705) in Mrs. McMahon's classroom. Twenty-three 4th grade students (14 females and 8 males) , ages 9-11, participated. Crestwood Elementary has a student demographic of 52% White, 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:

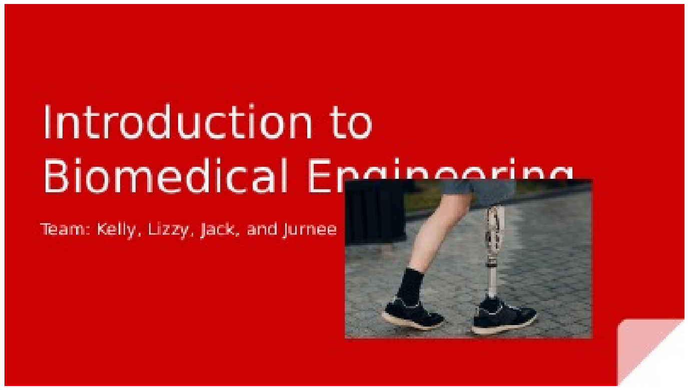
[1] "Explore Crestwood Elementary School in Madison, WI," *GreatSchools.org*. [Online]. Available:https://www.greatschools.org/wisconsin/madison/852-Crestwood-Elementary-School/#Students. [Accessed: 27-Nov-2019].



Conclusions/action items:

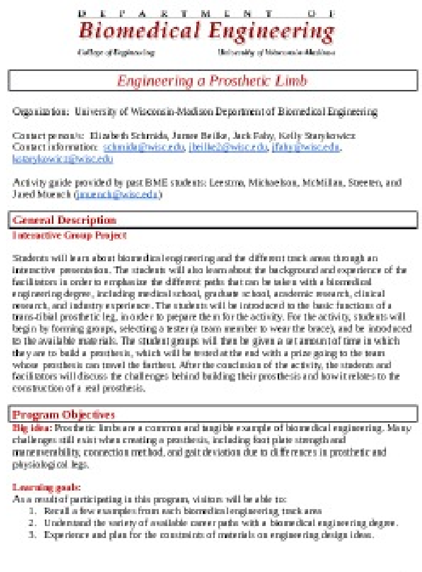
The above content will be submitted as part of our final deliverables for outreach (due 12/11). Attached below are the activity guide and power point presentation used during our classroom visit.

ELIZABETH SCHMIDA - Nov 27, 2019, 3:01 PM CST



Outreach_Presentation_.pptx(15.4 MB) - download

ELIZABETH SCHMIDA - Nov 27, 2019, 3:02 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, Streeten, 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, 3:12 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, 3:13 PM CST

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

ELIZABETH SCHMIDA - Nov 27, 2019, 3:15 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, 8:40 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:

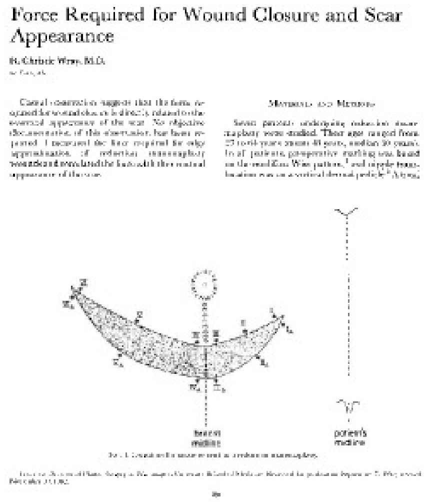
- Introduction
  - The force required to close a wound is related to the appearance of the scar
  - Forces required for edge approximation of mammaplasty wounds were measured and correlated with scar appearances after healing occurred
- Materials and Methods
  - Seven patients studied (27 to 64 years 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, 8:42 PM CDT



Force Required for Wound Closure and Scar Appearance

R. Christie Wray, M.D.

Materials and Methods

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

RONALD L. MOY, MD
BARRY WALDMAN, MD
DARRYL W. HEIN, MD

The art of suturing wounds is by no means a recent endeavor.

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, 1:18 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, 3:41 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:

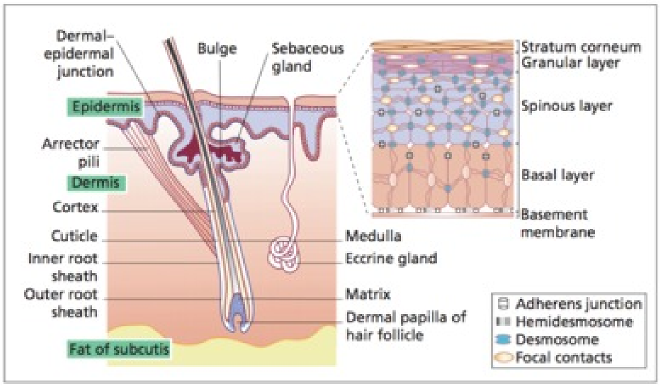
- Human skin consists of stratified, cellular epidermis and an underlying dermis of connective tissue
- The dermal-epidermal junction provides mechanical support for the epidermis and acts as a partial barrier against exchange of cells and large molecules
- Below the dermis is a fatty layer, panniculus 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, 1:49 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, 8:08 PM CDT

Title: Force Sensing in Surgical Sutures

Date: 09/30/19

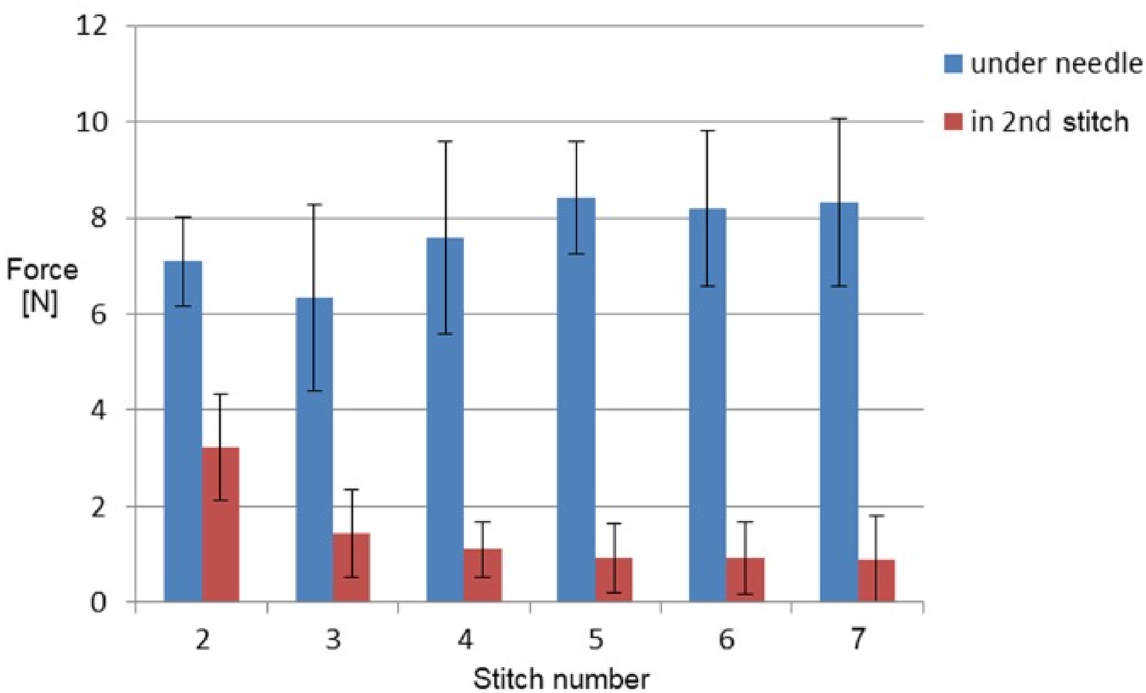
Content by: Jurnee Beilke

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, 7:37 PM CDT


PLOS

Force Sensing in Surgical Sutures

pone.0084466.pdf(2.1 MB) - download

09/30/19 Skin Tension Device

Jurnee Beilke - Sep 30, 2019, 8:11 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, 8:04 PM CDT


www.nature.com/scientificreports

SCIENTIFIC REPORTS

OPEN

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

srep30117.pdf(684.4 KB) - download

09/17/19 DermaBond Mini

Jurnee Beilke - Sep 17, 2019, 9:12 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, 9:11 PM CDT

felsu56agnpkp6nqtbqim31j3o.pdf(151 KB) - download

09/17/19 DermaClip

Jurnee Beilke - Sep 17, 2019, 10:34 PM CDT

Title: DermaClip

Date: 09/17/19

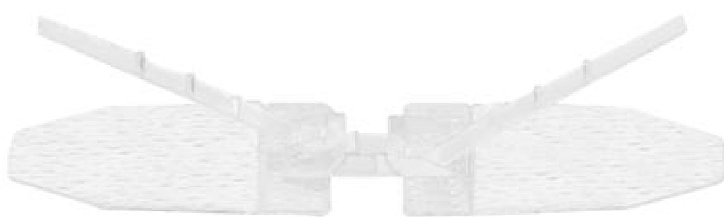
Content by: Jurnee Beilke

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

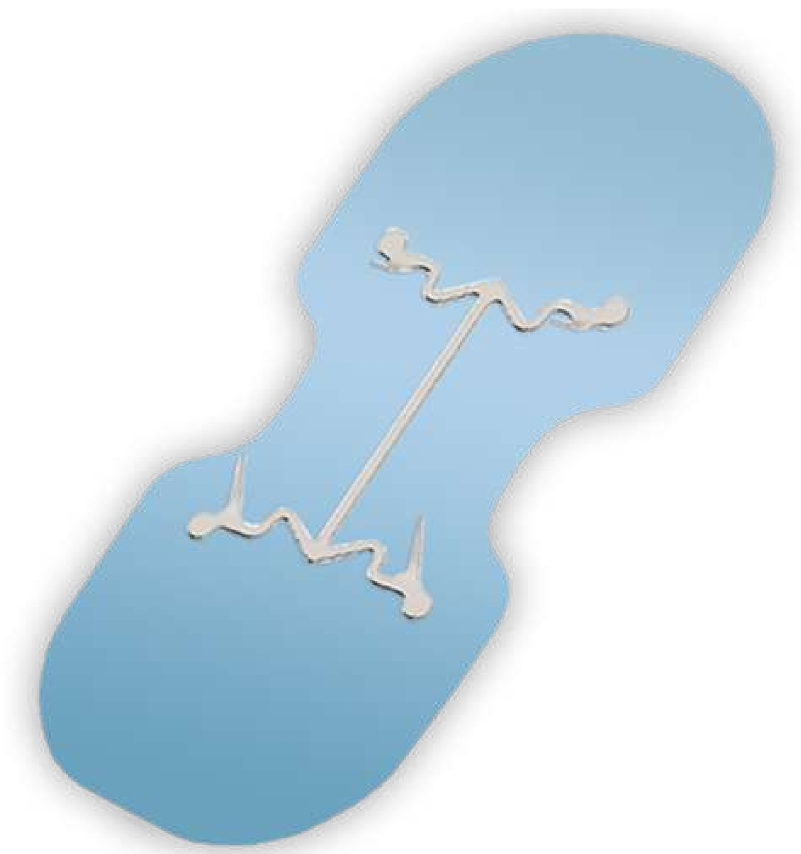
Content by: Jurnee Beilke

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, 7:34 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

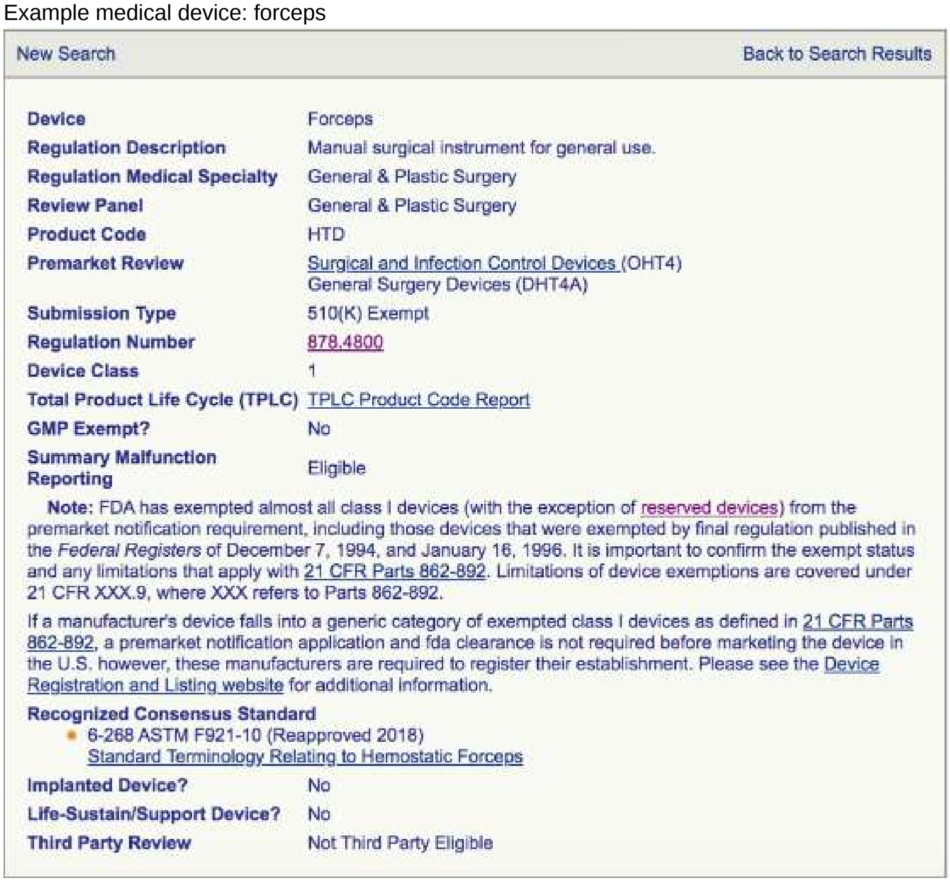
Content by: Jurnee Beilke

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

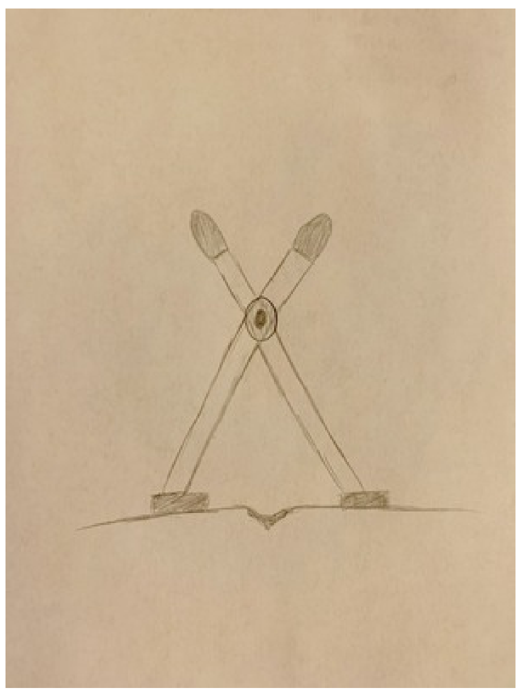


Image-3.jpeg(309.1 KB) - download

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

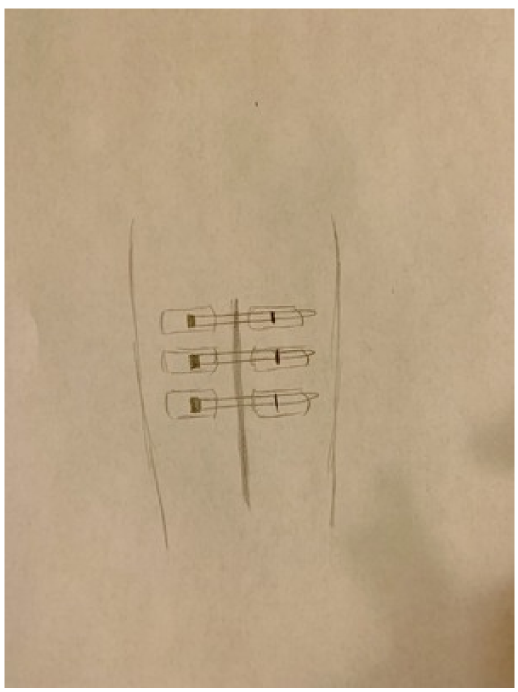


Image-4.jpeg(323.4 KB) - download

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

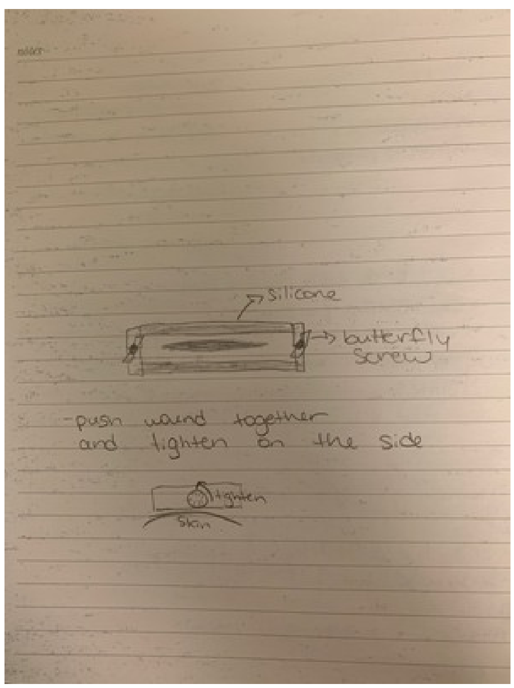


Image-13.jpeg(1.2 MB) - download

Jurnee Beilke - Sep 29, 2019, 10:23 PM CDT

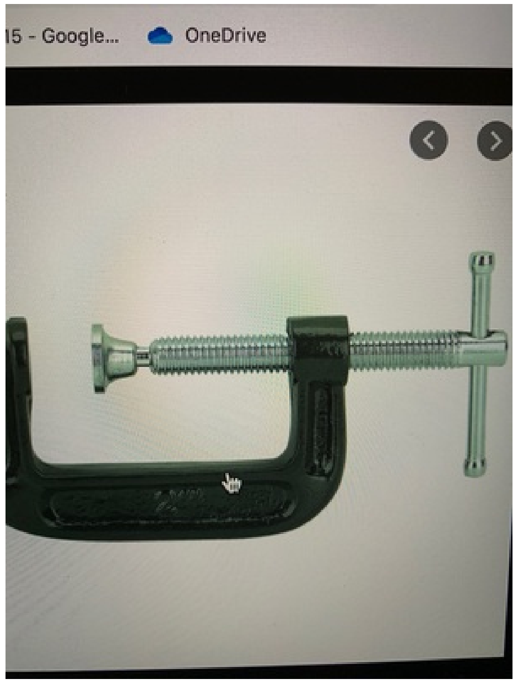
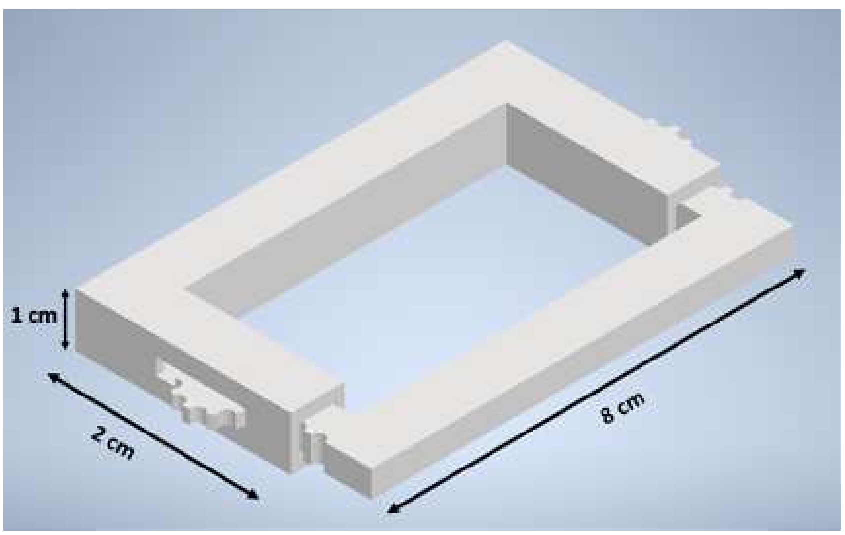


Image-12.jpeg(874.7 KB) - download I think this type of threaded rod and tube might be an interesting design to use to connect the two components of this device. The sides can be drawn together by turning the fastener and moving the threaded rod farther into the tube-shaped component.

Jurnee Beilke - Dec 09, 2019, 5:25 PM CST



Computer-modeled image of the rectangle design.

09/30/19 Skin Tension Forces

Jurnee Beilke - Sep 30, 2019, 8:27 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, 8:27 PM CDT

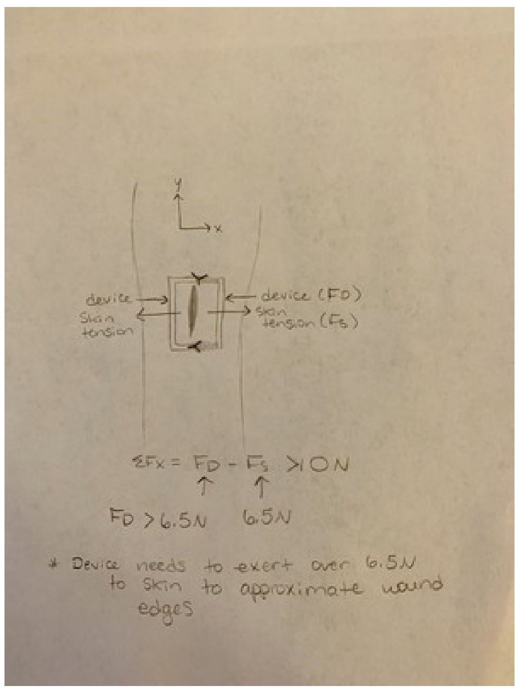


Image-14.jpeg(414.4 KB) - download

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, 8:47 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, 8:47 PM CDT

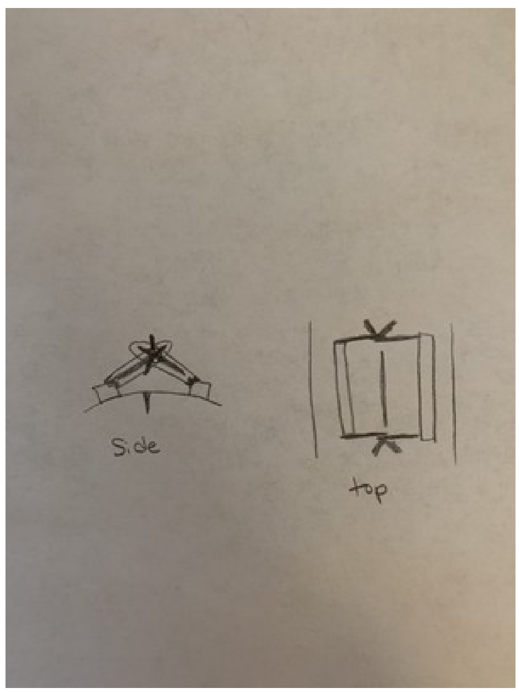


Image-26.jpeg(78.7 KB) - download

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:

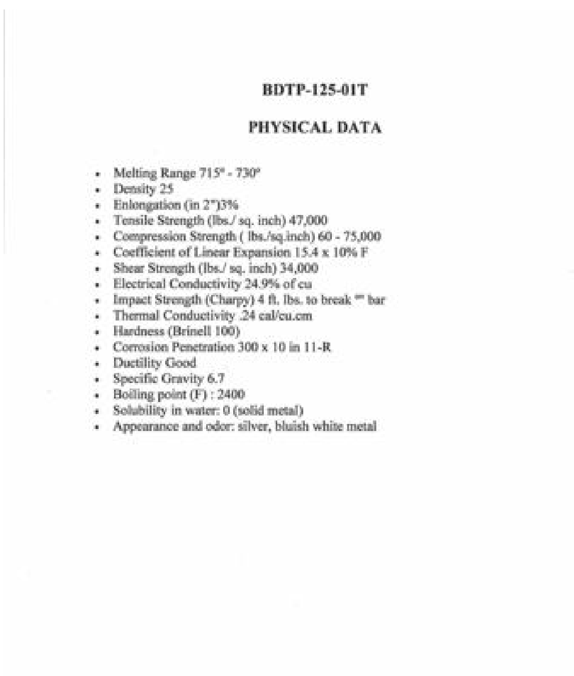
- Low temp - aluminum-zinc brazing rod
- Brazing can be used for materials that can be difficult to weld
- The brazing rod has an extremely low melting point (730 F)
- The rod can be melted with a propane torch
- Brazing can repair and combine many metal components
- The rod has excellent corrosion resistance
- 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, 5:19 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, 5:06 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, 5:27 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:

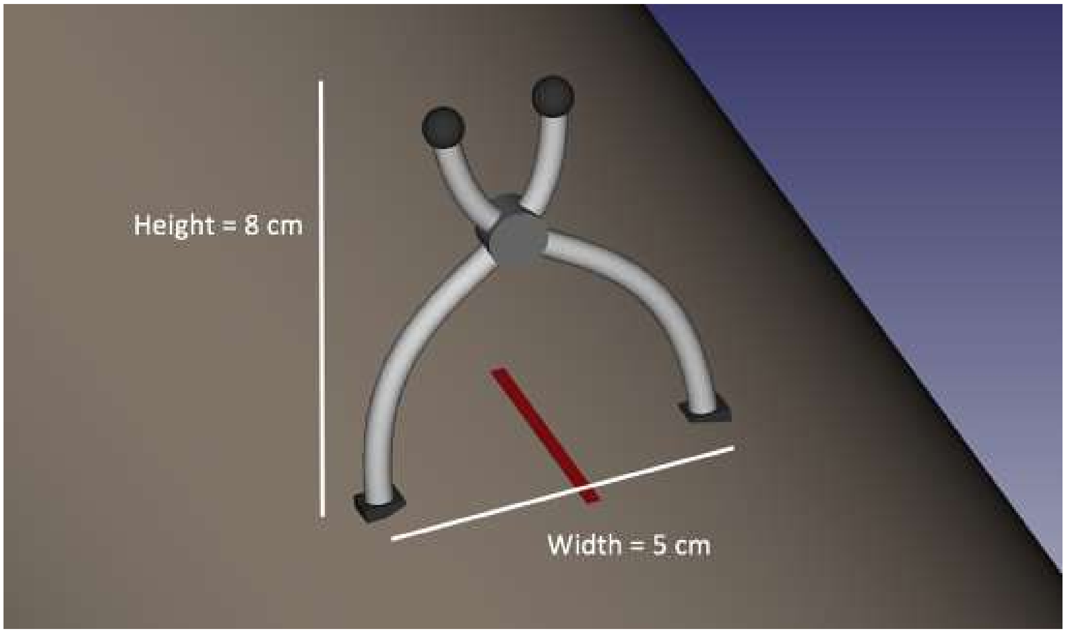


Figure 1: The bow-shaped design.

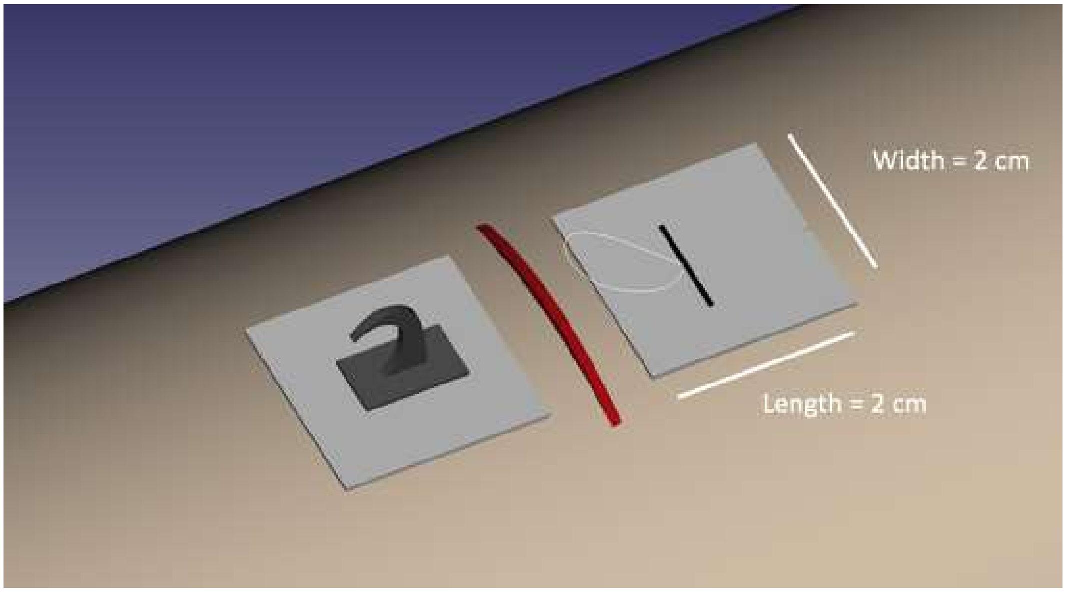


Figure 2: The hook in loop design.

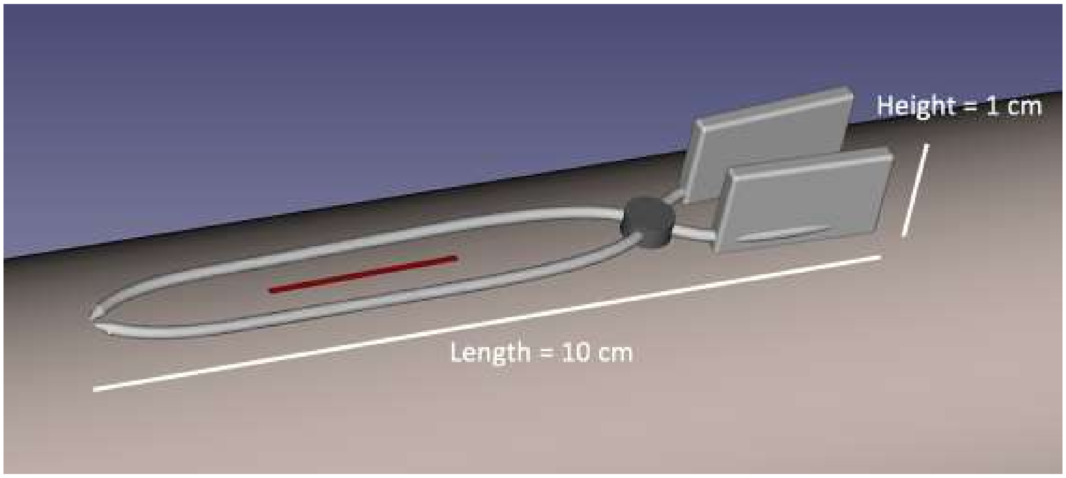
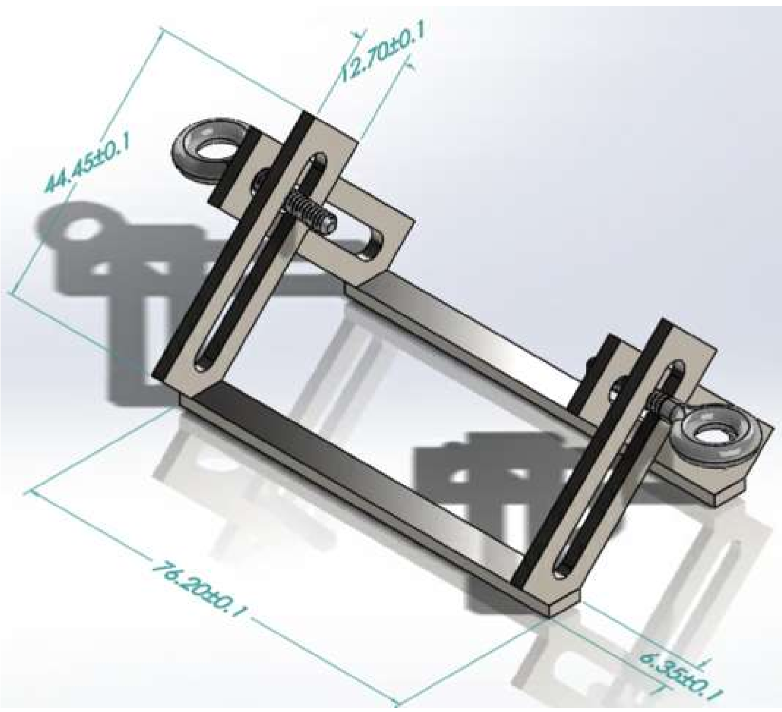


Figure 3: The barrette design.

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, 6:24 PM CST

Image.png(1.7 MB) - download

Tong Lecture

Jurnee Beilke - Nov 21, 2019, 9:06 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

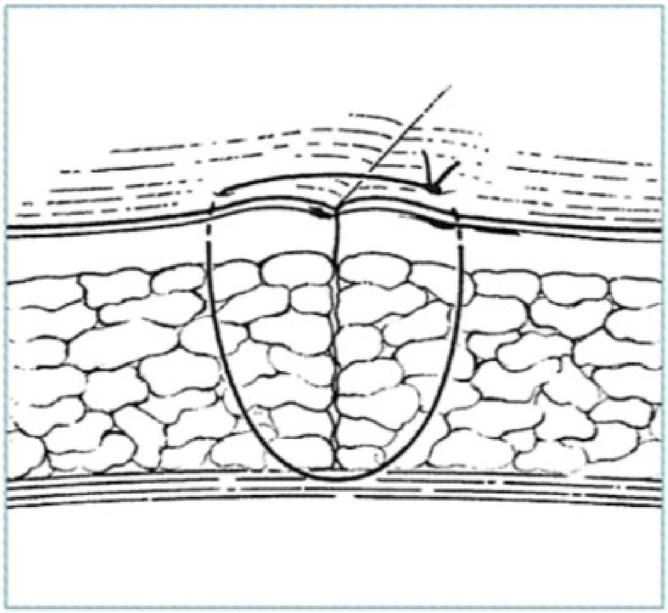
- "Size of suture 'bite' and interval between bites should be equal in length, proportional to thickness of tissue being approximated"
- Suture Techniques:
    - Interrupted Suture:
        - used to repair lacerations
        - allows for "good eversion" of wound edges
        - only used when minimal 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:

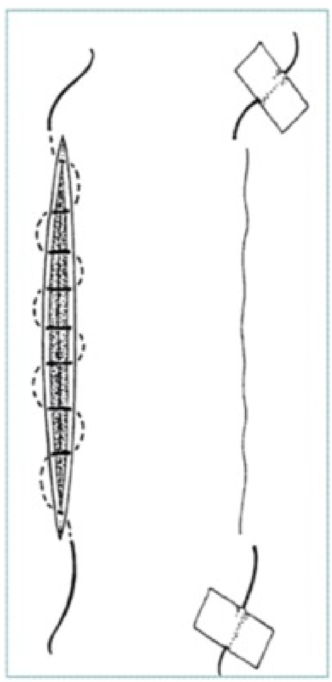
Verify whether our client will be using all of these suturing methods or only some

KELLY STARYKOWICZ - Sep 11, 2019, 10:27 PM CDT



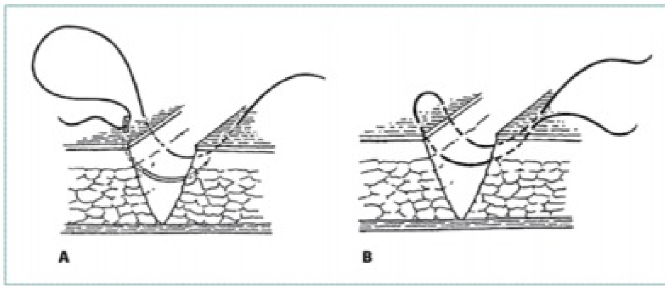
interrupted_suture.PNG(146.4 KB) - download Interrupted Suture

KELLY STARYKOWICZ - Sep 11, 2019, 10:28 PM CDT



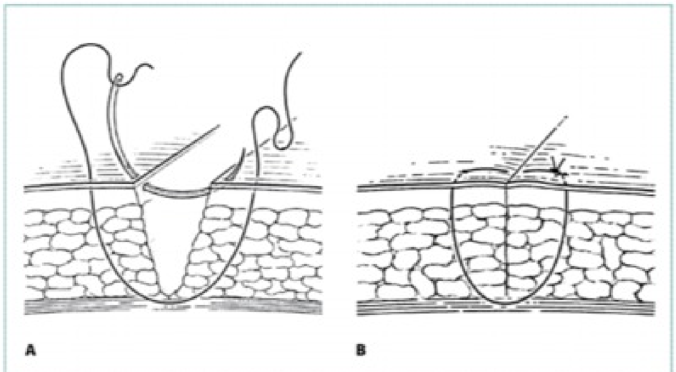
subcuticular_suture.PNG(72.2 KB) - download Subcuticular Suture

KELLY STARYKOWICZ - Sep 11, 2019, 10:29 PM CDT



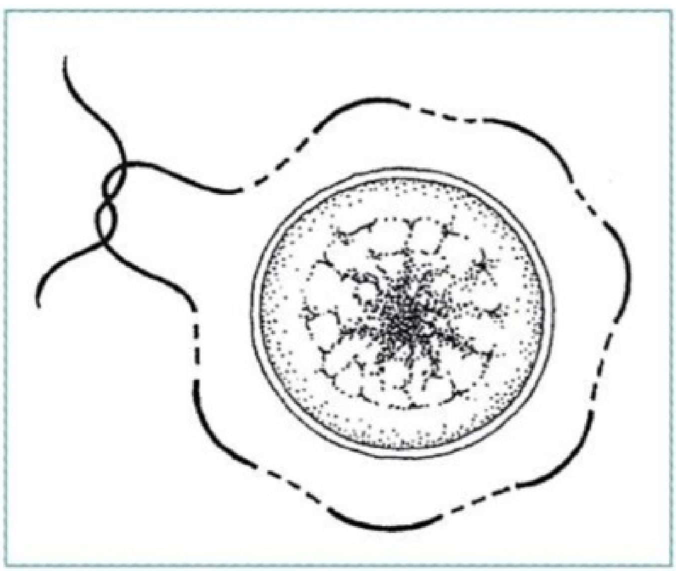
horizontal_mattress_suture.PNG(104.3 KB) - download Horizontal Mattress Suture

KELLY STARYKOWICZ - Sep 11, 2019, 10:29 PM CDT



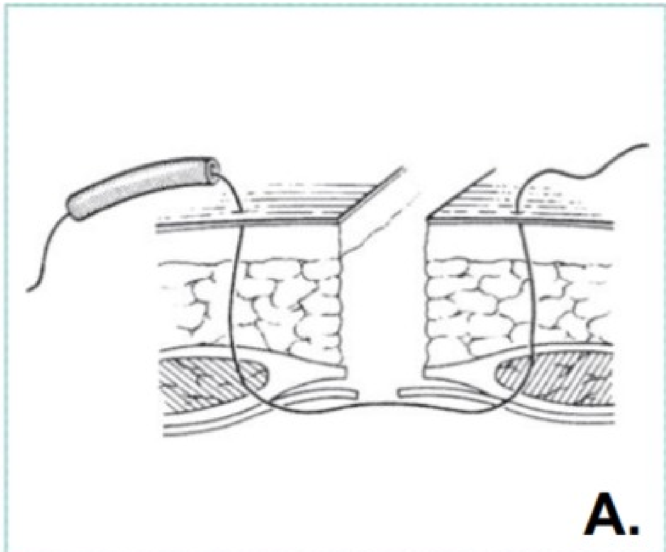
Vertical_mattress_suture.PNG(86.8 KB) - download Vertical Mattress Suture

KELLY STARYKOWICZ - Sep 11, 2019, 10:30 PM CDT



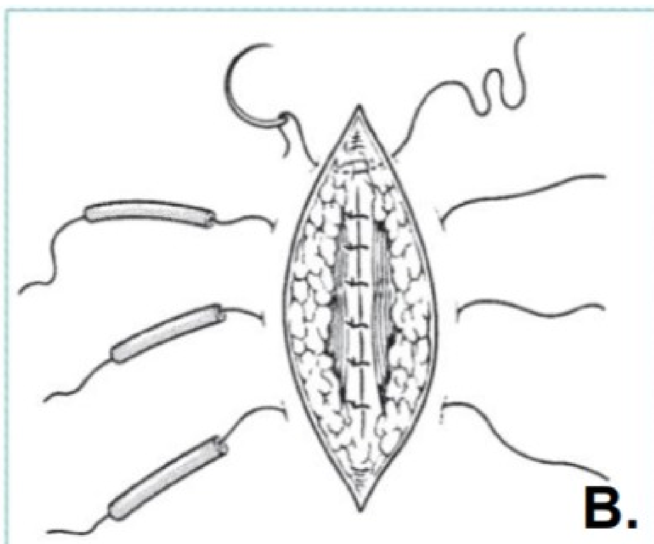
purse_string_suture.PNG(197.7 KB) - download Purse String Suture

KELLY STARYKOWICZ - Sep 11, 2019, 10:33 PM CDT



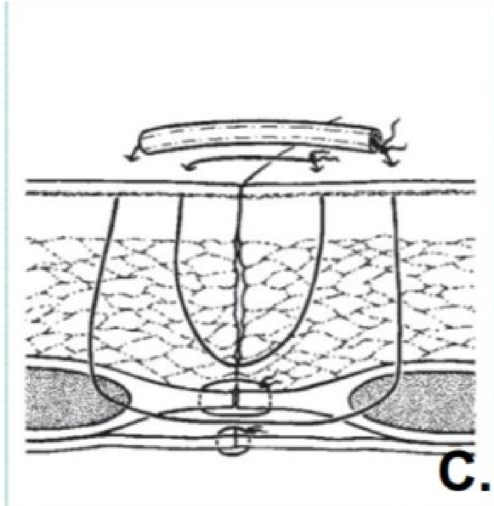
retention_suture_a.PNG(96.8 KB) - download Retention Suture Step 1/4

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



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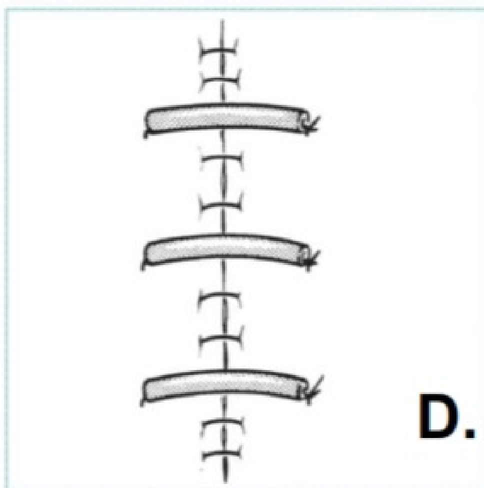
KELLY STARYKOWICZ - Sep 11, 2019, 10:33 PM CDT



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

DermaClip Non-Invasive Skin Closure

KELLY STARYKOWICZ - Sep 17, 2019, 9:56 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, 4:47 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, 9:37 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, 9:36 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 STAR

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_yn4mH9drgxLV38UySnpQ0FkaA
    - 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, 9:39 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, 8:50 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, 9:40 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=&hv 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=CjwKCAiAwZTuBRAYEiwAcr67ORp6ygZq0fV5
  - 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_a Locking_Clamps_and_Pliers::pla:pla:Airgas:tools_hardware::VIS2071905::PLA&gclid=CjwKCAiAwZTuBRAYEiwAcr67OUP3Hsb-tRYNzC26hh_cALxyZatON8Uj3GE3Sk-3lu6w
  - 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, 8:47 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:

Note: 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_VP6
    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-
    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=222222 276429799869&wl5=9018948&wl6=&wl7=&wl8=&wl9=pla&wl10=111838760&wl11=online&wl12=795861611&veh=sem&gclid=Cj0KCQiAk7TuBRDQARIsAMRrfUboj7icauq0CUGMSJ4
    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


email us at:
MONDfrontend@menards.com

Sale Transaction

THUMB SCREW 6/32X1/2
2017282 2 @0.39 0.78
6-32 HEX NUT 31PC
2323882 0.98
6-32 WING NUT
2323865 0.98

TOTAL 2.74
TAX DANE-WI 5.5% 0.15
TOTAL SALE 2.89
Discover Credit 1443 2.89
Auth Code:022508
Chip Inserted
a0000001523010
TC - 04d1661e1f079d69

TOTAL NUMBER OF ITEMS = 4

THE FOLLOWING REBATE RECEIPTS WERE
PRINTED FOR THIS TRANSACTION:
7609

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, 8:56 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:

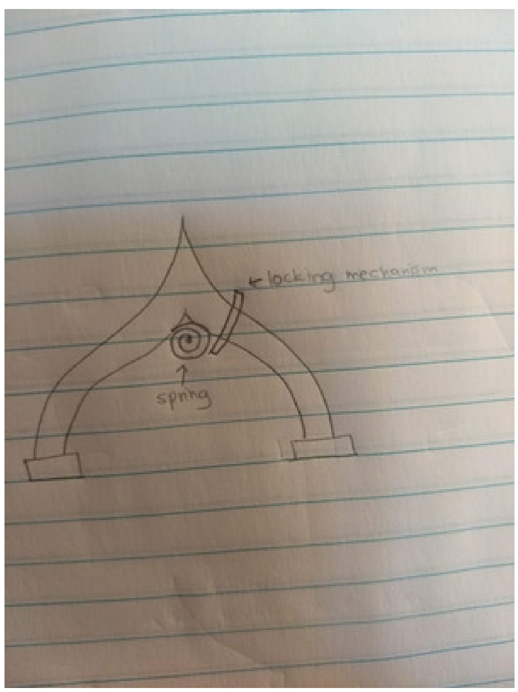
Design Features:

- 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, 8:51 AM CDT



bow-shaped_design.jpg(60.2 KB) - download

9/23/19 Railroad Track Design

KELLY STARYKOWICZ - Sep 24, 2019, 9:00 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:

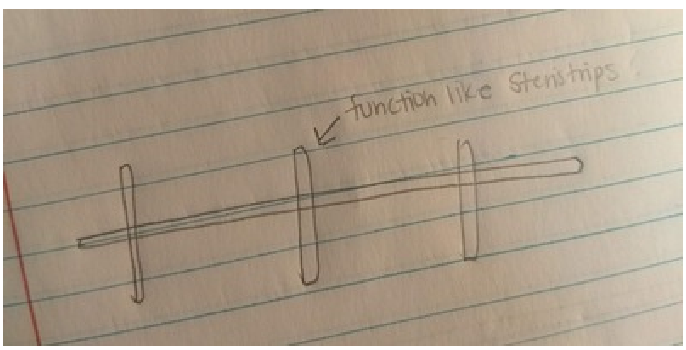
Design Features:

- 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, 8:51 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, 9:49 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, 8:23 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, 7:37 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

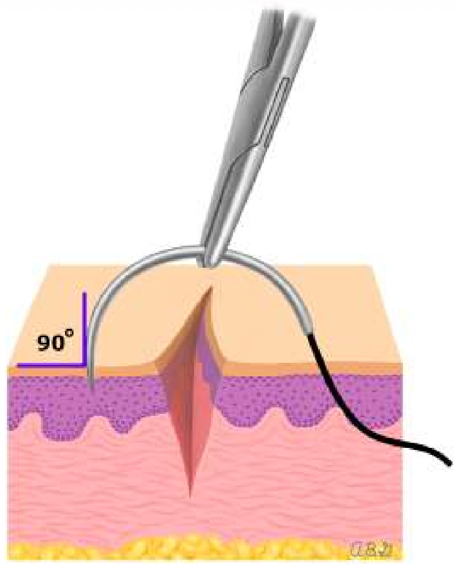
Other sources: https://www.ncbi.nlm.nih.gov/pubmed/29262163

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

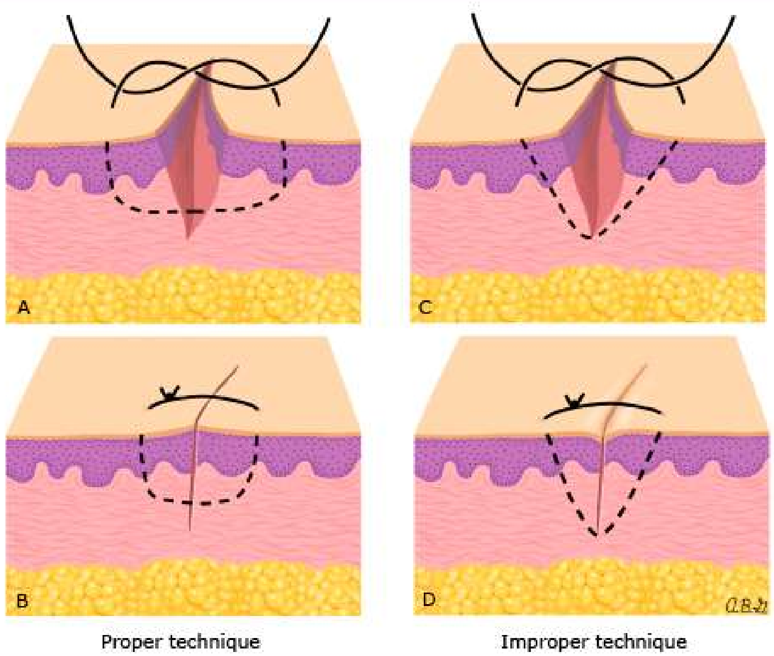
Needle insertion for eversion technique



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.

  -

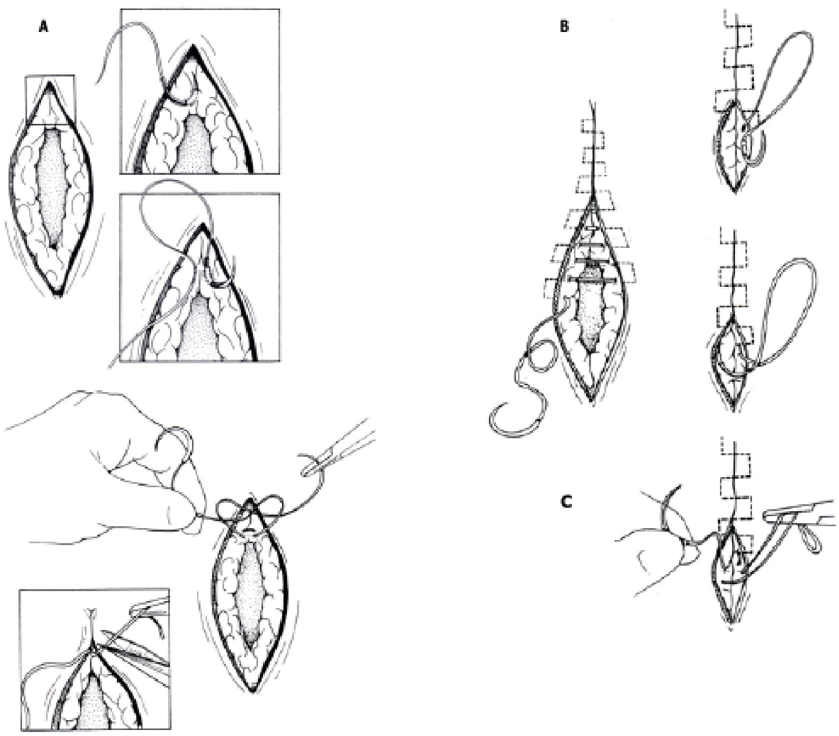
Proper technique for wound edge eversion



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, 1:42 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)

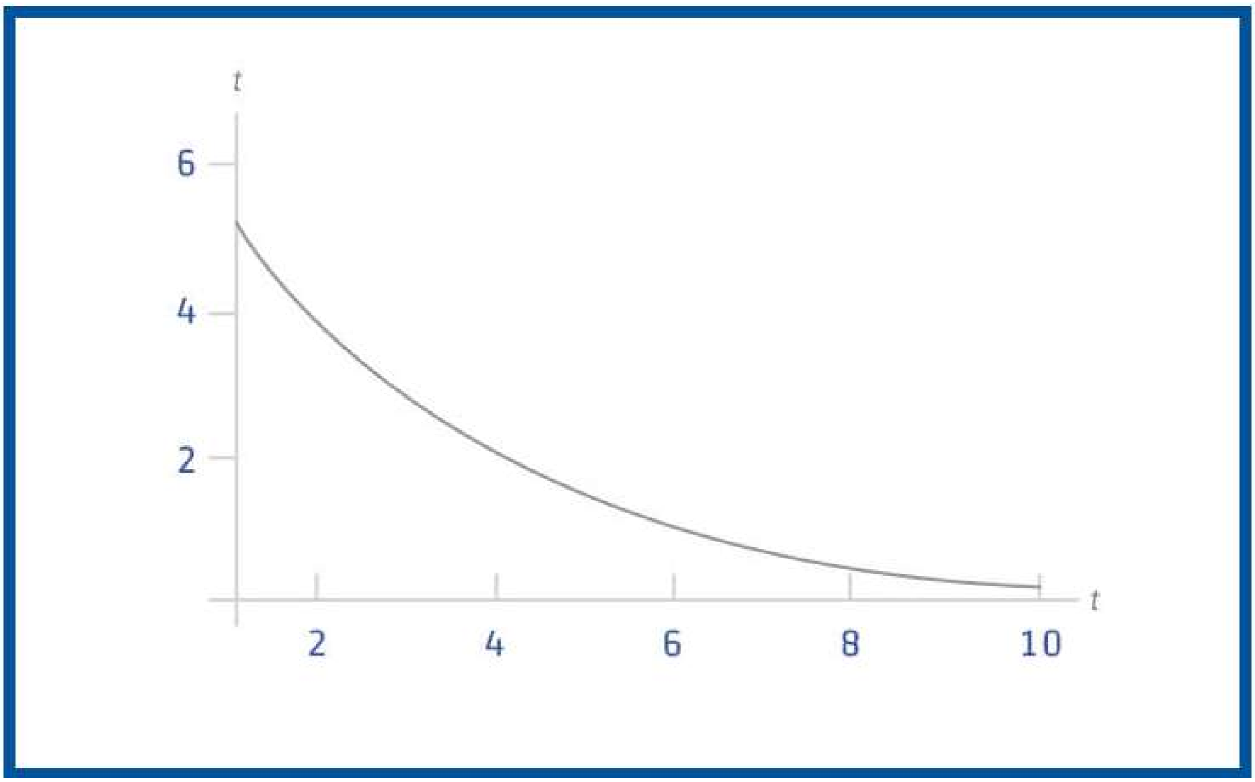


Figure 1. Function of the number of microorganisms left overtime.

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, 6:27 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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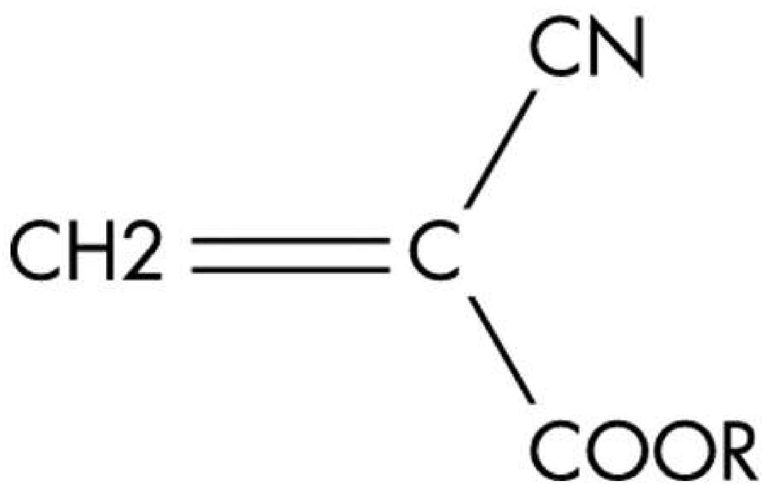


Figure 1. **The chemical structure of cyanoacrylates. R represents the variable alkyl group.**

- 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

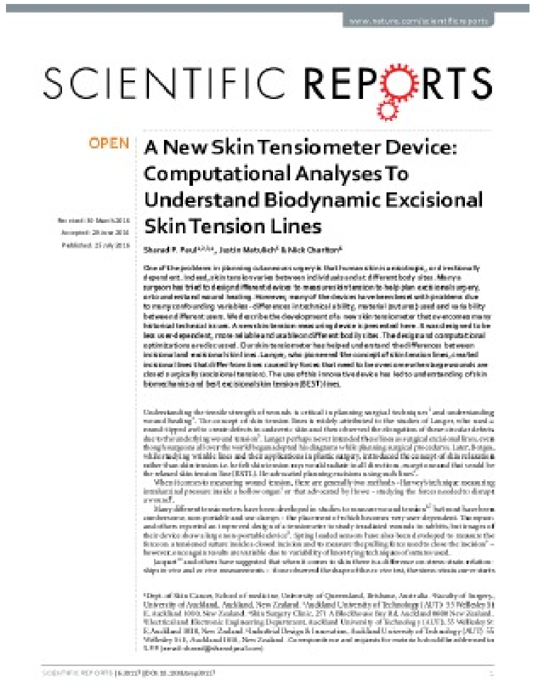
Figure 1

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

Skin_Tensiometer.pdf(684.4 KB) - download

9/30/2019 Skin Mechanics

ELIZABETH SCHMIDA - Oct 04, 2019, 5:50 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, 1:26 PM CDT

Title: Potential Impacts of Device

Date: 10/5/2019

Content by: Lizzy S

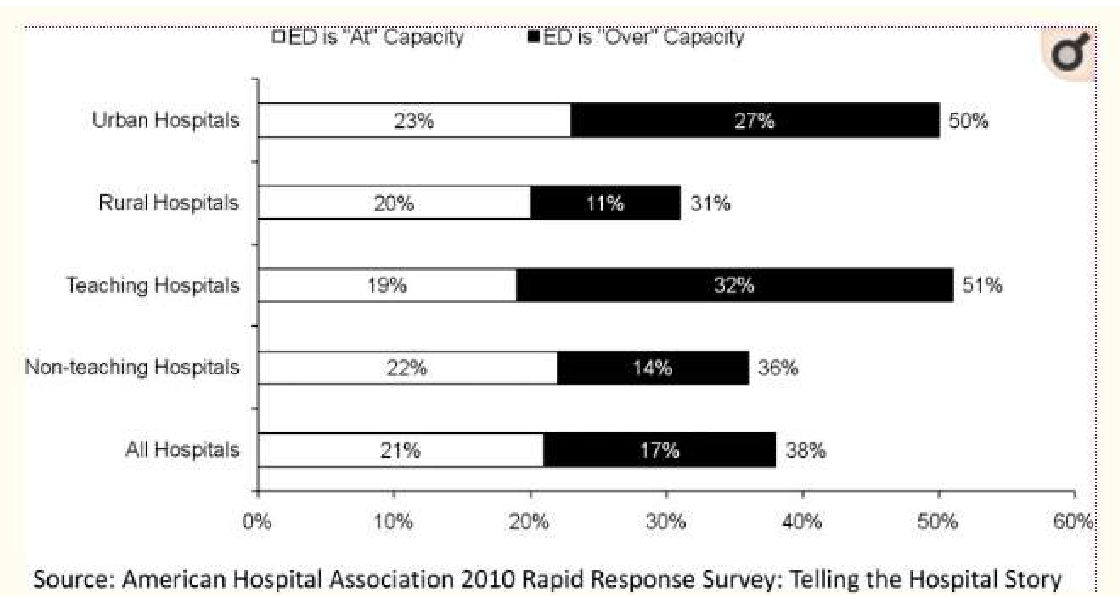
Present: N/A

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, 4:57 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, 4:57 PM CDT

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

ELIZABETH SCHMIDA - Nov 01, 2019, 4:57 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, 6:24 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, 5:34 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, 1:42 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

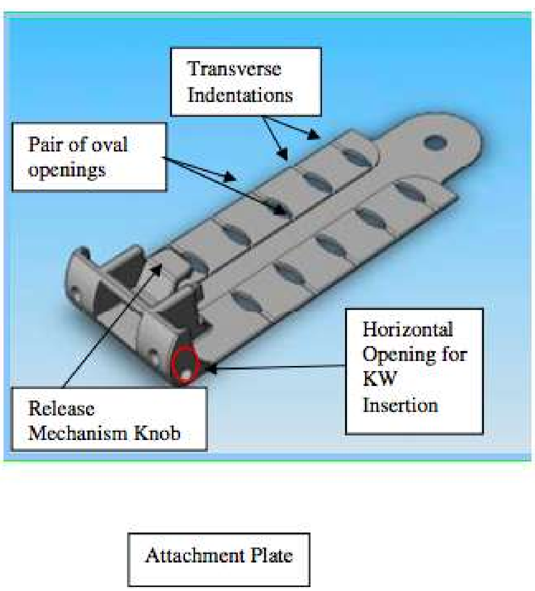


Figure 1. Attachment Plate with adhesive tape on bottom.

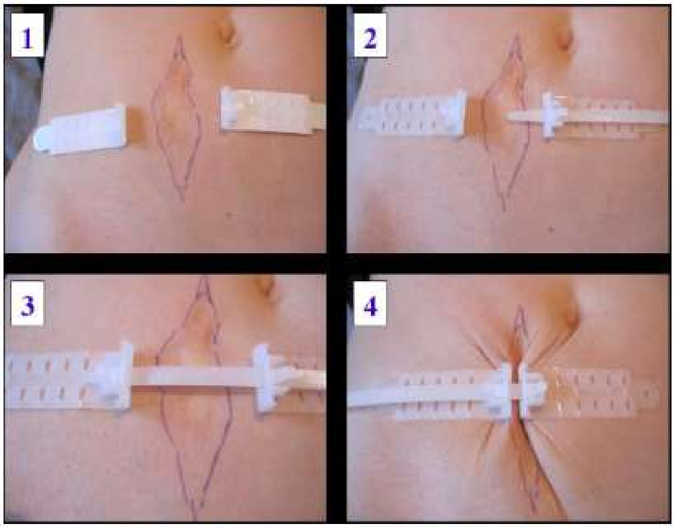
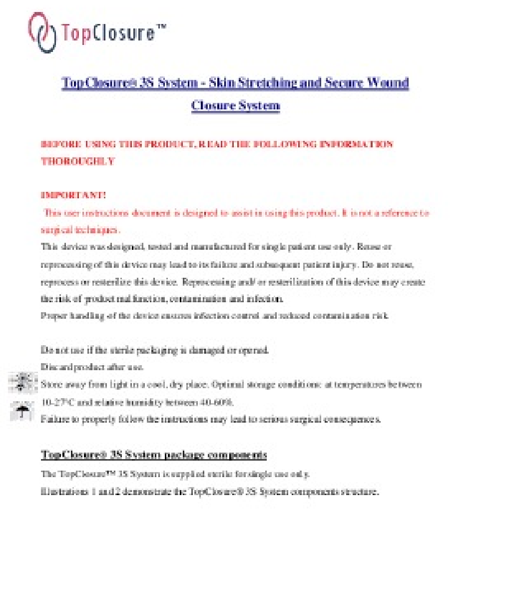


Figure 2. The four steps of using S3 System to close wound.

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, 7:39 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.

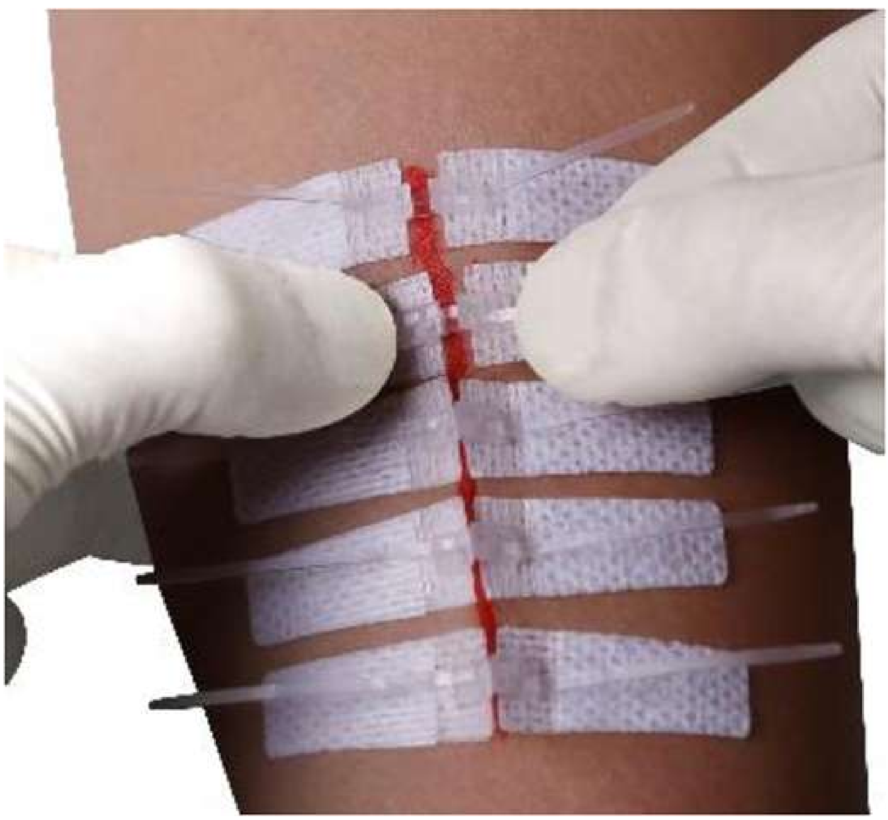


Figure 3. Closure of wound using multiple DermaClips.

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 polyproplyene 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, 8:11 AM CDT

MILITARY MEDICINE, 183, 3/4:472, 2018

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

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

ABSTRACT Injury is the leading health and readiness threat to the armed forces, with two million instances per year; therefore, innovating wound care solutions can help improve readiness. The DermaClip Skin Closure Device is a new, non-invasive, painless, and easy-to-apply wound closure device that does not require either needles or painful anesthesia injections or create additional damage to the wounded area. The efficacy of the device was tested in a 120-patient trial, composed of 60 experimental cases and 60 control cases. The trial of the DermaClip device demonstrated the device's efficacy in meeting the needs of clinical applications. Additionally, the experimental group had no adverse events in the product safety test. The efficacy of the device coupled with the features of ease of use and limited requirements for application make this a wound closure device particularly applicable to the emergency and battlefield setting.

INTRODUCTION

Injury is undisputedly the leading health and readiness threat to the armed forces.[1] A major portion of injuries to the warfighter involves cutaneous wounds requiring closure. Therefore, the search for a superior cutaneous wound closure device that can be efficiently and effectively used both in the field and in a hospital setting to treat cutaneous injuries as well as to expedite surgical closures has significant importance.[2] Recent observational studies indicate that the DermaClip device may fulfill that role.

Much has been written regarding the use of sutures, staples, and adhesives ("traditional closure methods") in wound closure. Previous studies, as well as in practical experience, with each of those traditional closure methods, demonstrate both positive and negative attributes. One study assessed patients' satisfaction with traditional closure methods and reported no significant difference between suture and staple closure media,[3] although Stockley and Elson[4] and Singh et al[5] reported that staples were invariably more painful to remove than sutures, an observation previously cited in the non-orthopedic literature.[6–8] Some authors have suggested that the time-saving benefits of staples might have a psychological effect on surgeons and theater staff, particularly after a long operation.[5,9,10] Given the lack of difference in the incidence of superficial wound infection,[11] and the limited empirical evidence for patients' or surgeons' preference, there is insufficient evidence to justify the use of staples over sutures.

Studies related to the use of glues further cloud the evidence. Gupta and Singh et al reported an advantage for glue over staples in wounds smaller than 10 cm but also referenced the significantly increased cost.[12] Also, most studies advocating the use of glues were done in patients anesthetized or having had local anesthetic. Along with the increased expense and need for anesthesia, there is a possibility of a severe allergic skin reaction that may last for weeks.

The subject of this article is a new, non-invasive, painless, needle-free, and easy-to-apply wound closure device that neither requires anesthesia injections nor creates additional damage to the wound area. The development of the DermaClip device addresses issues associated with traditional closure methods, rendering the device superior to those methods. A study of the DermaClip device was performed in China and is presented herein with an analysis of the potential implications of the use of the device in emergency and combat settings.

The DermaClip device itself is composed of two pieces of adhesive joined by a polypropylene bridge. The device is simple in design but quite advanced as a wound closure device.

The DermaClip device is applied to the approximated edges of a wound and is closed by pulling the polypropylene tabs in opposing directions until a "click" is heard, indicating that the device is locked. As the device closes, the angled faces of the polypropylene bridge encounter each other and create a lifting action of the wound edges, putting the viable dermis on each side of the wound into contact.

In other words, the design creates eversion of the skin edges on closure – eversion being the result a skilled surgeon seeks to accomplish – as it is widely believed that wound eversion is essential for minimizing scarring because it maximizes the chance for proper epidermal approximation and avoids the potential for inversion. Additionally, because the device is applied to the approximated edges of the wound,

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Additionally, the authors Jeffrey S. Freed, MD, and John Ko, MD, PhD are members of the [illegible] Company's Medical Advisory Board.

doi: 10.1093/milmed/[illegible]

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.

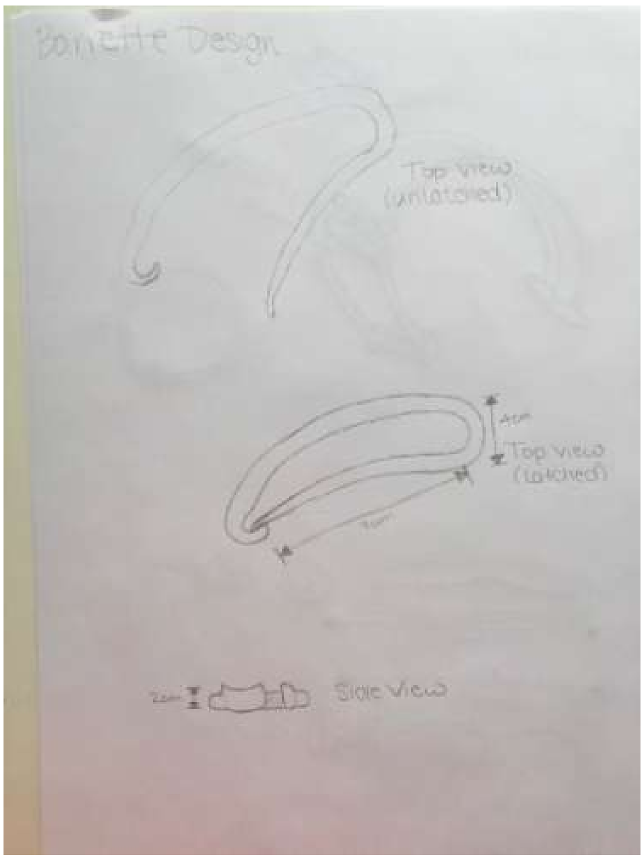


Figure 1. Sketch of the Barrette Design.

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.

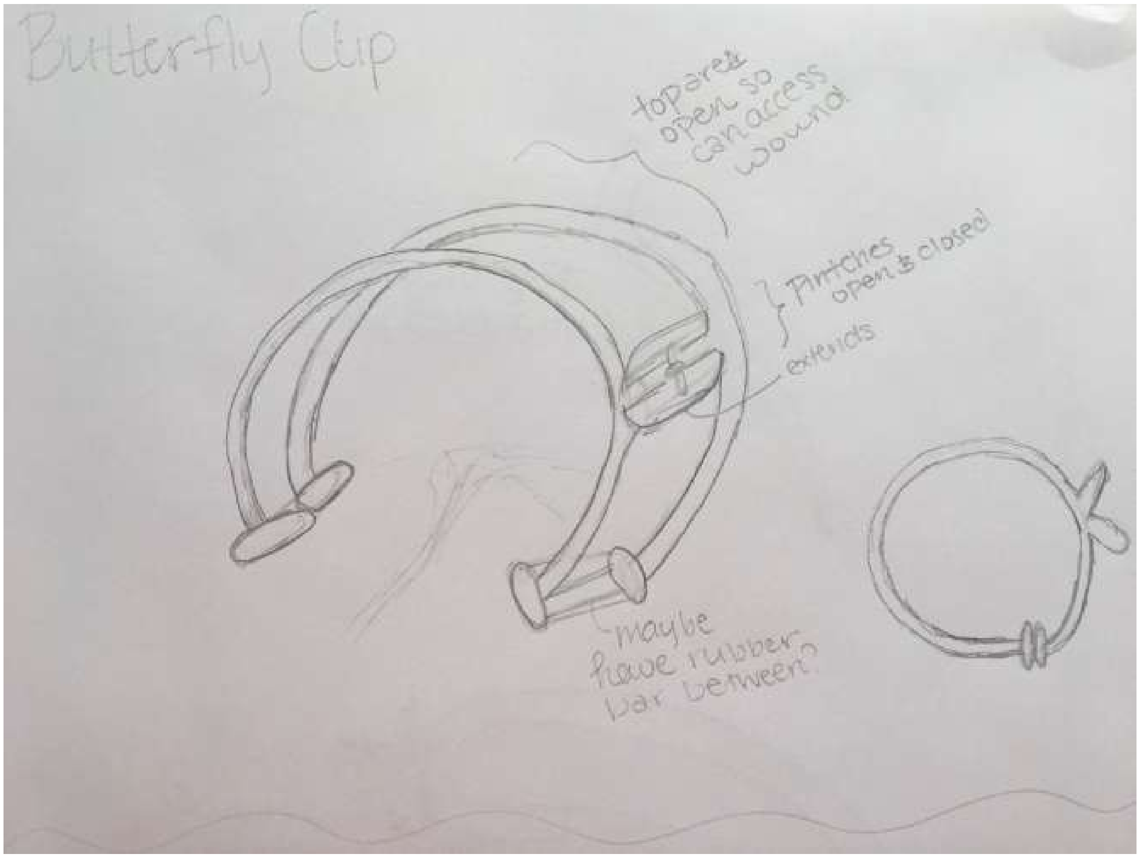


Figure 1. Sketch of Butterfly Clip Design

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, 6:12 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.

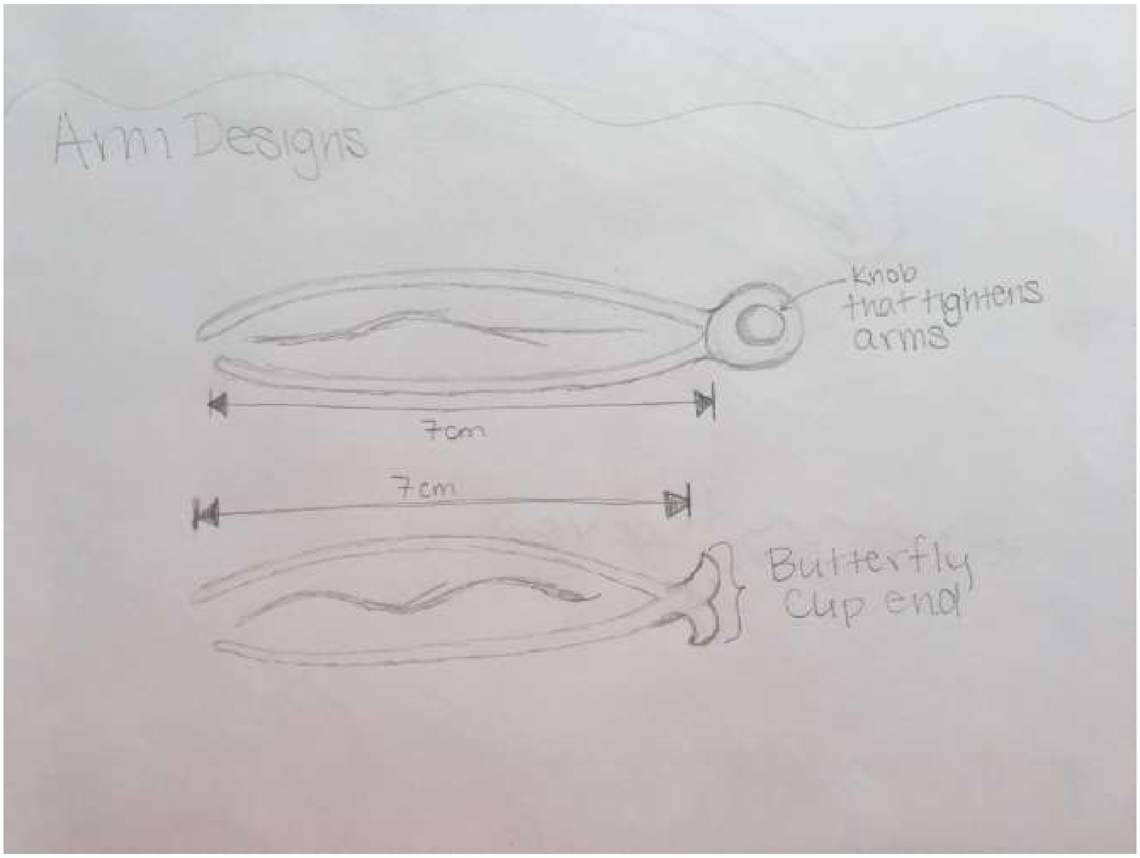


Figure 1. Arm Clip Sketches (knob and butterfly clip systems).

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).

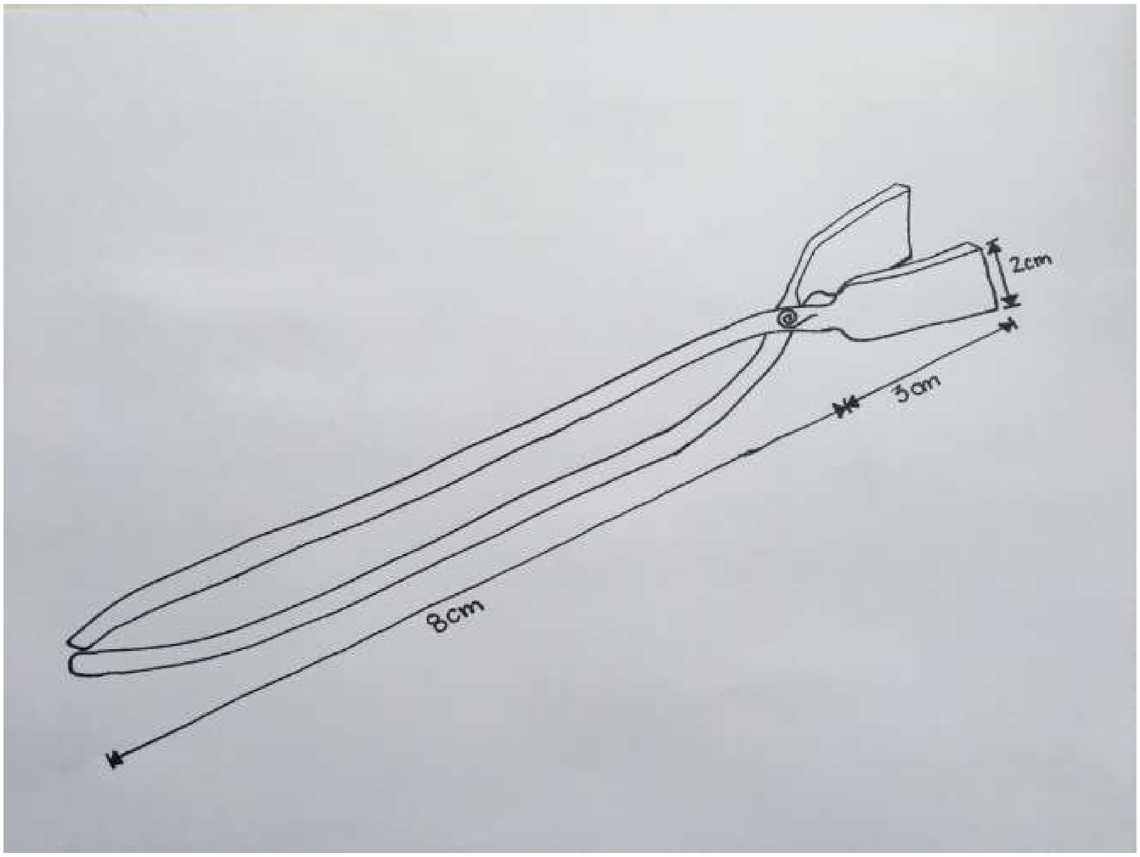


Figure 2. New and improved arm clip drawing that will be used in the prelim presentation. This version includes a spring hinge (like what find on a clothes pin).

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.

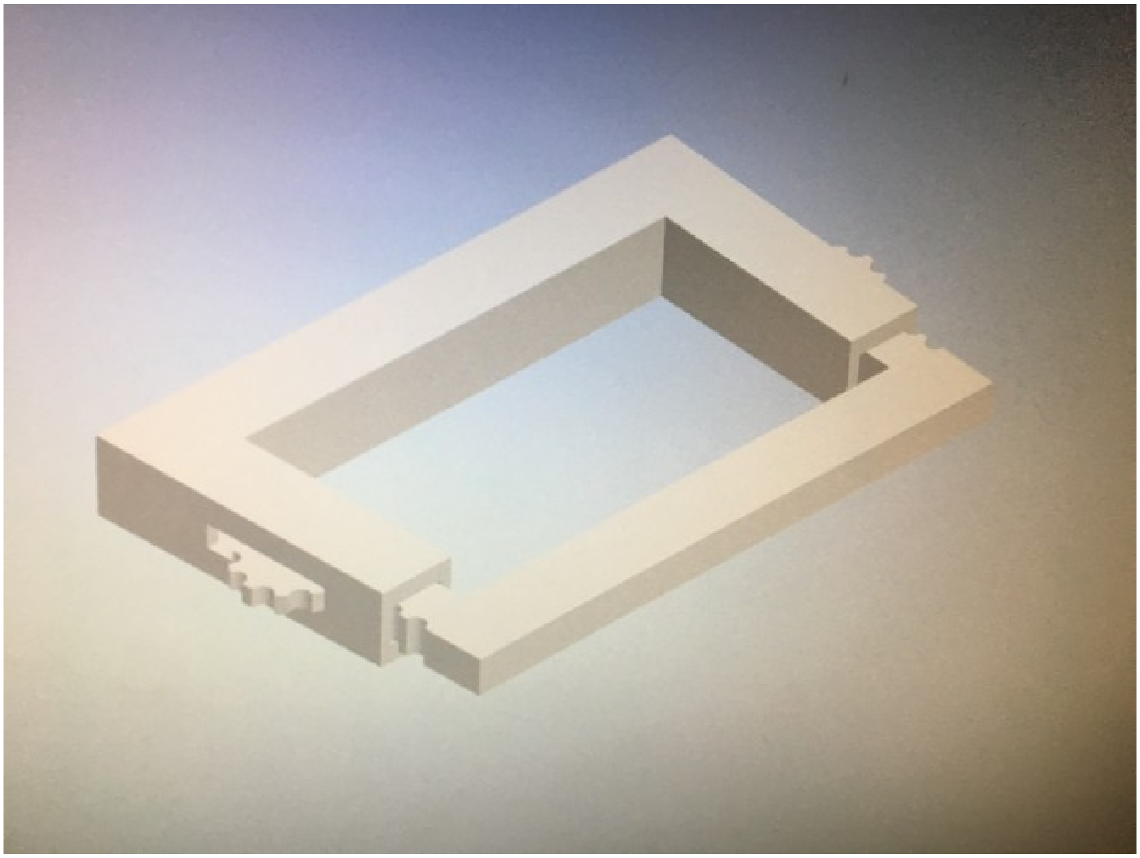


Figure 1. Image of rectangle assembly.

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).

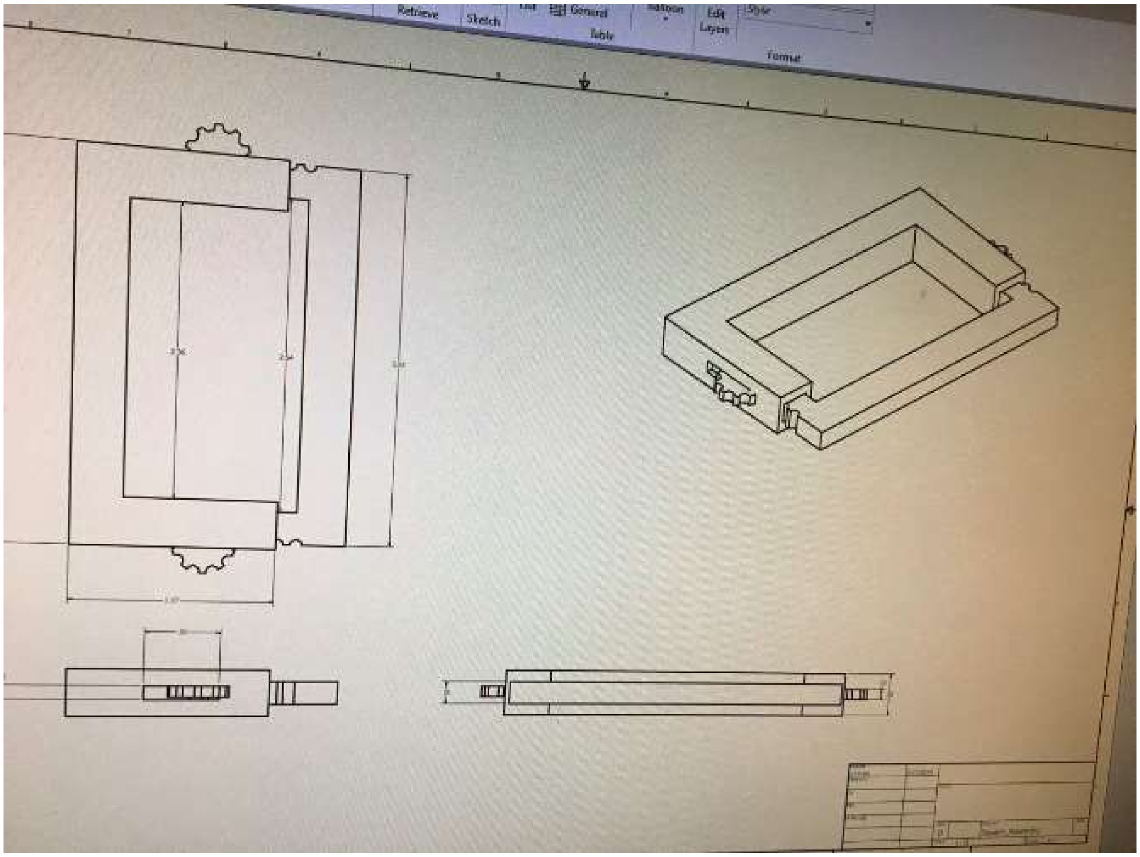


Figure 2. Image of preliminary drawing of the rectangle design (units needs to be converted from inches to cm).

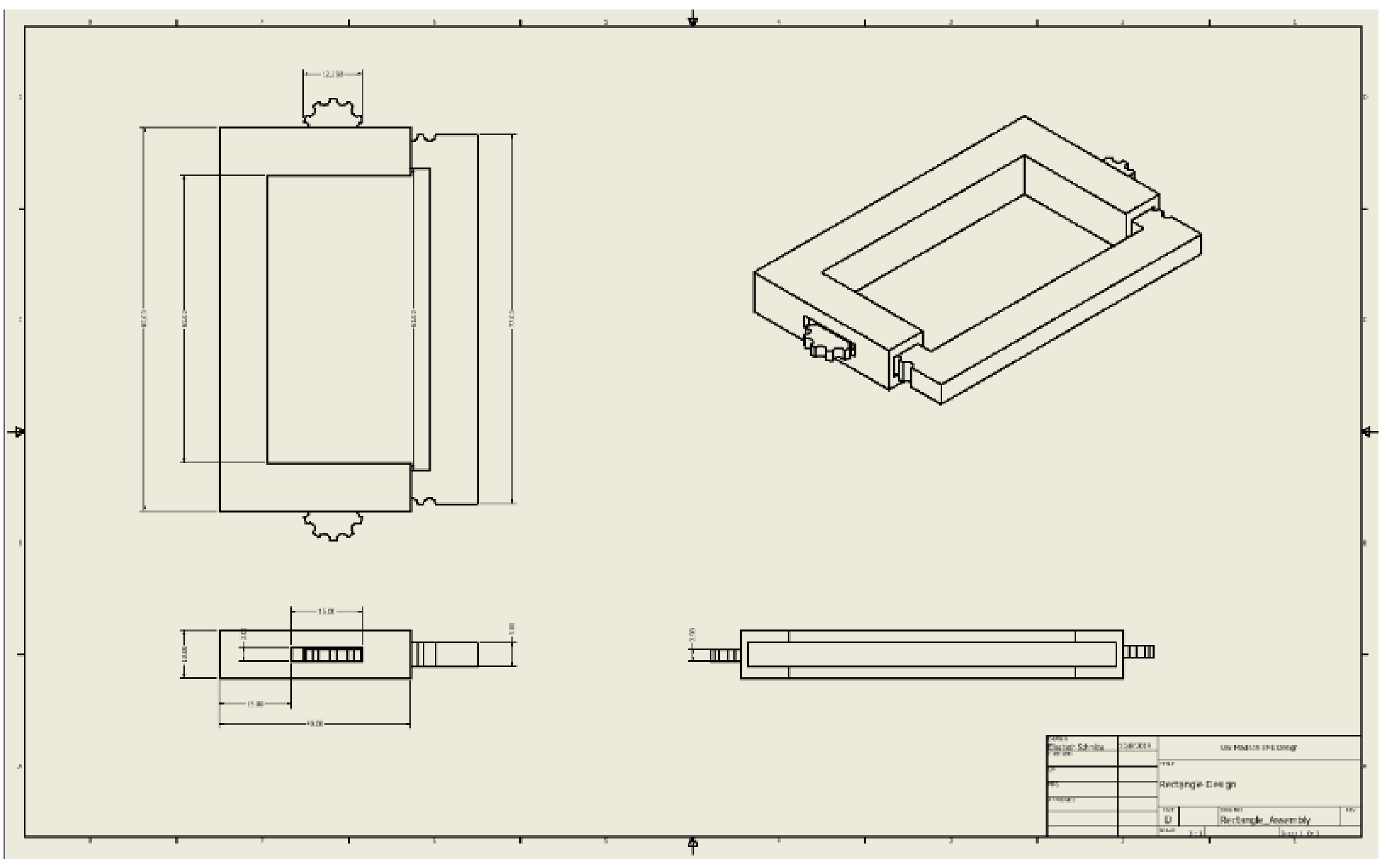


Figure 3. Updated drawing with dimensions in mm.

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, 1:57 PM CDT

Half_Roller.ipt(129.5 KB) - download

ELIZABETH SCHMIDA - Sep 27, 2019, 1:57 PM CDT

Inner.ipt(160.5 KB) - download

ELIZABETH SCHMIDA - Sep 27, 2019, 1:57 PM CDT

Roller.ipt(132.5 KB) - download

ELIZABETH SCHMIDA - Sep 27, 2019, 1:57 PM CDT

Sheath.ipt(157.5 KB) - download

ELIZABETH SCHMIDA - Sep 27, 2019, 1:57 PM CDT

Square_Assembly.dwg(247.4 KB) - download

ELIZABETH SCHMIDA - Sep 27, 2019, 1:57 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, 5:44 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, 5:33 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, 3:40 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, 5:59 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).

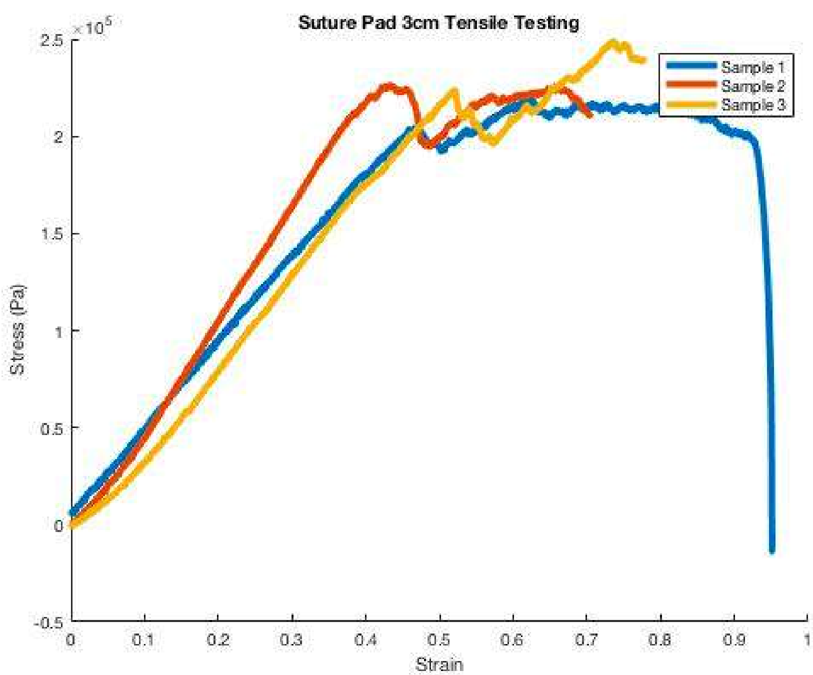
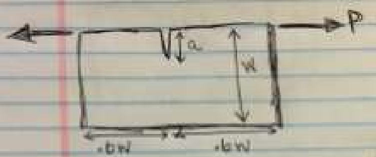


Figure 1. Stress strain curve with a yield strength at approximately 2.3x10^5 Pa.

MODE I FRACTURE MODEL

11/30/2019



~finite plate, edge crack tensile force~

b = thickness of plate

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

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

$Y = \frac{5.23 + \alpha(5.169\alpha - 5.88)}{1 - 1.07\alpha}$

~to use model must assume LEFM (linear elastic fracture mechanics): specimen must be sufficiently thick & crack length must exceed minimum length~

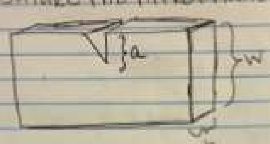
thickness → $t \geq 2.5\left(\frac{K_{IC}}{\sigma_y}\right)^2$

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

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

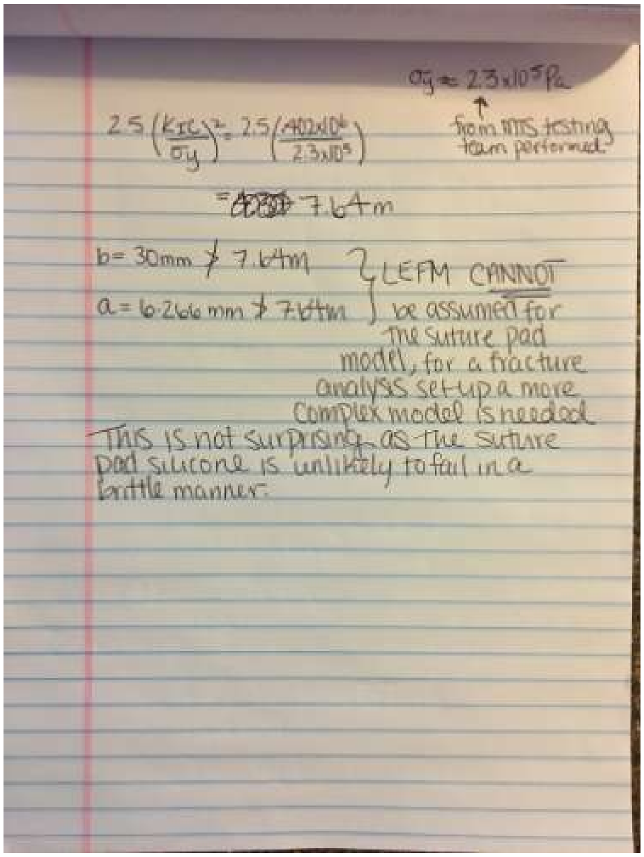
$Y = \frac{5.23 + (.6666)(5.16(.6666) - 5.88)}{(1 - 1.07(.6666))}$

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

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 $\not> 7.64$ m

$a = 6.266$ mm $\not> 7.64$ 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]

Primary Intention

- 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)

Secondary Intention

- 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.

Delayed Primary Closure

- 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, 3:48 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, 1:24 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, 1:42 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, 3:53 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, 4:29 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, 2:45 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, 5:03 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, 9:01 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, 2:50 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, 3:09 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, 3:54 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, 4:39 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

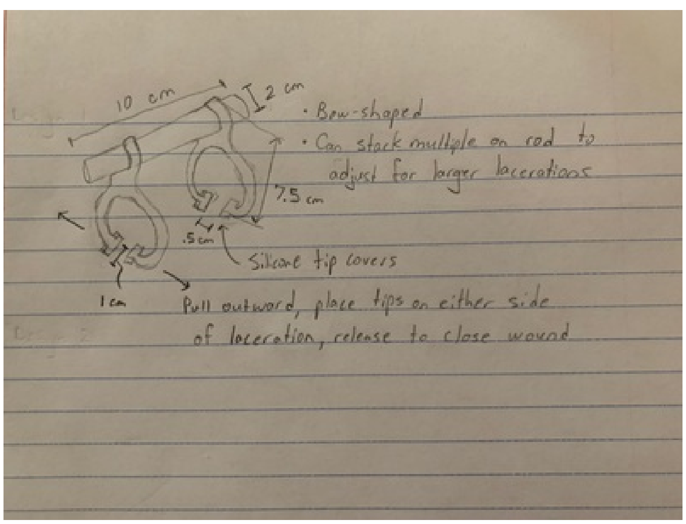
This design consists of "wishbone" shaped wound closers with two tips that are ~0.5-1.0 cm apart at rest. Silicone covers would be placed on the tips to provide added grip on skin. The closers themselves would be 7.5 cm in total length and the tips themselves would be ~1 cm in width. To close the wound, 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, 5:01 PM CDT



26DF660A-5AFB-4565-91EB-8E3DF4C93EF3.jpg(162.2 KB) - download

9/24/2019 Hook-Loop Design

Jack Fahy - Sep 24, 2019, 5:04 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:

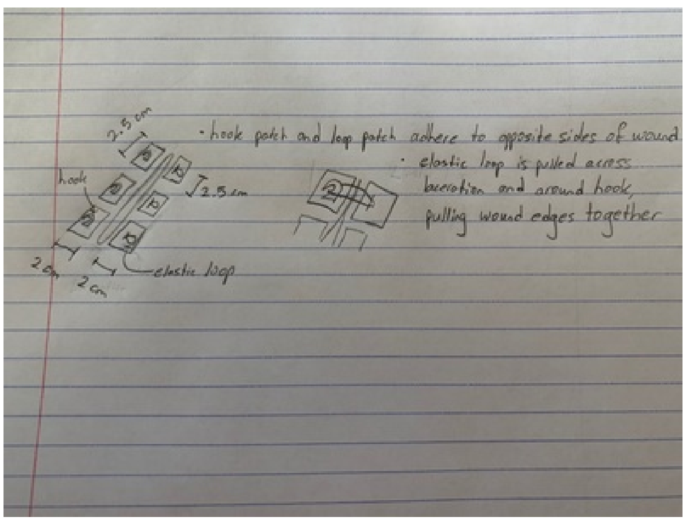
*Drawing of design at bottom of page

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, 4:58 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, 1:00 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:

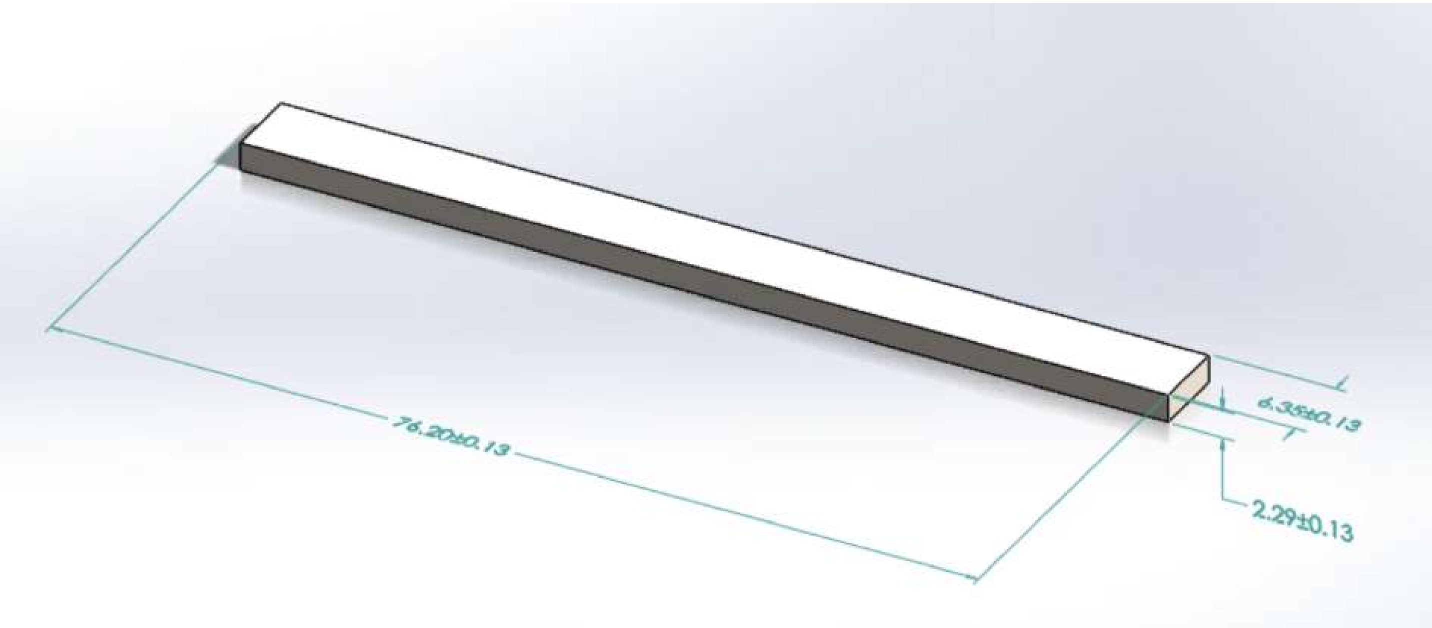


Figure 1. Model of long side of device. This is the part that contacts the patient's skin. Dimensions in mm

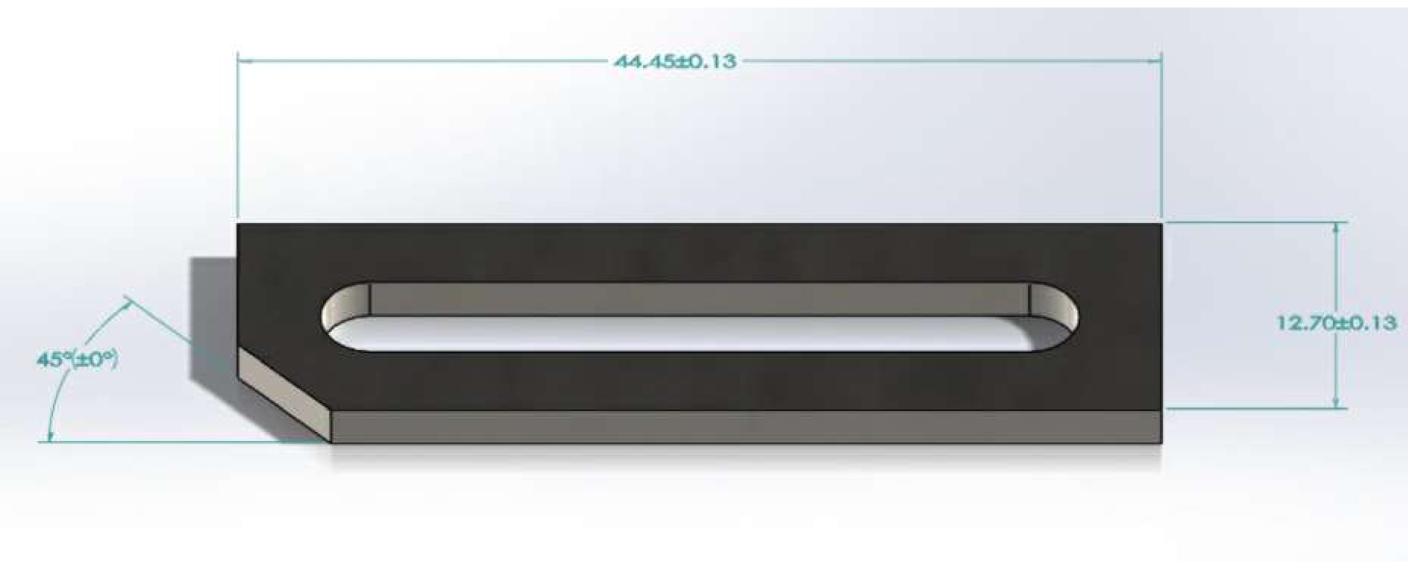


Figure 2. Model of slotted pieces. In accordance with our fabrication plan, one corner of the slotted pieces are sanded down to the width of the long piece so that they rest on the long pieces at a 45 degree angle. The angle at which the slotted pieces sit will not change how the device operates, so 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, 1:04 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:

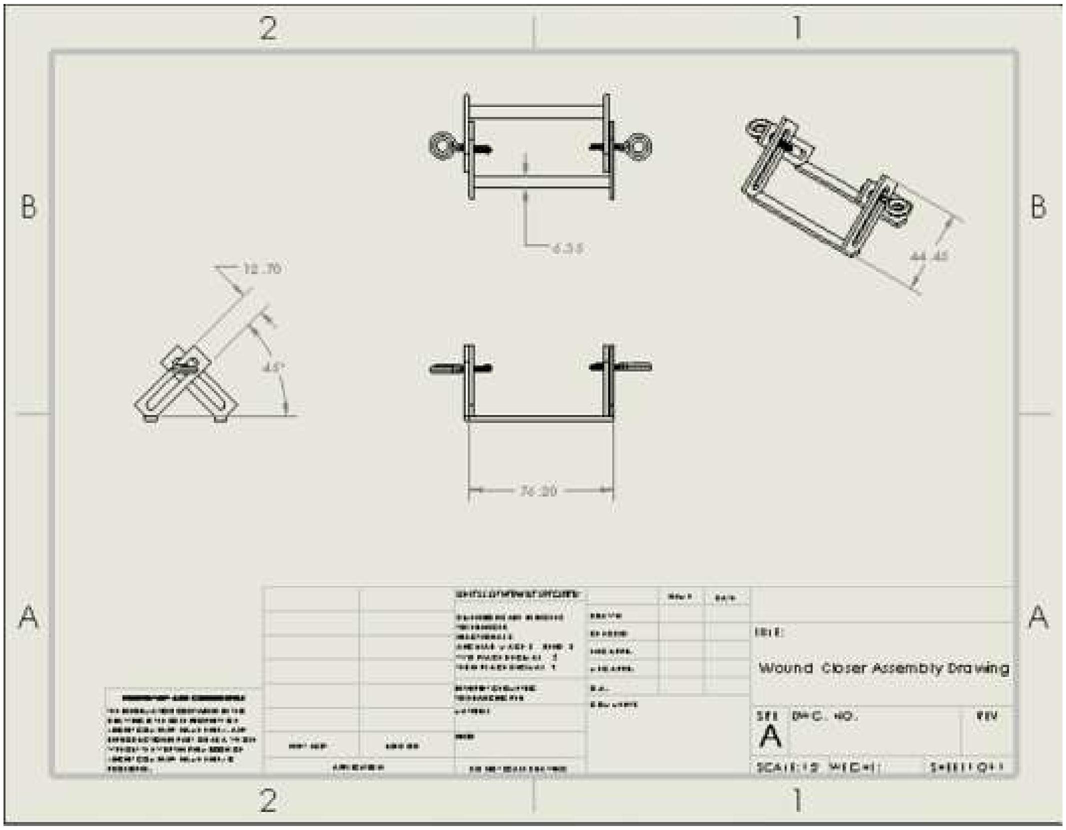


Figure 1. This Drawing defines important dimensions of the design and displays the assembly from a front view (middle), top view (top middle), side view (left), and isometric view (top right). All dimensions are in mm.

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, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: