BME Design-Fall 2020 - JOSHUA GIARTO
Complete Notebook

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JOSHUA GIARTO

on

Dec 09, 2020 @11:48 AM CST

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Team contact Information

JOSHUA GIARTO - Oct 07, 2020, 11:37 AM CDT

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Project description

JOSHUA GIARTO - Oct 07, 2020, 11:39 AM CDT

Course Number: BME200/300

Project Name: Automatic De-epithelialization Device

Short Name: Auto de-epper

Project description/problem statement:

De-epithelialization is a process that removes the epidermis from the rest of the skin. This technique is necessary in many surgeries routinely performed by the client, a plastic surgery resident. However, manual de-epithelialization is time consuming and tedious for surgeons. Additionally, the process can be frustrating due to lack of tension in the skin, which can lead to inconsistencies in cut depth. This current method poses high risk for patients, as the likelihood of damaging the underlying vasculature is heightened. The team has been tasked with creating a device to replace the need for manual de-epithelialization. In order for the device to be successful, it will need to create tension in the skin, allowing for a blade to make cuts of consistent depth. The device should also complete the de-epithelialization process faster than the currently used methods.

The client uses de-epithelialization most often during breast reduction surgeries. During the production of the design, the group will focus on creating a device targeted towards use during this type of surgery. However, the goal is that the device will be dynamic enough to be used any time de-epithelialization is necessary. The team hopes to eliminate the inefficiency and time it takes for this process as well as reduce inconsistencies in cut depth.

About the client:

The client Dr. Carol Soteropulos is currently a plastic surgery resident at a UW-Madison affiliated hospital. She routinely performs breast reduction mammaplasty and breast reconstruction, operations which require the de-epithelialization of breast tissue. She has asked the team to make a device that would facilitate this tedious and time consuming process.

Client Meeting 9/9/2020

JOSHUA GIARTO - Sep 09, 2020, 6:56 PM CDT

Title: Client Meeting Notes

Date: 9/92020

Content by: Josh, Young, Noah

Present: Team members and client

Goals: Meet up with client and learn more about the project

Content:

Budget

- $300, but if needed we can increase this budget
- BPAG needs to be up to date about budget

Access to materials

- Just more materials for surgery rather than anything else

More papers to research

- N/A

What approval do we need to observe the de-epithelialization process

- Look into the hospital shadowing process during COVID and see if we can get approved to go and see the procedure

Specific shape, size?

- Used for any de-epping process
- A “tool” for different surgeries, same application

Is tension the main issue that you come across in this procedure?

- The better the tension the better the cuts, so we need to find a way to get proper tension on the tissue
- Aim for uniform tension

Current technique is to score the skin and then cut the strips off

Competing designs:

Dermatome (instrument)

https://en.wikipedia.org/wiki/Dermatome_(instrument)#:~:text=A%20dermatome%20is%20a%20surgical,grade%203%20burns%20or%20trauma.

Problems: needs large area and tense skin

Conclusions/action items:

Main goal: Minimize time, Consistency (in terms of depth), Uniform tension (??)

Client Meeting 9/22/2020

JOSHUA GIARTO - Sep 23, 2020, 3:51 PM CDT

Title: Client Meeting Notes

Date: 9/22/2020

Content by: Josh, Noah

Present: Dr. Soteropulos (Client), Todd (Medical Student), Josh, Noah, Michael, Colleen

Goals: Receive feedback on the PDS from client and ask question on the specifics of the design

Content:

How does the PDS look, specifically?

- Accuracy, speed, tension need to go in more specifics about how to get things more taught.

This video shows the de-epping process https://journals.lww.com/plasreconsurg/pages/videogallery.aspx?autoPlay=false&videoId=1511

Towel clamps the use:

https://amblersurgical.com/34-508-backhaus-towel-clamp-forceps-3-1-2-ring-handle?gclid=CjwKCAjwwab7BRBAEiwAapqpTPW0iwg8XIhVCkMk5qWIaCBBdcKih4MmMUFoJB5Bi5DTMuey8esBIRoCZuEQAvD_BwE

https://ozmedix.com.au/humeca/dermatomes/

How can we improve upon this design?

- The design skips a lot, they use mineral oil in order to reduce the skipping.
- Want to make a precision device in order to use it for breast tissue instead of larger areas of tissue. So a smaller design that includes an easy way to cut and remove the delicate skin of the breast.

Do you have people that would be able to test our device if we come up with some preliminary designs?

- The client might be able to give us discard samples for us to test on. Soteropulos and todd will look into this more
- Maybe using pig feet or pig skin, or any animal model we can find in the store

Thickness of dermis

- 1/12000 of an inch
- 0.012 inch, 0.3 mm thick
- Todd: Thickness of the epithelial layer: Design for the 20-10 bottom % and 80-90 top %, will vary

Conclusions/action items:

Anything that will help them to make this process very much easier for the surgeon during this process.

2020/10/09 Advisor Meeting

YOUNG KIM - Oct 09, 2020, 3:05 PM CDT

Title: Advisor Meeting

Date: 2020/10/09

Content by: Young Kim

Present: Whole team and Advisor

Goals: Make sure the team understands the feedback received on the preliminary presentation and get some further insight into the future of the project.

Content:

Preliminary Presentation Feedback:

Tell a story, more exposition. The team understand the problem well, but the audience could benefit from a clear background section.

Better figures, labels. Even if the designs are scrapped, some thought should be put into them to make sure the team understands why the designs were insufficient.

Patents:

Currently, this shouldn't serve as a large barrier for progress. More considerations should be made when attempting to make money off of the design, which is still currently far into the future.

More research should be done on the Epicut itself and the patent behind it.

Testing:

Testing is still quite a ways out, but the client has been very helpful in reaching out to other sources to acquire tissue samples for the testing process.

Preliminary testing should be done by the team to ensure that the device is in working condition before handing it off to the client.

Likely, the prototype will be scaled up to make it reasonable for manufacturing. The client should be fully aware of this fact.

Manufacturing:

The team should look into materials that can be used in the Wendt Commons by a 3D printing machine.

Design:

The curvature of breast tissue should be considered. Maintaining contact between the bottom surface of the handle with breast tissue may pose an issue.

The length of the bottom surface and the position of the scalpel arms could be adjusted to help alleviate this issue.

Conclusions/action items:

The team has been doing good work and should continue doing so. Each member of the team understands what must be done next, and has received feasible goals they should accomplish in the foreseeable future.

2020/10/16 Advisor Meeting questions

YOUNG KIM - Oct 16, 2020, 8:31 PM CDT

Title: Advisor Meeting

Date: 2020/10/16

Content by: Young Kim

Present: Young Kim

Goals: Begin considering how the team will acquire pig and human tissue samples and where these tissues can be stored/worked on.

Content:

The team's medical student consultant, Todd Le, reached out to Dr. Gibson regarding tissue acquisition.

1) Is there any place you know of where animal tissues could be stored? I think it would be best if we had these tissues on hand. This would permit greater flexibility to the team and would allow us the ability to test the samples as soon as the prototype is developed.

2) Do you know of any place where the team could test the animal tissue?

2) Is there any place you know of where human tissues could be stored? Human tissue is BSL 2, and requires different practices and containment protocols. I saw that bloodborne pathogen training and hepatitis B immunization were required. Are there any more requirements that I am missing and do you know of how members could get started on the bloodborne pathogen training?

3) Do you know if BME students have access to a BSL 2 lab? If not, Todd and I are discussing other options, which include working at Dr. Gibson's lab or creating our own protocol to work in a separate facility.

Conclusions/action items:

These considerations are made for the testing phase of the engineering process, which is still in the future, but thinking about these items now will help the team be prepared for future work.

Contact Todd regarding the team's next steps.

YOUNG KIM - Oct 16, 2020, 8:26 PM CDT

BSL.pdf(0 Bytes) - download Franklin & Marshall's presentation on BSL.

2020/11/20 - Meeting with Dr. Wille

JOSHUA GIARTO - Dec 02, 2020, 1:08 PM CST

Title: Meeting with mechanical advisor

Date: 20 Nov 2020

Content by: Josh

Present: Josh and Young

Goals: Discuss how to test prototype and whether it is possible

Content:

Instead of tensile testing, what we initially wanted to do, Dr. Wille proposed that we do a bending test as that test and motion represents more accurately on the motion and forces our prototype will experience. More specifically, we would want to do a cantilever test, where we have the part of the arm that will be attached to the handle to be fixed in space and the machine will exert a compressive force on the part of the arm that the scalpel blade will attach to.

Conclusions/action items:

There are two major obstacles we face when we want to do the cantilever tesing:1 part of the arm is in the way for the machine to pass through and act on the targeted area, and 2 to fix the arm in space will require more equipment that we either do not have, like additional material to clamp, or we do not have time to prepare, like 3D printing a part that arm can securely attach to and then secure that part to the table.

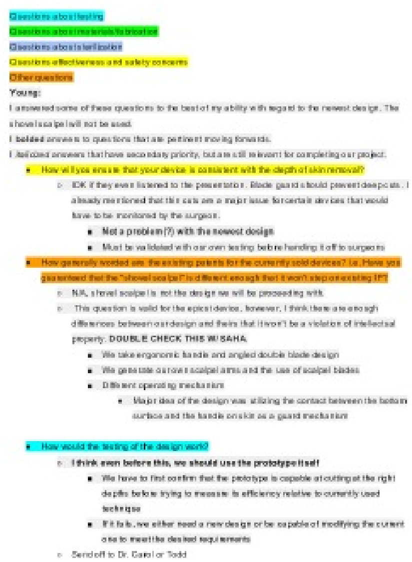
With the time limit and the limited resources, we concluded that we cannot do bending testing on our prototype and that we will instead do simulation testing on CAD or Solidworks.

Preliminary presentation questions

Noah Ruh - Dec 09, 2020, 1:07 AM CST

Title: preliminary presentation questions

Noah Ruh - Dec 09, 2020, 1:07 AM CST



Questions about testing
Questions about materials/fabrication
Questions about sterilization
Questions effectiveness and safety concerns
Other questions

Young:

I answered some of these questions to the best of my ability with regard to the newest design. The shovel scalpel will not be used.

I **bolded** answers to questions that are pertinent moving forwards.

I italicized answers that have secondary priority, but are still relevant for completing our project.

- How will you ensure that your device is consistent with the depth of skin removal?
  - IDK if they even listened to the presentation. Blade guard should prevent deep cuts. I already mentioned that thin cuts are a major issue for certain devices that would have to be monitored by the surgeon.
    - **Not a problem(?) with the newest design**
    - Must be validated with our own testing before handing it off to surgeons
- How generally worded are the existing patents for the currently sold devices? i.e. Have you guaranteed that the "shovel scalpel" is different enough that it won't step on existing IP?
  - N/A, shovel scalpel is not the design we will be proceeding with.
  - This question is valid for the epicut device, however, I think there are enough differences between our design and theirs that it won't be a violation of intellectual property. **DOUBLE CHECK THIS W/ SAHA**
    - We take ergonomic handle and angled double blade design
    - We generate our own scalpel arms and the use of scalpel blades
    - Different operating mechanism
      - Major idea of the design was utilizing the contact between the bottom surface and the handle on skin as a guard mechanism
- How would the testing of the design work?
  - **I think even before this, we should use the prototype itself!**
    - We have to first confirm that the prototype is capable of cutting at the right depths before trying to measure its efficiency relative to currently used technique
    - If it fails, we either need a new design or be capable of modifying the current one to meet the desired requirements
  - Send off to Dr. Garal or Todd

Peer_Questions.pdf(90.4 KB) - download

2020/12/08 Peer Final Questions

JOSHUA GIARTO - Dec 08, 2020, 3:13 PM CST

Title: Peer Final Questions

Date: 2020/12/08

Content by: Young Kim, Joshua Giarto

Present: Full Team

Goals: Answer questions raised during the final poster presentation session

Content:

- For De-ep team: how would testing with muscle layer instead of epidermis layer affect the conclusion that you've drawn from the results?
  - Greatly. The use of chicken and pork tissue was purely out of necessity. Acquiring relevant samples posed a significant challenge, as the team was inadequately prepared and had miscommunications regarding the acquisition of relevant samples. The use of chicken and pork was purely for validation of the prototype, but this still did not produce results the team were satisfied with.
- Is there a chance that with these replaceable parts in plastic that they are moving inside the device, and how will you fix this in the final surgical steel device while still keeping it reusable?
  - Adding grooves to the insertion point instead of a pure rectangle could help minimize the movement of the device. For example, introducing an extrusion on the rectangular insertion piece of the scalpel arms which insert into accurately sized grooves on the upper and lower portion of the relevant location in the handle's opening could minimize rotations that occur. This could result in mechanical weakness in certain areas, which would have to be tested and possibly reinforced. Having each piece precisely machined to exact dimensions would also assist in minimizing any movement which may occur.
- What was the most difficult part of your project regarding COVID-19?
  - The most difficult part of this project regarding COVID-19 would definitely be the fabrication of the prototype and organizing testing. Due to COVID-19, the team had a much more difficult time accessing tools to effectively augment the prototype to get it into working conditions. Thus, impromptu solutions were implemented, such as using a rubber band to secure a scalpel blade to the scalpel attachment arm. Additionally, it was difficult for the team to get adequate testing done. Initially, the team and client had plans to hand off a working prototype to the client so the client could attempt to use the device. However, the prototype was not finished in time.
- How accurately does the chicken and the pork represent human skin?
  - Pig skin have been uses as a practice sample for medical students practicing stitching. From this and other research that the team did, pig skin is a good substitute for human skin because of their composition. Pork was also recommended by our client and medical student. Chicken was used because there was no pork available for that team member.
- Is the device adjustable for skin thickness, or is .3mm pretty universal?
  - The 0.3mm thickness is relatively useful, but the team has thought of including additional scalpel arms that have different depression angles between the insertion plate and the scalpel attachment piece to either elevate or escalate the level of the blades. This would be manually done at the discretion of the surgeon.
- Did the texture of the chicken/pork cause problems while testing? if so, what were they?
  - A problem with the chicken was that it needed an initial cut in order for the device to work and since we are not sure how similar chicken is to human tissue, we are not sure if this is the same if human tissue was used. A pork with the pork was that the tissue was too slippery and device had trouble with the initial cut.
- What aspects of this device make it reusable as opposed to the single use Epi-Cut?
  - An aspect of this device making it reusable as opposed to the single use Epi-Cut is the utilization of disposable scalpel blades and an autoclavable material. The Epi-Cut is a singular device with non removable blades onto a plastic handle. They are specifically designed for single uses, with the website stating that upwards of 3 Epi-Cuts could be used per operation. Having a surgical steel handle and attachment arms would allow them to be sterilized after operations, with the blades being disposed of after each use.
- How does the pig skin compare to human skin? Do you think it would be more successful on human skin?
  - Pig skin is relatively similar to human back tissue regarding thickness. However, this would still not be representative of the human breast tissue the client desired to operate on. The team thinks that there is some potential it would be more successful on human skin, but without further testing, this claim cannot be thoroughly verified.
- Is the skin thickness up to the surgeon? it appeared as if it was manually cut

    - Yes, the client specifically wanted to use this device on the breast and the specific thickness needed is 0.3mm. This may not be the case for this process done on a different body part since the epidermis thickness varies depending on the body part
- How to you plan to adjust the device in the future to achieve better skin tautness?
    -
- What ways do you plan on further automating the process of de-ep?
    - We do not plan to fully automate the process. the goal is to make the de-epping process faster and more efficient for the surgeon. We believe that the surgeon will need to manually direct the device for safety purposes and the varying cutting techniques, size, and shapes that the surgeon will need to preform.

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2020/10/09 Further Design Considerations

YOUNG KIM - Oct 09, 2020, 2:50 PM CDT

Title: Design future considerations

Date: 2020/10/09

Content by: Young Kim

Present: Colleen Cuncannan, Michael Chiariello

Goals: Plan out next steps for the engineering process

Content:

The team is currently thinking about two major goals for the foreseeable future. 1) How can we make a secure scalpel attachment that can be 3D printed 2) What materials and methods will be used to make the prototype.

For the first goal, the team is looking into possible STL files that other individuals have created to serve as scalpel handles. The team is in possession of a scalpel blade at the moment, but designing this may pose a significant issue. The team is currently planning on taking the STL files and importing them to Solidworks, converting them to a useable filetype.

https://www.thingiverse.com/thing:2712629, https://www.thingiverse.com/thing:3239187, https://www.thingiverse.com/thing:2712629, https://www.thingiverse.com/thing:1488946

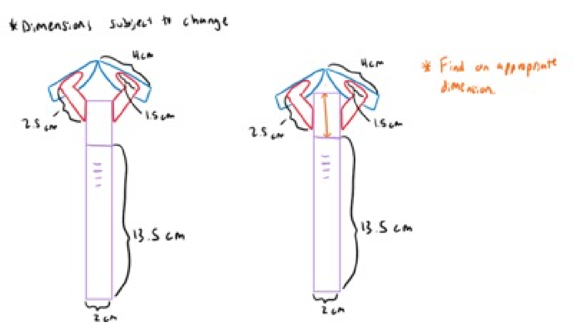
For the second goal, the team is planning on conducting further research to find a reasonable material that is compatible with the 3D printers within Wendt Commons.

Another design consideration the team realized was that accounting for the curvature with the modified epicut may be difficult, as the working principle entails contact between the bottom surface of the handle and the relevant tissue. To accommodate for this, the team is considering how long the bottom surface should be, along with the position of the scalpel arms relative to the bottom surface. Figure 1 demonstrates a possible solution that could be implemented.

Conclusions/action items:

Continue working on the project with the major goals in mind. Keep team members accountable and on track. Continue placing thought into the design and how to best complete the task at hand.

YOUNG KIM - Oct 09, 2020, 2:51 PM CDT



Design_revision.png(76.6 KB) - download Figure 1:Attachment of the arms could be moved backwards to help accommodate the curvature in breast tissue. The length of the bottom surface of the handle should be determined with the same consideration in mind.

Materials and expenses

Noah Ruh - Dec 08, 2020, 9:48 PM CST

Title: Materials and expenses

Date: Continual update

Content by: Michael

Present: N/A

Goals: Show the materials and expenses spreadsheet

Content:

Item	Part number	Place purchased	Cost	Quantity	Total
Pack of 100 Disposable Surgical Blades 10, Size 10 Scalpel Blades for Surgical Knife Scalpel, High Carbon Steel Dermablade Surgical Blades. Individually Wrapped 10 Blade, Sterile	B24-MEDH20-100BLADES10	Amazon.com	$13.88	1	$13.88
UW Makerspace Materials Fee		UW Makerspace https://making.engr.wisc.edu/	$50.00	1	$50.00
Prototype 1 Handle: The 3D printed handle of the modified epicut prototype made of tough PLA.	Print ID: 7776239	UW Makerspace https://making.engr.wisc.edu/	$2.56	1	$2.56
Prototype 1 Arms: The 3D printed arms of the modified epicut prototype made of High Temp Material.	Print ID: 6533294	UW Makerspace https://making.engr.wisc.edu/	$2.06	2	$4.12
Prototype 2: The entire 3D printed prototype of the modified epicut made of tough PLA.	Print ID: 3988519	UW Makerspace https://making.engr.wisc.edu/	$2.80	1	$2.80
Prototype 3: The entire 3D printed prototype of the modified epicut made of tough PLA.	Print ID: 7839888	UW Makerspace https://making.engr.wisc.edu/	$2.88	1	$2.88

2020/12/08 Issues and Improvements of final prototype

Noah Ruh - Dec 09, 2020, 1:03 AM CST

Title: Issues and Improvements of final prototype

Date: 2020/12/08

Content by: Young Kim

Present: Young Kim

Goals: Clarify what went wrong with the final prototype and specify areas that could see improvement.

Content:

Based on the results the team concluded that this device is able to periodically cut through and remove the tissue of samples, however not at the rate that was expected or needed. The low success rate of cuts means that the device the team created does not meet the requirements that were given. Along with the low success rate of cuts, the large standard deviation seen in Figure 15 means that even when the device did cut, it did not do so consistently. The t-test that was run on the data also showed that there was a significant difference between the tested cut depth and requested cut depth meaning the device was not able to create a cut that was a close match to the requested cut. One positive of the device was that once the cut was started maintaining tension on the skin was quite easily accomplished by grabbing the skin and holding on as it ran through the device.

There were several sources of error during the testing of this prototype that may have caused the results that were seen. The 3D printing of the devices was not as accurate as the CAD modelling resulting in the arms of the prototype being too large to fit into the handle correctly. To fix this the team filed the arms of the chicken testing device so both arms would fit in and for the porcine testing device one arm was secured in the device. Along with only one arm, the porcine testing device's scalpel was held in place using a rubber band as the attachment point for the scalpel did not print correctly. Another source of error comes from the team not being surgeons, this resulted in hesitation during testing and may have contributed to the lack of consistency of the cuts. In addition, to cut through the tissue of the chicken and pork, the team could not glide the blade across the skin, which would allow for smoother cuts. Instead, the team had to pull the blade directly against the skin, which resulted in choppy cutting, more similar to cutting down a tree with an axe instead of a saw.

Conclusions/action items:

In order to improve upon this device, we need to complete much more testing. We need to find a way to get this device to maintain a smooth cut and to cut smoothly in general. We think we can do this by changing the device to have a slanted blade so we are cutting in a sawing motion instead of a chopping motion, or the device may need to go back to the drawing boards and some other ideas be tested like the roller idea.

2020/11/17 - Testing protocol for ECB shared labs

JOSHUA GIARTO - Nov 18, 2020, 12:19 AM CST

Title: Testing Protocol for ECB shared lab

Date: 11/17/2020

Content by: Josh and Young

Present: De-epper team

Goals: Create Protocol for Testing

Content:

Protocol:

MTS Machine Preparation

1. Before using the MTS machine, identify emergency stop, potential crush and pinch points.
2. Use known maximum possible load to ensure the load cell and the fixture both match the test and load.
3. The appropriate load cell is 10 kN based on the known maximum possible load of 10 kN.
4. The clamps are used as the fixture since the samples are being tested in tension.
5. Attach the fixtures to the upper/lower clevis.
6. Set safety stops to prevent the top and bottom fixtures from touching.
7. Sand the nine samples and record the measurements of the length and diameter of each.
8. Clamp the part of the prototype arm that holds the scalpel to the base.
9. Clamp the part of the prototype arm that will insert to the handle to the top clamp..
10. Zero the system on the MTS computer screen.

Testing and Data Collection

1. Click the “Play” button to run the test.
2. Run the sample until the tensile force reaches 2kN or there is a failure.
3. Click the “Generate a report for the selected test run(s)” icon to obtain the graph and numerical results from the test run.
4. Repeat 3 more times.

Conclusions/action items:

This is part of the application for the testing protocol that will be submitted for use of the ECB room 2005 MTS machine.

2020/12/02 - Josh's Testing protocol for proof of concept

JOSHUA GIARTO - Dec 08, 2020, 8:12 PM CST

Title: Testing Protocol for proof of concept

Date: 12/02/2020

Content by: Josh

Present: Josh and Young

Goals: Create Protocol for proof of concept

Content:

Protocol:

Assembly

1. Receive prototype from MakerSpace

2. File off parts of the arm so that they can fit in the handle and that the scalpel can fit

3. If any of the parts do not if, either print another prototype, making adjustments based on current prototype errors or at least fit one arm with a blade attached to it

Preparation:

1. clean and sanitize a large flat surface, preferably a kitchen counter.

2. place a cutting board for the raw meat to but placed and tested on

3. cut portion of the pig tissue with a knife that is wanted for this test, the skin or near the skin if the sample does not have skin

Testing

1. carefully attempt to cut a layer of tissue off using the device by pulling on the handle and pushing down onto the sample

2. gather samples of layers of tissue that were cut off using the prototype

Analysis

1. examine the samples and describe them, check if they pass: long, consistent thickness cuts

2. If the samples are at least 4cms long with a relatively consistent width, then continue with analysis

3. preform t-test on whether the thickness is uniform if possible on the samples.

Conclusions/action items:

This is the protocol for the proof of concept test using pork tissue that will be done at Josh's and Young's apartment kitchen.

2020/12/02 - Noah's Testing protocol for proof of concept

Noah Ruh - Dec 08, 2020, 9:46 PM CST

Title: Testing Protocol for proof of concept

Date: 12/02/2020

Content by: Noah

Present: Noah

Goals: Create Protocol for proof of concept

Content:

Protocol:

Assembly

1. Receive prototype from MakerSpace

2. File off parts of the arm so that they can fit in the handle and that the scalpel can fit

3. If any of the parts do not if, either print another prototype, making adjustments based on current prototype errors or at least fit one arm with a blade attached to it

Preparation:

1. clean and sanitize a large flat surface, preferably a kitchen counter.

2. place a cutting board for the raw meat to but placed and tested on

3. Place a chicken breast onto the board and make an entry cut near one of the ends of the breast

Testing

1. carefully attempt to cut a layer of tissue off using the device by pulling on the handle and pushing down onto the sample

2. gather samples of layers of tissue that were cut off using the prototype

Analysis

1. examine the samples and describe them, check if they can be considered successful: long, consistent thickness cuts

2. If the samples are at least 3 in long with a relatively consistent width, then continue with analysis

3. preform t-test on whether the thickness is uniform if possible on the samples.

Conclusions/action items:

This is the protocol for the proof of concept test using pork tissue that will be done in Noah's living room.

2020/12/02 - Pork Testing

JOSHUA GIARTO - Dec 08, 2020, 8:13 PM CST

Title: Pork Testing

Date: 12/02/2020

Content by: Josh

Present: Josh and Young

Goals: Preform proof of concept test on pig tissue

Content:

Assembly

We had two prototypes with the arms made of two different materials, High Temp resin and Tough PLA resin. The handle of both prototypes were made of tough PLA. the arms had to be filed so it could fit into the handle. However, there were some difficulties filing the top and bottom to fit both arms in the handle. We decided that fitting one arm is enough for this test. Fitting the blade into the arm was very difficult and the portion that attaches to the blade snapped off in the High Temp arm and was filed off for the tough PLA arm as shown on the individual arm in figure 1 and 2. The blades had to be secured with a rubber band as shown in figure 3 and 4. Also shown by figure 3 and 4 is the position of the blade relative to the bottom of the handle. Since the tough PLA prototype has the blade below the bottom of the handle and the High Temp prototype has the blade above the bottom of the handle, the tough PLA prototype will be used for testing.

Preparation:

The kitchen counter was cleared and cleaned for testing. Three slices of pork were used for this test

Testing

Around 30 attempts of cutting off a layer of tissue were tried and only 3 successful continuous cuts were made as shown in figure 5. Each attempt did not use an initial cut to start the cut. The samples were short and inconsistent in thickness. Analysis on thickness was not done since the length of the samples were too short (around 2 cm) and with inconsistent width.

Conclusions/action items:

The prototype did not pass the proof of concept test.

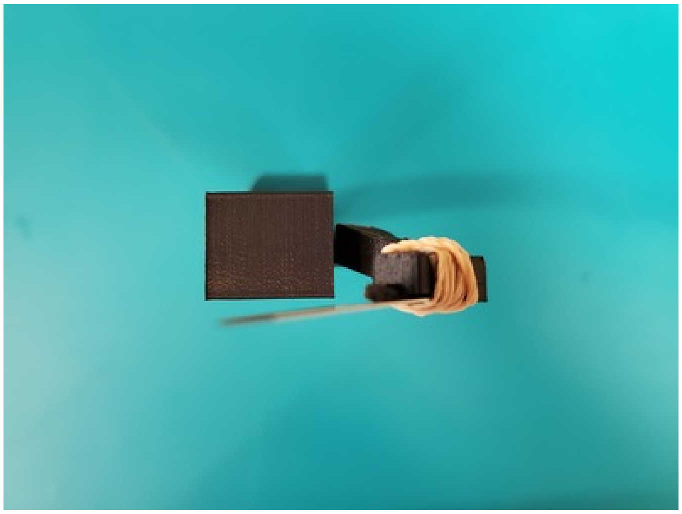
JOSHUA GIARTO - Dec 08, 2020, 5:30 PM CST

20201202_123909.jpg(3.8 MB) - download Figure 1: A 3D printed prototype using Ultimaker Tough PLA. The right arm was the only arm that was able to be inserted due to inaccuracies during printing of the device. The left arm is shown with an attached scalpel blade.

JOSHUA GIARTO - Dec 08, 2020, 5:30 PM CST

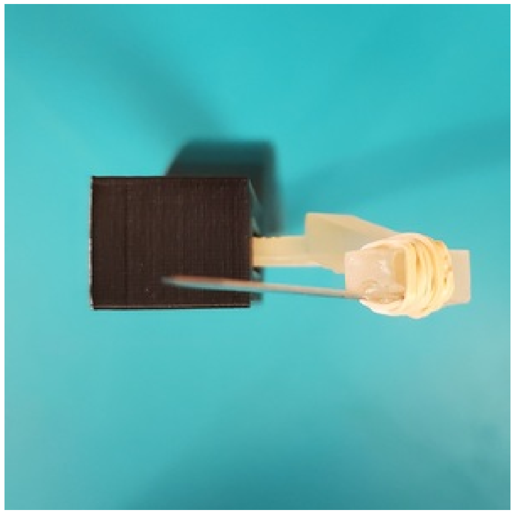
20201202_122259.jpg(4.1 MB) - download Figure 2: A 3D printed prototype using Formlabs High Temp resin. Only the right arm is inserted due to an error in printing. The scalpel blade is attached with a rubber band as a result of inaccurate printing.

JOSHUA GIARTO - Dec 08, 2020, 5:38 PM CST



20201202_125038.jpg(4.4 MB) - download Figure 3: The tough PLA prototype with one of the arms with the blade attached to it, inserted into the handle. This is a front view with the blade pointing out of the picture. The position of the blade shows that the prototype can be used for testing because the blade is below the bottom of the handle.

JOSHUA GIARTO - Dec 08, 2020, 5:37 PM CST



20201202_124957.jpg(912 KB) - download Figure 4: The High Temp prototype with one of the arms with the blade attached to it, inserted into the handle. This is a front view with the blade pointing out of the picture. The position of the blade shows that the prototype cannot be used for testing because the blade is above the bottom of the handle.

JOSHUA GIARTO - Dec 08, 2020, 5:51 PM CST

20201202_152844.jpg(4.5 MB) - download Figure 5: The result of the test showing the three successful cuts with the blade as reference for size.

Chicken breast testing - Copy

Noah Ruh - Dec 08, 2020, 9:33 PM CST

Title: Chicken Breast Test

Date: 11/30/2020

Content by: Noah Ruh

Present: Noah

Goals: Test the prototype device in order to see feasibility and see new possible design ideas

Content:

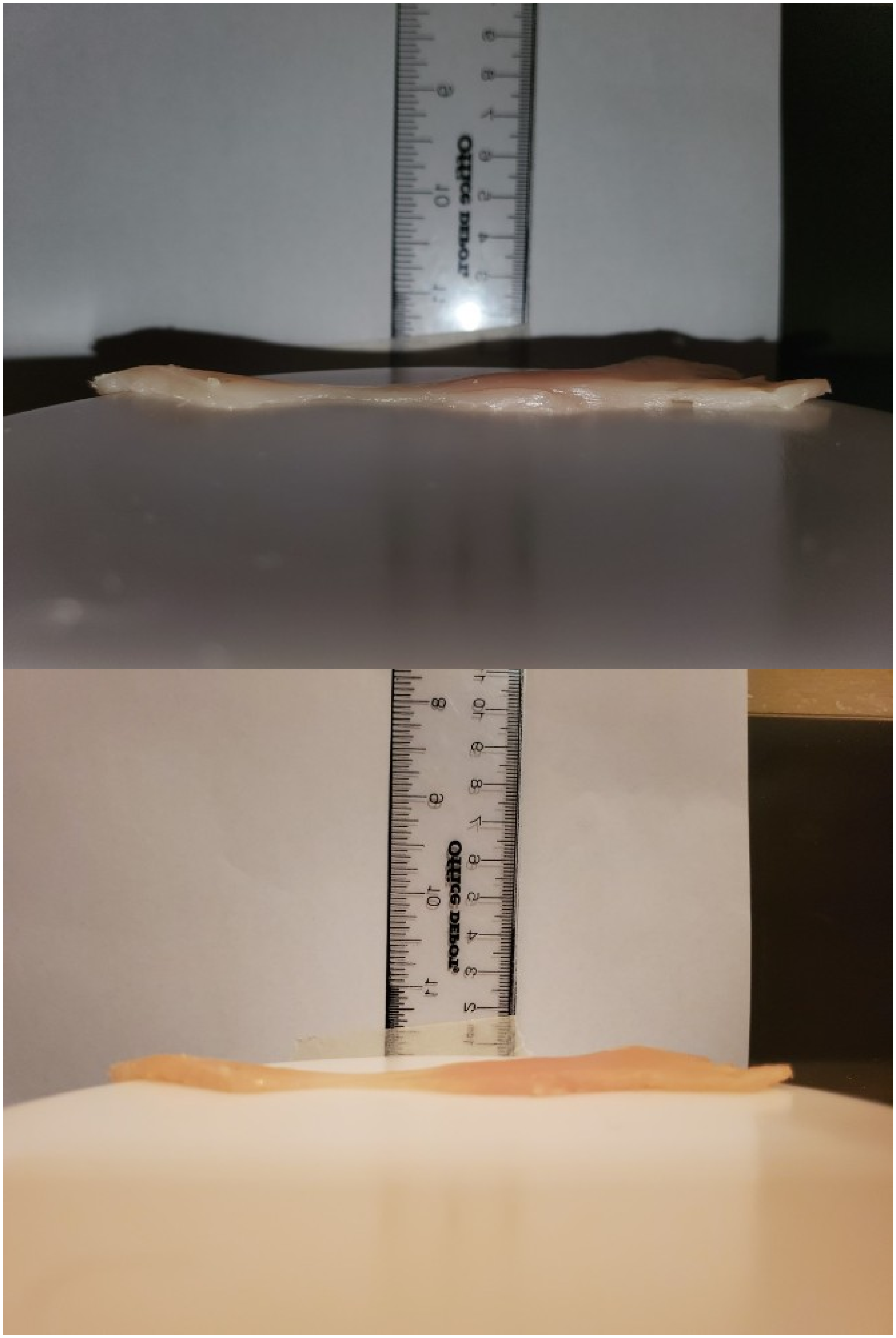


Figure 1: These are the same sample of chicken breast that was analyzed in Kinovea to test for cut depth.

Conclusions/action items:

Testing was done on 8 chicken breasts and the two figures show the same strip that was successfully removed from one of the breasts.

Results Chicken - Copy

Noah Ruh - Dec 08, 2020, 9:33 PM CST

Title: Testing Results

Date: 12/01/2020

Content by: Noah

Present: N/A

Goals: Discuss the results of the testing

Content:

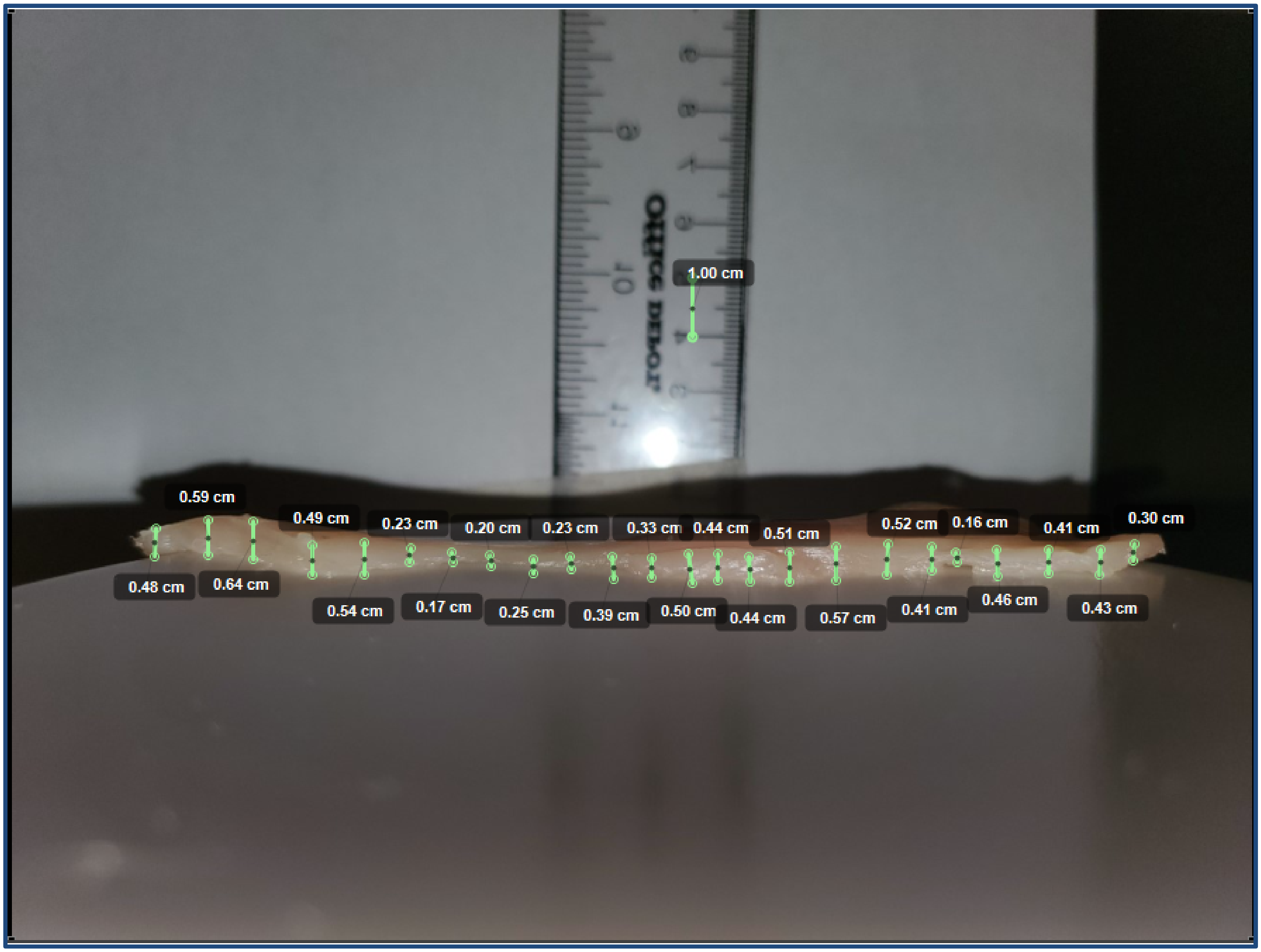


Figure 5 (above): Kinovea analyzed strip of cut chicken. 24 cut depth data points were collected from the cut of chicken shown in the testing page using Kinovea's calibration tool

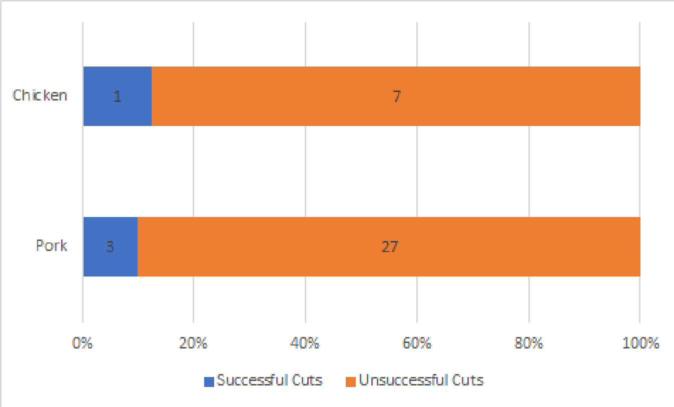


Figure 2:

Graph of the successful (blue) and unsuccessful (orange) trials for the Chicken and Pork tests in percentages.

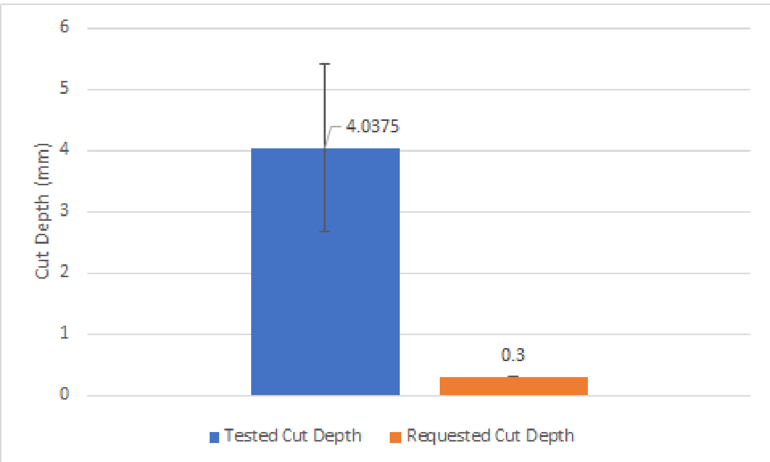


Figure 3:

Graph of the tested chicken cut depth (left) and the requested cut depth (right). The standard deviations of the two data sets do not overlap suggesting they are significantly different.

Conclusions/action items:

After testing 1 of the 8 chicken tests were deemed successful and 3 of the 30 porcine tests were successful based on the aforementioned requirements, resulting in a 12.5% and 10% respective success rate (Figure 2). Based on the chicken testing the team created a graph looking at the consistency of the cuts. The average cut depth of 4.0375 mm with a standard deviation of 1.3 mm is compared to the 0.3 requested cut depth and differs significantly from this value. seen in Figure 3.

Discussion

Noah Ruh - Dec 08, 2020, 9:41 PM CST

Title: Discussion

Date: 12/06/2020

Content by: Noah/Josh

Present: N/A

Goals: Discuss the results from testing

Content:

Based on the results the team concluded that this device is able to periodically cut through and remove the tissue of samples, however not at the rate that was expected or needed. The low success rate of cuts means that the device the team created does not meet the requirements that were given. Along with the low success rate of cuts, the large standard deviation seen in Figure NR3 means that even when the device did cut, it did not do so consistently. The t-test that was run on the data also showed that there was a significant difference between the tested cut depth and requested cut depth meaning the device was not able to create a cut that was a close match to the requested cut. One positive of the device was that once the cut was started maintaining tension on the skin was quite easily accomplished by grabbing the skin and holding on as it ran through the device.

There were several sources of error during the testing of this prototype that may have caused the results that were seen. The 3D printing of the devices was not as accurate as the CAD modeling resulting in the arms of the prototype being too large to fit into the handle correctly. To fix this the team filed the arms of the chicken testing device so both arms would fit in and for the porcine testing device, one arm was secured in the device. Along with only one arm, the porcine testing device's scalpel was held in place using a rubber band as the attachment point for the scalpel did not print correctly. Another source of error comes from the team not being surgeons, this resulted in hesitation during testing and may have contributed to the lack of consistency of the cuts. In addition, to cut through the tissue of the chicken and pork, the team couldn't glide the blade across the skin, which would allow for smoother cuts. Instead, the team had to pull the blade directly against the skin, which resulted in choppy cutting, more similar to cutting down a tree with an axe instead of a saw.

Preliminary PDS

JOSHUA GIARTO - Oct 07, 2020, 11:42 AM CDT

Title: PDS

Date: 7 Oct 2020

Content by: Team

Present: Team

Goals: Create Product Design Specification

Content:

PDS is attached

Conclusions/action items:

This is the PDS up to date as of 7 Oct 2020. Revisions will be added if needed

JOSHUA GIARTO - Oct 07, 2020, 11:42 AM CDT

Device for Automatic De-epithelialization
09/17/20
Client: Dr. Carol Soteropulos
Advisors: Dr. Krishnan Saha
Consultant: Todd Le
Team: Josh Giarto, Young Kim, Colleen Clemenson, Tatum Rebuli, Noah Roh, Michael Chiariello

Function: In many plastic surgeries, specifically breast reconstruction with free tissue transfer and breast reduction, surgeons must use de-epithelialization to remove the epidermis from the skin. However, the current methods used are both time consuming and the results are inconsistent due to lack of tension in the skin flaps. This product aims to efficiently and safely remove the epidermis from the skin while creating enough tension to cut at a consistent depth.

Client requirements:

- The device must be efficient and decrease the time it takes for surgeons to de-epithelialize the skin.
- The device must also be easy to use. There cannot be a significant learning curve for surgeons using this device for the first time.
- The device must be able to cut at a uniform depth by keeping tension on the skin so as to ensure the safety of the patient and a positive surgical outcome.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:*

I. The device must be able to remove the epidermal layer of skin during surgery.
II. Although it will be specifically beneficial for Bilateral Breast Reduction (BBR) surgeries, this device will be able to be used for any surgical procedure in which the epidermis must be removed.
III. The current amount of time it takes for manual de-epithelialization during a BBR is about 15.5 minutes. [1] Therefore, the device must be noticeably faster than 15.5 minutes.
IV. The current method of de-epithelialization is physically taxing for the surgeon. The device must ease the common physical demands and should be comfortable for the operator.
V. The device must keep tension on the skin and cleanly remove the epidermis without damaging or disturbing the dermis.

b. *Safety:*

I. The device must remove the epidermis, which has a thickness of approximately 0.1 millimeters.

De-Epper_PDS_1.pdf(108.4 KB) - download

Final Report

JOSHUA GIARTO - Dec 09, 2020, 11:39 AM CST

Title: Final Report

Date: 12/9/2020

Content by: Team

Present: Team

Goals: Create Final Report

Content:

Final Report is attached

Conclusions/action items:

This is the Final Report up to date as of 9 Dec 2020.

JOSHUA GIARTO - Dec 09, 2020, 11:39 AM CST

De-Epper_Final_Report.pdf(1.6 MB) - download

Poster

JOSHUA GIARTO - Dec 09, 2020, 11:41 AM CST

Title: Poster

Date: 12/9/2020

Content by: Team

Present: Team

Goals: Create Poster for Poster Presentation

Content:

Poster is attached

Conclusions/action items:

This is the poster for the poster presentation up to date as of 9 Dec 2020.

JOSHUA GIARTO - Dec 09, 2020, 11:43 AM CST

Poster_Presentation.pdf(2.5 MB) - download

Basic knowledge from papers given

JOSHUA GIARTO - Sep 08, 2020, 11:51 PM CDT

Title: Notes from paper given

Date: 9/8/2020

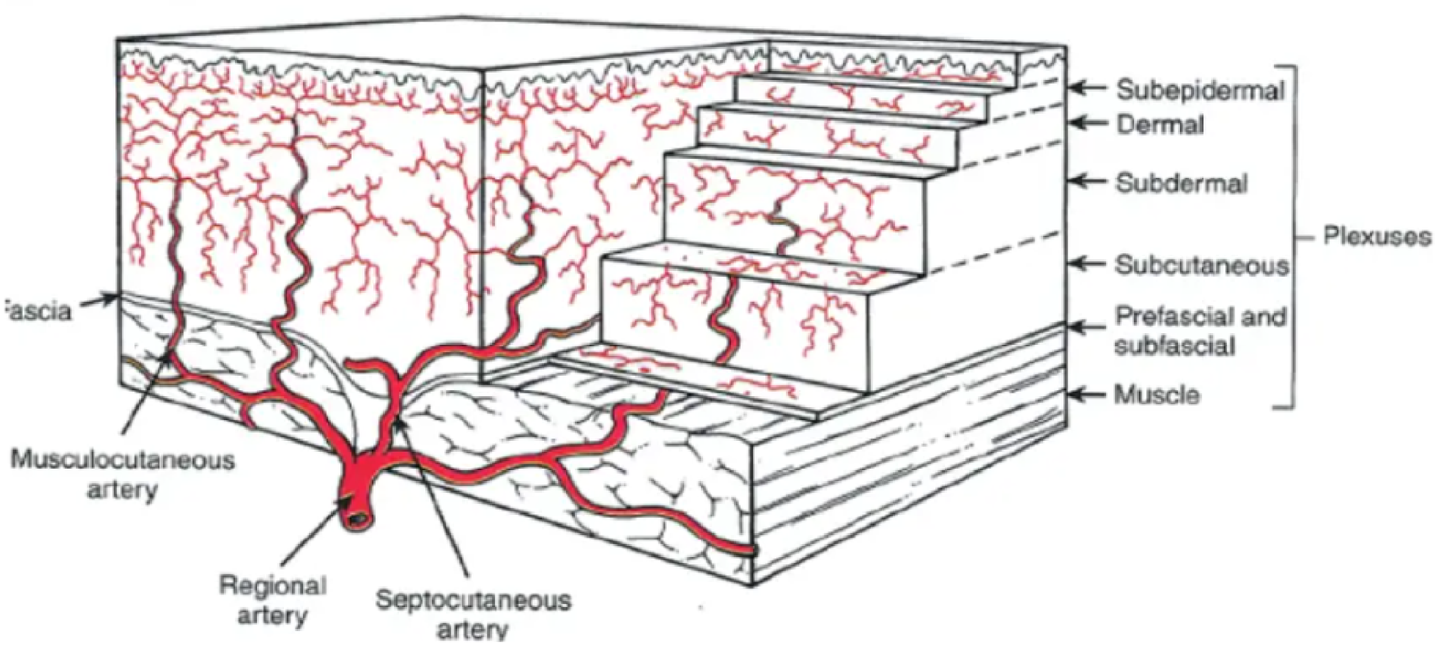
Content by: me

Present: me

Goals: Learn more about the project, the topic, and the problems

Content:

The reason why there is a need for an auto de epithelialization is because operating surgery is time-intensive and could be more effective with their time. This would reduce the time needed in the surgery, reducing the of blood lost and chance of fatigue and mistakes of the surgeon.[1,2] The process initial purpose was to continue blood supply to the nipple-areola complex (NAC) because there are many major blood vessel are present in the area. De-epithelialization preserves the subdermal plex in inferior-pedicle bilateral breast reduction (BBR).[2] Subdermal plexus is the main plexus that supplies blood to the skin.[3]



Gold standard of this process is using a scalpel. One method, called monobloc, is after making cuts on the marked area, the process starts at the submammarian fold to the nipple or vice versa. Once enough of the epidermal layer is cut, a hole is make so that the surgeon can put a finger through and allow to precisely apply enough tension to pull on the loose layer and continue with de-epithelialization. Gauze is placed over the de-epithelized area to reduce blood lost.[1] To be more specific for BBR, at the bottom of the breast a gauze is secured using a Kocher clamp (2 hemostats in [1]) as a tourniquet. Incisions are made by a number 10 scalpel. A toothed forceps is used to raise a corner of the epithelium. Once there is 2 cm of the loose epithelium, "button holes" are made to give the surgeon better control. The process overall allows for better control of direction of excision and tension .[2]

Conclusions/action items:

By the looks of it, this project is to reduce the time of plastic surgery. The de-epithelialization process is tedious and can lead to fatigue of the surgeon and lots of blood lost of the patient. The two papers given by the client are focused on surgeries on the breast and have a specific cut. **Is the project in need of a device that can produce the same size cut every time or will it be used in different plastic surgeries with different size and shape cuts?** Holes are cut in the loose epithelial skin for better tension. **There will be a need to research the physical properties of the skin.**

References:

[1] KELES MK, H. U., & Cepni, H. (2016). A sim-ple method for breast de-epithelializa-tion: The monobloc method [Video]. *Trichol Cosmetol Open J*, *1*(1), 19-20. (in google drive)

[2] O'Neill, T., & Regan, P. (2011). Button holes: novel deepithelialization technique in reduction mammaplasty. *Aesthetic surgery journal*, *31*(3), 358-359. (in google drive)

[3] https://www.theplasticsfella.com/blood-supply-to-the-skin/

Dermatome

JOSHUA GIARTO - Sep 16, 2020, 5:05 PM CDT

Title: Dermatome

Date: 9/16/20

Content by: Me

Present: me

Goals: learn about existing devices that could be improved

Content:

Device 1: https://ozmedix.com.au/humeca/dermatomes/#:~:text=The%20small%20head%20of%20the,to%20an%20exceptional%20985%20grams.

Mumeca, Skin Transplantation Technology, Cordless battery Dermatomes. There are two sizes: full size D80 and smaller size D42. Both are cordless, 7.4V battery powered and can adjust the thickness of the skin being cut from 0 to 1.2 mm in increments of 0.1 mm. D42 has width of 42mm and can be reduced to 36mm and 30mm. From the video, the device has a custom battery attached to a custom motor for the blade to cut. It is also placed in a porous metal container for it to be sterilized after use.

Device 2: https://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/common/skin-grafting/skin-grafting-family-the-power-of-precision.pdf

ZimmerBiomet, Skin Grafting Family. 3 types of dermatome, one powered by air, one powered by electricity, one does not say. The Air and Electric powered ones have a max thickness cut of 0.76mm and the other 0.6. There are no signs of dealing with the tension problem.

Conclusions/action items:

Second dermatome does not cut deep enough, bulky, is attached with a cord, and the width is too large. The first dermatome matches the ideal of the client. The first dermatome satisfy the thickness of skin cut which it can cut a max of 1.2mm. The epithelial layer of the skin is epidermis which is 0.1 mm thick and the dermis is around 2mm thick. (http://www.siumed.edu/~dking2/intro/skin.htm) The first dermatome could finish the job with a max of two run throughs. The width is also smaller than the normal size and can be shorten to 30mm wide. This seems to be perfect for the surgeon. Next client meeting: ask specific features that are problematic which the current device and how we can improve. The tension problem is still not solved.

EpiCut

JOSHUA GIARTO - Oct 07, 2020, 3:13 AM CDT

Title: EpiCut

Date: 9/30/20

Content by: Me

Present: me

Goals: learn about a new device Young found

Content:

Young found another more simple device that could help with coming up with a design

https://www.microaire.com/products/epicut/?fbclid=IwAR2CXVb_TLfZzpE8fC_66oBkjF26_ddLxoM94wrLvHlwnIKZkMwd10iFvcY

The purpose of the device is specifically for de-epithelialization. It is modeled as a curved handle for easy grip for the surgeons and a v-shape blade to cut the skin. The blades are facing outward, which means that the motion for the surgeon is a pushing mechanism. The problem with this design is that there is no guard or part that protects from cutting to deep nor is there a part to cut a consistent depth of skin. The pros of the device is that is it simple, which means more feasible, and it is easy to use, a low learning curve.

Conclusions/action items:

This will be used to model our new and improved design idea

Potato Peeler 1.0

JOSHUA GIARTO - Sep 23, 2020, 4:51 PM CDT

Title: First draft of the potato peeler

Date: 9/23/2020

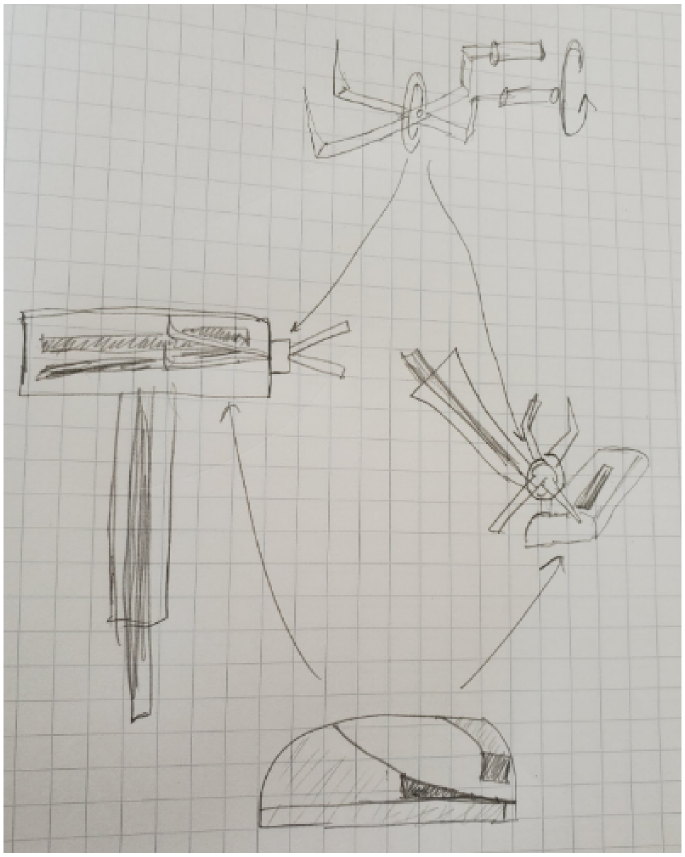
Content by: Josh

Present: me

Goals: Have basic idea of a design

Content:

This is my design for the design matrix.



The design has a handle for grip, a blade area with safety guards, and a clamp crank to hold the skin and increase the tension. As the epidermis is cut, the clamp rolls the loose skin so tension can still be applied.

Conclusions/action items:

This is only the basic idea so there is no specifics on the dimensions, material, and way of fabricating it yet. I will propose this to the team and see what they think

Shovel Roller

JOSHUA GIARTO - Sep 29, 2020, 11:56 PM CDT

Title: Improved design

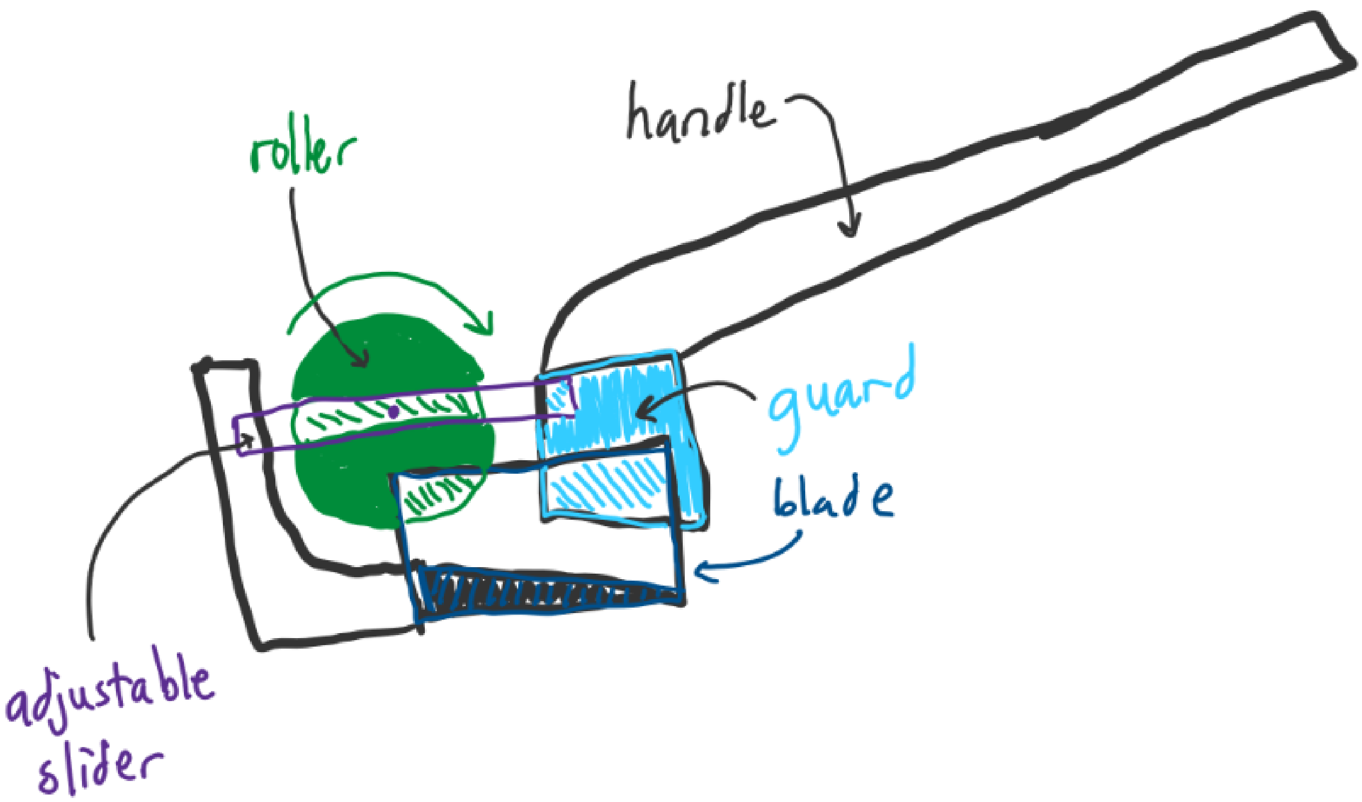
Date: 9/29/2020

Content by: Josh

Present: me and Young

Goals: Create a design that combines the shovel and the roller design

Content:



Above is a design combining the shovel design idea from Noah and the roller design from Michael. It has the same structure as the shovel but an added roller in top for increased tension on the loose skin. There will be an adjustable slide for the roller depending on the thickness of the skin needed to cut off. This was drawn in OneNote

Conclusions/action items:

We will show this to the client tomorrow as the fourth improved design and see how she likes it.

Shovel Rolle Feedback

JOSHUA GIARTO - Sep 30, 2020, 10:37 PM CDT

Title: Feedback on Improved design & Discussion

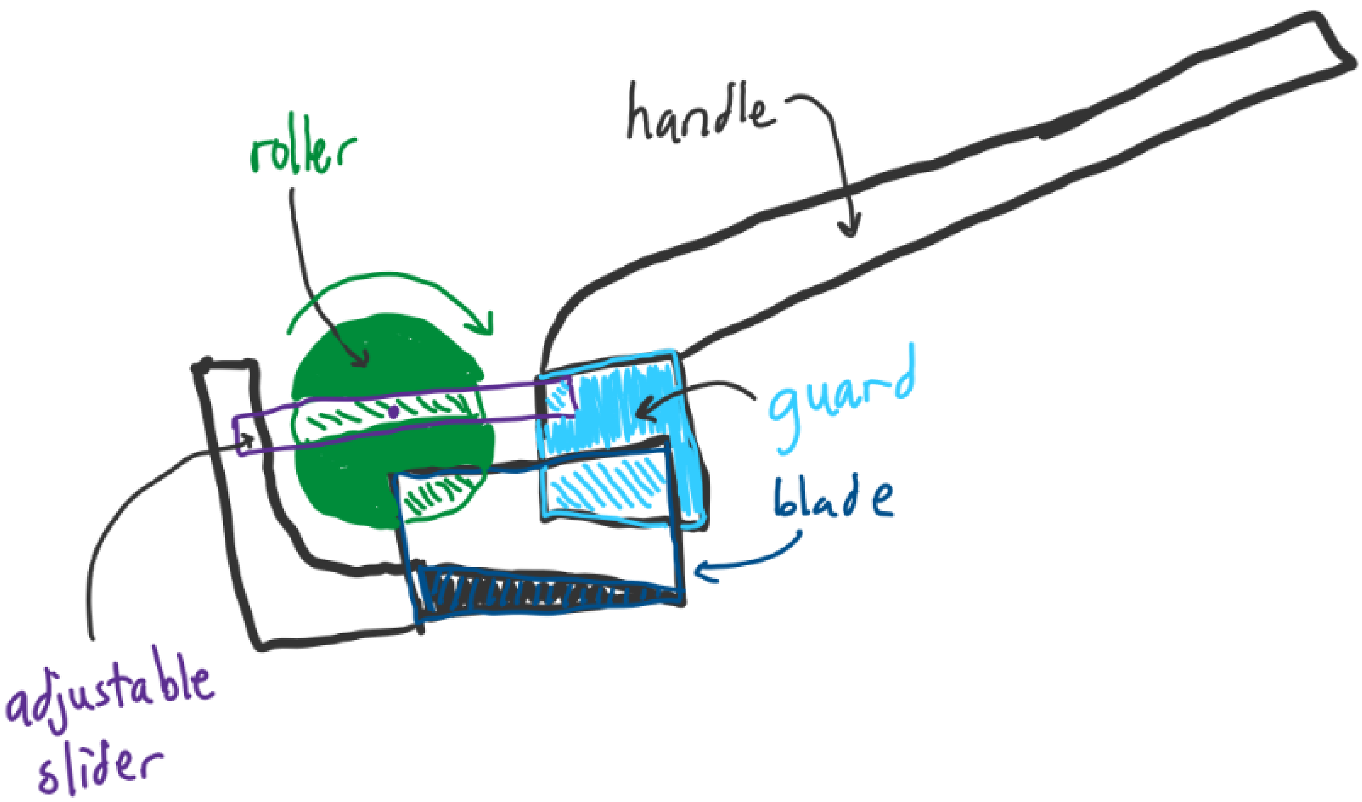
Date: 9/30/2020

Content by: Josh

Present: me, Young, Noah

Goals: Client's feedback on design

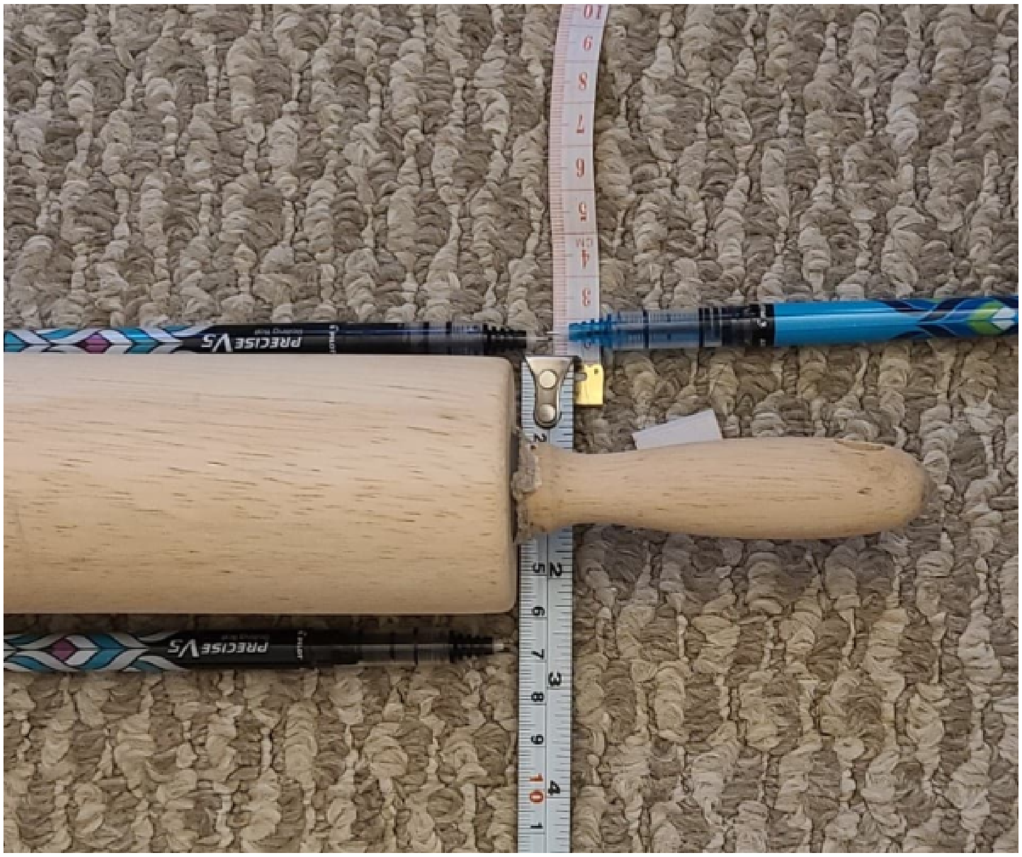
Content:



Client liked design of the combination of the shovel and the roller. She likes the idea of the shovel because out of the three designs, it is the most simple and most likely to be able to create a prototype for it. She also liked the idea of the roller for increased tension. She recommended that the roller would have spikes for better tension. She reminded us that the gap between the guard and the blade should be around 0.3mm and should be adjustable as well like the roller is. On previous design ideas, she was ok with the shovel design without the roller. She was ok with one hand on the device and another pulling on the skin.

Discussion

We decided that the design could be made simpler by removing the guard with the roller and the roller would be a guard and used for increasing tension. Noah started on the CAD design for us to get a sense of the scale. Later me and Young up the scale to get a visual sense of the roller size and the gap between it and the blade. Originally we planned to have the roller have a diameter of 2 cm and the gap between the roller and the blade of 0.3mm. We decided on this value to have enough surface area for the thumb to apply force and turn the roller with ease. This scale is very small and difficult to produce at this time during the pandemic. We decided that the prototype that we need to create will have to be scaled up. The following image is the scaled up by 3.3 with the measurements marked by the distance between the pen tips. The distance between the blue and black pen is 1mm and represents the gap. We chose this length because we feel this less than 1mm will lose some accuracy with the actual measurements and this is one of the most important part of the design. The distance between the two black pens is around 6.6 cm which represent the diameter of the roller which is also compared to a size of a rolling pin:



Conclusions/action items:

This design is starting to be unreasonable with the expectation of being accurate with the 0.3mm gap. We either need to quadruple check with the client if this is right measurement because based on the videos send by the client, the epidermis taken off seems to be thicker. Or we need to come up with a more reasonable design.

Bent Arm (Balpel?) 2.0

JOS

Title: New design idea for the project

Date: 9/30/2020

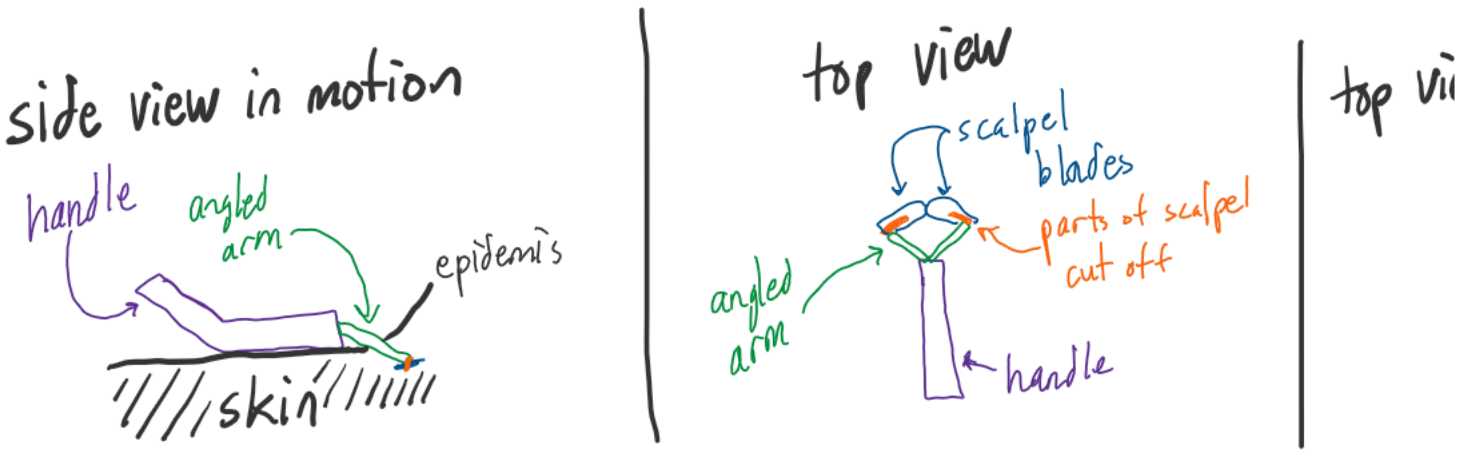
Content by: Josh

Present: me

Goals: Come up with a different viable design

Content:

Young found another competing device and created a design idea based on that. I added and improved the design. The design is based on the EpiCut (see competing devices). Young's idea v scalpel blades the surgeons should already have which could be disposable. The bent handles would create a flat consistent level for the blades to cut. The blades would be pointed inwards. I the handle could be flatly pressed on the skin and give a consistent depth which the skin is being cut. This gives good stability and control for the surgeon.



Conclusions/action items:

This was made by bouncing ideas back a forth with Young. We will propose this idea to the group and the client after preliminary presentations.

Young came up with the idea to make different angled arms at different angles to solve the different depth problem. The handle can attach to different angle angled arms for parts of the body tl

EPPER

JOSHUA GIARTO - Oct 05, 2020, 7:54 PM CDT

Title: SolidWorks of the final design idea

Date: 10/5/2020

Content by: Josh

Present: me

Goals: Create solidworks design for report

Content:

The following images were made in Solidwork. The idea is based on Youngs design of the modified EpiCut with some added ideas of my own. There are two separate parts of the modified EpiCut: the handle and the hinge. Right now the hinge does not have the attachment for the scalpel blades because we are still unsure on how to attach them are if we want to make our own which requires us to know the dimensions of that part of the scalpel.

First is the handle as shown in figure 1. The handle has two main parts: the flat part and the angled part. The angled part is at an angle of 60 with side measurements of 50mm and 86.6mm, which has been done by creating a 30,60,90 triangle as shown in figure 2.The flat part has a width of 25mm, a length of 50mm, and a height of 10mm shown in figure 3. the height of the angled part is the same as the flat part. All sides of the handle are filleted with a radius of 1mm and the bottom side is filleted to smoothly connect the angled and flat parts. On the flat part there are two holes, one for the hinge to attach and the other is for a screw to hold both parts in place. The hole for the hinge part is 2mm tall, 5mm wide, and 10mm deep, which will perfectly fit the extra bit of the hinge. The hole for the screw is in the middle, 5mm from the edge with a 3.175mm diameter as shown in figure 5.

Next is the hinge, which is shown in figure 6 with the dimension of the part that fits into the hole in the handle. The hole in this part will align with the hole for the screw in the handle. when placed together, the holes should line up and are the same size for the screw to slide in. The body part of the hinge is 3mm by 7.5mm which has the same ratio as the part that will go in the handle. It is also 5mm long. Figure 7 shows a front view of the hinge with some dimensions of the body. The arms of the hinges are angled in all three planes (front, top, and side planes). It stretches 8.75mm out, 6.8mm down, and 10mm to the front. The hinge lowest part is 0.3mm lower than the handle when attached. This is the right depth needed for the blades to be to cut 0.3mm on the skin.

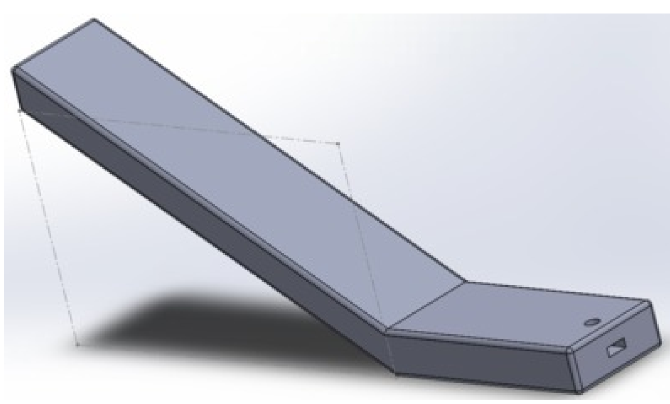
Figure 11 is what the device would look like when placed together and Figure 12 shows that the hole aligns.

Materials used would probably be metal because it can be placed in an autoclave for sterilization.

Conclusions/action items:

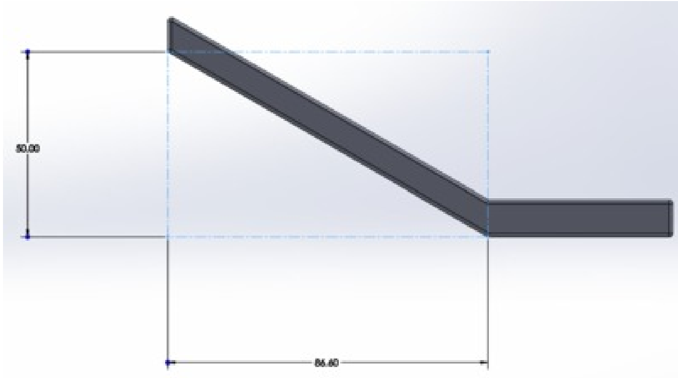
These images will go on our preliminary report as our fourth design idea. If we are to actually fabricate this, we would need to figure out the hole for the screw dimensions and the scalpel inserters thoroughly. Everything else, the dimensions are set. This a good start for the prototype. Another thing we would need to look for is the material we would use.

JOSHUA GIARTO - Oct 05, 2020, 6:40 PM CDT



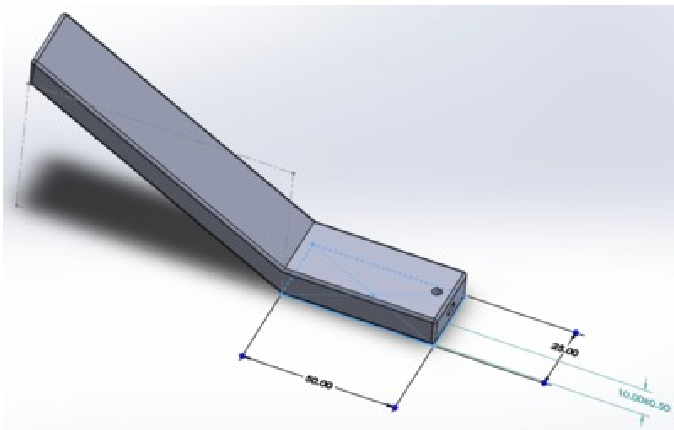
EPPERhandle1.png(135.7 KB) - download Figure 1: An oblique view of the EPPER handle as a whole without dimensions

JOSHUA GIARTO - Oct 05, 2020, 6:40 PM CDT



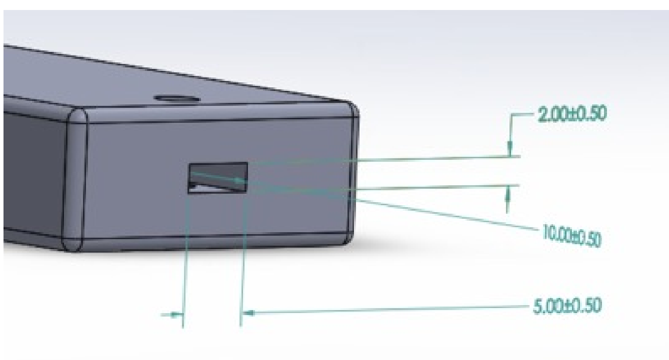
EPPERhandle2.png(86.5 KB) - download Figure 2: Side view of the handle showing the measurements of the angled portion

JOSHUA GIARTO - Oct 05, 2020, 6:47 PM CDT



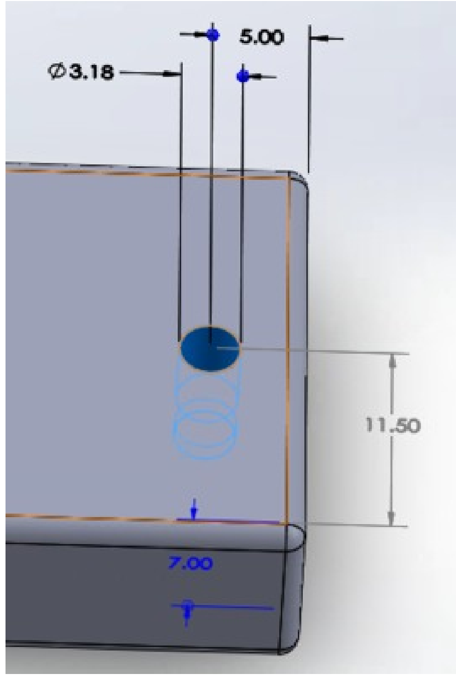
EPPERhandle3.png(135.1 KB) - download Figure 3: Oblique view of the handle showing the dimensions of the flat part.

JOSHUA GIARTO - Oct 05, 2020, 6:55 PM CDT



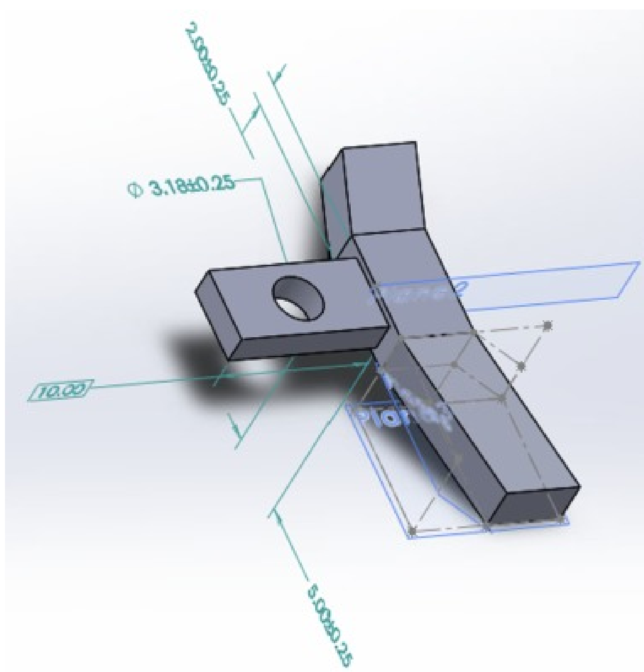
EPPERhandle4.png(31.6 KB) - download Figure 4: An oblique front view to show the hole and the dimensions where the hinge part of the modified Epicut will go in

JOSHUA GIARTO - Oct 05, 2020, 7:15 PM CDT



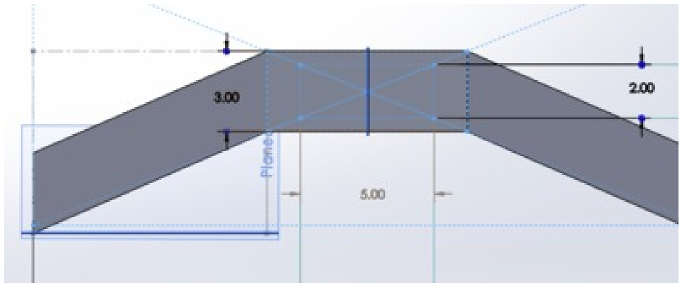
EPPERhandle5.png(40 KB) - download Figure 5: Top-side view of the handle showing the dimensions of the hole for the screw.

JOSHUA GIARTO - Oct 05, 2020, 7:25 PM CDT



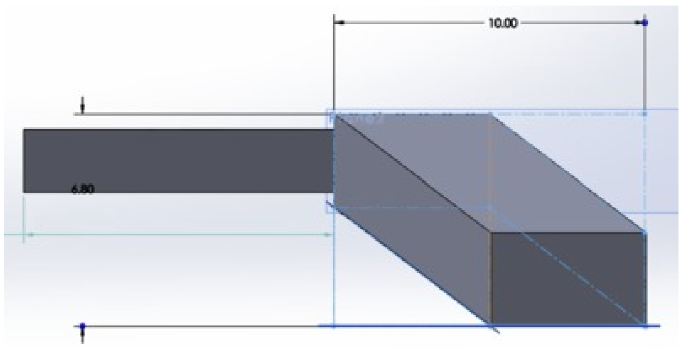
EPPERhinge1.png(82.6 KB) - download Figure 6: An oblique view of the hinge part of the modified EpiCut showing the dimensions of the part that will slide into the handle part.

JOSHUA GIARTO - Oct 05, 2020, 7:44 PM CDT



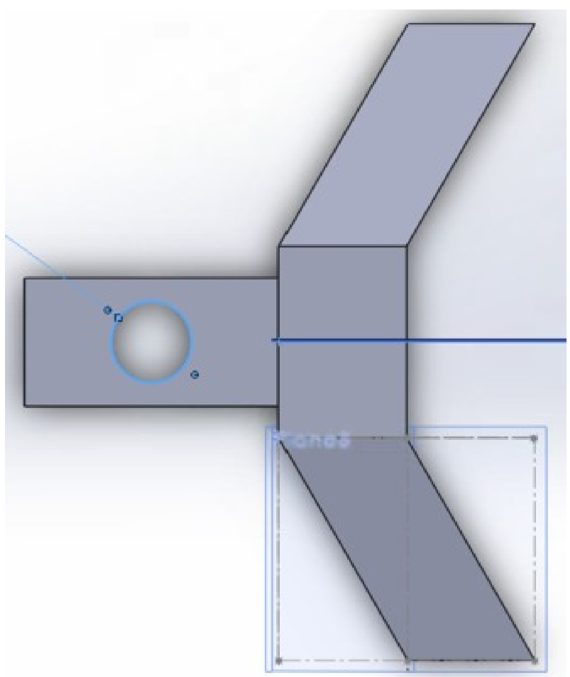
EPPERhinge2.png(63.2 KB) - download Figure 7: Front view of the hinge showing dimension of the body

JOSHUA GIARTO - Oct 05, 2020, 7:41 PM CDT



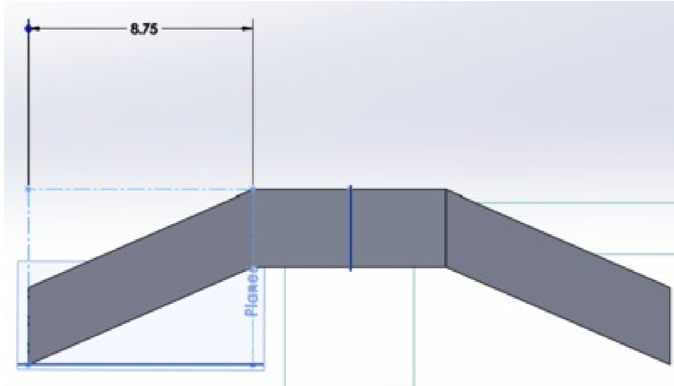
EPPERhinge3.png(46.7 KB) - download Figure 8: Side view of the hinge

JOSHUA GIARTO - Oct 05, 2020, 7:38 PM CDT



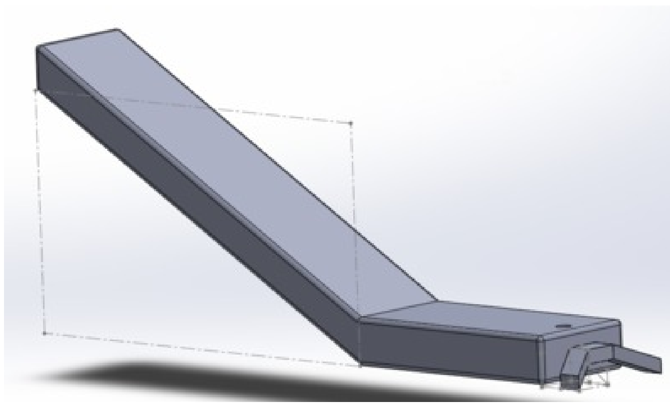
EPPERhinge4.png(86.8 KB) - download Figure 9: Top view of the hinge

JOSHUA GIARTO - Oct 05, 2020, 7:44 PM CDT



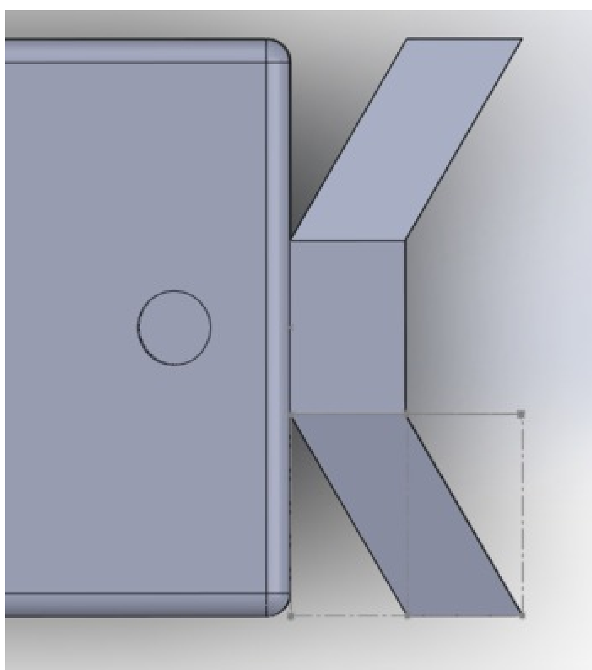
EPPERhinge5.png(28.7 KB) - download Figure 10: Front view of the hinge showing arm dimensions

JOSHUA GIARTO - Oct 05, 2020, 7:55 PM CDT



EPPERboth1.png(112.7 KB) - download Figure 11: The modified EpiCut assembled

JOSHUA GIARTO - Oct 05, 2020, 7:56 PM CDT



EPPERboth2.png(76.8 KB) - download Figure 12: The hole for the screw being aligned in both parts

2020/10/07-EPPER updated 1.1

JOSHUA GIARTO - Oct 07, 2020, 2:07 AM CDT

Title: Updated EPPER design with blades

Date: 07 Oct 2020

Content by: Josh

Present: Josh

Goals: Present idea of blades to EPPER

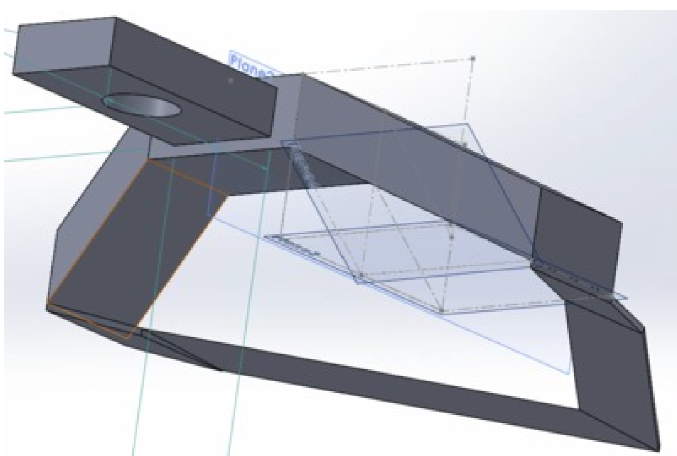
Content:

In the previous design, blades were not added to the design because we did not have the proper dimensions of the blade and the blade inserter. For now, even though we do not have the exact measurements, an adjustment on the solidworks design was made to present our idea on where the blades will be placed and how the blades will work within our design. As shown in figures 1 and 2, the blades will be oriented in front of the arms. The blades are pointed inwards so that the surgeons will use a pulling motion for this device. There are two parts added to the hinge, one is the inserter of the blades and the other is the blades itself. The inserter will be attached to the bottom of the arm so that when the blades are inserted, the top of the blade will be the same level as the bottom of the arm, which will cut a depth of 0.3mm of the skin. Figure 3 show what the design will look like as a whole when the handle and the hinge are placed together.

Conclusions/action items:

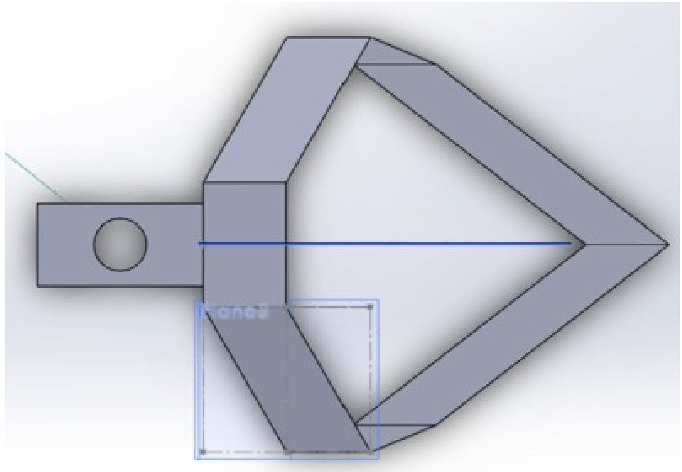
This will be added to the preliminary report and I will have to discuss with the group and the client if we are able to get scalpels and measure them/ get measurement from what the client has.

JOSHUA GIARTO - Oct 07, 2020, 2:02 AM CDT



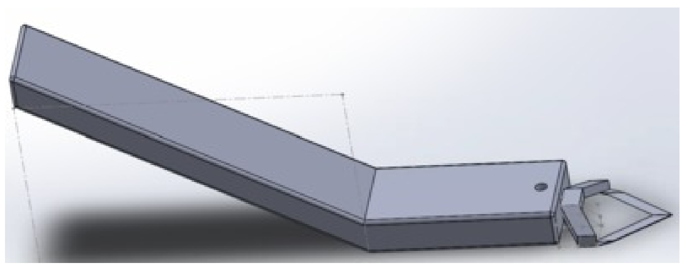
EPPERhinge2.1.png(136.1 KB) - download Figure 1: A bottom view of the hinge part with the blades to show how they are oriented and which direction it is facing

JOSHUA GIARTO - Oct 07, 2020, 2:02 AM CDT



EPPERhinge2.2.png(151.8 KB) - download Figure 2: Top view of the hinge part with the blades

JOSHUA GIARTO - Oct 07, 2020, 2:03 AM CDT



EPPERboth2.1.png(150.7 KB) - download Figure 3: The modified EpiCut with the blades added to the hinge part

2020/10/20 - Update of design

JOSHUA GIARTO - Oct 20, 2020, 3:04 PM CDT

Title: Updates, changes, and ideas for design

Date: 10/20/2020

Content by: Josh

Present: me

Goals: Update design to fit client's wants and feasibility

Content:

As a group we decided to make two major changes to the design. The first change is to push back the arms and the blades so that the blades contact point with the skin would be closer to the device contact with the skin. We want these two points to be as close as possible because the breast surface will be curved and we want to have a consistent cut of 3mm. The curved surface may change the depth of the cut and lead to a more shallow or even miss the skin if the blades are too far in front. To solve this problem we decided to place the arms on the side of the flat part of the handle. Another problem we came across was how the blades would be inserted. Looking at some videos of how normal scalpel blades are placed, they are clicked in by sliding in from the front. This creates another problem. Since we want the two blades to be on the same height and to be touching at the tips, so that all the skin across the blades would to cut off, sliding the blades in would be difficult to do and also a safety hazard when attempting to take off because there is another blade right next to it. To solve this, we decided to insert the arms through the side and have two separate arms, so that the surgeon can slide in the two blades then attach the arms. We will also continue with the idea of the screw holding the handle wot both arms as we think it is the most simple and effective way to secure the blades and arms.

The machine we are looking to use is the Formlabs because according to the MakerSpace, this machine is the highest resolution that they offer. The two materials that either will be chosen for this project is Formlabs High Temp or Formlabs DentalSG. Formlabs High Temp has the highest heat of deflection of 238C. Even though this is not higher than the temperature of an autoclave, this is the heat of deflection which means, if the material does not have external forces applied to it, the material should not deform. This material is cheaper compared to Dental SG. The Dental SG does not have a heat of deflection on the technical data sheet, but the description says that the material can be uses in an autoclave. The goal for this design to be an improvement of the EpiCut: For this decive to be **autoclavable** and **reusable**, since the EpiCut is a one-time use for around $300.

Formlabs High Temp Technical Data Sheet: https://formlabs-media.formlabs.com/datasheets/High_Temp_Technical.pdf

Formlabs Dental SG Technical Data Sheet: https://formlabs-media.formlabs.com/datasheets/DentalSG-DataSheet.pdf

Formlabs High Temp Safety Data Sheet: https://formlabs-media.formlabs.com/datasheets/Safety_Data_Sheet_EN_-_High_Temp.pdf

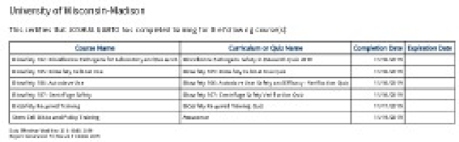
Formlabs Dental SG Safety Data Sheet: https://formlabs-media.formlabs.com/datasheets/Safety_Data_Sheet_EN-EU_-_Dental_SG.pdf

Conclusions/action items:

Noah, Colleen, and Tatum are in charge of the CAD design. Me, Young, and Michael are in charge of finding materials and ways to produce the prototype.

chem and bio lab training

JOSHUA GIARTO - Feb 12, 2020, 8:55 AM CST



University of Wisconsin-Madison

Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	

Certificate_of_Completion_for_JOSHUA_GIARTO.pdf(109.9 KB) - download

JOSHUA GIARTO - Feb 12, 2020, 8:55 AM CST

chemicalSafetyTraningCertificate.pdf(361.1 KB) - download

JOSHUA GIARTO - Mar 02, 2020, 9:10 PM CST

Title: Bio and Chem training

Date: 3/2/19

Content by: me

Present: me

Goals: Show which Bio and Chem training I have completed

Content:

I got Bio training and Chem training during the fall of 2019

Conclusions/action items:

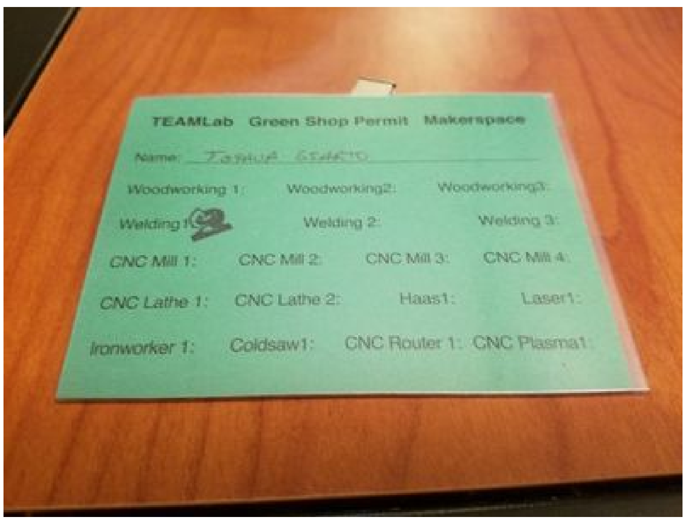
Training is used for both research and BME design classes

Green Permit

JOSHUA GIARTO - Oct 16, 2019, 11:20 PM CDT

1571286016348.JPEG(34.9 KB) - download

JOSHUA GIARTO - Oct 16, 2019, 11:24 PM CDT



1571286288629.JPEG(33.6 KB) - download

JOSHUA GIARTO - Mar 02, 2020, 9:07 PM CST

Title: Proof of Green Permit

Date: 3/2/19

Content by: me

Present: me

Goals: Prove that I have a Green permit

Content:

On 4/4/2019 I got my green permit.

Conclusions/action items:

I got my green permit. I will use it when needed for a project. Yay

2020/9/10 De-Epithelialization

YOUNG KIM - Sep 10, 2020, 10:12 PM CDT

Title: De-Epithelialization

Date: 2020/09/10

Content by: Young Kim

Present: Young Kim

Goals: Learn about the De-epithelialization process to gain a deeper understanding of the problem at hand.

Content:

The human skin has 3 primary layers, including the epidermis, dermis, and the hypodermis.

The epidermis is the first layer of skin to be encountered, and is the layer that is removed during the de-epithelialization process. It is responsible for generating new skin cells and providing protection for the body from foreign materials. The thickness of this layer varies throughout the body, depending on the level of frictional forces it encounters. [1] On average, this value is approximately 0.1 mm. [2] The epidermis itself has 5 layers, including the stratum basale, stratum spinosum, stratum granulosum, stratum lucidum, and stratum corneum.

The dermis follows, with two primary zones. These are the papillary dermis and reticular dermis. The dermis is thicker than the epidermis, but still varies across the body, with an average thickness of approximately 1 to 4 mm. [1]

Finally, the hypodermis. This layer is also called the subcutaneous tissue layer. The hypodermis is responsible for absorbing shock, storing energy, and maintaining heat within the body.

De-Epithelialization is a process in which the epidermis is separated from the dermis by use of a sharp tool. The resultant de-epithelialized flaps have further use in reconstructive surgeries. [3] A key component of this process is maintaining skin tension and traction, which facilitates the removal of the epidermis. In the process of reduction mammoplasty, an operation where de-epithelialization is performed (specifically by the client), several work arounds can be found in published literature. These range from the use of a cable tie, a novel cutting technique, and the use of a pedicle to form "button holes". De-epithelialization is performed during reduction mammoplasty to minimize complications that arise regarding adequate blood supply to the nipple areola complex and necrosis of skin. By de-epithelializing skin around the areola, blood supply to the areola can be preserved [4]. A primary concern regarding de-epithelialization is the time consuming nature of the process, adding approximately 8-10 minutes. [5] This, along side the need for adequate tension, are key issues the team seeks to address.

Sources:

[1] T. Poonawalla, “Dermatology,” Anatomy of the Skin, 2008. [Online]. Available: https://www.utmb.edu/pedi_ed/CoreV2/Dermatology/page_03.htm. [Accessed: 10-Sep-2020].

[2] H. Yousef, “Anatomy, Skin (Integument), Epidermis,” StatPearls [Internet]., 27-Jul-2020. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK470464/. [Accessed: 11-Sep-2020].

[3] J. A. Croley, H. C. Malone, and R. F. Wagner, “Deepithelialized Flaps and Grafts: Applications in Dermatologic Surgery,” MDedge, 10-Jan-2019. [Online]. Available: https://www.mdedge.com/dermatology/article/160167/aesthetic-dermatology/deepithelialized-flaps-and-grafts-applications. [Accessed: 11-Sep-2020].

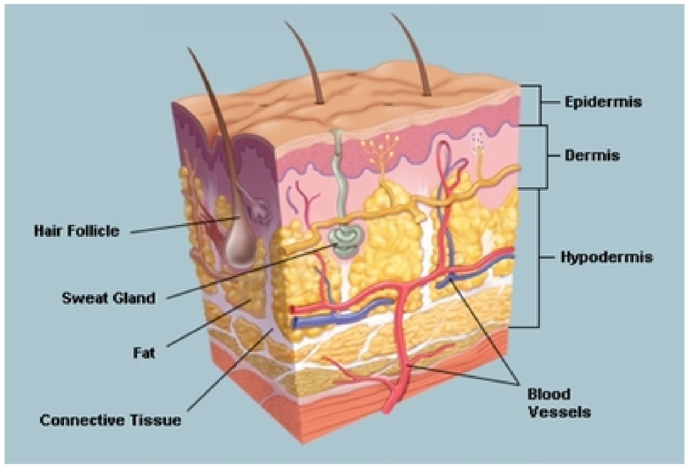
[4] M. Bellioni, G. D. Santi, A. Loreti, and M. L. Pinta, “Shortening Deepithelialization Time in Reduction Mammaplasty: The Braces Technique,” Plastic and Reconstructive Surgery, vol. 117, no. 3, pp. 1065–1066, 2006.

[5] I. Evren, H. I. Canter, and E. Yucel, “Deepithelialization of breast in reduction mammoplasty using cable tie as breast tourniquet,” Indian journal of plastic surgery : official publication of the Association of Plastic Surgeons of India, Jan-2013. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3745109/#:~:text=Deepithelialization is the first stage,there is no assistant available. [Accessed: 11-Sep-2020].

Conclusions/action items:

This entry mainly addresses key foundational knowledge I will need for brainstorming possible solutions. I still want to learn more about the process itself, and plan on doing so by watching a video of the procedure itself.

YOUNG KIM - Sep 10, 2020, 2:06 PM CDT



skin.jpg(114.5 KB) - download Figure 1) A diagram depicting the three major layers of skin.

2020/09/16 Humeca Dermatome

YOUNG KIM - Sep 17, 2020, 12:59 AM CDT

Title: Humeca Dermatome

Date: 2020/09/16

Content by: Young Kim

Present: Young Kim

Goals: Understand a competing design and think of possible areas of the design which could be improved upon

Content:

The dermatome is a medical device that is used to remove thin slices of skin. It is commonly used to graft wounds and remove skin defects. There are various dermatomes from different providers, with several different designs.

The client stated that the major issues they had with this design was that the size of blade was too large, and that skin tension was not maintained. A large blade size means that the areas of the body in which the tool can be utilized is restrained, as areas such as the breast, for reduction mammoplasty, would be difficult to operate on given their contour. The lack of tension means that without a secondary surgeon or nurse, hampering the efficiency of cuts. This adds unnecessary time to the operation. Both these factors increase the risk of surgical error, and should be addressed in future designs.

After reviewing several different possible designs, the most adequate for the client's needs appears to be the Humeca Dermatome. Firstly, the size of the blade. This specific dermatome comes in two different configurations. The smaller version has a blade width of 42 mm, while the larger blade is 80 mm in width. Though much slimmer that other products, the client should still be contacted to ensure that this width is sufficient. Another notable aspect of this design is the lack of a cord. Other dermatomes utilize a pneumatic blade, requiring the intake of pressurized gas. The cord could be a source of irritation during an operation. Thus, a battery powered dermatome, such as the one manufactured by Humeca would be superior. Their dermatome utilizes a rechargeable Li-Ion battery of 1200 to 2400 mAh. The battery is easily removed and recharged. The device itself is relatively small and lightweight, with a total weight of 1.115 Kg for the D 42 configuration. It is 295 m in length and a total head width of 64 mm. Compared to other dermatomes on the market, the Humeca D42 is the smallest available. The dermatome also comes with a case for sterilization within an autoclave. This is an important addition, as patient safety is the number one concern when manufacturing medical devices.

Certain amendments to the design could be some additional traction tool, which could be held in the other hand of the surgeon. This would allow the operation to be conducted smoothly with a single surgeon. However, besides this, the current design seems to be sufficient. The client should be contacted to understand their perspective which could lead to further improvements to this design. Perhaps a more ergonomic handle could benefit the surgeon, but this is a minor adjustment that isn't very impactful.

https://www.eurosurgical.co.uk/wp-content/uploads/2012/01/IFU-D42-D80-ENG-Li-Ion-v11-01-op-A5-small-file.pdf

Conclusions/action items:

The Humeca D 42 Dermatome appears to be a solid tool that could be used by the client in their specific use case. Further questions should be asked to improve the design.

YOUNG KIM - Sep 17, 2020, 12:16 AM CDT

Humera_Dermatome.png(80.3 KB) - download Figure 1) The Humera Dermatome. This design of a dermatome is the most applicable for the client's needs.

2020/09/30 MicroAire Epicut

YOUNG KIM - Sep 30, 2020, 8:34 PM CDT

Title: MicroAire Epicut

Date: 2020/09/30

Content by: Young Kim

Present: Young Kim

Goals: Understand a competing design and think of possible areas of the design which could be improved upon

Content:

Unlike the Humeca Dermatome, the Epicut takes a manual approach at de-epithelialization. It also is made specifically for the use case the client provided. The client stated that often times traction between the blade and the skin was insufficient, thus skipping would occur. This would lead to inconsistent cuts and would complicate the process. With a manual device, however, this problem would be alleviated. Additionally, the client preferred a smaller device capable of making precise cuts of a small area. Again, the dermatome is outcompeted by the Epicut, as this device appears to be much smaller (dimensions not listed on website, no product specification sheet available). It is much more capable of performing the operation the client is most interested in. The Epitcut is designed with patient safety in mind, with raised tips and an angled blade to ensure that the width and depth of epithelial straps of tissue can be reliably cut, as seen in Figure 1. The handle is also ergonomically designed for an angled grip that a surgeon could take advantage of to make controlled cuts, as seen in Figure 2.

A clear barrier of this device is the price, as the only available option (until a response from Advantech Surgical) is 371.99 for a single disposable device. Additionally, the website states that multiple Epicuts could be necessary during a single operation, which would end up costing a significant amount. A way to improve this design could be making some version of this device that makes use of disposable scalpel blades and an autoclave compatible handle.

Another improvement to this device could be to make the tips of the blade converge at a point instead of diverge from a point. This would be feasible to design considering the size of #10 scalpel blades the client said was readily available (though other scalpel blades are probably available). Additionally, the client stated that a motion pulling towards the surgeon could be preferred, although pushing away from the surgeon would permit greater visibility of the cut.

Conclusions/action items:

This design appears to be very capable and is the only one on the market tailored for the de-epithelialization of breast tissue. Another client meeting should be had to further discuss the improvements that could be made.

YOUNG KIM - Sep 30, 2020, 8:09 PM CDT

Epicut_angle.png(75.6 KB) - download Figure 1: An image of the blades of the Epicut. The angled design allows for a controlled removal of epithelial tissue.

YOUNG KIM - Sep 30, 2020, 8:09 PM CDT

EpiCut_grip.png(70 KB) - download Figure 2: An image of the grip used when operating the Epicut.

2020/09/30 Post Design Matrix Design

YOUNG KIM - Sep 30, 2020, 10:06 PM CDT

Title: Post Design Matrix Design

Date: 2020/09/30

Content by: Young Kim

Present: Young Kim

Goals: Discuss the current working design after several client meetings and creation of the design matrix

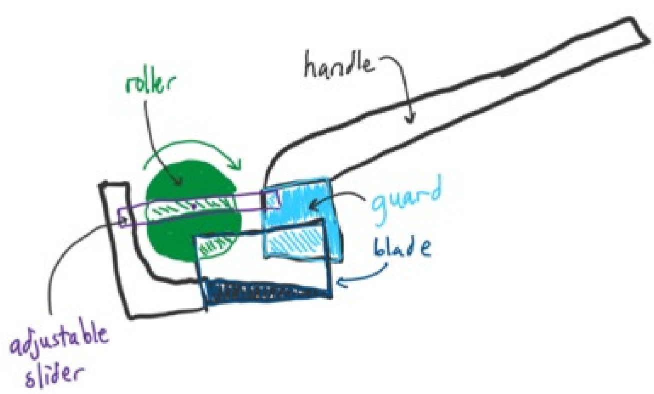
Content:

After thinking through relevant criteria desired for the final product and disucssing the potential design ideas with the client, the team came to a consensus that the ideal design would be one merging properties from the shovel design and the spikey roller design. The client thought that being able to pull the blade towards the surgeon could be beneficial and ease the cutting process. The client was also interested in having a roller, though their input was relatively limited. They simply stated that as long as the roller design would be safe enough for the patient and effective, it would be a useful addition. From these statements, Josh designed a modified shovel design, as seen in Figure 1. This design takes advantage of the client's preferences of having a functional roller and a pulling motion. The roller will . Considerations should be made regarding the material choices of each component. Each portion of the device must be able to withstand multiple cycles of autoclaving. Though this design has promise, there are some glaring issues that arise when considering information the client gave to the team. The client specified that the depth of skin should be around 0.3mm-0.4mm. This value is extremely small. For the roller to effectively generate tension on the skin, it must be a smaller width than the thickness of the skin. After discussion with the team, it would be impractical to design around this idea. Additionally, trying to add guard adjustments and roller adjustments to fit for each possible deviation in skin thickness would be too difficult to accomplish.

Conclusions/action items:

The current design appears to be too difficult to be accomplished with the current resources available to the team. More ideas should be generated in its place.

YOUNG KIM - Sep 30, 2020, 8:36 PM CDT



Modified_shovel.png(100.9 KB) - download Figure 1: A modified shovel design incorporating a roller.

2020/09/30 Modified Epicut

YOUNG KIM - Oct 01, 2020, 12:56 AM CDT

Title: Modified Epicut

Date: 2020/09/30

Content by: Young Kim

Present: Young Kim

Goals: Explain the new design based upon the Epicut competing device.

Content:

The post design matrix attempt to utilize a roller seems to be futile. Instead an alternative approach should be taken. This idea takes inspiration from the Epicut device while trying to minimize cost and can be seen in Figure 1. To achieve this, the design will be fully reusable except the blades. The design will utilize scalpel blades which are commonly available in hospitals. Specifically, the client stated that #10 blades are frequently used for this operation. Using scalpel blades is also advantageous because they are made with surgery in mind and therefore will be held to medical grade standards.. The handle itself will be made from materials capable of withstanding the autoclave for multiple rounds without deforming. The materials should also be fully biologically inert, as it will come into contact with human tissue during the operation.

The device operates with the use of 2 #10 scalpel blades attached to two arms built with the proper attachment system. The arms will then be connected to the handle of the device. The best method of attachment is yet unknown, but should secure the arms such that they do not deviate from their initial position throughout the course of the operation. They should withstand any force applied by the surgeon. The arms will be positioned at an angle such that the bottom surface of the device is in contact with the skin, the blades should make cuts at precisely 0.3-0.4mm. Ideally, the arms holding the scalpel blades would be adjustable. However, this seems like a difficult component of the design to incorporate. Therefore, different arms could be made to attach at different angles. This would allow for the surgeon to choose which arms to use depending on the thickness of the epidermis of the specific patient, as seen in Figure 2.

Before, members of the team discussed how having a blade guard would ensure that a cut exceeding the desired depth would be prevented, but thinner cuts would pose an issue. The team decided that it would be up to the capabilities of the surgeon to make precise cuts that wouldn't be too thin, requiring them to make repeat cuts lengthening the operation. With this design, there is no fluctuation in depth. The blades are at a set depth and the handle lays on top of the skin, allowing for a consistent cut to be made throughout the desired area.

The learning curve for this device would be minimal. The surgeon only needs to make a skilled initial incision, capturing precisely the right amount of epithelial tissue. After this first step, however, they simply have to pull the blade through. The sturdy attachment of the arms to the body ensures the consistency in depth of the cut, as long as excessive force is not used causing the deformation of skin the surgeon is operating on. Surgeons will be thoroughly familiar with the process of installing and removing scalpel blades, thus the process should be simple and straight forward.

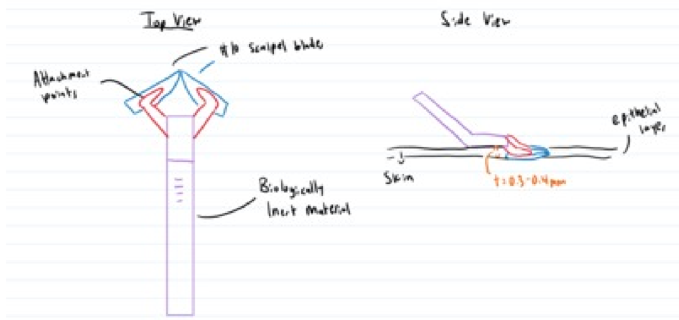
A major flaw of this design is the fact that the #10 scalpel blade would be too long. The Epicut solves this issue by having proprietary blades with a minimal width. More consideration should be put into this design shortcoming. One solution could be to have the blades converge not at the tip, but at a point somewhere along the curvature. Otherwise, some method of angling the scalpel attachments so only a certain portion of the blades are in contact with the skin would suffice.

Some design ideas taken from the Epicut is the incorporation of blades. Having two angled blades assists in creating controlled cuts at a consistent width and depth. Additionally, having an angled handle allows for further control and an easier operation.

Conclusions/action items:

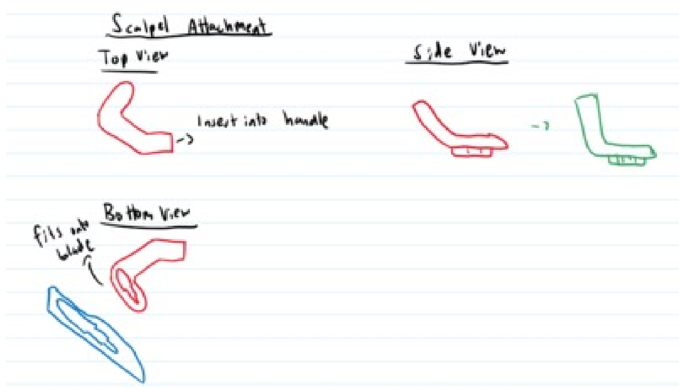
Overall, this idea has greater potential than the scalpel-roller. The scalpel-roller is not feasible with the resources available to the team. This design is much simpler and appears more effective, instead of trying to make sub 0.3mm gaps between the roller and rear platform. This design should be further discussed with the team, client, and advisor.

YOUNG KIM - Oct 01, 2020, 12:56 AM CDT



Modified_Epicut.png(69 KB) - download Figure 1: A modified Epicut utilizing two converging #10 scalpel blades.

YOUNG KIM - Oct 01, 2020, 12:56 AM CDT



Modified_scalpel_attachment.png(57.5 KB) - download Figure 2: A side arm attachment for #10 scalpels. Different versions of this attachment could be made to allow for different depths of epithelial tissue to be removed.

2020/10/02 Peer questions

YOUNG KIM - Oct 02, 2020, 5:44 PM CDT

Title: Peer questions

Date: 2020/10/02

Content by: Young Kim, Noah Ruh, Colleen Cuncannan

Present: Whole Team

Goals: Address some of the questions that arose after the preliminary design presentation.

Content:

Questions about testing

Questions about materials/fabrication

Questions about sterilization

Questions effectiveness and safety concerns

Other questions

Young:

I answered some of these questions to the best of my ability with regard to the newest design. The shovel scalpel will not be used.

I **bolded** answers to questions that are pertinent moving forwards.

I *italicized* answers that have secondary priority, but are still relevant for completing our project.

- How will you ensure that your device is consistent with the depth of skin removal?
  - IDK if they even listened to the presentation. Blade guard should prevent deep cuts. I already mentioned that thin cuts are a major issue for certain devices that would have to be monitored by the surgeon.
    - Not a problem(?) with the newest design
    - Must be validated with our own testing before handing it off to surgeons
- How generally worded are the existing patents for the currently sold devices? i.e. Have you guaranteed that the "shovel scalpel" is different enough that it won't step on existing IP?
  - N/A, shovel scalpel is not the design we will be proceeding with.
  - This question is valid for the epicut device, however, I think there are enough differences between our design and theirs that it won't be a violation of intellectual property. **DOUBLE CHECK THIS W/ SAHA.**
    - We take ergonomic handle and angled double blade design
    - We generate our own scalpel arms and the use of scalpel blades
    - Different operating mechanism
      - Major idea of the design was utilizing the contact between the bottom surface and the handle on skin as a guard mechanism

- How would the testing of the design work?
  - I think even before this, we should use the prototype itself
    - We have to first confirm that the prototype is capable at cutting at the right depths before trying to measure its efficiency relative to currently used technique

        - If it fails, we either need a new design or be capable of modifying the current one to meet the desired requirements
    - Send off to Dr. Carol or Todd
        - they will be making judgments as to the efficiency, ease of use, and effectiveness if they do the testing. afterwards, they can report her findings to the group and changes can be made to the design
        - We can give them some tips on testing the design, but if Dr. Carol is the one who does the testing, she will probably be able to determine its effectiveness better than any of the group members because she knows the procedures it will be used for the best, and if it's easier to use than current methods
    - Testing protocol would somewhat look like:
        - Have equivalent tissue samples and record times surgeons need to de-epp
            - Start with scalpel or start with our design and record time it takes
            - Take a survey on the ease of the operation
        - There may be significant bias without multiple trials, as it would be the first time for surgeons utilizing this tool.
- Is the device meant to be for a single-use or do you plan to sterilize and reuse it? If reusable, how do you plan to sterilize it?
    - All devices would be designed with materials capable of undergoing autoclaving indefinitely (if even possible) without any material deformations
- For de-ep: What types of materials do you plan to test your chosen device on and what is your criteria for choosing these materials?
    - Very relevant question, requires more research
    - As of now, bovine/pig tissue
    - The criteria for choosing these materials should be a similar thickness of the epithelial layer of skin
        - I feel like some may be more difficult to remove than others?
            - Not sure what I have to research to answer this question.
- How does the design take into account areas of skin that are less consistent (ie areas that are more or less flat) or does that require a more specialized tool?
    - Great question
    - The surgeon should be able to follow the contour of the breast
        - They should be experienced enough to practice with the device and develop familiarity.
        - The device should be able to accommodate any cuts the surgeon desires to make.
    - Tough because our current design is very flat
        - Having a small angle between the blades might play into this point. Smaller cuts should be more manageable, but I am still not sure/don't have any experience.
        - Look into this, we should use the prototype ourselves first on contoured materials to get a better understanding of this
- How will the device be tested safely? What systems are there for testing tools like these?
    - Discarded skin samples.

    - Pig or bovine tissue.
    - Depending on what we have access to, we will have to evaluate the ways in which the tissue will differ from what the device will be used on.
    - There is no “system” in place. We would design our own testing protocol, which is answered earlier in the document.
- How do you guys plan on testing the efficiency of your final design?
    - If Dr. Carol does the testing, then she will be making judgments as to the efficiency, ease of use, and effectiveness. Afterwards, she can report her findings to the group and changes can be made to the design.
- How will you quantify any advantages your design has over traditional de-epithelialization techniques
    - It takes a significantly less amount of time than the current de-epping techniques / actual trials with surgeons using our device and a control (<10 minutes).
        - Even if not statistically significant, some decrease in the time it takes should be enough to prove that the design has some potential moving forwards.
    - It cuts at a consistent depth and doesn’t damage the vasculature below the epidermis
        - The depth of cuts made by the surgeon when using the surgeon vs using our device could be compared and analyzed.
        - If the device can effectively achieve both criteria, then it will have maintained sufficient tension and will serve as a successful method of de-epping.
- for de-epper - how would you be able to clean the device as it has the guard that might get stuck on tissue?
    - Tissue won’t be “stuck” indefinitely.
        - The newest design has removable arms and blades which will allow for an easy washing+autoclaving protocol to effectively sanitize the device.
- How will you test this device with regard to its safety?
    - Make sure that the blade can consistently make cuts of equal depths
        - Look for a tolerance.
- How does your team think they can continue to lower cost of fabrication to allow for greater distribution?
    - Utilize reusable scalpel blades which allow the entire device to be autoclaved and the blades to be replaced.
    - Should be more cost effective than replacing an approximately $380(?) dollar device with each surgery
        - Potentially multiple times a surgery
    - Look into the cost of manufacturing our device
        - This should happen after our selection of a material.
- Would any different methods of sterilization need to be used on the device to ensure that the tool is safe to use for another surgery?
    - What? Autoclaving should be sufficient? I may be wrong here, not sure.
        - I think if surgeons already use an autoclave on their devices it would be sufficient.
- If the angle of the shovel scalpel changed slightly what would keep it from cutting into the dermis?
    - Great question.

  - Not very sure, look into this
    - Maybe for testing because I am not quite sure without trying the process itself
- Can you reevaluate the potato peeler design, with given complexity and ability to give to the tension of the skin, why was it measured as the same efficiency as the other designs?
  - No, the design is scrapped.
    - Not feasible given the extremely thin layer of skin we are responsible for cutting.
- Are there specific reasons why surgeons use the epicut in specific angles 35 and 55 degrees?
  - Excellent question, can't answer with my current knowledge.
    - I also assume this information will not be disclosed to the public by the company that manufactured the Epicut.
- How will you take into account the varying thickness of the dermis?
  - Adjust the scalpel attachment arms
    - At different angles, the depth of the scalpel underneath the bottom surface of the handle should change accordingly
    - We should design around this capability, finding angles where the blade depth would be within the 0.3mm to 0.4mm range at varying increments
      - Not sure what increments to do, or what are even feasible.
      - Our tolerance seems very limited.

Conclusions/action items:

Some very good questions were asked about the next steps of the design process. The most important question that must be answered immediately is what material the device would be made of. Other following questions that must be answered are the effectiveness of the device, not infringing on the intellectual property of others, and maintaining an effective device with the contour of the breast. These questions should be answered with the team in upcoming team meetings.

2020/10/20 Prototype Material Choice

YOUNG KIM - Oct 20, 2020, 2:28 PM CDT

Title: Prototype Material Choice

Date: 2020/10/20

Content by: Young Kim

Present: Young Kim

Goals: Look at the machines available at Wendt commons and choose a suitable material.

Content:

Out of the available 3D printing machines at Wendt commons, the Formlabs machines appear to be the most suitable. The Form 3 is capable of developing parts that have increased part clarity and superior surface finish. Additionally, when considering the testing process, the prototype will likely undergo the autoclaving process. This is because it will be in contact with human tissue in a BSL 2 lab and could potentially carry harmful microbes. Thus, the material of choice should be able to withstand the conditions within a standard autoclave. Otherwise, multiple prototypes would have to be made to dispose the part after each use. Standard autoclaves operate at temperatures above approximately 121° C at 15 psi for 30 minutes [1].

There are two candidates materials that the Formlab is capable of printing with, either the Formlabs High Temp or the Formlabs Dental SG. The High Temp's spec sheet indicate that it will be capable of withstanding the aforementioned conditions. The Dental SG is made to be biocompatible and is specifically stated to be capable of steam sterilization in an autoclave or gamma-ray sterilization. The High Temp costs $0.29/mL and the Dental SG costs $0.35/mL. However, these materials must undergo a post-curing process before they attain these properties. The data sheets state that the reported values are after curing in their proprietary Form cure machine. Further research should be done regarding the availability of the Form Cure machine or alternative methods that would effectively cure the materials.

A potential alternative is printing a mold with a capable filament, then casting the final shape using an alternative material that can withstand the desired conditions.

[1] Ehs.princeton.edu. n.d. *Autoclave Use*. [online] Available at: <https://ehs.princeton.edu/book/export/html/380> [Accessed 20 October 2020].

Conclusions/action items:

More research should be put into the materials available to the team and alternative curing methods for the Formlabs Dental SG and High Temp.

YOUNG KIM - Oct 20, 2020, 1:40 PM CDT


MATERIAL DATA SHEET

Dental SG

Biocompatible Photopolymer Resin for Form 2

Formlabs Dental SG Resin produces strong, accurate, biocompatible parts ideal for a dental surgical guide and similar applications, and is specifically designed to work with your Form 2 3D Printer. After being post-cured, this material can be steam sterilized in an autoclave, or by gamma-ray sterilization.

FLDGOR01

formlabs

DentalSG-DataSheet.pdf(203.3 KB) - download

YOUNG KIM - Oct 20, 2020, 1:40 PM CDT


MATERIAL DATA SHEET

High Temp

High Temp Resin for Heat Resistance $199 / L

High Temp Resin offers a heat deflection temperature (HDT) of 238 °C @ 0.45 MPa, the highest among Formlabs resins. Use it to print detailed, precise prototypes with high temperature resistance.

Hot air, gas, and fluid flow

Molds and inserts

Heat resistant mounts, housings, and fixtures

FLHTAM02

formlabs

High_Temp_Technical.pdf(225.9 KB) - download

11/26/19 Green Pass

YOUNG KIM - Dec 09, 2019, 5:43 PM CST

Title: Green Pass

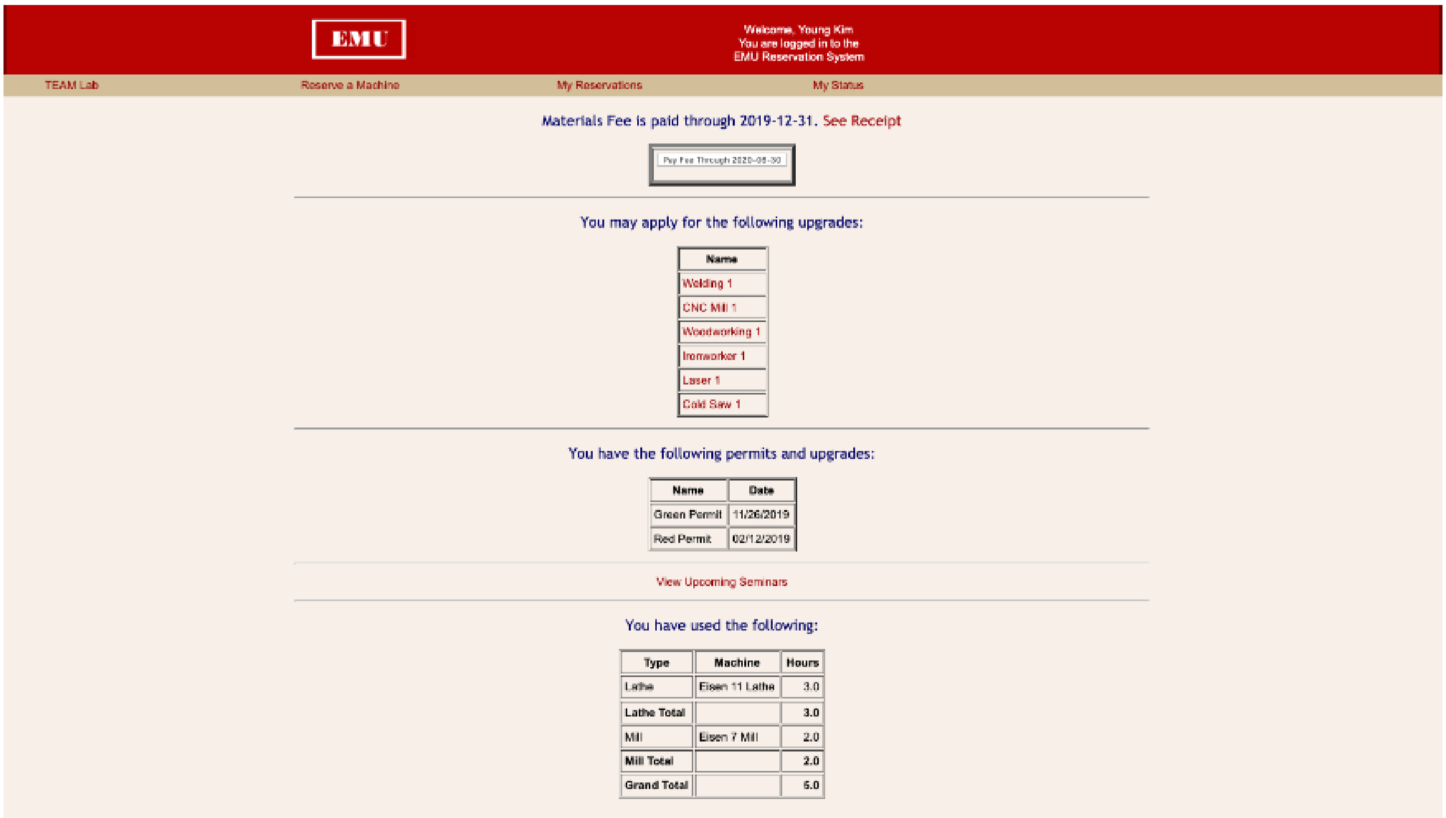
Date: 11/26/10

Content by: Young Kim

Present: Young Kim

Goals: Complete necessary quizzes and training to make green part and receive Green Pass

Content:



EMU

Welcome, Young Kim
You are logged in to the
EMU Reservation System

TEAM Lab | Reserve a Machine | My Reservations | My Status

Materials Fee is paid through 2019-12-31. See Receipt

Pay Fee Through 2020-08-30

You may apply for the following upgrades:

Name
Welding 1
CNC Mill 1
Woodworking 1
Ironworker 1
Laser 1
Cold Saw 1

You have the following permits and upgrades:

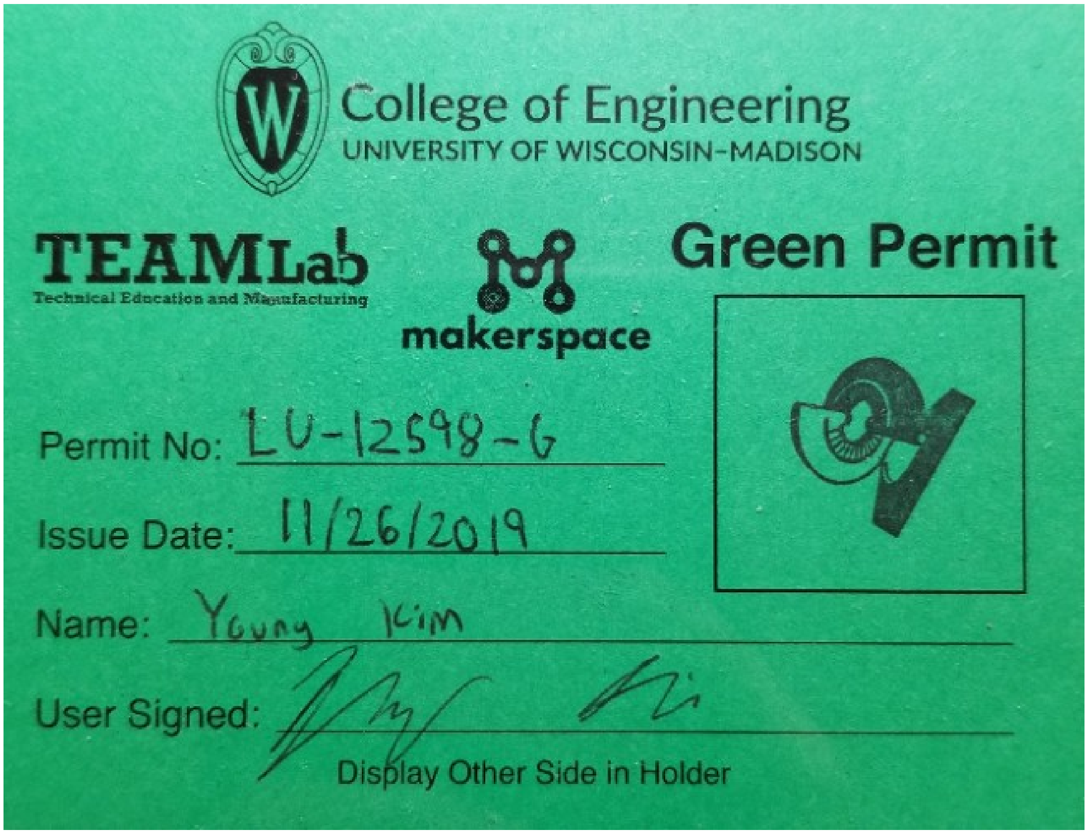
Name	Date
Green Permit	11/26/2019
Red Permit	02/12/2019

View Upcoming Seminars

You have used the following:

Type	Machine	Hours
Lathe	Eisen 11 Lathe	3.0
Lathe Total		3.0
Mill	Eisen 7 Mill	2.0
Mill Total		2.0
Grand Total		5.0

After completing the quizzes and attending the seminar, the green part was completed and Permit obtained.



Conclusions/action items:

Now, I have access to the mill and lathe in the MakerSpace. This step was completed preemptively for my enrollment in BME 201, and was recommended by several people to be done before break.

2020/03/26 Biosafety Training

YOUNG KIM - Mar 26, 2020, 7:53 PM CDT

Title: Biosafety Training

Date: 2020/03/26

Content by: Young Kim

Present: Young Kim

Goals: Complete my biosafety training for use in future labs/design projects.

Content:

University of Wisconsin-Madison

This certifies that YOUNG KIM has completed training for the following course(s):

Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date
2019-20 HIPAA PRIVACY & SECURITY TRAINING	HIPAA QUIZ	1/20/2020	
BIOSAFETY REQUIRED TRAINING	BIOSAFETY REQUIRED TRAINING QUIZ	3/26/2020	

Data Effective: Thu Mar 26 14:21:14 2020
Report Generated: Thu Mar 26 19:49:07 2020

Conclusions/action items:

Although I will not be able to access any labs that require biosafety training in the foreseeable future, having it completed and ready will allow me to enter labs if needed in future design projects or labs.

Skin Research

Noah Ruh - Oct 05, 2020, 12:10 AM CDT

Title: Skin Research

Date: 09/11/2020

Content by: Noah Ruh

Present: N/A

Goals: Get a better understanding of the thickness of the skin that the team needs to be able to remove and get a better understanding of how the skin reacts to being taught.

Content:

The skin is made of 3 primary layers; The epidermis, dermis, and subcutaneous tissue.

1. The epidermis is what the team is focusing on removing for this project. It is made up of 5 layers that will all need to be removed including the basement membrane that binds it to the dermis of the skin. The epidermis is the bodies first line of defense against the outside world and acts to keep water, bacteria, and other potentially harmful things out, and keeps the underlying tissue protected from slight blunt damage. Cells are continuously replaced in this layer and dead cells constantly fall from this layer while new cells replace them [1].

2. The dermis is the next layer of the skin, this layer is the layer that the team does not want to damage in the process of removing the epidermis. This tissue contains the blood vessels and lymphatic vessels that supply nutrients to the cells and remove waste [1]. Damaging this layer of the skin results in bleeding and puncturing this layer leads to complications in surgery as gauze is required to stop the bleeding, potentially elongating procedure times (the opposite of what the client wants).

3. The subcutaneous tissue contains fats and stores energy for the body. The team shouldn't have to worry about this layer of the skin at all. If this tissue is removed by the device it has failed miserably.

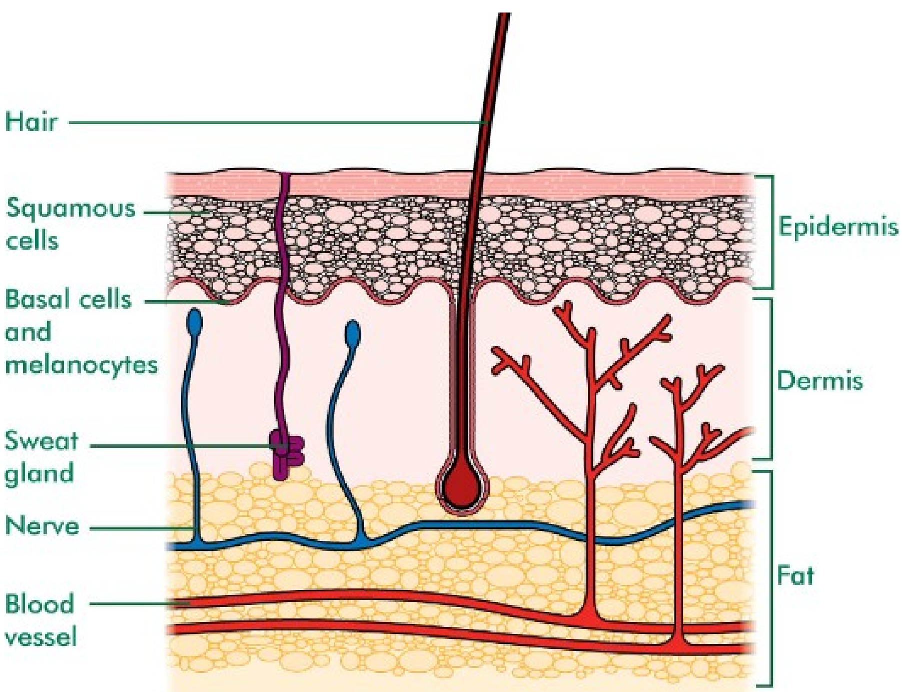


Figure 1: This figure show the layers of the skin. The team is trying to remove only the epidermal layer in order to oblige with the clients requests.

The epidermal layer of the skin is very difficult to pin down an exact thickness for. This is due to the fact that different areas of the body have different thicknesses due to contact with surfaces and the environment. The epidermis in the palms and soles of the feet are magnitudes larger than the epidermis of the abdominal or breast tissue [2]. Along with varying depths of epidermis the amount of collagen (one of the primary factors for skin tightness) varies with age and sex as well, meaning that the thickness of the skin we want to remove may be difficult to pinpoint. As people age collagen decreases in skin tissues throughout the body, which may have an effect on the device that we are trying to create [2].

Sources:

[1] “Skin: Structure and function explained,” Jan. 11, 2018. https://www.medicalnewstoday.com/articles/320435 (accessed Oct. 04, 2020)

[2] S. Shuster, M. M. Black, and E. McVitie, “The influence of age and sex on skin thickness, skin collagen and density,” *The British Journal of Dermatology*, vol. 93, no. 6, pp. 639–643, Dec. 1975, doi: 10.1111/j.1365-2133.1975.tb05113.x.

Conclusions/action items:

Skin Grafts

Noah Ruh - Oct 06, 2020, 1:11 PM CDT

Title: Epidermal Skin Grafting issues

Date: 09/23/2020

Content by: Noah

Present: N/A

Goals: Understand the process of epidermal skin grafting

Content:

When there are small wounds then epidermal skin grafts are used, or in the teams case, when they only need to replace the epidermal layer of the skin. The best way to get a graft to be accepted is to have is consistent and have adequate granulated tissue. There is usually not need for general anesthesia and the grafts are usually collected via dermatome and scored slightly to allow for stretching in the healing process [1]. The device that the team is making will be like a dermatome and may be useful for surgeon to use instead of the electric machine. The problem that the surgeons have when using the dermatome is precision [1] which is what the team is going to be solving with the design.

Performing ESG's on tissue that is not too thin or soft is relatively easy to do with new techniques, however getting clean and good cuts on more sensitive tissues is a problem that surgeons still run into, resulting in longer procedure times and more work for the surgeons than would normally be necessary.

References:

[1] I. Herskovitz, O. B. Hughes, F. Macquhae, A. Rakosi, and R. Kirsner, "Epidermal skin grafting," *International Wound Journal*, vol. 13, no. S3, pp. 52–56, 2016, doi: 10.1111/iwj.12631.

Conclusions/action items:

Using this information the team will work hard to come up with preliminary designs that allow for procedures to be done quickly and accurately on less ideal skin surfaces.

Breast Tissue

Noah Ruh - Dec 08, 2020, 5:00 PM CST

Title: Breast Tissue morphology

Date: 12/07/2020

Content by: Noah Ruh

Present: N/A

Goals: Get research on breast tissue for the final paper

Content:

De-epithelialization of the breast tissue is part of one of the most commonly performed plastic surgeries, reduction mammoplasty. Practitioners propose that keeping the underlying vasculature of the breast tissue results in fast healing of the surgery [1].

The tissue that is removed is extremely thin compared to the rest of the body and contains many more nerve endings and vasculature. This means that the surgeons need to be precise when they remove this skin or run the risk of destroying the underlying layers [2].

Conclusions/action items:

The breast tissue is extremely sensitive and needs special treatment during surgeries that involve it.

References:

[1]

S. A. Ovadia, E. Bishop, Y. Zoghbi, R. Gasgarth, W. Kassira, and S. R. Thaller, “Pedicle De-epithelialization in Reduction Mammoplasty: A Systematic Review of the Literature,” *Aesthetic Plast Surg*, vol. 42, no. 1, pp. 100–111, Feb. 2018, doi: 10.1007/s00266-017-1024-7

[2]

A. O. Wamalwa, T. Stasch, F. W. Nangole, and S. O. Khainga, “Surgical anatomy of reduction mammaplasty: a historical perspective and current concepts,” *S Afr J Surg*, vol. 55, no. 1, pp. 22–28, Mar. 2017.

Chicken breast vs skin

Noah Ruh - Dec 09, 2020, 12:59 AM CST

Title: Comparison of chicken breast vs human skin

Date: 12/01/2020

Content by: Noah

Present: N/A

Goals: Understand how closely related chicken is to human skin

Content:

Chickens have a similar structure to human skin with an epidermis, dermis, and hypodermis. The chicken has more types of skin based on where on the body the skin is, but the breast is pretty much the same morphologically as humans.

[1] "Integumentary (surface of the bird)," *Poultry Hub*. http://www.poultryhub.org/physiology/body-systems/integumentary-surface-of-the-bird/ (accessed Dec. 09, 2020).

Conclusions/action items:

This proves that I can test on chicken and at least glean some information about using the device on human skin.

Dermatome

Noah Ruh - Oct 05, 2020, 11:13 PM CDT

Title: Dermatome research

Date: 09/16/2020

Content by: Noah

Present: N/A

Goals: Learn more about competing devices and get a better handle on what the team can do to help the client.

Content:

The dermatome is a device that is designed to be used by surgeons to easily, quickly, and accurately remove skin for skin grafts. It consists of a simple handle with a blade that vibrates extremely quickly in order to create a consistent cut while the surgeon is using it.

Humeca supplies a range of high quality blades for different types of dermatomes. Humeca supplies symmetrical and double facet grinded blades for minimum resistance and uniform graft thickness. The blade moves at about 7000 strokes per second to achieve maximum consistency [1].

The dermatome boasts some impressive statistics including the following list

> "Extremely small head of D42 allows precision cutting, especially in problematic zones and pediatric surgery
> Cordless, battery operated and lightweight design offers optimum maneuverability and mobility
> Precise thickness of the graft from 0.0 to 1.2 mm (0.000 – 0.048") in 0.1 mm (0.008") increments
> Graft width of 42 mm (1.65″) assures optimum performance in combination with the MEEK technique
> The use of width-reducing clamps on the dermatome head allow cutting of smaller graft widths
> Battery and motor of the instrument are not sterilized, thus guaranteeing optimum durability
> Thickness adjustment can be fixed to prevent accidental change of graft thickness during cutting
> Safe and quick blade replacement
> Powerful Li-Ion batteries with no memory effect allow long time cutting without intermediate charging"

The problems that this device has is the size of the blade that is used for it. This device is used for large transformations of skin, which is not what the client wants at all. She wants a delicate device that is able to accurately and consistently remove the epidermal layer of the skin, which is not what the dermatome doesn't quite do. The team may want to use this device as a model to make smaller and more accurate.

References:

[1] "Cordless dermatomes and blades – Humeca." https://humeca.com/cordless-dermatomes-and-blades/ (accessed Oct. 05, 2020).

Conclusions/action items:

Use the Dermatome as a base for preliminary designs and start to brainstorm for the next team meeting.

Noah Ruh - Oct 05, 2020, 11:11 PM CDT

OIP.jpg(15.1 KB) - download Figure 1: The two Dermatome devices that are offered by Humeca at the moment

Epicut

Noah Ruh - Oct 05, 2020, 11:23 PM CDT

Title: Epicut Research

Date: 2020/09/30

Content by: Noah

Present: N/A

Goals: Learn about the epicut and figure out how to improve upon the basic idea

Content:

The epicut is much different than the dermatome competing device earlier in the notebook. Instead of being propelled by a motor to induce cutting, the epicut is a handheld and hand powered device. By using a hand instead of a motor a surgeon can drastically reduce the amount of skipping that occurs because consistent pressure can be applied. The amount of work done by both devices is most likely the same, due to having to control the dermatome and keep it from skipping. The epicut seems to be a more precision oriented device as well and is quoted to be used in breast reduction surgeries already. Consistent cuts are achieved by consistent pressure from the surgeon. The angled blades shown in Figure 2 allows for the blades to remove only the epidermal layer and not pierce the underlying vascular tissue. Along with ensuring patient safety the design is also ergonomic as can be seen in Figure 2.

A clear barrier of this device is the price, as the only available option (until a response from Advantech Surgical) is 371.99 for a single disposable device. The literature also states that there may be a need for multiple epicuts per surgery as well, driving medical costs up for relatively simple parts of a procedure.

Another improvement to this device could be to make the tips of the blade converge at a point instead of diverge from a point. This would be feasible to design considering the size of #10 scalpel blades the client said was readily available (though other scalpel blades are probably available). Additionally, the client stated that a motion pulling towards the surgeon could be preferred, although pushing away from the surgeon would permit greater visibility of the cut.

Conclusions/action items:

This design appears to be very capable and is the only one on the market tailored for the de-epithelialization of breast tissue. Another client meeting should be had to further discuss the improvements that could be made.

Noah Ruh - Oct 05, 2020, 11:13 PM CDT

Epicut_angle.png(75.6 KB) - download Figure 1: An image of the blades of the Epicut. The angled design allows for a controlled removal of epithelial tissue.

Noah Ruh - Oct 05, 2020, 11:13 PM CDT

EpiCut_grip.png(70 KB) - download Figure 2: An image of the grip used when operating the Epicut.

Chicken breast testing

Noah Ruh - Dec 08, 2020, 4:41 PM CST

Title: Chicken Breast Test

Date: 11/30/2020

Content by: Noah Ruh

Present: Noah

Goals: Test the prototype device in order to see feasibility and see new possible design ideas

Content:

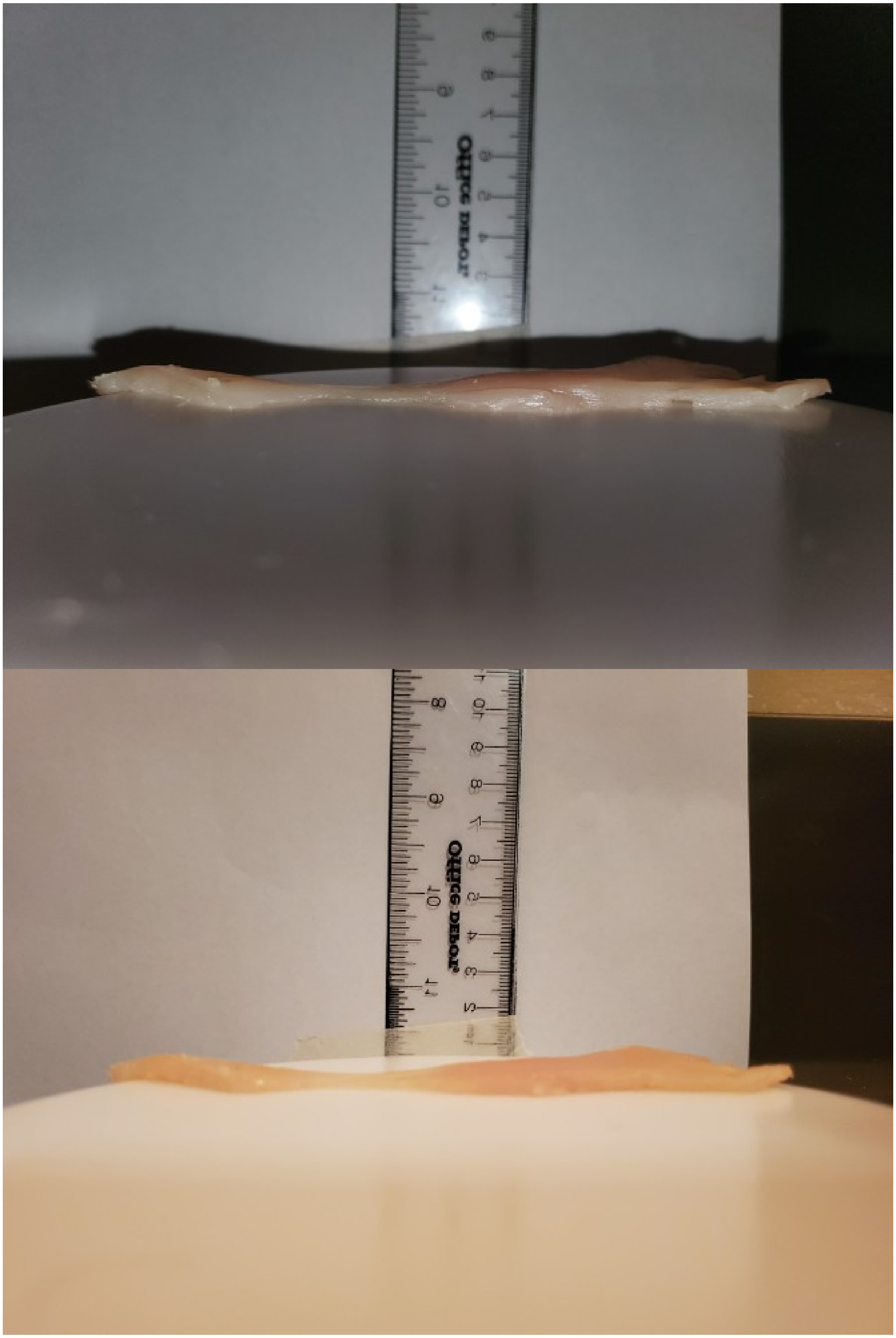


Figure 1: These are the same sample of chicken breast that was analyzed in Kinovea to test for cut depth.

Conclusions/action items:

Testing was done on 8 chicken breasts and the two figures show the same strip that was successfully removed from one of the breasts.

Results

Noah Ruh - Dec 08, 2020, 4:44 PM CST

Title: Testing Results

Date: 12/01/2020

Content by: Noah

Present: N/A

Goals: Discuss the results of the testing

Content:

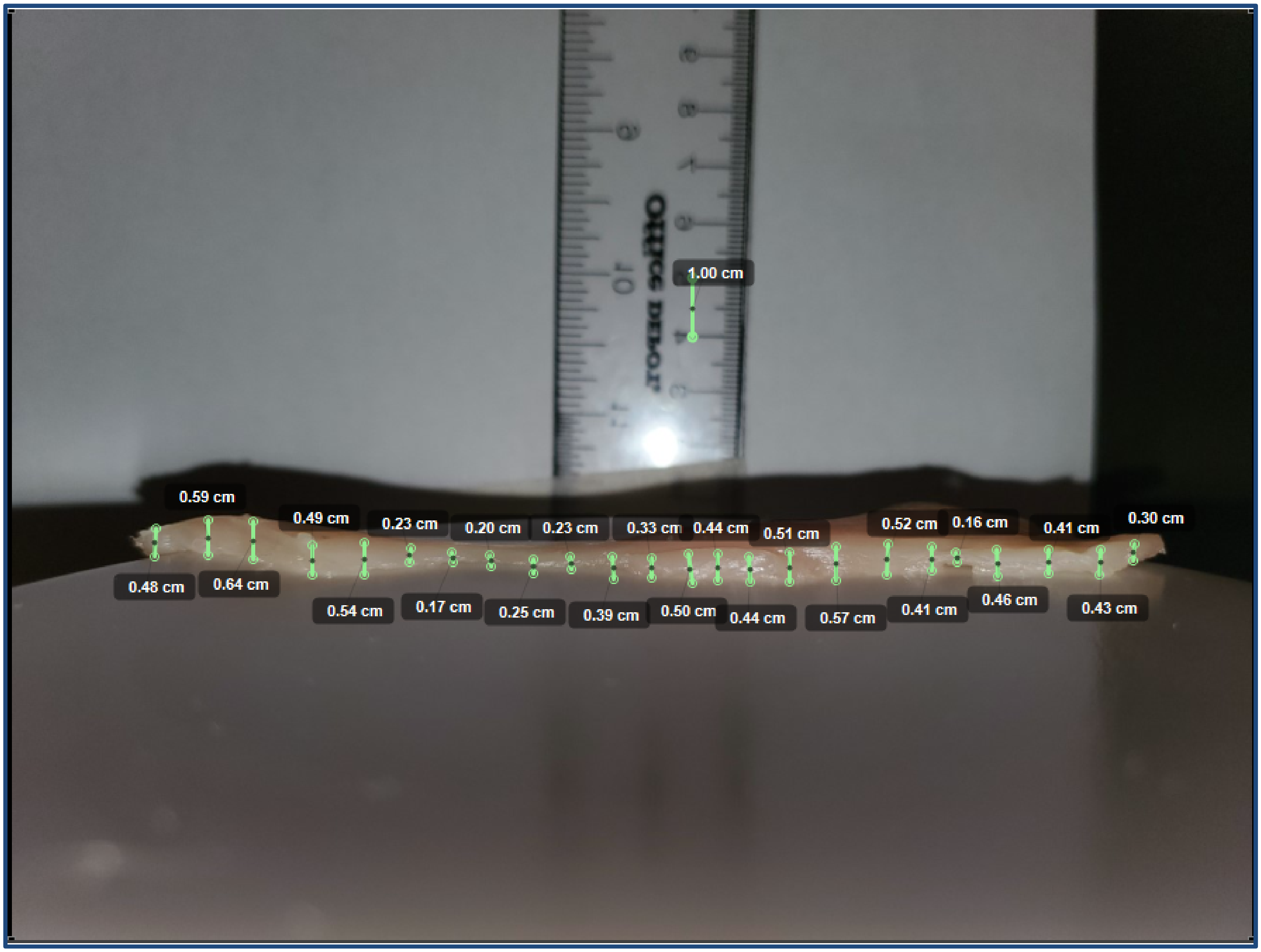


Figure 5 (above): Kinovea analyzed strip of cut chicken. 24 cut depth data points were collected from the cut of chicken shown in the testing page using Kinovea's calibration tool

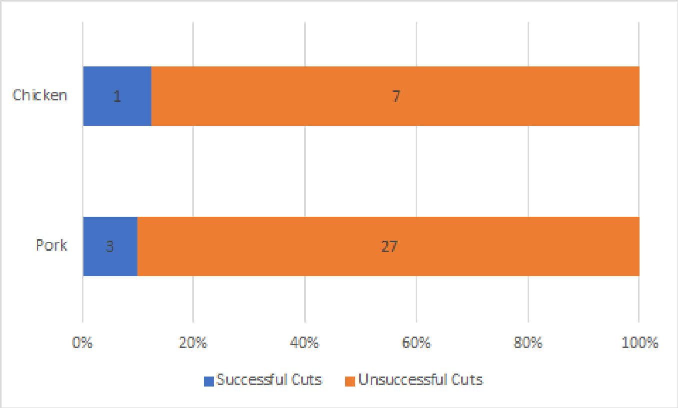


Figure 2:

Graph of the successful (blue) and unsuccessful (orange) trials for the Chicken and Pork tests in percentages.

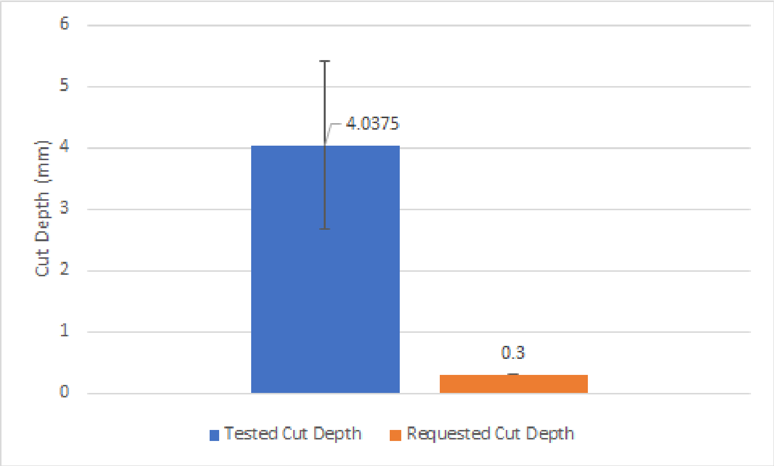


Figure 3:

Graph of the tested chicken cut depth (left) and the requested cut depth (right). The standard deviations of the two data sets do not overlap suggesting they are significantly different.

Conclusions/action items:

After testing 1 of the 8 chicken tests were deemed successful and 3 of the 30 porcine tests were successful based on the aforementioned requirements, resulting in a 12.5% and 10% respective success rate (Figure 2). Based on the chicken testing the team created a graph looking at the consistency of the cuts. The average cut depth of 4.0375 mm with a standard deviation of 1.3 mm is compared to the 0.3 requested cut depth and differs significantly from this value. seen in Figure 3.

Discussion

Noah Ruh - Dec 08, 2020, 4:46 PM CST

Title: Discussion

Date: 12/06/2020

Content by: Noah

Present: N/A

Goals: Discuss the results from testing

Content:

Based on the results the team concluded that this device can sometimes cut through and remove the tissue, however not at the success rate that was expected or needed. The low success rate of cuts means that the device the team created does not meet the requirements that were given. The large standard deviation seen in figure 3 of the results page means that even when the device did cut, it did not do so consistently.

Shovel Scalpel

Noah Ruh - Oct 05, 2020, 12:23 AM CDT

Title: Shovel Scalpel prelim design

Date: 09/25/20

Content by: Noah

Present: N/A

Goals: Come up with a design idea that would be theoretical and would be able to do what the client asks

Content:

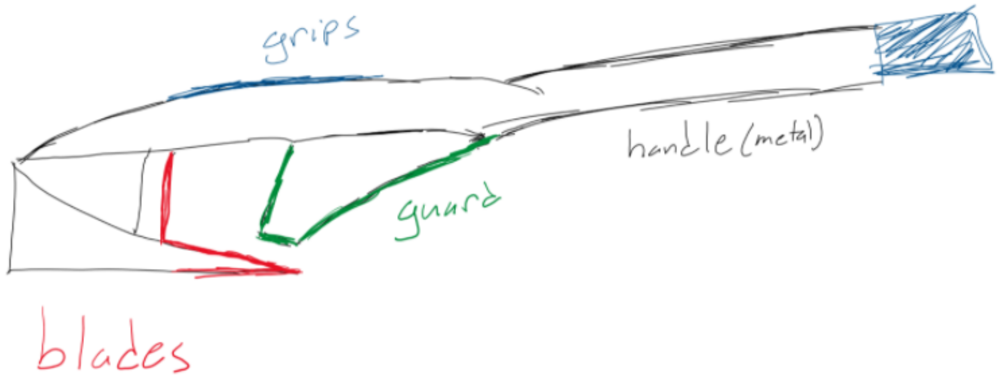


Figure 1: This is the preliminary design idea that I came up with called the Shovel Scalpel.

The shovel scalpel design idea came from the idea that it would be easier to control tension if the surgeon is pulling towards themselves with their dominant hand and pulling the cut tissue through the device with the other. The design features three blades in red that would create the basic shape of a shovel head, but backwards. The guard is implemented to control depth of cut and will be adjustable in order to accommodate different areas of the body. The surgeon would place their palm on the handle grip and their pointer and middle fingers(or any they deem appropriate) on the grip above the blade to apply pressure. The surgeon would then pull the device towards themselves and would be able to grab the tissue that is cut from the left side of the device. With a grip on the already cut tissue and the device the surgeon would slowly pull the device across the skin, while using the skin to add tension.

Conclusions/action items: This device will allow the surgeon to have consistent tension and will allow for precise removal of the epidermal layer. The next thing to do is meet with the group in order to compare design ideas and to make sure that we are able to choose the best design moving forward.

Design Matrix design

Noah Ruh - Oct 05, 2020, 12:27 AM CDT

Title: Preliminary device design

Date: 09/30/20

Content by: The team

Present: The team

Goals: Show the preliminary device that the team came together to create

Content:

Modified_shovel.png - Figure 1: A modified shovel design incorporating a roller.

Figure 1: This is the device that the team came up with.

The device that the team ended up going with is a combination of the shovel scalpel and roller designs. The team believes that by incorporating the roller into the shovel scalpel device instead of a guard will help with the tension that seems to be the main issue the team is coming across. The procedure is the same as the shovel scalpel except instead of pulling the device towards them, the device will be rolled along the skin in order to maintain tension.

Conclusions/action items: In the future the team will need to polish this design and come up with a plan to actually create the final product for the client.

Non-roller design

Noah Ruh - Oct 05, 2020, 10:55 PM CDT

Title: Non-roller device

Date: 10/01/20

Content by: Noah/Young

Present: N/A

Goals: Come up with a new design that takes more from the epicut

Content:

Modified_Epicut.png - Figure 1: A modified Epicut utilizing two converging #10 scalpel blades.

Figure 1: This is the device that we came up with drawing inspiration from the epicut

Modified_scalpel_attachment.png - Figure 2: A side arm attachment for #10 scalpels. Different versions of this attachment could be made to allow for different depths of epithelial tissue to be removed.

Figure 2: This shows a closer look at the arms of the new device

This design takes the competing epicut and modifies it into a cheaper and more sustainable product. The main problems that the epicut currently face are that they are expensive, single use items. This device will be compatible with #10 blade scalpels. This is important because this device will be able to be used multiple times, unlike the epi-cut which is a one time use item. The blades connect to the arms as shown in Figure 2 and the device is pushed across the skin as shown in Figure 1. The better things about this device compared to the design matrix designs is that the concept has already been proven and shows promise. The thing that it doesn't allow for is an inexpensive and reusable device.

Conclusions/action items: Discuss this idea with the client and see if she thinks there is more merit in this design than the original one. We will also meet with the client in order to further our research.

Peer Review

Noah Ruh - Oct 05, 2020, 10:59 PM CDT

Title: Peer questions

Date: 2020/10/02

Content by: Young Kim, Noah Ruh, Colleen Cuncannan

Present: Whole Team

Goals: Address some of the questions that arose after the preliminary design presentation.

Content:

Questions about testing

Questions about materials/fabrication

Questions about sterilization

Questions effectiveness and safety concerns

Other questions

Noah:

I answered some of these questions to the best of my ability with regard to the newest design. The shovel scalpel will not be used.

I **bolded** answers to questions that are pertinent moving forwards.

I *italicized* answers that have secondary priority, but are still relevant for completing our project.

- How will you ensure that your device is consistent with the depth of skin removal?
  - The blade guard in the previous designs was there to keep from cutting too deep and the surgeon should be able to control the depth easily this way
- How generally worded are the existing patents for the currently sold devices? i.e. Have you guaranteed that the "shovel scalpel" is different enough that it won't step on existing IP?
  - This question is valid for the epicut device, however, there should be enough different with our device that this isn't a problem. **DOUBLE CHECK THIS W/ SAHA.**
    -
      - We take ergonomic handle and angled double blade design
      - We generate our own scalpel arms and the use of scalpel blades
      - Different operating mechanism
        - Major idea of the design was utilizing the contact between the bottom surface and the handle on skin as a guard mechanism
- How would the testing of the design work?
  - I think even before this, we should use the prototype itself
    - We have to first confirm that the prototype is capable at cutting at the right depths before trying to measure its efficiency relative to currently used technique
    - If it fails, we either need a new design or be capable of modifying the current one to meet the desired requirements

  - Send off to Dr. Carol or Todd
    - they will be making judgments as to the efficiency, ease of use, and effectiveness if they do the testing. afterwards, they can report her findings to the group and changes can be made to the design
    - We can give them some tips on testing the design, but if Dr. Carol is the one who does the testing, she will probably be able to determine its effectiveness better than any of the group members because she knows the procedures it will be used for the best, and if it's easier to use than current methods
  - Testing protocol would somewhat look like:
    - Have equivalent tissue samples and record times surgeons need to de-epp
      - Start with scalpel or start with our design and record time it takes
      - Take a survey on the ease of the operation
    - There may be significant bias without multiple trials, as it would be the first time for surgeons utilizing this tool.
- Is the device meant to be for a single-use or do you plan to sterilize and reuse it? If reusable, how do you plan to sterilize it?
  - All devices would be designed with materials capable of undergoing autoclaving indefinitely (if even possible) without any material deformations
- For de-ep: What types of materials do you plan to test your chosen device on and what is your criteria for choosing these materials?
  - Very relevant question, requires more research
  - As of now, bovine/pig tissue
  - The criteria for choosing these materials should be a similar thickness of the epithelial layer of skin
    - I feel like some may be more difficult to remove than others?
      - Not sure what I have to research to answer this question.
- How does the design take into account areas of skin that are less consistent (ie areas that are more or less flat) or does that require a more specialized tool?
  - Great question
  - The surgeon should be able to follow the contour of the breast
    - They should be experienced enough to practice with the device and develop familiarity.
    - The device should be able to accommodate any cuts the surgeon desires to make.
  - Tough because our current design is very flat
    - Having a small angle between the blades might play into this point. Smaller cuts should be more manageable, but I am still not sure/don't have any experience.
    - Look into this, we should use the prototype ourselves first on contoured materials to get a better understanding of this
- How will the device be tested safely? What systems are there for testing tools like these?
  - Discarded skin samples.
  - Pig or bovine tissue.

    - Depending on what we have access to, we will have to evaluate the ways in which the tissue will differ from what the device will be used on.
    - There is no "system" in place. We would design our own testing protocol, which is answered earlier in the document.
- How do you guys plan on testing the efficiency of your final design?
    - If Dr. Carol does the testing, then she will be making judgments as to the efficiency, ease of use, and effectiveness. Afterwards, she can report her findings to the group and changes can be made to the design.
- How will you quantify any advantages your design has over traditional de-epithelialization techniques
    - It takes a significantly less amount of time than the current de-epping techniques / actual trials with surgeons using our device and a control (<10 minutes).
        - Even if not statistically significant, some decrease in the time it takes should be enough to prove that the design has some potential moving forwards.
    - It cuts at a consistent depth and doesn't damage the vasculature below the epidermis
        - The depth of cuts made by the surgeon when using the surgeon vs using our device could be compared and analyzed.
        - If the device can effectively achieve both criteria, then it will have maintained sufficient tension and will serve as a successful method of de-epping.
- for de-epper - how would you be able to clean the device as it has the guard that might get stuck on tissue?
    - Tissue won't be "stuck" indefinitely.
        - The newest design has removable arms and blades which will allow for an easy washing+autoclaving protocol to effectively sanitize the device.
- How will you test this device with regard to its safety?
    - Make sure that the blade can consistently make cuts of equal depths
        - Look for a tolerance.
- How does your team think they can continue to lower cost of fabrication to allow for greater distribution?
    - Utilize reusable scalpel blades which allow the entire device to be autoclaved and the blades to be replaced.
    - Should be more cost effective than replacing an approximately $380(?) dollar device with each surgery
        - Potentially multiple times a surgery
    - Look into the cost of manufacturing our device
        - This should happen after our selection of a material.
- Would any different methods of sterilization need to be used on the device to ensure that the tool is safe to use for another surgery?
    - What? Autoclaving should be sufficient? I may be wrong here, not sure.
        - I think if surgeons already use an autoclave on their devices it would be sufficient.
- If the angle of the shovel scalpel changed slightly what would keep it from cutting into the dermis?
    - Great question.
    - Not very sure, look into this

        - Maybe for testing because I am not quite sure without trying the process itself

- Can you reevaluate the potato peeler design, with given complexity and ability to give to the tension of the skin, why was it measured as the same efficiency as the other designs?
    - No, the design is scrapped.
        - Not feasible given the extremely thin layer of skin we are responsible for cutting.
- Are there specific reasons why surgeons use the epicut in specific angles 35 and 55 degrees?
    - Excellent question, can't answer with my current knowledge.
        - I also assume this information will not be disclosed to the public by the company that manufactured the Epicut.
- How will you take into account the varying thickness of the dermis?
    - Adjust the scalpel attachment arms
        - At different angles, the depth of the scalpel underneath the bottom surface of the handle should change accordingly
        - We should design around this capability, finding angles where the blade depth would be within the 0.3mm to 0.4mm range at varying increments
            - Not sure what increments to do, or what are even feasible.
            - Our tolerance seems very limited.

Conclusions/action items:

The team needs to meet with the client in order to move forward with the new design idea. This will hopefully come to fruition soon so that the team is able to use these questions and any concerns that the client has to further our designs.

Design CAD drawing

Noah Ruh - Oct 19, 2020, 10:59 PM CDT

Title: CAD Drawing for device

Date: 10/18/2020

Content by: Noah

Present: Josh/Young/Noah

Goals: Create the Device in AutoCAD in order to better understand and print the device

Content:

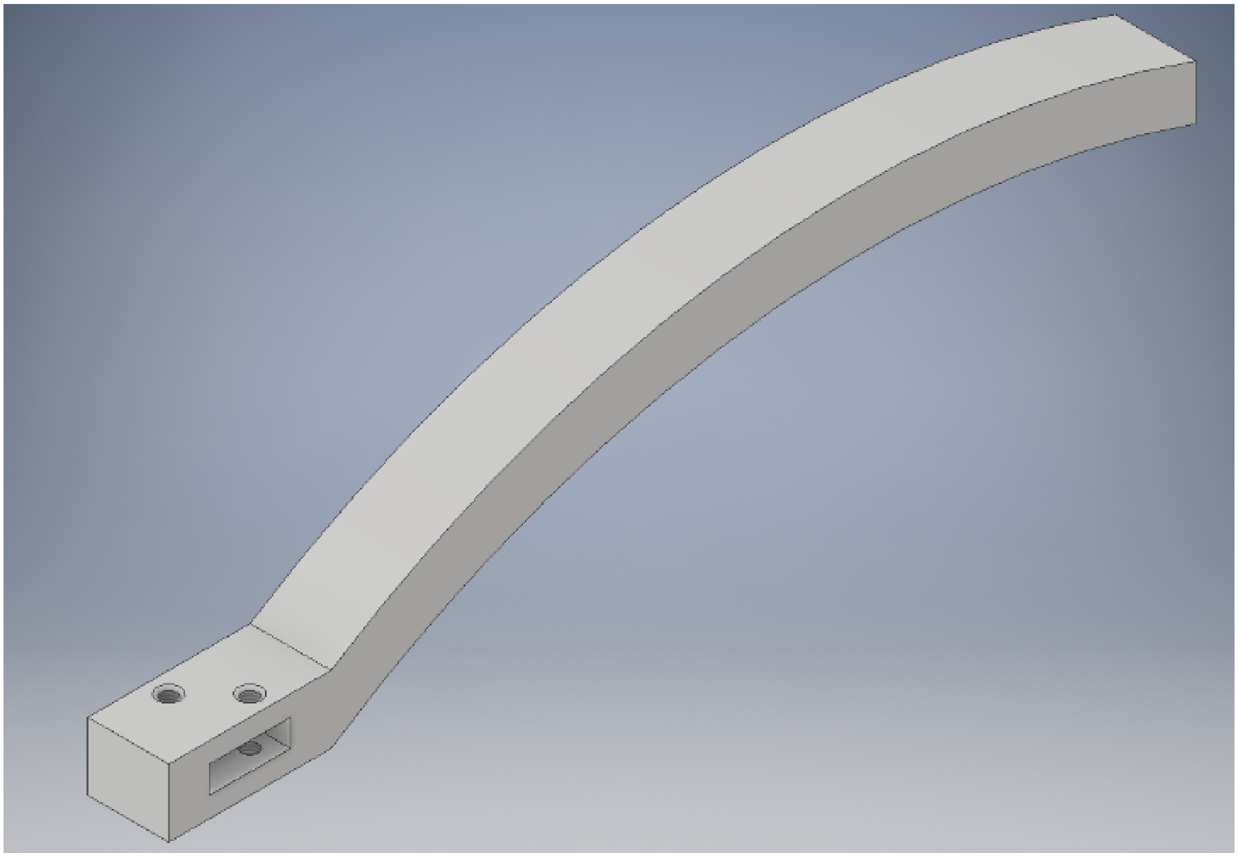


Figure 1: The handle for the device

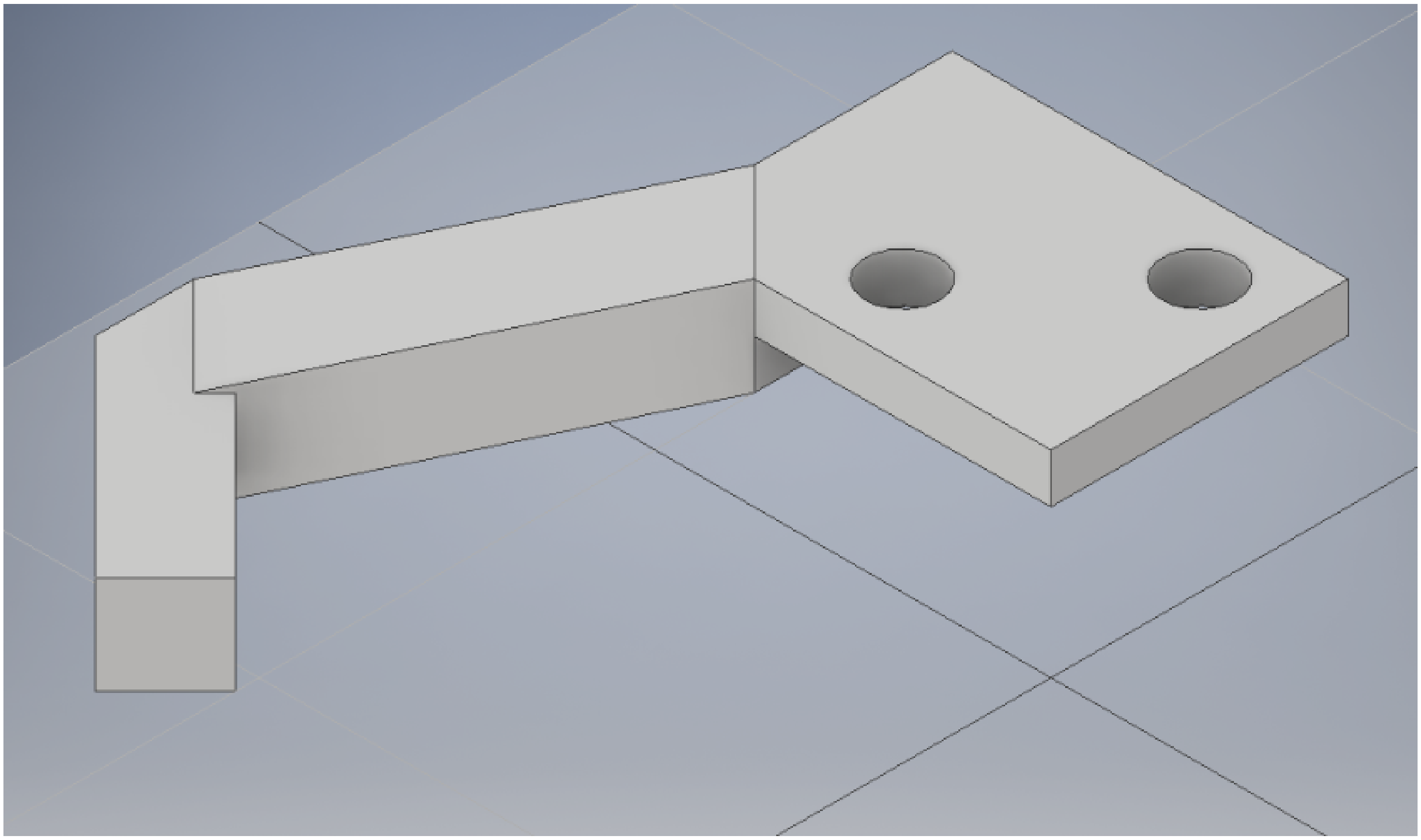


Figure 2: The right arm for the device

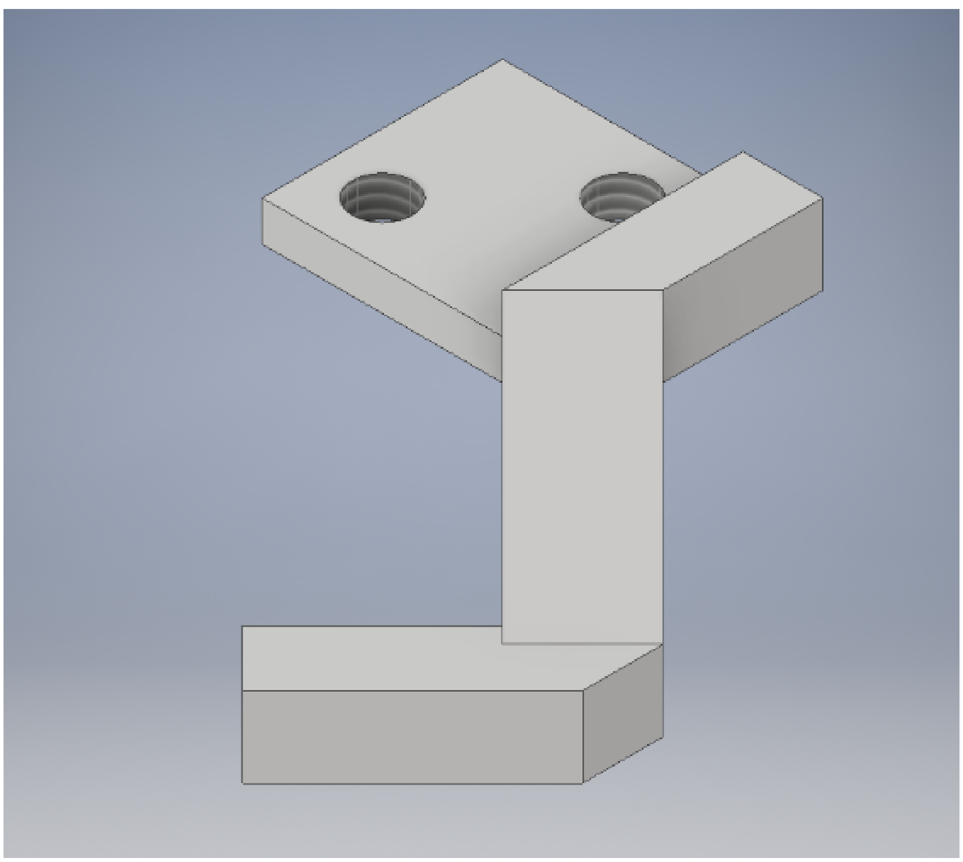


Figure 3: The left arm for the device

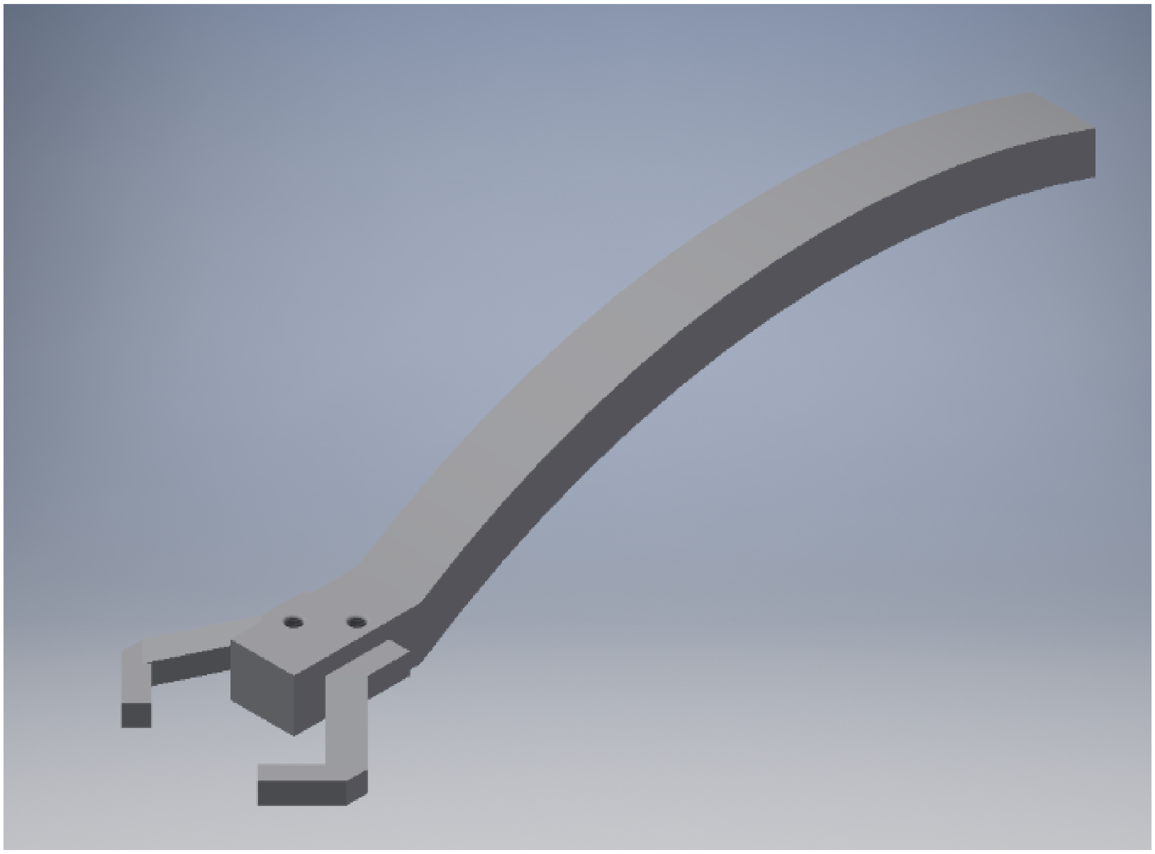


Figure 4: The assembly for the device

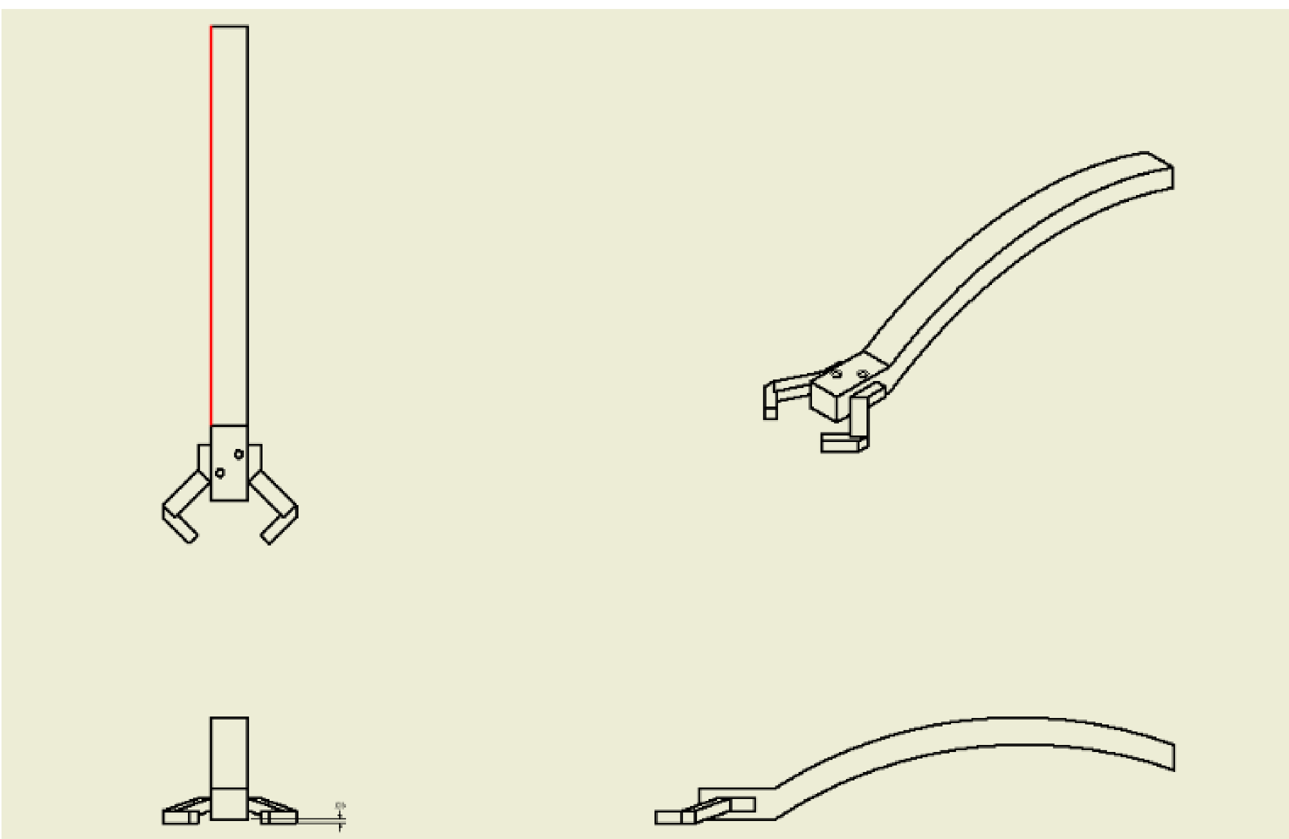


Figure 5: Drawing for the device to be completed with dimensions soon.

Conclusions/action items: The device has been designed and now needs to be approved by the client.

Biosafety

Noah Ruh - Feb 24, 2020, 8:57 PM CST

Title: Biosafety Training

Date: 2/24/2020

Content by: Noah Ruh

Present: N/A

Goals: Prove my training

Content:

University of Wisconsin-Madison

This certifies that NOAH RUH has completed training for the following course(s):

Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date
BIOSAFETY REQUIRED TRAINING	BIOSAFETY REQUIRED TRAINING QUIZ	1/22/2020	

Data Effective: Wed Jan 22 16:55:29 2020
Report Generated: Mon Feb 24 20:56:13 2020

Conclusions/action items: This proves I have completed the biosafety training course

Red Permit

Noah Ruh - Mar 08, 2020, 8:15 PM CDT

Title: Red Permit Training

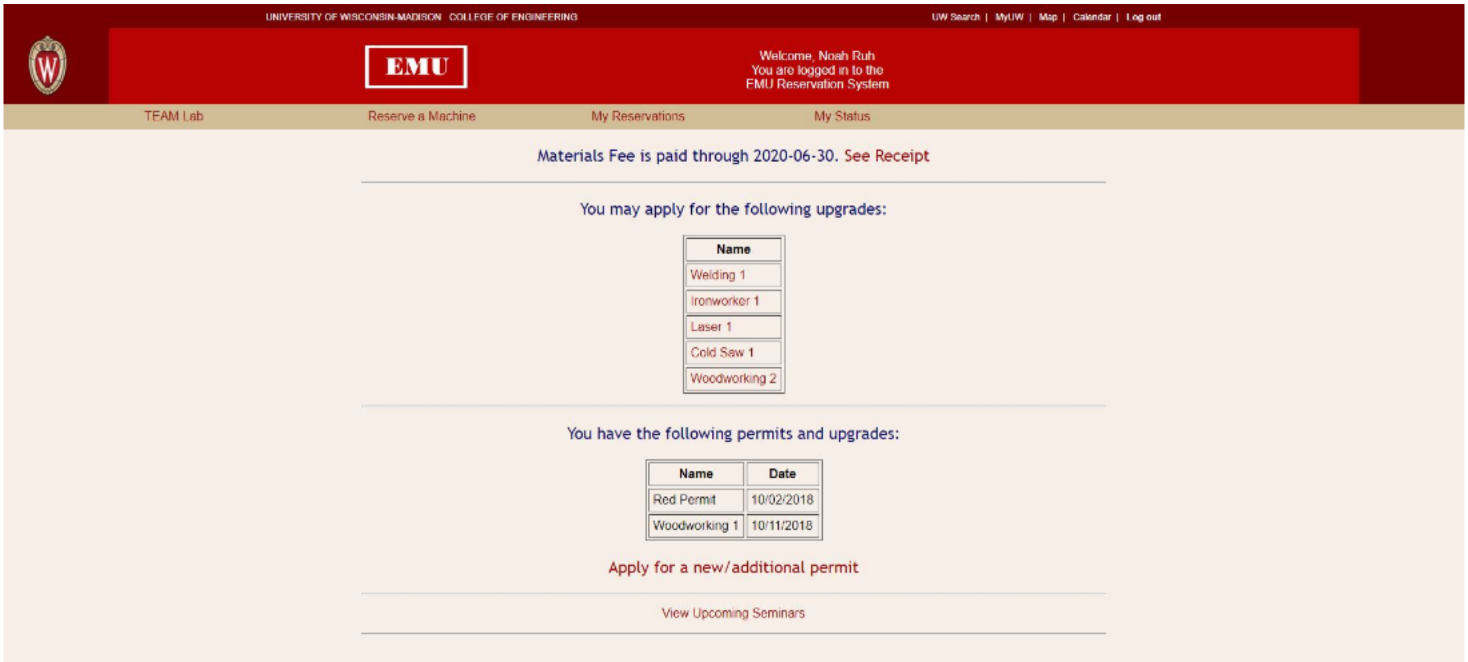
Date: 03/08/2020

Content by: Noah

Present: N/A

Goals: Show red permit training

Content:



Conclusions/action items: In the future I will need to get my Laser 1 upgrade and also the green permit

Sept 25, 2020- Pig Skin Comparison

TATUM RUBALD - Sep 25, 2020, 2:12 PM CDT

Title: Pig Skin Comparison

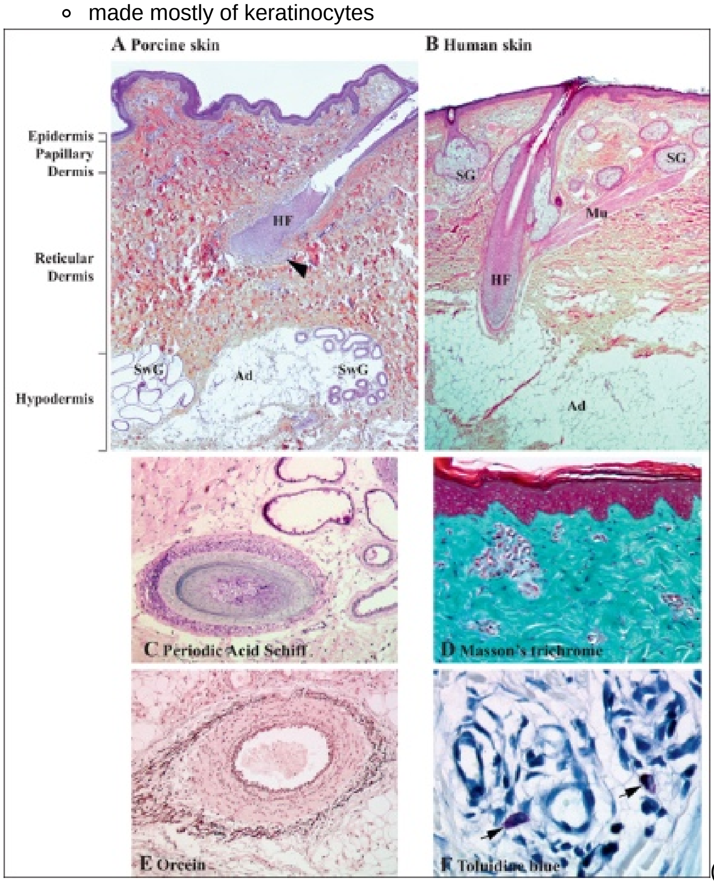
Date: Sept 25, 2020

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: To compare pig skin (what we will be testing our product on) to the epidermis of human skin.

Content:

- animals used to study skin: rabbits, guinea pigs, rats, and mice
    - Pigs are used less often (simply due to longer gestation time makes it harder to obtain)
- Pig skin (and human skin) is composed of 3 layers: epidermis, dermis, hypo dermis
    - We are interested in the epidermis
- Pig skin has a similar epidermis as human skin
    - comparable thickness
    - made mostly of keratinocytes
- 

(porcine skin is pig)

Criteria	Human	Pig
Skin attachment	Firm	Firm
Hair coat	Sparse	Sparse
Epidermis	Thick	Thick
Dermis	Thick	Thick
Panniculus carnosus	Absent	Absent
Healing mechanism	Re-epithelization	Re-epithelization

- Notice how all criteria are the same between pig and human skin
- Pig epidermis: 30 - 140 µm (dependent on location)
    - Human epidermis: 20 - 120 140 µm (dependent on location)
- vascularization of both human and pig skin is similar
    - Both have about 95% collagen and 2% elastic fibers in their extra cellular matrix

Geoskin, 2020. *Top Differences Between Human And Animal Skin | Genoskin*. [online] Genoskin. Available at: <https://www.genoskin.com/human-vs-animal-skin/> [Accessed 25 September 2020].

Conclusions/action items:

Pig skin will be a great alternative for our testing. We should make sure our pig skin sample is taken from an area that has a similar thickness as the epidermis on a female breast.

Oct 6- Research on operating rooms

TATUM RUBALD - Oct 06, 2020, 9:34 PM CDT

Title: Operating room efficiency

Date: Oct 6, 2020

Content by: Tatum rubald

Present: Tatum rubald

Goals: To find out how efficient operating rooms are because our device is targeted at making breast de-epp more efficient.

Content:

Each lost minute in a hospital operating room costs an average of $60 [1]. Operating rooms are expensive to run, and the main goal of almost every hospital is efficiency [2]. All of this additional work does not simply throw away money, but also diverts residents, surgeons, physicians, and nurses from performing other necessary tasks and taking care of patients.

Conclusions/action items:

Our device will save hospitals money and time, further ensuring efficiency of a hospital.

[1] Strate, C., 2020. *The Cost Of A Lost Minute In The OR*. [online] Accessefm.com. Available at: <https://www.accessefm.com/blog/the-cost-of-a-lost-minute-in-the-or> [Accessed 7 October 2020].

[2] James G. Wright, A., 2020. *Improving On-Time Surgical Starts In An Operating Room*. [online] PubMed Central (PMC). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878988/> [Accessed 7 October 2020].

Nov 15: Testing Product Ergonomics

TATUM RUBALD - Nov 15, 2020, 11:10 PM CST

Title: Testing Product Egronomics

Date: Nov 15, 2020

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I will complete research on how to effectively test the ergonomics of our device. This will be useful in our fabrication and testing document.

Content:

Having an ergonomic design will help reduce the physiological and biomechanics stresses that occur during surgery; it can also increase the safety of the patient.

Things to test:

Break into two categories: Design and usage

- The body of the scalpel
    - Weight
    - Shape
    - Angle
    - Grip
    - Balance
- Usage
    - "Skipping"
    - Cut precision
        - depth
        - thickness
    - Ease of use
    - Insertion
    - Force

How to test:

Severity scores of user experience data:

1. I don't believe there is a usability problem at all

2. Cosmetic problem only: does not need to be fixed unless extra time is available for the project

3. Minor usability problem: fixing this should be given low priority

4. Major usability problem: important to fix, should be given high priority

5. Usability catastrophe: imperative to fix before product can be released

Notes and questions for the group:
Surgeons make the initial incision at a 90 degree angle. Once successful, they switch to a 45 degree angle. How will the surgeon use our device to make the initial incision? What angle is intended for after the initial incision is made?

Conclusions/action items:

I have used these notes to create a testing sections for Dr. S:

We will ask our users to answer a series of questions provided to guide them in testing the product. They will rank their experience on a scale of severity scores for user experience:

Severity scores of user experience data:

1. I don't believe there is a usability problem at all

2. Cosmetic problem only: does not need to be fixed unless extra time is available for the project

3. Minor usability problem: fixing this should be given low priority

4. Major usability problem: important to fix, should be given high priority

5. Usability catastrophe: imperative to fix before product can be released

After a rank is given, a short explanation should be written by the user to help guide further prototyping of the product.

We have broken the different testing measurements into two categories: design and usage.The design category will answer questions about weight, shape, angle, grip and balance. The usage section will test, "Skipping", cut precision (both depth and thickness), ease of use, incision insertion, cutting length in time, and force.

Design:

This series of questions should be answered while actively using the device.

1. Weight and Balance
    1. While cutting how is the weight and the weight distribution? Too heavy or too light?
2. Shape
    1. Is the shape of the handle comfortable? Do you prefer the rectangular structure or do you wish there was more?
3. Angle
    1. Is the angle of your wrist comfortable while cutting? Do you feel like you can safely perform a procedure with the angle of the blades and handle?
4. Grip
    1. Is there enough grip on the handle? Is it slippery? Will it slide out of your hand during the procedure?

Usage

1. “Skipping”
    1. Do the blades run smoothly across the skin?
2. Cut precision
    1. Were you able to achieve the depth you wanted?
    2. Was the strip of skin removed a satisfying width? Do you wish to cut off more or less skin during the procedure?
3. Ease of use
    1. Are you able to complete the procedure effectively? Does it feel safe?
4. Incision insertion
    1. Were you able to insert the device? How did you do it? Did it feel safe and comfortable?
5. Length of time for procedure
    1. How long did it take you to complete the procedure? Would this time go down further once more comfortable with the device?

6. Force
    1. How much force (qualitatively) did you have to apply to the device during “skin stripping”? Did it feel similar to regular scalpels? Did it feel safe and comfortable?

Nov 18- Final Product Material

TATUM RUBALD - Nov 18, 2020, 9:36 PM CST

Title: Final Product Material

Date: 11/18/2020

Content by: Tatum Rubald

Goals:

Research a material for our final product that can be autoclaved.

Content:

Our product must be able to withstand autoclaving environments. All surfaces being sterilized must be able to withstand exposure to pure saturated water vapor at 273.2 degrees F.

- Plastics [1]
  - TECAPEEK MT shows no loss of mechanical properties even after more than 1,500 sterilization
  - TECASON P MT shows no loss of mechanical properties after 800 sterilizations.
  - TECAFORM AH MT shows no loss of mechanical properties after 800 sterilizations, but has discoloration after 200 cycles.
  - TECAPRO MT shows no loss of mechanical properties after 800 sterilizations, but has discoloration after 200 cycles (doesn't apply to the black color)
- Metals
  - stainless steel
    - AISI 316L "surgical steel"- very tough and resistant to corrosion
    - Can withstand temperatures higher than 400 degrees C
  - titanium
  - tantalum
  - platinum
  - palladium

[1] https://www.ensingerplastics.com/en-us/shapes/plastic-material-selection/sterilisable-autoclavable

[2] https://matmatch.com/blog/metals-commonly-used-surgical-instruments/

Conclusions/action items:

As a team, we wanted to use metal for our final product. However, I think plastic is a viable option. If not, stainless steal seems like the most commonly used for medical devices.

12/07- Skin Tissue

TATUM RUBALD - Dec 07, 2020, 3:32 PM CST

Title: Epidermis Research

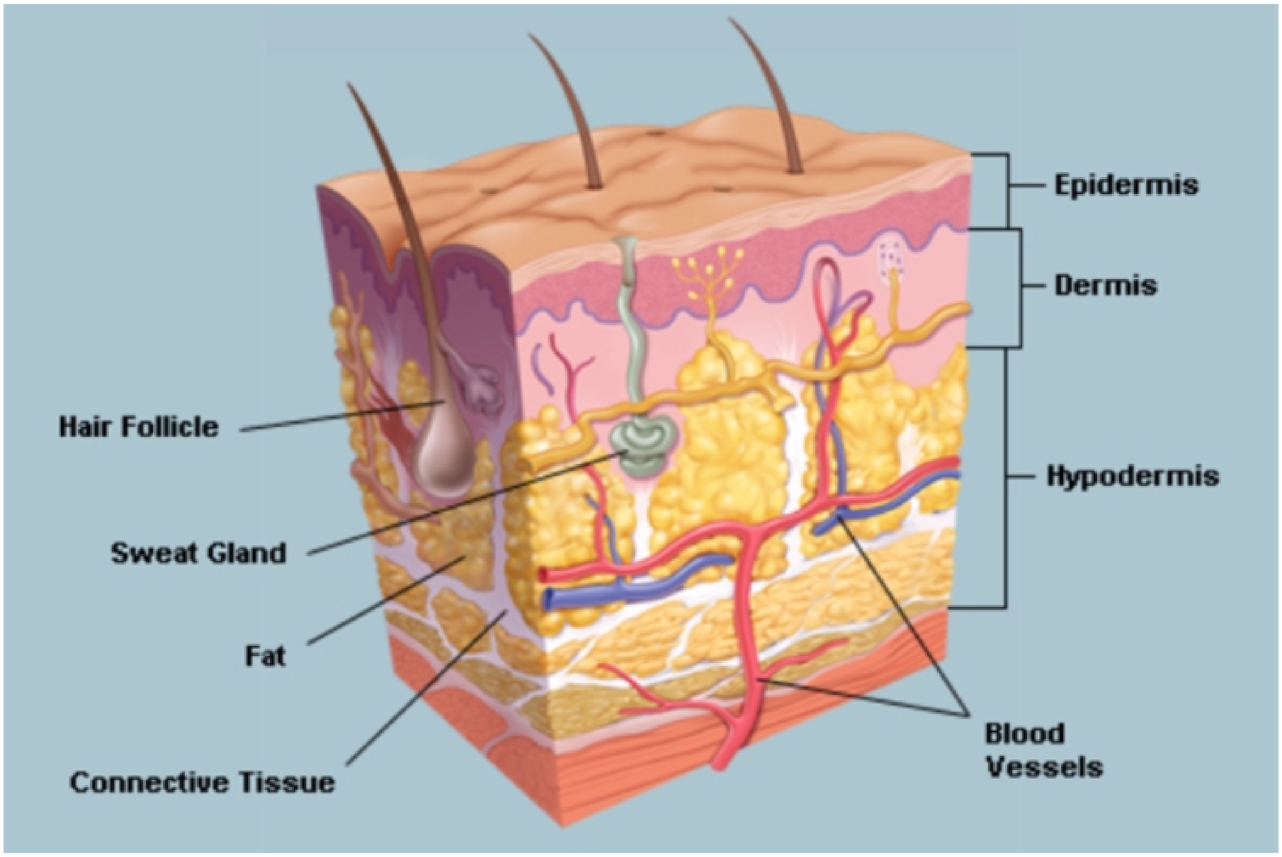
Date: Dec. 12, 2020

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I will find more information on the epidermis of human skin.

Content:



The skin is the largest organ in the body and has a total area of about 20 square feet. The skin protects humans from microbes and the elements. It also helps regulate body temperature and permits sensory sense of touch.

The epidermis provides a waterproof barrier and creates skin tone by special cells called melanocytes which produce melanin.

The dermis contains tough connective tissue, hair follicles and sweat glands.

The hypodermis is made of fat and connective tissue.

Conclusions/action items:

This information will be used in the background section of our paper.

[1] M. Hoffman, “The Skin (Human Anatomy): Picture, Definition, Function, and Skin Conditions,” *WebMD*, 07-Aug-2019. [Online]. Available: https://www.webmd.com/skin-problems-and-treatments/picture-of-the-skin. [Accessed: 07-Dec-2020].

12/07- Epidermis specifics and fragility

TATUM RUBALD - Dec 07, 2020, 3:48 PM CST

Title: Epidermis: Specifics and Fragility

Date: 12/07

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I want to learn more about why the epidermis is so fragile. Also, I am looking for any specific facts about the epidermis that could be relevant to our project.

Content:

The epidermis has four different layers to it. It is composed of stratified and squamous epithelial cells. The four layers of the epidermis are layered according to the maturation of cells. There is the stratum germinativum, stratum spinosum, stratum granulosum, and stratum corneum.
The outermost layer is the stratum corneum, and the innermost is the stratum germinativum which adjoins the epidermis and dermis.

The thickness of the epidermis depends on the level of protection needed at that site on the body, For example, the soles of the feel have a relatively thick epidermal layer, up to 2.3 mm, whereas the thickness on the eyelids is about 0.05 mm thick.

There is no direct blood supply to the epidermis, thus it must rely on the underlying dermis for supply of nutrients. This occurs via diffusion through the dermoepidermal junction, which lies below the stratum germinativum of the epidermis.

Conclusions/action items:

[1] Y. Smith, “What is the Epidermis?,” *News*, 23-Aug-2018. [Online]. Available: https://www.news-medical.net/health/What-is-the-Epidermis.aspx. [Accessed: 07-Dec-2020].

12/08: Breast Reconstruction Issues

TATUM RUBALD - Dec 08, 2020, 3:18 PM CST

Title: Breast Reconstruction Issues

Date: 12/08

Content by: Tatum rubald

Present: Tatum Rubald

Goals: I want to discover what are common issues that arise during breast reconstruction surgeries.

Content:

All from source [1]

- Skin flap quality is an important determinant of surgical outcome
- There are many factors that can increase the risk of wound complications during surgery
    - These include: high BMI's, smoking status, diabetes, steroid use, location and type of incision
- One commonly used technique used to minimize risk in high risk patients is excising the portions of the skin that seem non-viable upon visual assessment
    - Removing the non-viable skin makes it easier to use viable tissue and have a successful surgery.

Conclusions/action items:

[1] Cauley, Ryan P. MD; Liao, Eric C. MD, PhD Deepithelialization and Extended Dermal Apposition: A Technique for Closure of High-risk Incisions in Breast Reconstruction, Plastic and Reconstructive Surgery - Global Open: July 2016 - Volume 4 - Issue 7 - p e802 doi: 10.1097/GOX.0000000000000791

12/08: Epithelium Nutrients

Title: Epithelium

Date: 12/08

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I am going to research why the epithelium does not have blood vessels, and how it receives nutrients.

Content:

The epidermis has no blood vessels, and cells in the deeper layers of the epithelium are nourished by diffusion from blood capillaries present in the upper layers of the dermis.

The papillary of the dermis is made of loose areolar connective tissue. It is the papillae on the dermis's papillary layer that extend up to the epidermis and have terminal networks of blood capil

Conclusions/action items:

I found out how the epidermis receives its nutrients, this should go in our final research paper under the background section.

[1] Libretexts, “5.4E: Blood Supply to the Epidermis,” *Medicine LibreTexts*, 14-Jul-2020.
[Online]. Available:https://med.libretexts.org/Bookshelves/Anatomy_and_Physiology/Book:_Anatomy_and_Physiology_(Boundless)/5:_Integumentary_System/5.4:_Functions_of_the_Integume
[Accessed: 09-Dec-2020].

Sept 13 - Competing Devices

TATUM RUBALD - Sep 13, 2020, 10:15 PM CDT

Title: Zimmer Skin Graft Blade

Date: Sept. 13, 2020

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I want to find the price and other information on competing medical devices.

Content:

- Manufacturer: Zimmer
- Application: Skin Graft Blade
- Price: $825.99 for 10 devices
- Website: https://serfinitymedical.com/products/zimmer-skin-graft-blade-sterile-zimmer-880000010?variant=30757970837579&gclid=Cj0KCQjwhvf6BRCkARIsAGl1GGiH_oj0_Elns_GVM9kgilIe3HwCalQXU0-MY9sxZSlYCBKwKi9PvzsaAhdXEALw_wcB

Conclusions/action items:

I will continue to research other devices on the market.

TATUM RUBALD - Sep 13, 2020, 10:15 PM CDT

235478_241x211.jpg(4.9 KB) - download

Oct 6- Epicut

TATUM RUBALD - Oct 06, 2020, 9:18 PM CDT

Title: Epicut

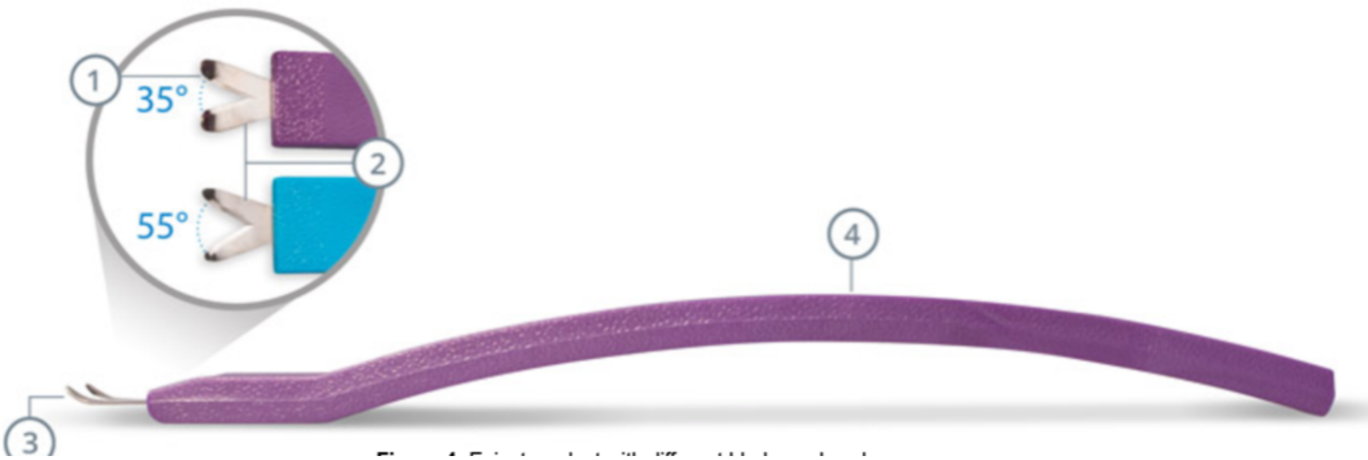
Date: Oct 6

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: Determine how the device is used and the different features it has.

Content:



There is a current device used for breast de-epithelization known as the "Epicut". This device resembles a slightly modified scalpel with one v-shaped curved blade. The curves in the blade control the depth at which the epidermis is stripped. The angle of the v-blade is either 35 degrees or 55 degrees. The different angles allow controlled and precise skin removal while cutting ensuring that the vascularity of the dermis is not compromised. A surgeon would use the epicut by dragging it across the skin, removing the epidermis in thin strips. [1]

Conclusions/action items:

This design will be important while creating our design due to the fact that it is exactly what the doctor is looking for. We will incorporate different aspects of this design into our own.

[1] MicroAire Surgical Instruments, LLC. 2020. *Microaire Epicut™ De-Epithelialization Device*. [online] Available at: <https://www.microaire.com/products/epicut/> [Accessed 1 October 2020].

Oct 14- Scalpel Dimension and Overview

TATUM RUBALD - Oct 14, 2020, 10:44 PM CDT

Title: Scalpel Dimension and Overview

Date: Oct 14, 2020

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I will find the dimensions of a scalpel, along with the weight and angle at which a doctor holds a scalpel. We will use these dimensions and integrate them into our design to make the product feel normal to a surgeon.

Content:

[1]

- Every surgical blade is numbered to indicate its size and its shape
    - handles numbered from 1-9 and surgical blades a number from 10-20
- Surgical blade handles vary in size, weight, and length to provide the surgeon with the optimal precision, balance and visibility.
- Blade is usually discarded, handle is sterilized and reused

[2]

- I found a source where surgeons rated different scalpel handles
    - They rated different aspects of the prototypes
- Too heavy of a scalpel- fatigue
- too light- limited precision
- 43-66 g was the optimal weight
- Also must think about balance
- "the round design allows them to more easily make precise and curved cuts than with a traditional scalpel"

Conclusions/action items:

The second source I found is an entire biomedical engineering research paper on the ergonomics of an optimal scalpel. I think this paper is extreamly relevant to our project. We should incorporate the ideas and findings of this research paper into the handle of our design.

[1] USA Medical and Surgical Supplies. 2020. *Surgical Blades: Which Scalpels Are Right For Your Operating Room?*. [online] Available at: <https://www.usamedicalsurgical.com/blog/surgical-blades-which-scalpel-is-right-for-your-operating-room> [Accessed 15 October 2020].

[2] paper attached as a PDF

TATUM RUBALD - Oct 14, 2020, 10:45 PM CDT

2020-05-13

Designing of Ergonomic Scalpel Handles with Optimized Weight and Balance

Olivia West Martin
Worcester Polytechnic Institute

Priscilla Thanh Truc Pham
Worcester Polytechnic Institute

Rachel Schiebel
Worcester Polytechnic Institute

Wesley Paul
Worcester Polytechnic Institute

Designing_of_Ergonomic_Scalpel_Handles_with_Optimized_Weight_and.pdf(4.5 MB) - download

Sept 16, 2020- Design Brainstorm

TATUM RUBALD - Sep 16, 2020, 6:36 PM CDT

Title: de-epithelialization Device Idea

Date: Sept 19th, 2020

Content by: Tatum Rubald

Present: Tatum Rubald

Goals: I will sketch one of the first ideas I had about this device.

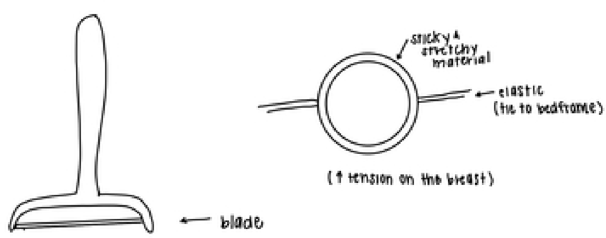
Content:

Photo Below.

Conclusions/action items:

I will continue to produce more product ideas.

TATUM RUBALD - Sep 16, 2020, 6:37 PM CDT



IMG_0481.jpg(154.1 KB) - download

Pig's Skin Research

COLLEEN CUNCANNAN - Oct 05, 2020, 11:17 PM CDT

Title: Pig's Skin Research

Date: 9/15/2020

Content by: Colleen Cuncannan

Present: Colleen Cuncannan

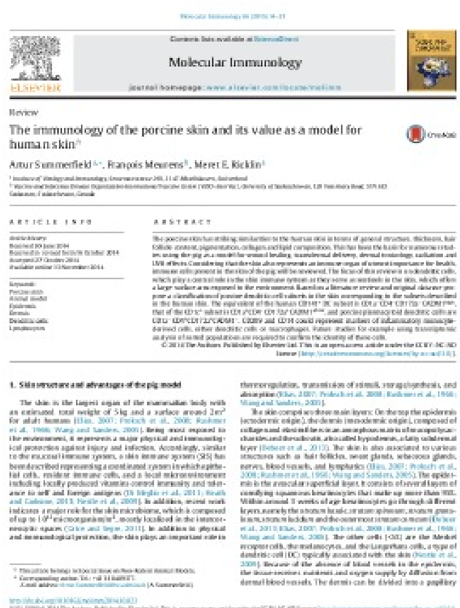
Goals: To better understand if the epidermis of pig's skin is comparable to that of human skin.

Content:

The research article below indicates that pig skin is extremely comparable to human skin as indicated by their similar thickness, hair follicle content, collagen and lipid composition. Therefore, if the group only has access to pig skin for the testing process of the device, it would be reasonable to assume that if the device was successful during use on pig skin, then it should have a modicum of success on human skin. However, if this is the case, more in depth research should be conducted to further detail why pig skin is acceptable for the testing of our device. This research would include more specific epidermis thickness values, tissue tension and toughness data. Additionally, if the samples are excess after a procedure or study, they will most likely be dried out. This could impact our testing in ways the group should research to foresee.

Conclusions/action items: Pig and human skin are comparable enough that the group's device could be tested on it and the results could be reasonably extrapolated to determine the effectiveness of the device on human skin.

COLLEEN CUNCANNAN - Sep 25, 2020, 1:56 PM CDT


Molecular Immunology

Review

The immunology of the porcine skin and its value as a model for human skin

Artur Summerfield, François Meurens, Meret E. Ricklin

1-s2.0-S0161589014002880-main.pdf(2 MB) - download

Human skin thickness

COLLEEN CUNCANNAN - Oct 05, 2020, 11:20 PM CDT

Title: Skin thickness research

Date: 10/1/2020

Content by: Colleen Cuncannan

Present: Colleen Cuncannan

Goals: To better understand the thickness of human breast tissue, so our device can be tailored to that area of the body.

Content:

The PDF below is a study on the thickness of human breast tissue. Knowledge of this information is essential to the success of the team and thus the creation of the device because without an understanding of the thickness of breast epidermis, the device could cut too shallow or cut too deep and damage the underlying vasculature. The study demonstrated the breast tissue had epidermis thickness ranging from 1.44mm - 0.25mm. This range is extremely large, meaning that the device will need to be dynamic in order to accommodate for varying skin thickness.

Conclusions/action items: In order for the group's device to be successful and safe for use during surgery, it will need to be dynamic enough to deal with varying epidermis thicknesses.

COLLEEN CUNCANNAN - Oct 01, 2020, 1:44 PM CDT

Technical Note: Skin thickness measurements using high-resolution flat-panel cone-beam dedicated breast CT

I. INTRODUCTION

II. METHODS AND MATERIALS

Skin_Thickness_Research_Article.pdf(605.9 KB) - download

Epidermis Research

COLLEEN CUNCANNAN - Dec 06, 2020, 1:59 PM CST

Title: Epidermis research

Date: 12/6/2020

Content by: Colleen Cuncannan

Present: Colleen Cuncannan

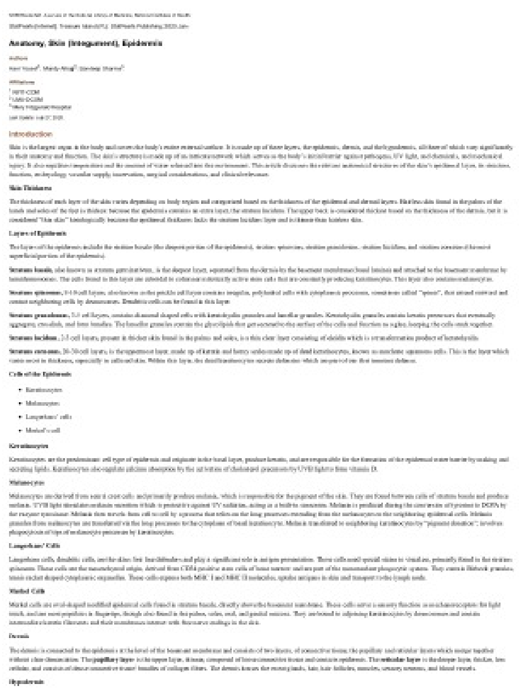
Goals: To better understand human breast tissue so our device can be tailored to that area of the body.

Content:

The PDF below is a research paper detailing that human skin is composed of three layers, the epidermis, the dermis, and the subcutaneous tissue. De-epithelialization is the process by which the epidermis is removed from the rest of the skin. The epidermis is the exterior layer of the skin and is composed of Keratinocytes, Melanocytes, Langerhans' cells, and Merkel's cells. Keratinocytes make up the majority of the epidermal layer and produce the protein keratin as well as help create a water barrier on the skin's exterior. Melanocytes produce melanin, which gives skin its pigment and protects cells from UV radiation. Langerhans' cells or dendritic cells are a part of the body's adaptive immune response and contribute to antigen presentation. Merkel cells are responsible for our light touch sensation and are found in high concentrations on the fingertips. Unlike underlying vasculature, the epidermis lacks blood vessels and receives its supply of nutrients from the dermis through diffusion, meaning its largely dependent from the dermal layer beneath it. However, in order to preserve the underlying vasculature in the dermis and subcutaneous tissue, the process of de-epithelialization must be precise as the epidermis of breast tissue is only about .3mm thick.

Conclusions/action items: The fragility of this skin layer combined with its lack of tension makes device creation increasingly challenging as damage to the dermis can pose serious complications for the patient. Additionally, the current methods for de-epithelialization possess significant room for inconsistencies in cut depth. Extensive knowledge concerning the properties of breast tissue are essential in understanding the nuance and complexity needed to fabricate a successful device.

COLLEEN CUNCANNAN - Dec 06, 2020, 2:01 PM CST


Anatomy, Skin (Integument), Epidermis

Introduction

Anatomy_Skin_Integument_Epidermis_-_StatPearls_-_NCBI_Bookshelf.pdf(445.2 KB) - download

Dermatome Research

COLLEEN CUNCANNAN - Oct 05, 2020, 11:26 PM CDT

Title: Dermatome and other skin grafting tools research

Date: 10/1/2020

Content by: Colleen Cuncannan

Present: Colleen Cuncannan

Goals: To better understand how existing designs work and what makes the effective/ineffective.

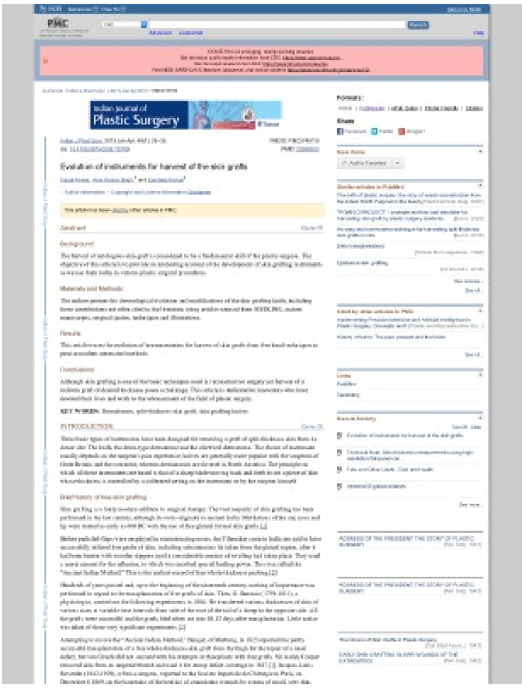
Content:

The article goes into detail about the dermatome's history, evolution, and function. The dermatome is designed to remove skin on areas where tissue tension is high. However, the tissue our client works on is low in tension, which is why a dermatome would be inefficient and ineffective. In order for the team's device to be successful, increasing skin tension will be essential.

Conclusions/action items:

Though the dermatome has merit in terms of skin grafting when tension in the skin is high, the device would be ineffective for use on breast tissue. However, the group should look at the design as a baseline for our own.

COLLEEN CUNCANNAN - Oct 01, 2020, 1:56 PM CDT



Indian Journal of Plastic Surgery

Evolution of instruments for harvest of the skin grafts

Evolution_of_instruments_for_harvest_of_the_skin_grafts.pdf(1.6 MB) - download

Epicut Research

COLLEEN CUNCANNAN - Dec 06, 2020, 2:07 PM CST

Title: Epicut Research

Date: 12/6/2020

Content by: Colleen Cuncannan

Present: Colleen Cuncannan

Goals: To better understand how the Epicut functions so the group can maximize the success of our own device with this knowledge in mind.

Content:

The PDF below is a study on the efficacy of the Epicut for de-epithelialitazion. This device resembles a slightly modified scalpel, however, it has one v-shaped, curved blade. The curves in the blade control the depth at which the skin is removed. The angle of the v-blade is set at either 35 degrees or 55 degrees. The different angles allow controlled and precise skin removal, ensuring that the vascularity of the dermis is not compromised. A surgeon would use the epicut by dragging it across the skin, removing the epithelial layer of skin in thin strips.

Conclusions/action items: The group can use this knowledge to compare the current prototype to the Epicut and its ability to be successful.

COLLEEN CUNCANNAN - Dec 06, 2020, 2:07 PM CST

VIEWPOINTS

GUIDELINES

Viewpoints

Sentinel Lymph Node Biopsy in the Setting of Conjunctival Melanoma

212e www.PRSjournal.com

Efficacy_of_Epicut_Deepithelization_Blade_in.86.pdf(9.5 MB) - download

Connectivity of Scalpel Blades

COLLEEN CUNCANNAN - Oct 20, 2020, 9:53 AM CDT

Title: Scalpel Blade Connectivity Notes

Date: 10/20/2020

Content by: Colleen Cuncannan

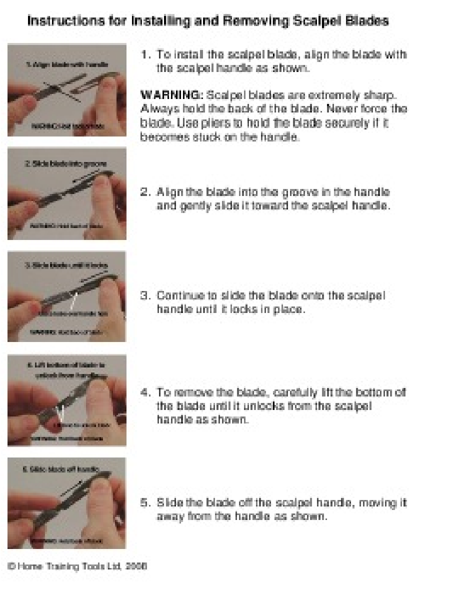
Present: Colleen Cuncannan

Goals: To better understand the way scalpel blades connect to their handles, so we can model the arms of our device in a way that the blades will connect in the same way.

Content: The PDF below shows visuals of the way a scalpel is connected to a handle. This gives the group a general idea about the mechanics of this process, so the group can come up with realistic design ideas moving forward. As evidenced by the visuals below, the group will need to know the specific dimensions associated with the size 15 scalpel blade and mimic the scalpel blade it attaches to exactly.

Conclusions/action items: In order for the connectivity in our device to be correct and effective, the arms of our device must be tailored to the scalpel blade we seek to attach to it. This is essential because if we don't, the blades may be wobbly, creating increased patient and surgeon risk. There was talk that there were already 3D models that have exact measurements already in solid works, so that would be a viable option as long as we check the accuracy.

COLLEEN CUNCANNAN - Oct 20, 2020, 9:43 AM CDT


Instructions for Installing and Removing Scalpel Blades

1. To install the scalpel blade, align the blade with the scalpel handle as shown.

WARNING: Scalpel blades are extremely sharp. Always hold the back of the blade. Never force the blade. Use pliers to hold the blade securely if it becomes stuck on the handle.

2. Align the blade into the groove in the handle and gently slide it toward the scalpel handle.

3. Continue to slide the blade onto the scalpel handle until it locks in place.

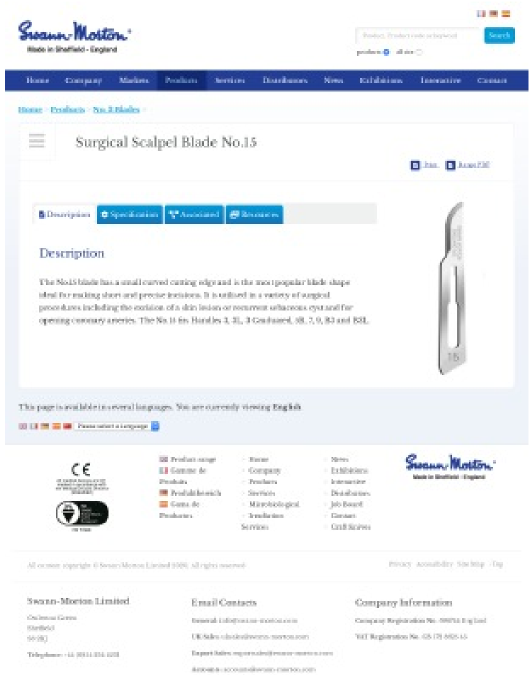
4. To remove the blade, carefully lift the bottom of the blade until it unlocks from the scalpel handle as shown.

5. Slide the blade off the scalpel handle, moving it away from the handle as shown.

© Home Training Tools Ltd. 2008

Scalpel_Connectivity.pdf(51.8 KB) - download

COLLEEN CUNCANNAN - Oct 20, 2020, 9:54 AM CDT



Surgical_Scalpel_Blade_No.15._Swann-Morton_Ltd.pdf(94.5 KB) - download

current methods of maintaining skin tension during deepithelialization

MICHAEL CHIARIELLO - Sep 22, 2020, 4:15 PM CDT

Title: "Deepithelialization of breast in reduction mammoplasty using cable tie as breast tourniquet" research article summary and analysis

Date: 9/22/2020

Content by: Michael Chiariello

Goals: individual work

Content:

Deepithelialization is an arduous, but necessary process that occurs before every breast reduction surgery. Tension in the skin must be maintained in order to accurately remove the epidermis. An assistant usually ensures this tension on the skin by applying traction. However, maintaining tension without the aid of an assistant is much more difficult. One current method for maintaining tension is tying the breast with sterile gauze. Another method of maintaining tension is tying the breast with a tourniquet made of an 8 1/2 inch glove and Kocher forceps. The suggested new method for maintaining skin tension in the breast is a standard plastic cable tie that has been sterilized.

Conclusions/action items:

All current methods of maintaining tension during deepithelialization of the breast include tying the breast with a tourniquet. The materials from which the tourniquet is made varies. However, the general idea remains the same. I will ask the client if there are any more ways in which skin tension can or is currently being applied during breast reduction surgery.

MICHAEL CHIARIELLO - Sep 22, 2020, 3:54 PM CDT


Indian Journal of
Plastic Surgery

Deepithelialization of breast in reduction mammoplasty using cable tie as breast tourniquet

Deepithelialization_of_breast_in_reduct...y_using_cable_tie_as_breast_tourniquet.pdf(330.2 KB) - download

skin anatomy

MICHAEL CHIARIELLO - Dec 04, 2020, 8:37 AM CST

Title: Anatomy of the Skin in Relation to a De-epithelialization Device

Date: 12/4/2020

Content by: Michael Chiariello

Goals: individual work

Content:

There are two important aspects of skin anatomy in relation to de-epithelialization. One is the connection between the epidermis and the dermal layer. The deepest layer of the epidermis is the stratum basale. Mitotically active stem cells in the stratum basale constantly produce keratinocytes, epidermal skin cells. The most superficial layer of the dermis is the papillary layer, a thin layer of loose connective tissue. These layers differ in the type of cells of which they are composed. The epidermis is composed of ectodermal tissue whereas the dermis is composed of mesodermal tissue.

The other important aspect of skin anatomy is the vasculature of the dermal layer. The epidermis has no blood supply of its own. The Dermis however has blood vessels of its own. This is why epidermal skin cells can be scraped off of the skin, and no bleeding will follow.

Conclusions/action items:

This article simply differentiated between the epidermis and dermis, and did not detail the connection between these two layers. This section was somewhat unhelpful. The vasculature of the dermis is significant however. Serious damage to blood vessels in the dermis could occur if our device cuts too deep or is at all imprecise. Therefore, the guard that we are using for our device only allows incisions of 0.3 mm deep into the skin. This ensures only the epidermal layer is removed.

MICHAEL CHIARIELLO - Dec 04, 2020, 8:38 AM CST

Warning: The NCBI web site requires JavaScript to function. more...

NCBI Bookshelf. A service of the National Library of Medicine, National Institutes of Health.

StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-.

Anatomy, Skin (Integument), Epidermis

Authors

Hani Yousef[1]; Mandy Alhajj[2]; Sandeep Sharma[3].

Affiliations

[1] NYIT-COM
[2] LMU-DCOM
[3] Mery Fitzgerald Hospital

Last Update: July 27, 2020.

Introduction

Skin is the largest organ in the body and covers the body's entire external surface. It is made up of three layers, the epidermis, dermis, and the hypodermis, all three of which vary significantly in their anatomy and function. The skin's structure is made up of an intricate network which serves as the body's initial barrier against pathogens, UV light, and chemicals, and mechanical injury. It also regulates temperature and the amount of water released into the environment. This article discusses the relevant anatomical structures of the skin's epidermal layer, its structure, function, embryology, vascular supply, innervation, surgical considerations, and clinical relevance.

Skin Thickness

The thickness of each layer of the skin varies depending on body region and categorized based on the thickness of the epidermal and dermal layers. Hairless skin found in the palms of the hands and soles of the feet is thickest because the epidermis contains an extra layer, the stratum lucidum. The upper back is considered thickest based on the thickness of the dermis, but it is considered "thin skin" histologically because the epidermal thickness lacks the stratum lucidum layer and is thinner than hairless skin.

Layers of Epidermis

The layers of the epidermis include the stratum basale (the deepest portion of the epidermis), stratum spinosum, stratum granulosum, stratum lucidum, and stratum corneum (the most superficial portion of the epidermis).

Stratum basale, also known as stratum germinativum, is the deepest layer, separated from the dermis by the basement membrane (basal lamina) and attached to the basement membrane by hemidesmosomes. The cells found in this layer are cuboidal to columnar mitotically active stem cells that are constantly producing keratinocytes. This layer also contains melanocytes.

Stratum spinosum, 8-10 cell layers, also known as the prickle cell layer contains irregular, polyhedral

Anatomy_Skin_Integument_Epidermis_-_StatPearls_-_NCBI_Bookshelf.htm(54.6 KB) - download

"Peeling Orange" method

MICHAEL CHIARIELLO - Sep 22, 2020, 3:49 PM CDT

Title: "Peeling Orange" research article summary and analysis

Date: 9/12/2020

Content by: Michael Chiariello

Goals: Individual Work

Content:

This article describes an alternative method for deepithelialization. This procedure is specific to breast reduction surgery. It is performed by first cutting the skin into vertical strips about one to two mm apart with a scalpel. These strips are then removed individually by quick strokes with the scalpel blade while simultaneously being pulled perpendicularly to the surface.

Conclusions/action items:

This method is significant because the client recommended an article, "Button Holes: Novel Deepithelialization Technique in Reduction Mammaplasty," that disputes this practice. The article she endorsed recommended long purposeful strokes rather than many quick strokes with the scalpel blade. The longer strokes supposedly result in a more consistent thickness of the dermis following deepithelialization.

MICHAEL CHIARIELLO - Sep 12, 2020, 12:52 PM CDT

CLINICAL INSIGHTS

Peeling Orange: Rapid Deepithelialization in Reduction Mammaplasty

peeling-orange-deepithelialization.pdf(88.6 KB) - download

Materials for Device Prototype

MICHAEL CHIARIELLO - Oct 20, 2020, 11:56 AM CDT

Title: Materials for the Device Prototype Notes

Date: October 20, 2020

Content by: Michael Chiariello

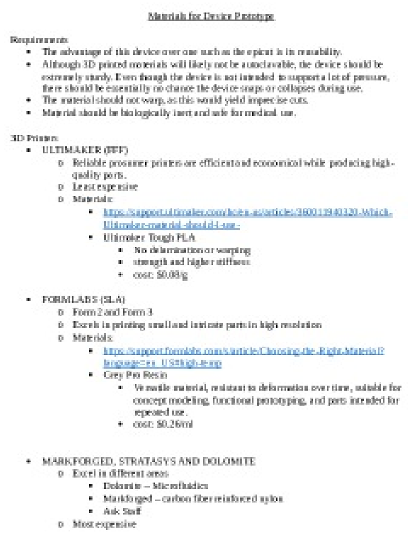
Goals: Individual Work

Content: notes attached

Conclusions/action items:

The design prototype must be constructed with a material that cannot be warped. In addition, this material should be extremely sturdy. Breaking during use should not be a concern for the surgeon during an operation. Therefore, of the 3D printing materials available at the UW Makerspace, there are two viable candidates. Tough PLA could be used to make the device. This material uses an Ultimaker (FFF) 3D printer. It costs $0.08/g which is inexpensive relative to the other materials. PLA is the most common material used for 3D printing. Tough PLA has similar properties to PLA, but is more sturdy and less resistant to warping. Another material that could be used for the device is grey pro resin. This material uses a Formlabs (SLA) 3D printer, which specializes in making smaller parts with great detail. Similarly to the Tough PLA, the grey pro resin is durable, resistant to warping, and sturdy. This material costs $0.26/ml. It should be noted that these materials would be ideal for the prototype. Neither of these materials are autoclavable or medical grade. However, these two materials would be more than sufficient for building and testing the design.

MICHAEL CHIARIELLO - Oct 20, 2020, 11:34 AM CDT



Materials for Device Prototype

Requirements:
- The advantage of this device over one such as the epicut is in reusability.
- Although 3D printed materials will likely not be autoclavable, the device should be extremely sturdy. Even though the device is not intended to support a lot of pressure, there should be essentially no chance the device snaps or collapses during use.
- The material should not warp, as this would yield imprecise cuts.
- Material should be biologically inert and safe for medical use.

3D Printers:
- ULTIMAKER (FFF)
  - Reliable prosumer printers are efficient and economical while producing high-quality parts.
  - Least expensive
  - Materials:
    - https://support.ultimaker.com/hc/en-us/articles/360011940320-Which-Ultimaker-material-should-I-use-
    - Ultimaker Tough PLA
      - No delamination or warping
      - strength and higher stiffness
      - cost: $0.08/g
- FORMLABS (SLA)
  - Form 2 and Form 3
  - Excels in printing small and intricate parts in high resolution
  - Materials:
    - https://support.formlabs.com/s/article/Choosing-the-Right-Material?language=en_US#high-temp
    - Grey Pro Resin
      - Versatile material, resistant to deformation over time, suitable for concept modeling, functional prototyping, and parts intended for repeated use.
      - cost: $0.26/ml
- MARKFORGED, STRATASYS AND DOLOMITE
  - Excel in different areas
    - Dolomite – Microfluidics
    - Markforged – carbon fiber reinforced nylon
    - Ask Staff
  - Most expensive

Materials_for_Device_Prototype.docx(16 KB) - download

Materials for the Final Design

MICHAEL CHIARIELLO - Nov 29, 2020, 10:08 PM CST

Title: Materials for the Final Design

Date: November 29, 2020

Content by: Michael Chiariello

Goals: Individual Work

Content:

The prototype of the modified epicut device was 3D printed in two different materials with varying levels of success. When the High Temp material was used, it yielded a product with warped edges rather than clean and accurate edges. This prototype could not be assembled. When the device was printed with Tough PLA, the edges were much more precise and accurate. The pieces fit together perfectly. Although this material worked for assembling the prototype, the final product should be made of a much more durable material that can, without a doubt, withstand autoclave cleaning.

In order to find the ideal material for the final product, it is important to examine similar products that are currently on the market. These materials are proven, durable, trusted by medical professionals. Therefore, the materials of similar handheld medical devices, such as a scalpel, should be seriously considered. The most significant difference between a device such as a scalpel and the modified epicut is amount of direct contact with the skin. The modified epicut is designed to glide across the skin. Therefore, the material should neither catch on the epidermis, nor impede movement while being pulled across the surface of the skin.

The two most common materials used for the handles of reusable scalpels are medical grade stainless steel and a silicone material. Both these materials can be autoclaved. However, the silicone grip, if used for the modified epicut, would impede movement of the device across the skin. Therefore, the medical grade stainless steel is the ideal material for the final product of the modified epicut.

I will attach the url to two companies that describe their use of stainless steel in their scalpel blades:

https://www.blacksmithsurgical.com/surgical-instruments/scalpel-handles

https://us.vwr.com/store/category/scalpel-handles/22028970

Conclusions/action items:

Although the 3D printed prototype of the modified epicut is a good representation of how the design, stainless steel appears to be the most ideal material for creating the handle and arms of the final modified epicut product.

Roller Design

MICHAEL CHIARIELLO - Oct 06, 2020, 4:59 PM CDT

Title: Roller Design First Draft

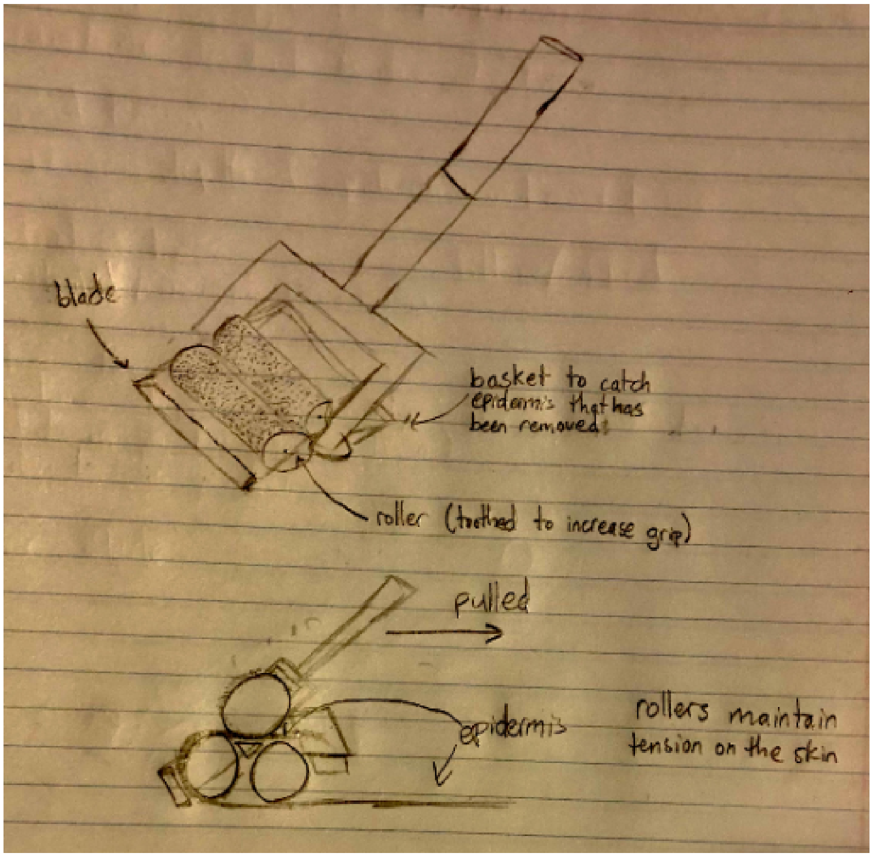
Date: 9/24/2020

Updated: 10/24/2020

Content by: Michael Chiariello

Goals: show first draft of the roller design

Content:



This design consists of three rolling cylinders. As the device is pulled backwards on the surface of the skin, the rollers will pull the epidermis taught as the blade separates the epidermis from the dermis.

Conclusions/action items:

This design was made with the intention of solving the issue of lack of tension in the skin. Tension is necessary for achieving precise and accurate removal of the epidermis. The rollers would help maintain this tension. This is only a preliminary design, and will be improved upon.

Update:

Although rollers would maintain adequate tension in the skin, it is likely that this design would cause the epidermis to tear. Because the epidermis is only about 0.3 mm thick, it can be fragile. In addition, the assembly of this prototype is not feasible. The rollers would have to be about 0.3 mm apart in order to properly grip the epidermis that is being removed. Therefore, this idea is being abandoned.

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: