AUTOMATIC DE-EPITHELIALIZATION DEVICE

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Abstract

De-epithelialization is a technique used to remove the epithelial layer of skin. Though necessary, this process is tedious, time consuming, and requires multiple people to maintain tension. In addition, the surgeon is responsible for maintaining the thickness of the removed layer of skin, ensuring that the underlying vasculature of the patient remains unharmed. The client often performs de-epithelialization for breast reduction mammaplasty and breast reconstruction and desires a device that can facilitate this process, reducing the time it takes and increasing the efficiency of the process while maintaining patient safety and procedure effectiveness. The Epicut is a competing device made specifically for the de-epithelialization of breast tissue. However, its price and limited usage time serve as a significant barrier. The team's current solution to this problem is a Modified Epicut design, which takes advantage of the working principle behind the Epicut while implementing design changes that allow for the device to be reused. The final 3D printed prototypes did not reflect the final design, with several flaws with the scalpel attachment arms and handle arising as a result of the fabrication method. The testing data did not validate the team's goals, with an average success rate of 11.25% and a failure to meet the 0.3mm thickness the client desired. In the future, the team sees the fabrication method and material as an area of improvement. Instead of attempting to 3D print the device, surgical steel and relevant machining techniques should be used. Additionally, different testing protocols should be implemented to obtain results that will better reflect the device's performance in actual operations.

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I. Introduction

Motivation

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]. Wasted time diverts residents, surgeons, physicians, and nurses from performing necessary tasks and taking care of patients.

The team's device will increase efficiency in the operating room, saving time and money. The device will focus on reducing the time it takes for a surgeon to perform the de-epithelization (the removal of the upper most layer of skin, the epidermis) of breast tissue during breast reconstruction. Along with this function,, we hope to apply this device to other de-epping operations to decrease operating time across many surgeries.

Current Methods

De-epithelialization is the surgical process by which the epidermis is removed from the rest of the skin [3]. The current protocol for de-epithelialization consists of a surgeon manually scoring the skin with a scalpel down to the dermis and removing the strips of skin between scores with sharp scissors or a scalpel. Some surgeons prefer the "buttonhole" technique where holes are created in skin that has already been removed. This allows the surgeon to create more tension on the tissue that has yet to be removed [4]. However, these processes can be time consuming depending on the location of the procedure, as skin thickness and tension vary across different parts of the body [5]. The client mostly uses de-epithelialization during breast reduction surgeries, so the group will focus on creating a device targeted towards use during this procedure; however, the overarching goal is that the device will be dynamic enough to be used for any operation where de-epithelialization is necessary. The team hopes to eliminate the inefficiency and reduce the time it takes for this process to less than 15 minutes, as well as reduce inconsistencies in cut depth that can lead to damage of the patient's vasculature [6].

Problem Statement

De-epithelialization is a process in which a surgeon removes the epidermal layer from 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. The process can also be frustrating due to lack of tension in the skin, which can lead to inconsistencies in cut depth. The current method poses risk for patients, as damaging the underlying vasculature is easily done with the lack of restriction in terms of cut depth. The team has been tasked with creating a device to replace the current techniques for manual de-epping.

For the device to be considered successful, it should create tension in the skin and significantly reduce the time required to complete the procedure.

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 for other de-epithelialization procedures around the body.

II. Background

Relevant Biology and Physiology

Human skin is composed of three layers, the epidermis, dermis, and subcutaneous tissue (hypodermis) as seen in Figure 1 [7]. 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 [8]. 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 [9]. Merkel cells are responsible for our light touch sensation and are found in high concentrations on the fingertips. Unlike the underlying vasculature, the epidermis lacks blood vessels and receives its supply of nutrients from the dermis through diffusion, meaning its largely dependent on the dermal layer beneath it [10]. It is the papillae, specifically on the dermis's papillary layer that extend up to the epidermis and have the terminal networks of blood capillaries to nourish the epidermis. The papillary of the dermis is made of loose areolar connective tissue [11]. The dermal layer is where the skin's tough connective tissue, hair follicles, and sweat glands reside as well [12].

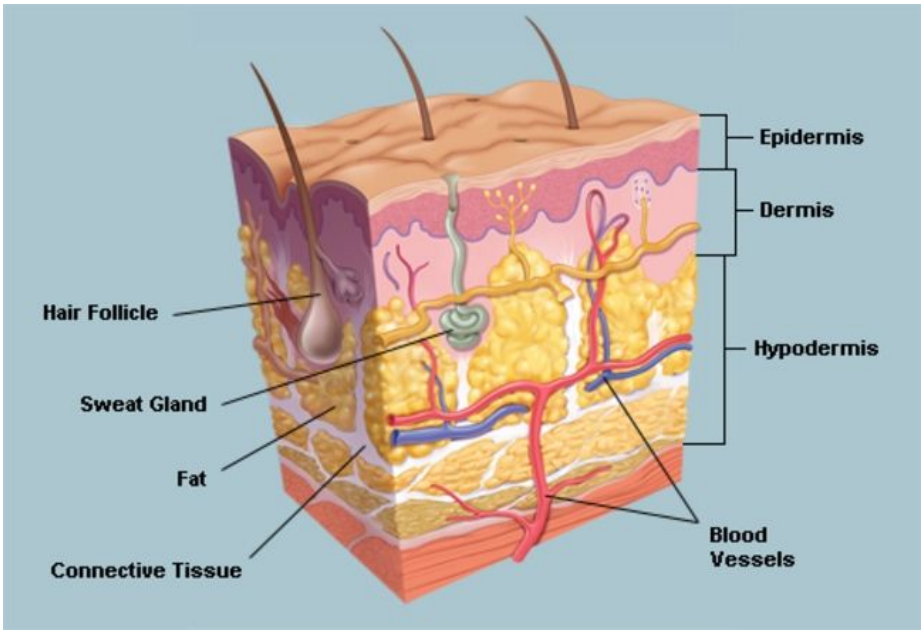

Figure 1:
This shows the three layers of the skin and the pieces that make up each level. The epidermis has no blood vessels, hair follicles, or sweat glands. These are instead contained in the dermis and hypodermis layers of the skin [13].

In order to preserve the underlying vasculature that lies in the dermis and subcutaneous tissue, the process of de-epithelialization must be precise. 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 [14]. In relation to this project, we will focus on the thickness of the epidermis of breast tissue, which is only about 0.3mm thick [15]. 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. In addition, there are many life-style choices of the patient that can increase risk during surgery such as: high BMI's, smoking status, diabetes, steroid use, location, and type of incision [16].

Competing Designs

There is currently a device used specifically for breast de-epithelization known as the "Epicut." This device resembles a modified scalpel with one v-shaped, curved blade. The curves in the blade allow the surgeon to control the depth at which the skin is removed and the angle of the v-blade is set at either 35 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. After removing skin, the epicut would be discarded, making this a one time

use device [17].

Materials and Machines

The team's prototype was 3D printed at the MakerSpace. Requirements used in determining the correct material for the device parallel the needs of the client and structural integrity of the device itself. It was necessary that the material is able to withstand any force, within reason, that may be applied by the surgeon. In addition, the material must be biologically inert. Thus, the team chose to use the Formlabs (SLA) because based on the description on the MakerSpace website, this printer is better at printing high resolution compared to the Ultimaker, which was extremely important considering the intricacy of the design and the thickness of epithelial breast tissue. Additionally, Formlabs (SLA) is cost efficient compared to Stratasys and uses resin. Clearly the best option, Formlabs (SLA) will be used as it is the most cost efficient and is able to withstand the forces that will be applied to it [18]. However, it was deemed the Ultimaker should be used to create the handle for the device due to size restrictions. In order to test multiple materials, another device was printed using the tough PLA of the Ultimaker to aid in more testing, as COVID prevented members from meeting.

Client Information

Dr. Carol Soteropulos is 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 will assist in this tedious and time consuming procedure.

Design Specifications

The most important design specifications include: efficiency, a small learning curve, and a uniform cut. The client says the process of de-epping takes too much time, about 15.5 minutes, and puts too much strain on her fingers and hands. As a team we focused on reducing this time sufficiently. We also want it to be simple and easy to use, so the learning curve should not be significant. Lastly, the device must be able to cut at a uniform depth. To do this, Dr. S suggested a device capable of keeping tension on the skin. This will in-turn ensure the safety of the patient and a positive surgical outcome. Please refer to the full PDS in appendix A for more information on design specifications.

III.Preliminary Designs

Potato Peeler

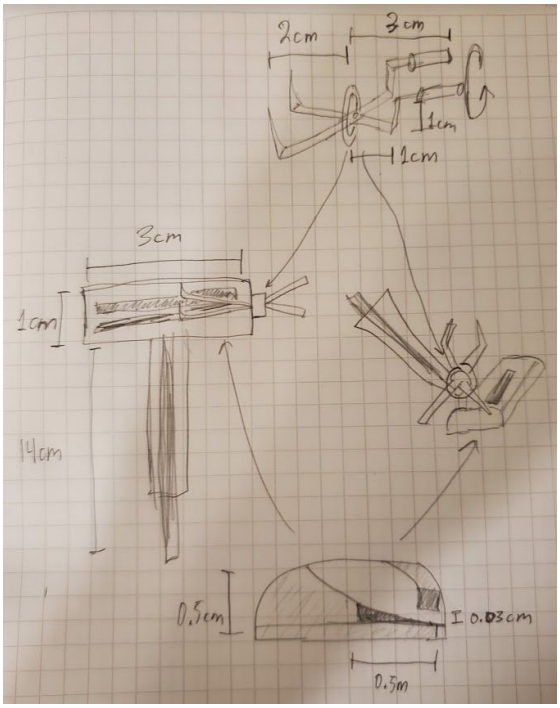

Figure 2: Drawing of the Potato Peeler with dimensions. Shown is the rotating forcep mechanism on the top with dimensions. In the middle are the bottom view (left) and the top-front view (right) of the whole design with dimensions. The bottom shows the blade portion of the device with the guard and the space where the loose skin will pass through. Dimensions of the blade portion are also shown.

This design was modeled after a potato peeler. Potato peelers share a similar function to the team's device, as their job is to remove the top layer of the potato that contains the outer skin. Despite the fact that a potato has vastly different properties than human skin, important design information can be gleaned from the mechanics of a potato peeler, thus explaining why the design was derived from such a device. The Potato Peeler design contains a handle allowing for the user to apply leverage and control the motion. Additionally, the device contains a single blade with a guard to protect the patient and user as well as ensure accuracy in cut depth. The handle is located on the same side as the back side of the blade, as shown in Figure 2, which allows for the device to work in a pushing mechanism. Forceps are attached above the blade that can freely rotate and grip loose skin cut by the blade. The forceps addresses the problem of tension by constantly gripping the skin to keep it taught. This is done by cranking the forceps with the non-dominant hand. Despite the merits of this design, the width and thickness of skin cut cannot be adjusted, limiting its ability to be dynamic and used in different types of surgeries where de-epithelialization is necessary. Additionally, the device is complicated and would be

extremely difficult to fabricate. Finally, it forces the surgeon to use both hands, which could pose difficulties, as the client requested a device with limited to no learning curve. However, this device would most likely take surgeons multiple times before mastering its usage, which is not optimal or safe for the patient.

Shovel Scalpel

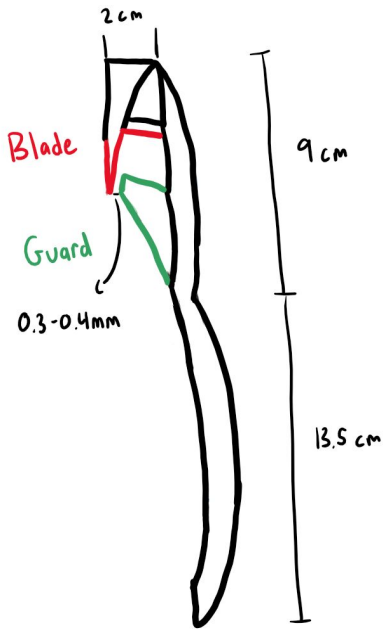

Figure 3: A drawing of the Shovel Scalpel design with dimensions. The device is made of a handle similar to that of a scalpel, but with a curve to facilitate ergonomics. The blade section of the device resembles a snow shovel head, with the sides replaced by blades, that faces back towards the handle. Just in front of the blades is a guard that protects the user, and helps to maintain a constant cut depth.

The shovel scalpel is designed to allow the surgeon to drag down a surface of interest to remove the epithelial layer of skin. The side blades would keep the width of the cut consistent. The pulling motion of the device was favored by the client, who suggested it could allow for greater control during the removal of the skin. An adjustable guard is set in place to ensure that the removal of skin is not too deep (figure 3). Removing too much of the desired layer could cause injury to the underlying vasculature of the patient. Though the guard should prevent deep cuts, excessive pressure generated by the surgeon could still lead to potential harm. More complications arise with this design when considering cuts that are too thin. The surgeon would be responsible for assessing the depth of the cut. Additionally, this design fails to address the necessary tension required to smoothly remove this layer of skin. The non-dominant hand would

pull the skin as it is being removed to provide adequate tension. Learning this device will not pose a major issue for the client either, as the working principle is relatively simple.

Spiky Roller

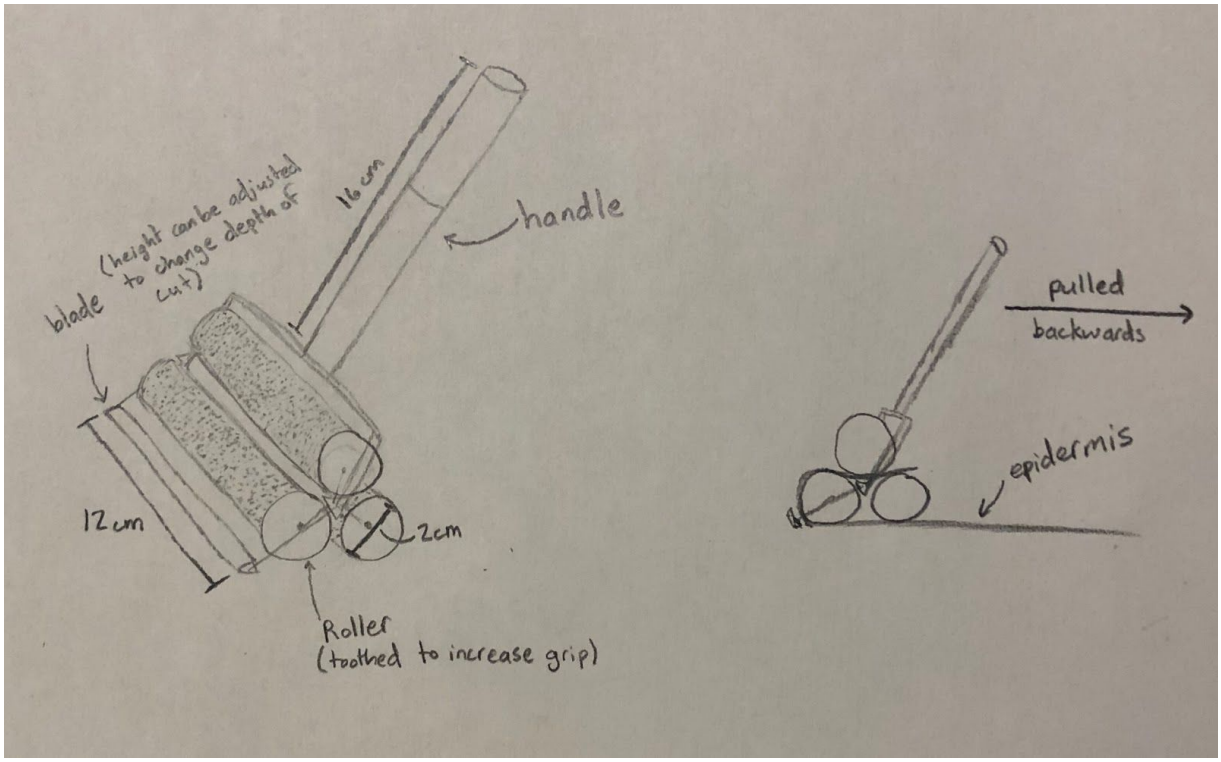

Figure 4: A drawing of the Spiky Roller design.This device is made of three rollers stacked with two on the bottom and one on the top, a blade behind the two bottom rollers, and a handle that connects the three rollers and blade. The rollers have a 0.3 mm clearance with each other and are set 0.3 mm above the blade. Once the skin is cut by the blade it is fed back through the rollers to create tension.

The Spiky Roller is a design that specifically addresses the issue of maintaining skin tension during the process of deepithelialization. This design consists of three cylindrical rollers, the surface of which are covered in miniature teeth, and a blade attached to a handle. Two rollers exist underneath a third centered roller in a triangular formation. In close proximity to this group of rollers, there is a blade that can be adjusted to different depths in order to accommodate varying thicknesses of the epidermis. The operator of this device would drag the device backwards, rather than pushing it forwards (figure 4). As the device is being dragged across the surface of the skin, the rotating rollers will grip the epidermis. The epidermis will be tightly pulled upward and around the top of the bottom rollers. Because tension is maintained in the skin, the blade can accurately and easily separate the dermal and epidermal layers.

Modified Epicut

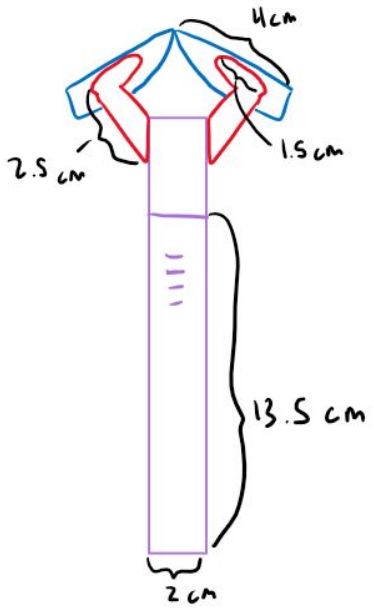

Figure 5: A drawing of the modified Epicut design. The design is made of a curved handle attached to a flat head with a hole through the lateral side. Two mirrored arms are inserted into this hole and scalpel blades are attached to each of these arms. This model features the use of 2 #10 scalpel blades.

The Modified Epicut takes inspiration from the Epicut, the only competing device for the de-epithelialization of breast tissue. This design features an ergonomic handle and angled blades, design choices from the Epicut, to facilitate the removal of the epithelial layer of breast tissue. Specifically, these choices allow the surgeon to make precise, controlled cuts with ease. Though similar to the epicut, this design seeks to reduce the cost of having a specific tool to perform de-epithelialization. The Epicut costs approximately $380 per disposable device, with the possibility of multiple devices being used each surgery. This design makes use of disposable #10 scalpel blades. These blades are ubiquitous in their use for a wide range of surgical operations. The client stated that the current protocol utilizes these blades and that they would be readily available. Thus, the Modified Epicut employs a customized attachment that would secure the #10 blades into place (figure 5). To account for the variability in the depth of the epithelial layer, there would be multiple arms created spanning the depth of 0.3 to 0.4mm. Additionally, this design was created to maintain tissue consistency. A major problem with the other designs was that though they had mechanisms in place to avoid deep cuts, without precise usage, the tools could create tissue sections that were too thin. This would mean that the client would have to repeat the process, lengthening the operation time. The Modified Epicut utilizes the bottom surface of the handle as a guard. As long as the surgeon keeps the handle on the surface of the skin, the guard ensures that little to no variance in tissue depth will be present.

IV. Preliminary Design Evaluation

Design Matrix

Table I. *Design Matrix. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores out of 5. *Displayed as: score/5 | weighted score*

	Potato Peeler		Shovel Scalpel		Spiky Roller		Modified Epicut	
Safety (30)	3/5	18	4/5	24	3/5	18	4/5	24
Efficiency (25)	4/5	20	4/5	20	4/5	20	5/5	25
Precision (20)	3/5	12	4/5	16	3/5	12	5/5	20
Feasibility (15)	1/5	3	4/5	12	2/5	6	3/5	9
Learning Curve (5)	5/5	5	5/5	5	3/5	3	5/5	5
Cost (5)	2/5	2	3/5	3	2/5	2	3/5	3
Total (100)	60		80		61		86	

In order to evaluate and compare each design, the team identified six categories deemed important to the success of the device. A promising design should possess each of the given qualities, be sufficient in every category, and score highly in most in order for the design to be seriously considered as a final design candidate.

This device will be used to remove the patient's epidermis. By virtue of this close contact, the device has the potential to cause harm to the patient. Serious damage could occur if the device were to malfunction or cut into deeper tissue. For this reason, the safety category was given the most weight. The Shovel Scalpel and the Modified Epicut were considered the most safe of the design ideas as both employ mechanisms that ensure a uniform cut. The shovel scalpel has an attached guard for the blade, which makes disturbing underlying tissue nearly impossible. Similarly, the base of the handle on the Modified Epicut acts as a guard, preventing cuts below the expected depth. Although the other designs were not considered unsafe for the patient, the Shovel Scalpel and Modified Epicut are easily controlled and minimize the chance of a mishap during the process of deepithelialization.

Efficiency of the device is also a major priority, and was given the second highest weight

of the six categories. The current process of deepithelialization with a scalpel is a regular procedure that occurs frequently. However, it is a time-consuming and tedious process for the surgeon. This device would only be advantageous for the surgeon if it is significantly faster than the current process of deepithelialization. No surgeon would learn a new tool and technique for a process that has no temporal benefit. The Modified Epicut is the most efficient design. Although each design is moved across the skin at a similar rate, it is more likely the Potato Peeler, Shovel Scalpel, and Spiky Roller experience complications such as skipping a portion of skin or clogging with removed skin. Complications such as these would prolong the use of the device. Because the Modified Epicut is much less likely to experience these complications, the process of deepithelialization can be performed and completed in a much more efficient manner.

After safety and efficiency, precision is the next most significant attribute of the potential device. Not only does the device have to be accurate in removing the epidermis from the dermis during deepithelialization, but it must also be consistent. The device will not be used in surgeries if it does not yield consistent and predictable results. It was determined that the Modified Epicut was the most precise of the designs. This is due to the fact that the operator must simply drag the Modified Epicut across the surface of the skin. The base of the handle, acting as a guard, will maintain a consistent depth to the removed epidermis. The operator of this particular design need not personally alter the angle in which it is applied to the skin. Therefore, the Modified Epicut is the most precise of the designs.

Feasibility of constructing the prototype is the fourth highest priority in the design evaluation. Accounting for restraints of time and resources, as well as limited access to facilities during the COVID-19 pandemic, developing the prototype of some designs would be much more challenging than others. For example, the prototype of the Potato Peeler and Spiky Roller would be challenging to construct due to their inherently complex design. The prototype that would be the most feasible to assemble is the Shovel Scalpel. Its simplistic design consists of only a few different parts. The prototype of this design would be the least difficult to build given the team's current resources.

The learning curve for this device is not as significant a concern as safety, efficiency, precision, or feasibility, but it should still be considered when evaluating the designs. The learning curve of the device essentially describes its ease of use. A design that is rated highly for learning curve would be easily learned and operated, whereas a design with a poor learning curve score would be challenging to learn and complicated in practice. The Potato Peeler, Shovel Scalpel, and Modified Epicut were all given perfect scores, due to their intuitive design. For each of these, the entire process of deepithelialization is clear. The operation of these designs entails dragging or pulling the device over the surface of the skin. Because of this, these three designs scored the highest in terms of their learning curve.

The final and least prioritized category is cost. The client has given the team a budget of about $300 to assemble a prototype. However, she did say that this is an approximate number and it is flexible. The more simplistic designs are advantageous relative to more complex designs in terms of cost. Therefore, the team has predicted that the Modified Epicut and Shovel Scalpel

would both be the least expensive to construct, compared to the more complex designs of the Potato Peeler and Spiky Roller.

Proposed Final Design

Initially, the first three designs were the only ones generated by the team. However, the team realized how thin 0.3 mm truly was. To put this value into perspective, a roller 2 cm in diameter is approximately 66.67 times greater in thickness than the desired thickness of skin. Thus, to maintain traction on the removed skin, the distance between the rollers would have to be less than this value, which was determined to be unfeasible for this semester. This invalidated both the Potato Peeler and Spiky Roller designs, as they both attempt to use the skin as a point of traction. The shovel scalpel was predicted to be the final design, but the possible inconsistencies in depth that would arise during surgery lead the team to continue researching alternatives. The Modified Epicut solves both issues, as it does not attempt to use the removed skin to generate traction and minimizes the discrepancies in width. The Modified Epicut would also be the safest option, barring any misuse by the operator. It would be significantly more efficient, as the surgeon would simply need to maintain contact with skin. It would generate skin of consistent depth as long as the previous provision was maintained. The design is still challenging to fabricate, but would be extremely easy for a surgeon to learn and would be relatively cost effective.

V. Fabrication/Development Process

Materials

The proposed final design, the Modified Epicut, has a simple composition. One prototype was 3D printed, and made of Tough PLA material, while another was printed using High Temp material. Tough PLA was chosen for the prototype because of durability and price. This material is extremely inexpensive, at only $0.08 per gram [18]. However, Tough PLA is not able to withstand sterilization by autoclave. High Temp is a clear resin that can withstand exposure to temperatures up to 238 degrees Celsius [19]. This material can be sterilized by autoclave without warping. In addition this material is durable and somewhat inexpensive, at $0.29 per milliliter [18]. However, this material must undergo a curing process in order to ensure these properties. This curing process, if done improperly, may contribute to a warping of the material Two size 10 scalpel blades will be used as the blades of the device. These scalpels are medical grade, and regularly used in surgery.

For the final design material, the team intends to use stainless steel, specifically AISI 316L, commonly known as surgical steel because of its use in the medical field today. It is tough and corrosion resistant, and most scalpels are made out of this same metal [20]. This material was chosen because it can withstand high heats, up to 400 degrees Celsius and is already used in

surgeries. This material can be precisely machined and its high heat tolerance means the device can be autoclaved and reused after each use.

Methods

The device was drawn and dimensions were created based on current scalpel and Epicut lengths. The drawn devices were then created as 3D models on Autodesk Inventor as seen in Appendix 3. The three pieces of the device were created separately and joined together in Autodesk to prove the device was viable.

The modified epicut prototype was 3D printed at the UW-Madison Makerspace using the design files from Autodesk Inventor (see appendix C). The arms of one prototype were 3D printed with High Temp material using the Formlabs printer. The handle of this same prototype was printed with the Tough PLA material and the Ultimaker printer, due to the fact that the handle was too large to fit in the Formlabs printer. Another prototype, including both the arms and the handle, was printed with the Tough PLA material using the Ultimaker printer.

Final Prototype

The Modified Epi-Cut final design for this project took inspiration from the Epi-Cut competing device. A dimensioned CAD drawing can be seen in Figure 6, with . It consists of a handle and two scalpel attachment arms, as seen in figure 18 of Appendix C. The handle's curvature is designed to allow for the surgeon to maintain a relaxed grip while maximizing control when performing the operation. At the front of the handle is the site where the scalpel attachment arms are inserted. The height of the hole in the front of the handle is dimensioned to fit each attachment arm when they are stacked on top of each other. Two screw holes are present on the top surface, allowing for the attachment arms to be secured into place. The scalpel attachment arms are mirrored and have insertion plates occupying two different halves of the opening in the handle. Once fully assembled, the blades will sit at a distance of 0.3mm from the bottom surface of the front portion of the handle as seen in figure 7. This ensures that cuts deeper than 0.3mm will not be made, eliminating any potential risk to the patient.

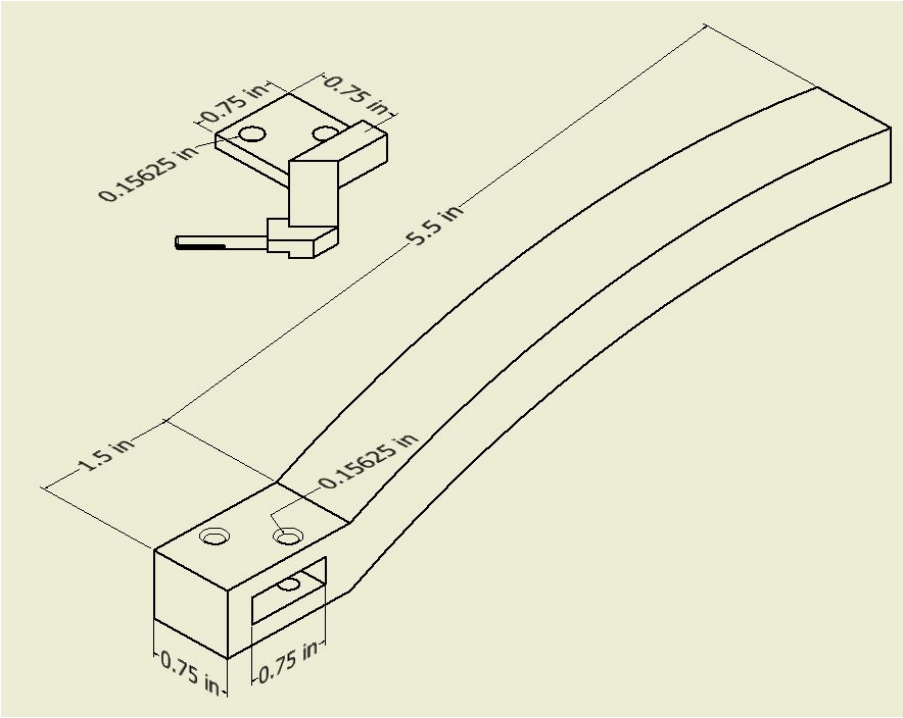

Figure 6:
A dimensioned CAD model of the Prototype design. The design shows the left arm and handle. The left arm has a mirrored right arm, and both are inserted into the opening at the base of the handle.

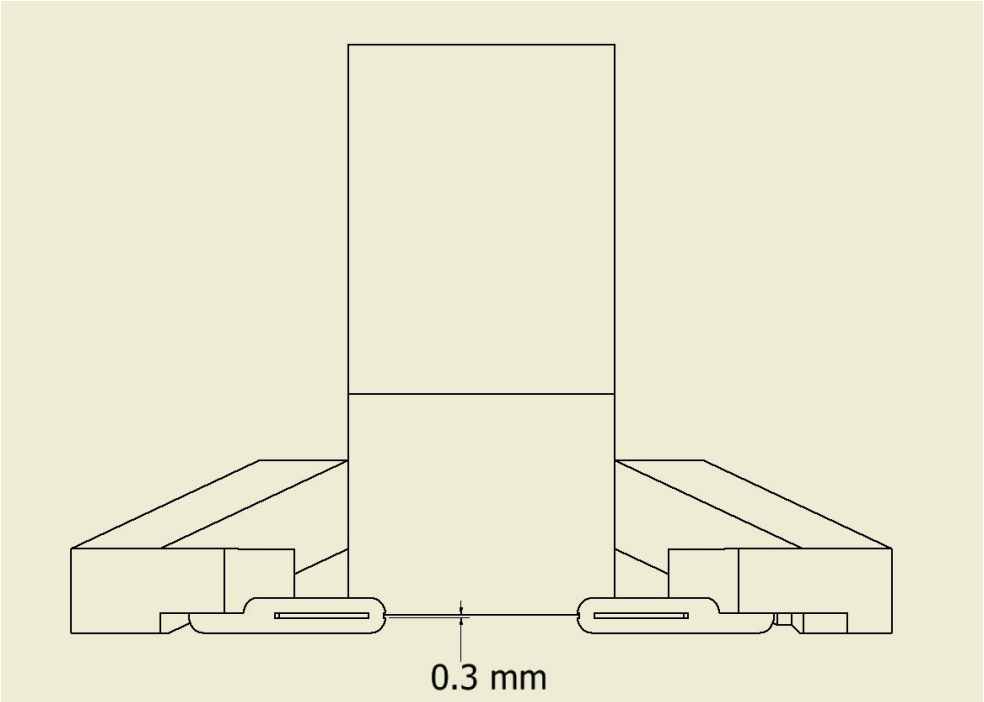

Figure 7:
A Solidworks model of the assembled device from the front. Both arms are inserted in the handle and the dimensioning shows where the scalpel will be placed. The blade of the scalpel will sit 0.3 mm below the base of the handle, which will result in a 0.3 mm cut.

Two copies of the final prototype were made using 3D printing. The first prototype, as seen in Figure 8 utilized Formlabs High Temp Resin for the scalpel arms and Tough PLA resin for the handle. The second prototype, as seen in Figure 9, utilized Tough PLA resin for both the scalpel arms and the handle. Several issues existed with these prototypes, primarily regarding the insertion hole in the handle and the scalpel attachment points. Firstly, the insertion hole in the handle was not printed correctly, only being capable of housing a single arm at a time. Additionally, the scalpel attachment point was also printed incorrectly and needed to be modified to hold a scalpel with a rubber band, as seen in Figure 8.

Figure 8:
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.

Figure 9:
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.

Testing

Preliminary testing for the prototype was done on both porcine and chicken tissue. These two tissues were selected because of their similar resistance to human skin [21]. Four chicken breasts were collected from the local supermarket and kept in a standard refrigerator until testing was performed. First, an entry incision was made onto the breast perpendicular to the prototypes cut direction. The prototype was then pulled across the surface of the chicken removing a small strip of tissue from the breast. This process was repeated 7 more times on the front and back of the remaining chicken breast samples resulting in strips like that of Figure 10. The cut strips were then assessed as either successes or failures based on the consistency as well as length of cut. A minimum of 4 inches of continuous flesh was needed for a trial to be considered a success. The successes were then analyzed in Kinovea to measure the consistency and depth of the cuts and were compared to the model 0.3 mm cut depth.

Figure 10:
A strip of chicken that was removed during testing (proximal). The cut is rough and an entry incision on the breast was needed to begin the process of de-epithelialization.

For porcine testing the two prototypes were used. Fitting the blade onto the arm was very difficult and the portion that the blade attaches to broke off in the High Temp arm and was filed off for the tough PLA arm as shown on the individual arm in figures 9 and 8. The blades had to be secured with a rubber band as shown in figures 11 and 12. Also shown by figures 11 and 12 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 could cut skin and will be used for testing. Three slices of pork, that were bought from a local market, were used for this test. Around 30 attempts of cutting off a layer of tissue were tried and only 3 successful continuous cuts were made as shown in figure 13. Each attempt did not use an initial cut to start but tried to make the initial cut by pressing down on the handle and arm then sliding the device across the slice of pork. Analysis on thickness was not done since the length of the samples were too short (around 2 cm) with inconsistent width.

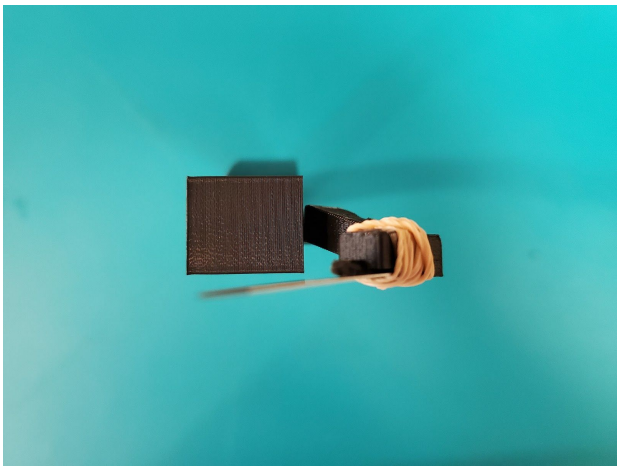

Figure 11:
The tough PLA prototype with one of the arms with the blade attached to it, inserted into the handle. This is a front view with the blade pointing out of the picture. The position of the blade shows that the prototype can be used for testing because the blade is below the bottom of the handle.

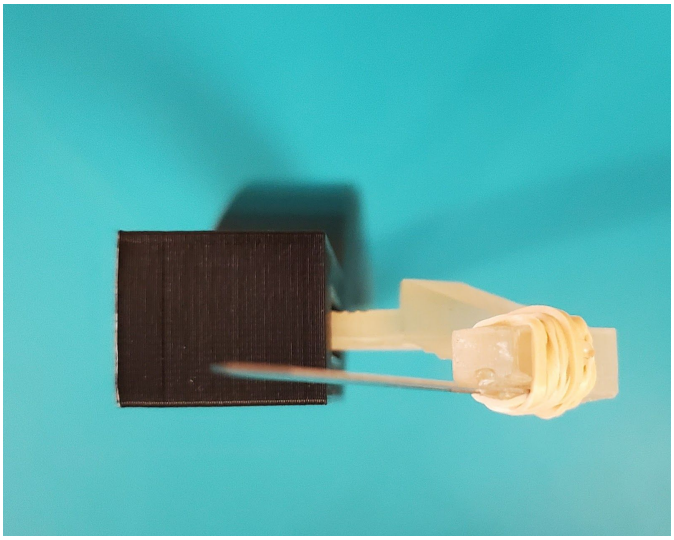

Figure 12:
The High Temp prototype with one of the arms with the blade attached to it, inserted into the handle. This is a front view with the blade pointing out of the picture. The position of the blade shows that the prototype cannot be used for testing because the blade is above the bottom of the handle.

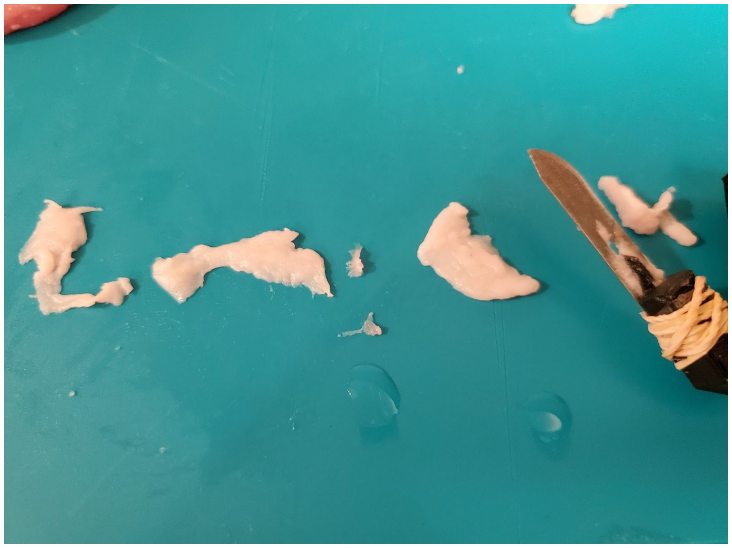

Figure 13:
Results of the porcine proof of concept test. Shown are the three samples gathered by using the prototype to cut. The samples are short, inconsistent in width and thickness. The scalpel blade on the left is shown for size reference.

Testing of the device by Dr. S and Todd Lee should be done once more testing has been completed and an updated final design has been created. An outline of the testing procedure for this procedure can be found in Appendix D.

VI. Results

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 seen in figure 14. 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 15.

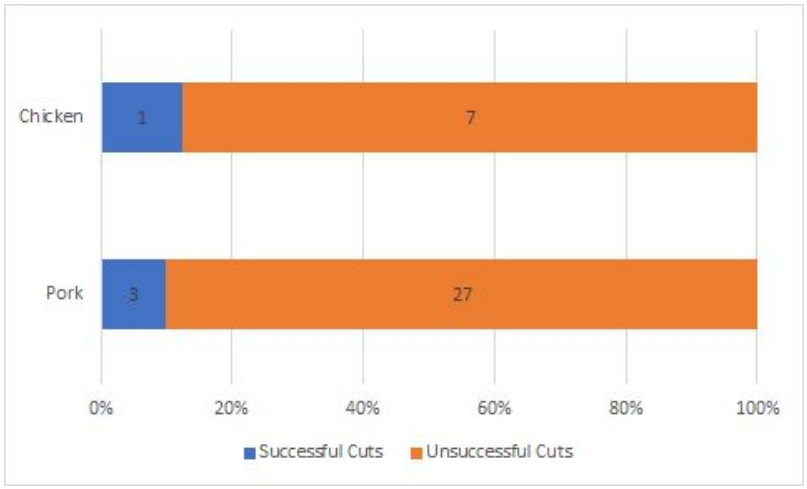

Figure 14:
Graph of the successful (blue) and unsuccessful (orange) trials for the Chicken and Pork tests in percentages.

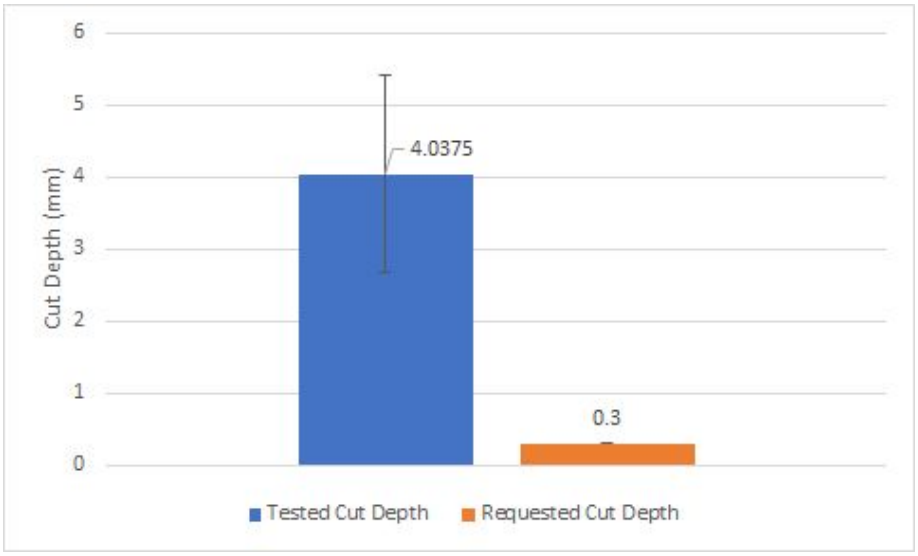

Figure 15:
Graph of the tested chicken cut depth (left) and the requested cut depth (right). The standard deviations of the two data sets do not overlap suggesting they are significantly different.

A one-tailed t-test was done on the data collected from the successful chicken cut and the requested cut depth. It was found that there was a significant difference between the cut depth and the requested cut depth ($p < 0.00001$).

VII. Discussion

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.

The testing of the device was done on pig and bovine flesh for proof of concept, which did not raise ethical concerns as the tissue was purchased from the local supermarket. No live tests occurred meaning no ethical dilemmas were created by the initial testing. Once testing moves to preserved skin samples the team must go through the proper procedures and ensure that the tissue's owner has approved the use of their tissue for research. Once approval is obtained the team will be able to continue testing with the new tissue types. After this testing has been completed, the device will move to live tissue testing. This testing will be the testing that brings in the most ethical considerations. The team must get approval from the patient and have proven that the device will not cause harm and will work as intended.

The method of fabrication should be adjusted when considering the future of this project, as 3D printing was not reliable in generating accurate parts that would function properly. Surgical steel should be utilized to develop both the handle and the scalpel attachment arms. This material can be machined with high precision and is capable of withstanding temperatures exceeding those expected during standard autoclaving.

Alongside this newly developed device, the testing protocols should be altered. Instead of attempting to use chicken and porcine tissue, human skin samples should be acquired and tested

upon, as it would allow the results of testing to be reflective of what the client would experience. Additionally, the client should be given the device and an opportunity to use the device and provide feedback in accordance with Appendix D. This would offer insight into areas where the design could be further improved.

VIII. Conclusions

Removing the epidermis is a tedious task that has to be done in breast reduction surgeries [22]. In order to do this surgeons score and then cut the tissue away. The process takes about 15 minutes and results in a fairly consistent cut, with minor bleeding resulting from inconsistent cut depth. This process could be simplified with a device capable of maintaining tension on the skin and creating a clean and consistent cut.

Dr. Soteropulos has requested the team design and fabricate a device to aid in this process by making it faster, more consistent, and overall easier on the surgeon. Considering the client and patient requirements, the team researched skin biology and competing products in order to create the preliminary designs. The team decided on the modified Epicut design, which incorporates pieces of the other preliminary designs and aspects of the Epicut device.

Throughout the design process it was helpful to discuss thoughts and questions with the client. The client was not only able to offer insightful input regarding the logistics of procedure but also equipment used in the procedure. The team struggled to obtain precision machines at this time which may inhibit the team's ability to test the entirety of the procedure.

The team had difficulty meeting to test the device and analyze the device. The team originally planned to hand the device over to the client and consultant for testing, however the samples that the client had access to became unavailable. This caused the team to have to quickly find alternative methods for testing, resulting in porcine and chicken tissue. Another difficulty that arose during the semester was the limited access to precision machinery, the team had hoped to utilize the TeamLab to create the intricate pieces of the device, but instead had to resort to 3D printing at the makerspace.

Meeting consistently with the client was an extremely helpful aspect of the semester and helped to keep the team on track for the first part of this project. If the team were to re-do this project, finding a consistent weekly meeting time would have been beneficial instead of meeting at different times. Additionally, it may have been helpful if the team was able to meet in person allowing the 300s and 200s to get to know each other better. This would in turn allow for the development of stronger relationships and therefore better communication and progress.

For future work, the team plans to adjust the prototype to improve accuracy and consistency, a commonly occurring issue during testing. The team was also unsuccessful in obtaining skin tautness at the beginning of the cut, so the device needs to be remodeled to overcome this issue as well. After modifications to the design are complete, the team will continue testing the device on porcine or chicken tissues and further investigate any other

problems that arise. After enough testing has been done, the team may begin final production of the device using a CNC milling machine for more precise and accurate dimensions and create a final prototype made of surgical steel that can be used for live testing.

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X. Appendix

A. Product Design Specification (PDS)

Device for Automatic De-epithelialization

09/17/20
Client: Dr. Carol Soteropulos
Advisors: Dr. Krishanu Saha
Consultant: Todd Le
Team: Josh Giarto, Young Kim, Colleen Cuncannan, Tatum Rubald, Noah Ruh, 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 deepithelialization during a BBR is about 15.5 minutes. [23] Therefore, the device must be noticeably faster than 15.5 minutes.
IV. The current method of deepithelialization 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.
II. Damage to the dermis or subdermal complex could be dangerous to the patient. Therefore, there should be no damage to the dermis or subdermal plexus caused by the device.
III. Before every use, blades should be changed in order to ensure the sterile nature of the device.
IV. After every use, the device should be sterilized as a whole and the sterilizing process should not affect the device in any way.
V. Device malfunction and user error are also possible sources of risk.

c. *Accuracy and Reliability*:

I. The device must completely remove the 0.1 millimeter thick epidermal layer without disturbing the dermis or subdermal plexus.
II. Because manual removal of the epidermis with a scalpel already exists, this device must be both absolutely precise and accurate in order to be incorporated into surgeries. The operator of the device must be able to trust that this device will assist them with deepithelialization, without concern that the device may yield inconsistent results.

d. *Life in Service*:

I. The device will be used regularly for multiple operations per day.
II. Blades must be replaced before every use of the device.

e. *Shelf Life*:

I. This device should last for upwards of 5 years in a dry, sterile, and non-corrosive environment.
II. The blades used on the device will last upwards of 5 years.

f. *Operating Environment*:

I. This device will be used within an operating room.
II. The device will be fully functional within standard operating room conditions. These include a relative humidity of 20 to 60%, and a temperature between 68 and 75 °F. [24]
III. It should be stored in a designated sterile storage room.

g. *Ergonomics*:

I. The device should be easily gripped by the operator to ensure maximum control.
II. Vibrations caused from the motor should be minimized.

III. Post operation, this device should be easily inserted into an autoclave for sterilization.
IV. When not in use, the device should be easily stored away in a storage room.

h. *Size*:

I. The device should not exceed 12 inches in length, 4 inches in width, and 3 inches in height.
II. The handle should be under 3 inches in diameter.

i. *Weight*:

I. Should weigh around 800 g.
II. Should not exceed 1000 g which is around the weight of the best competing device that fits the requirements of the client. [25]

j. *Materials*:

I. Materials should be lightweight, water resistance, and non-corrosive

k. *Aesthetics*, *Appearance, and Finish:*

I. Aesthetics should not add unnecessary weight or be a movement limiter for the device
II. The device should be as ergonomic as possible to decrease hand stress for users

2. Production Characteristics

a. *Quantity*:
One device is needed.

b. *Target Product Cost*:
$300, however this is slightly flexible. A similar product on the market, the *Zimmer Skin Graft Blade,* is sold for $6,886.99. [26]

3.Miscellaneous

a. *Standards and Specifications*:
If the device reaches clinical use, the design and manufacturing of the device would need to be approved by the FDA and follow all regulations in place for medical devices including [27];
I. Establishment Registration - 21 CFR Part 807
II. Investigational Device Exemption (IDE) - 21CFR Part 812
III. Quality System Regulation (QS regulation) - 21 CFR Part 820
IV. Labeling - 21 CFR Part 801
V. Medical Device Reporting - 21 CFR Part 803

b. *Customer*:

Customers of this device would be surgeons interested in removing the epithelial tissue without removing any tissue underneath that layer. In order to keep patients safe, this device must be effective, precise, and accurate.

c. *Patient-related concerns*:

The device must be covered during use, and the heads need to be sterilized and remain sterile until use. The device will need to be accurate and safe so that the patient will not receive excessive injuries beyond epidermal removal.

d. *Competition*:

There is currently a device put out by Zimmer Biomet known as a 'Dermatome' which is used to remove skin for transplants. [28] This device is similar to the device that the team plans on creating, however the skin needs to be taught for this device to work well, which is what the team is trying to overcome with the new device.

There is currently a device known as an Epicut that is used to remove the epidermis of breast tissue. This device was helpful in modelling the teams device and its insights helped with development of the device.

B. Expenses and Purchases

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:	Print ID: 6533294	UW	$2.06	2	$4.12

The 3D printed arms of the modified epicut prototype made of High Temp Material.		Makerspace https://making.engr.wisc.edu/			
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

C. Final Product SolidWorks Images

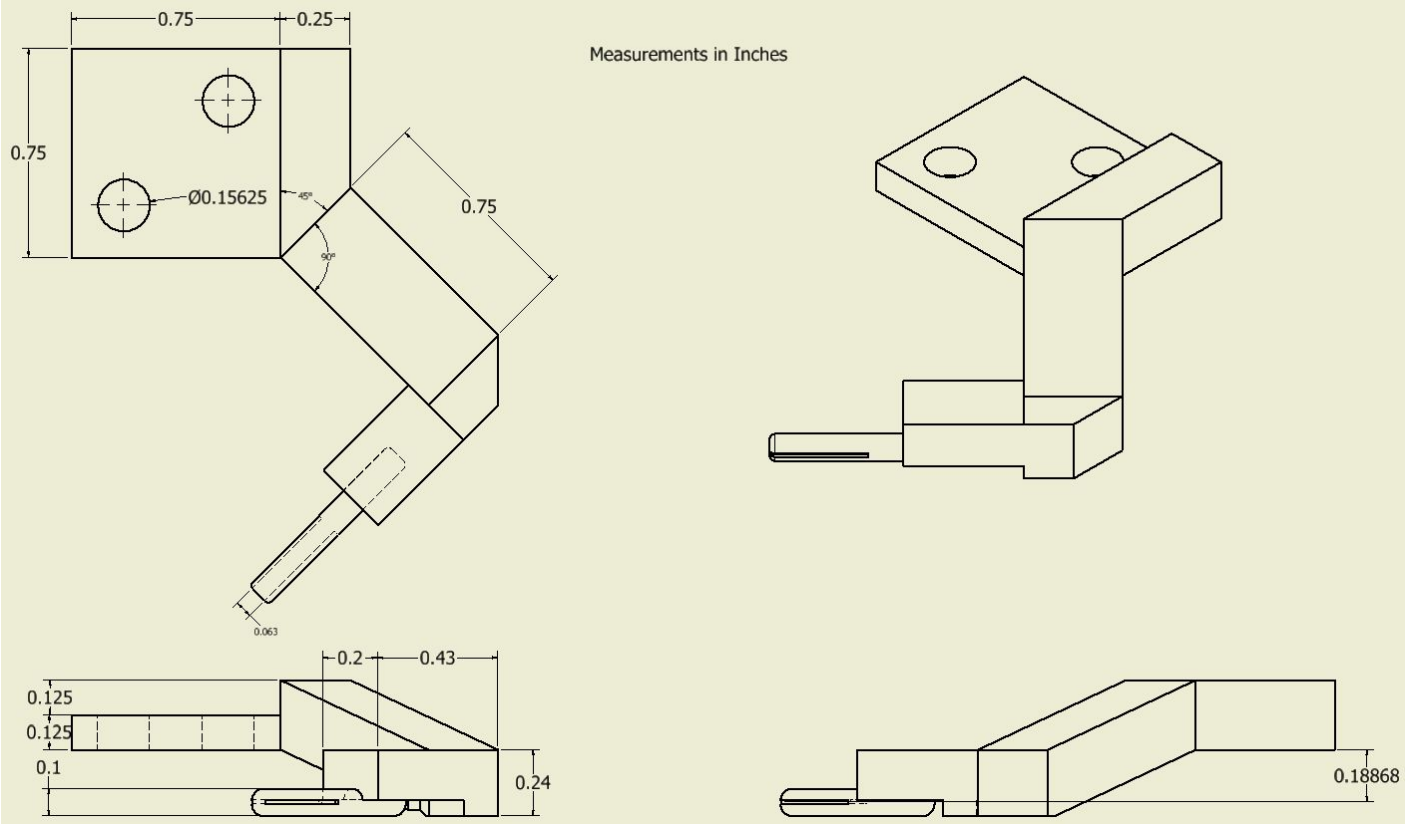

Figure 16:
Dimensioned drawing of the left arm of the device. This was combined with the handle and right arm to create the final

prototype device. It consists of a 0.75” x 0.75” base that is inserted into the handle as well as an extended arm portion that is used to position the blade the correct depth below the handle. The right arm is a mirrored version of the left arm, with the 0.75” x 0.75” on the upper half of the arm, rather than the lower half.

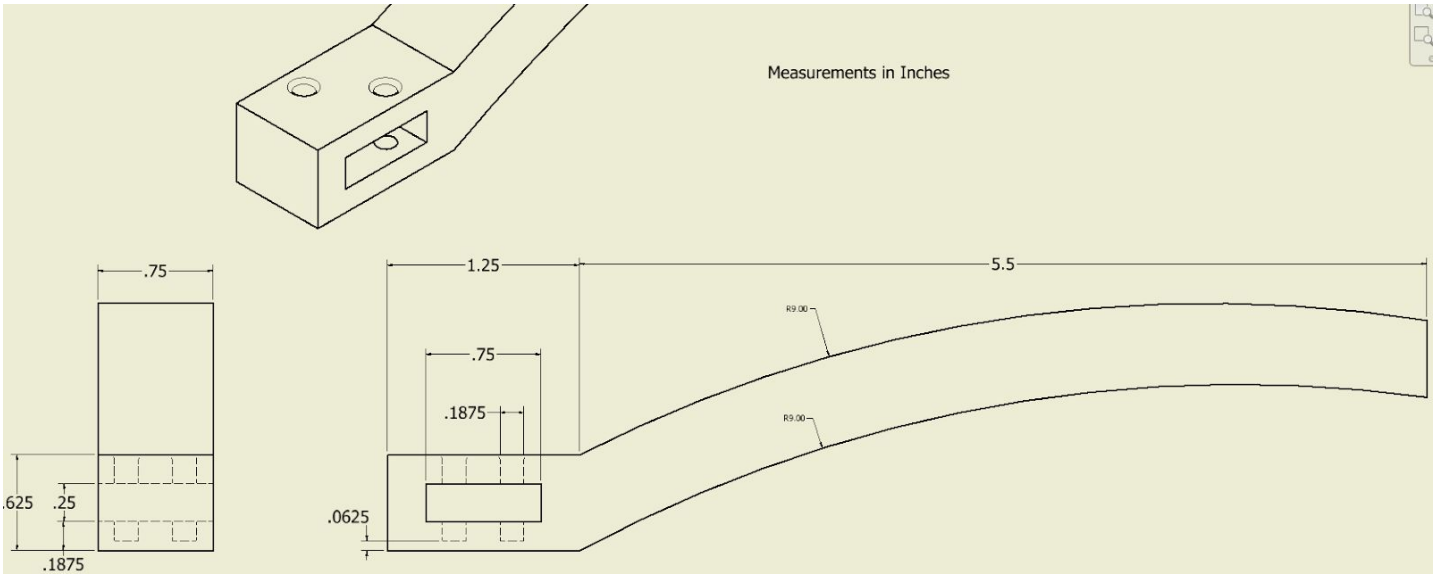

Figure 17:
Dimensioned drawing of the handle of the device. It consists of a curved rear portion and a flat head, which has a hole that the two arms are inserted into. Screws are then placed into the holes on the top of the head and the arms are secured into the device.

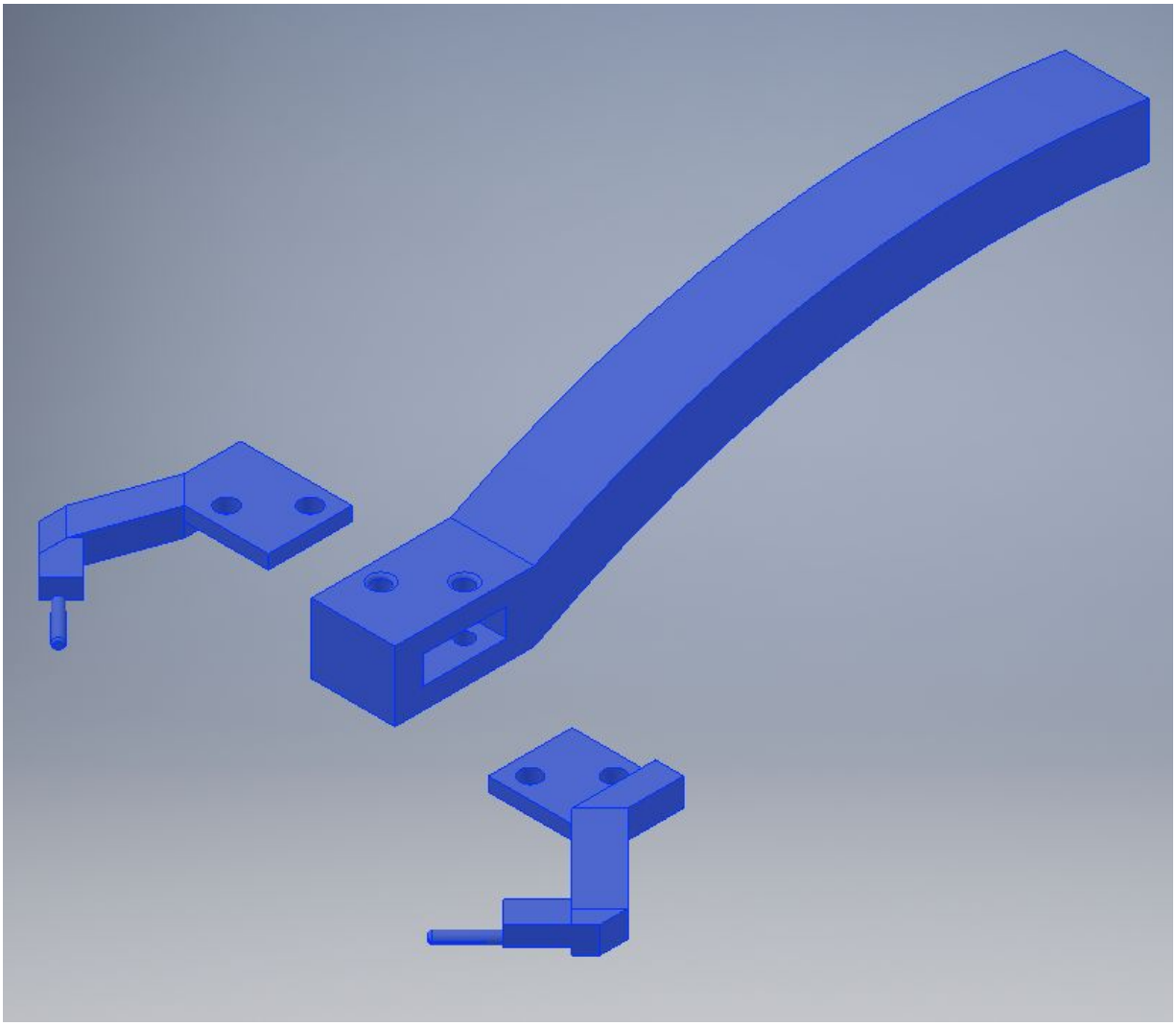

Figure 18:
This shows the three pieces of the device ready to be put together to create the final prototype. The left arm (bottom) and right arm (top) slide into the hole located in the head of the handle and are secured by screws that are placed in the holes that run through the device.

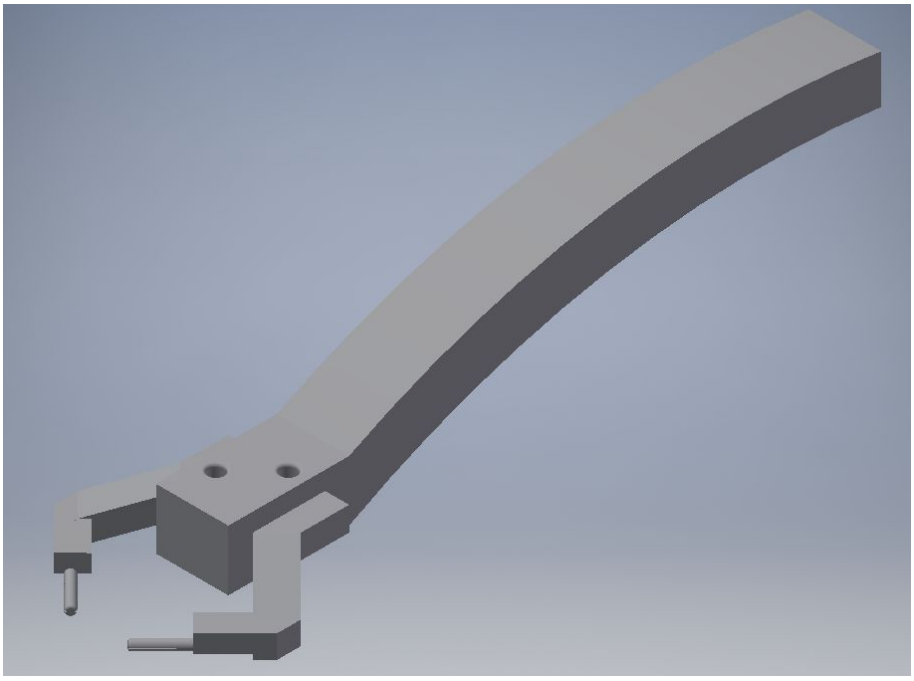

Figure 19:
Shown is the assembled device. The two arms are inserted into the hole of the handle and are ready for scalpel attachment.

D. Doctor and Med Student Testing/Feedback Report

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 do not 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
    a. While cutting how is the weight and the weight distribution? Too heavy or too light?
2. Shape
    a. Is the shape of the handle comfortable? Do you prefer the rectangular structure or do you wish there was something different?
3. Angle
    a. 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
    a. Is there enough grip on the handle? Is it slippery? Will it slide out of your hand during the procedure?

Usage

1. “Skipping”
    a. Do the blades run smoothly across the skin?
2. Cut precision
    a. Were you able to achieve the depth you wanted?
    b. 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
    a. Are you able to complete the procedure effectively? Does it feel safe?
4. Incision insertion
    a. Were you able to insert the device? How did you do it? Did it feel safe and comfortable?
5. Length of time for procedure
    a. How long did it take you to complete the procedure? Would this time go down further once more comfortable with the device?
6. Force
    a. 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?