

Improving the Precision of Small Human Tissue Biopsy Processing

Final Report

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Abstract

Around one million burn related injuries occur yearly in the US, almost 50,000 of these requiring medical attention. Burn wounds can have detrimental impacts on the health of a patient, with high rates of morbidity and mortality in more serious cases. The client, Dr. Angela Gibson, works with traumatic injury and burn patients to improve the healing process. To support her clinical work, Dr. Gibson and her lab manager, Bailey Donhue, work in the Wisconsin RENEW Lab to study porcine skin epidermis and cell migration in response to burn wounds. In order to analyze wound healing behavior, all fat must be removed from the samples to increase their viability. With this device, Dr. Gibson wishes to streamline the porcine tissue sample preparation process via a cutting mechanism that slices multiple samples at a time with accurate thicknesses. The device should securely hold multiple cylindrical samples in place for cutting and produce samples with little thickness variation to achieve extended sample viability. One design matrix was created during the research and design stage to decide on the overall form and cutting mechanism of the device. After analyzing the matrices, the Biopsy Press design was chosen, which utilizes sample slots, a pressure application tool, and cut tracks to ensure thickness accuracy and repeatability between samples during preparation. After an iterative prototyping process, the final design, featuring horizontal and vertical slicing sections, a pressure applicator, hinged wings, and a razor blade handle was 3D printed in PLA and nylon. The final design was tested through sanitization, FEA, and usability survey testing. The design performed well throughout the testing process and results were presented to Dr. Gibson, Bailey, and UW-Madison faculty and the peers. The final prototype will be delivered to the client to further continuation of testing and improving the design.

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Introduction

Motivation

Every year in the US, there are around one million burn-related injuries, about 50,000 of these requiring patient hospitalization [1]. This class of injury is underappreciated in its frequency and severity, potentially leading to life-threatening health complications with sepsis, shock, or organ failure [2]. Non-fatal burn injuries are a worldwide leading cause of morbidity, having long-lasting physical and psychological impacts on patients. There is a clear bimodal age distribution of burn injuries, the majority occurring in young children and those of working age, particularly working-aged men with occupational complications [1][3]. Burn injury survival rates have been steadily improving thanks to the application of different skin grafting measures over the past decade. However, there is still much to be done towards improving treatment technologies with skin substitutes and autologous skin regeneration [4].

At Wisconsin's RENEW – Regeneration, Engineering, and Novel Epidermal Wound-healing – Lab, burn wounds are studied to better understand the skin's healing process. Through the development of comparative models for wound healing research, the lab aims to develop clinical advancements for patients with burn injury, hoping to expedite the healing process. With the usage of pig skin samples for translational burn healing research, wound behavior can be analyzed and findings will contribute to the progression of burn healing therapies. In the long term, the lab aspires to develop novel autologous burn wound regeneration technologies in humans to improve morbidity and mortality rates of burn injury [4]. Ultimately, this device aims to streamline and standardize the work of the RENEW Lab through the efficient and consistent production of viable pig skin samples that can be successfully imaged and analyzed by removing additional fatty tissue.

Existing devices

To remove the fat from their biopsy samples, lab technicians currently hold the sample with forceps and carefully slice off excess fat with a scalpel. This method is very tedious, only being able to slice a singular sample at a time. Additionally, it introduces lots of variability to the samples through human error and jeopardizes the physical integrity of the samples, needing to tightly hold such a small, rounded piece of tissue. There are many tissue slicing devices intended

for lab use currently on the market, though many are very expensive and not suitable for this particular usage.

Tissue slicing matrices are manufactured by many different lab supply companies, aiming to provide a consistent method of freehand slicing irregularly shaped whole organs and tissues for testing and imaging. The sample is held within an indentation of its approximate shape and size as the user brings down a lab blade through the uniformly spaced slots in the matrix. This allows the user to slice their sample at 1-2 mm intervals depending on matrix size. In particular, models from Ted Pella Incorporated like that in *Figure 1* are available in a large variety, ranging from matrices intended for whole adult monkey brains to small tumors. These are fabricated from stainless steel, making them very durable and autoclavable. However, these matrices range in price from \$299.00 to \$3630.70 depending on their size and are only useful if a sample aligns with an available slicing matrix [4].

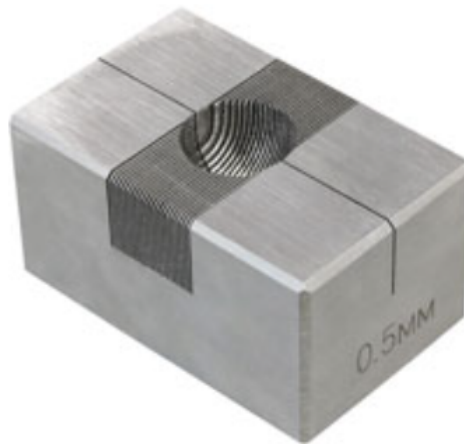


Figure 1: Ted Pella Incorporated 12 mm tumor matrix with 0.5 mm slices, \$299 [5].

Among other tissue slicing apparatus available on the market, the TruSlice Specimen Cut-Up Grossing System from Ted Pella Incorporated (*Figure 2*) is also intended for creating tissue slices of consistent thickness. This system uses cut inserts to dictate the slice thickness in different millimeter increments, allowing the user to set it to their desired dimensions. The specimen is set on a flat base and supported with an immobilization plate holding it in place. A long lung knife is then brought down through the slot to slice the tissue. The apparatus is

manufactured with stainless steel, improving durability and allowing easy sterilization. However, the TruSlice system is incompatible with common small laboratory blades and less suited for rounded sample shapes. Additionally, the TruSlice system itself costs \$1878.75 with add-on accessory items such as immobilization plates or the calibration set also available, ranging from \$45.70 to \$456.95 [5].

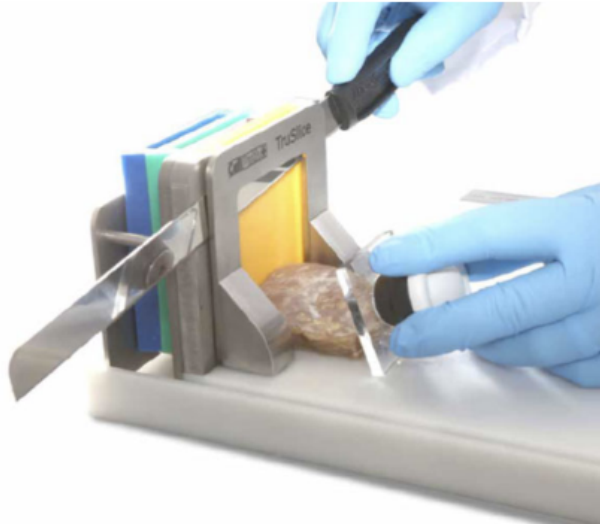


Figure 2: TedPella, Inc. TruSlice Specimen Cut-Up Grossing System \$1878.75 [6]

The client has also drawn up an initial design using the OnShape CAD modeling software. This device holds the samples within the indents on the back wall of the main body and the samples are held in place with a block that is inserted into the main body of the device. The user brings a standard lab razor blade down the slot, slicing the biopsy samples to the desired length. The sides are open for ready visibility and easy removal of the sample.

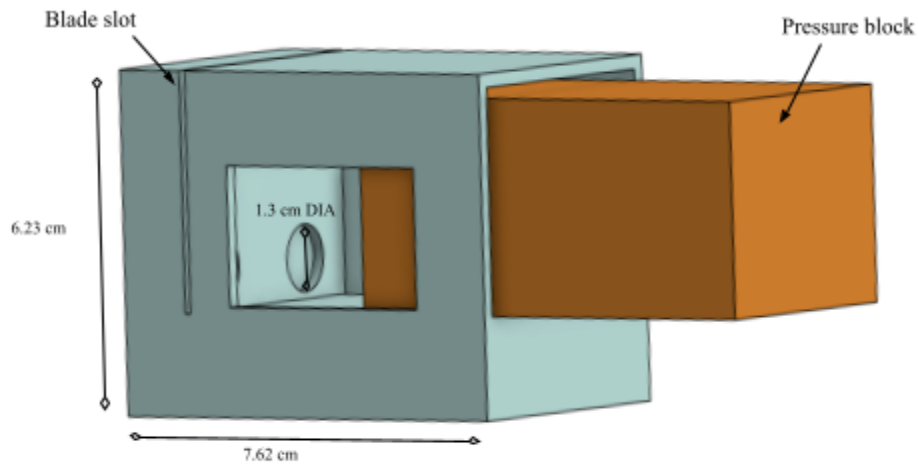


Figure 3: OnShape CAD drawing of client initial prototype [Bailey Donahue]

Problem Statement

In the treatment of extensive burns or wounds, patients rely on emerging treatment research in the field of tissue growth and healing. Currently, studies into the wound healing properties of porcine skin are conducted to visualize how viable epidermis cells migrate over the site of the wound to promote cell regrowth. However, once in a culture, the porcine tissue samples cannot remain viable unless all fat is removed and the cells are able to absorb the culture media. Removing fat by holding the small samples with tweezers and slicing with a blade is tedious and inefficient. Additionally, this process of creating samples is not standardized, resulting in samples of varying sizes with jagged edges, which limits the accuracy of sample preparation. To solve this, fabricating a tool that incorporates multiple sample slots, uniform sizing, and a fixed blade will help to streamline research efficiency and produce more viable samples that can be successfully imaged.

Background

Skin Physiology and Practices in Laboratory

The skin is the body's largest organ, having the most exposure to the external environment and thus being the most susceptible to burn injury. A burn occurs when the skin is damaged by heat, radiation, electricity, or chemicals [3]. This causes the death of skin cells, leading to fluid loss that can detrimentally impact burn patients. The burned skin is very vulnerable to pathogens with the loss of protective intact skin layers, posing a large threat of infection to burn patients. Healthy skin is very important for maintaining homeostasis and protecting the body from environmental factors.

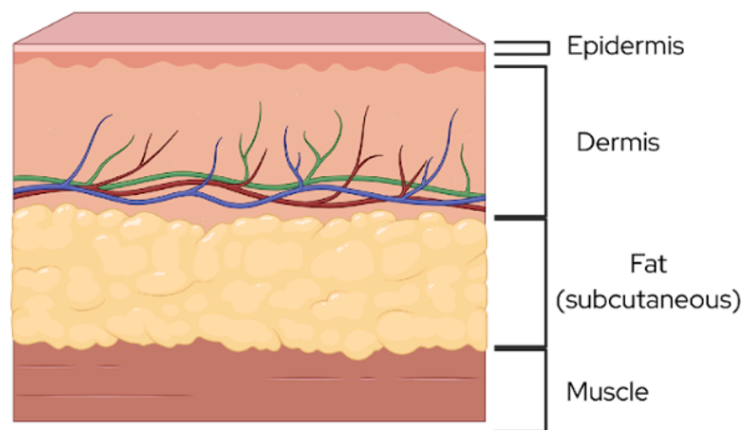


Figure 4: Major layers of the skin – epidermis, dermis, subcutaneous fat (hypodermis).
[Bailey Donahue]

Shown in *Figure 4*, the skin has three major layers: the epidermis, dermis, and the subcutaneous tissue, each having a complex composition of cell types that contribute to their function. The first external layer is the epidermis. It is primarily composed of stratified cells called keratinocytes, acting as the main barrier between the internal body and the environment. Beneath this is the dermis, a thick layer of connective tissue functioning as protection and structural support. The dermis is primarily composed of fibroblasts which produce collagen, elastin, and different growth factors. These cells are critical for wound healing and skin

remodeling. Between the dermis and the muscle is a layer of subcutaneous fat, otherwise known as the hypodermis. This layer is composed of very hydrophobic fat cells or adipocytes [3].

When a burn is inflicted on the skin, the healing process to regenerate tissue varies based on the severity of the injury. Generally, still viable keratinocytes surrounding the wound migrate across the area and multiply to restore the epidermis. The fibroblasts within the dermis layer rebuild the skin structure by producing collagen, elastin, and fibronectin to scaffold the new tissue [3]. In order for the RENEW Lab to observe wound healing, these cells must remain viable and able to regenerate tissue. In their experimental procedure, the subcutaneous fat and muscle layers are removed from a slab of pig skin. Small 4 mm diameter contact burns are inflicted on the skin surface and biopsy samples are taken with a 12 mm diameter biopsy punch. These small cylindrical samples are about 4 to 5 mm in thickness and still contain some remaining subcutaneous fat tissue lying underneath the dermis. The lab has found that this residual fat creates a hydrophobic layer that effectively inhibits sample viability.

To explore the impact of additional fat remaining on the biopsies, samples with and without the removal of additional fat were stained with Lactate Dehydrogenase (LDH) to indicate viability. A dark blue coloring on the samples indicates viable tissue.

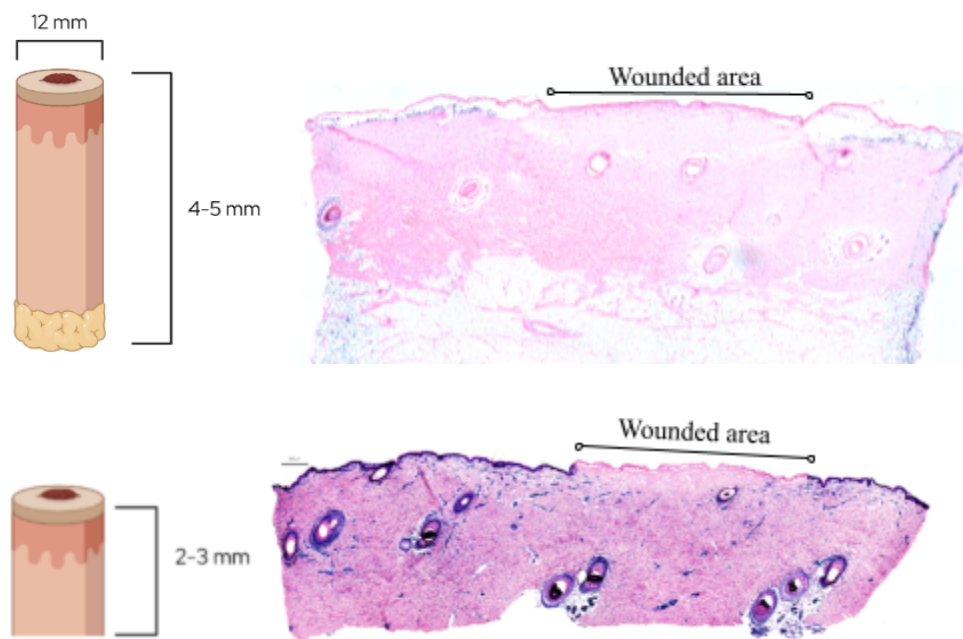


Figure 5: LDH stained pig skin samples without additional fat removal (top image) and with additional fat removal (bottom image); blue staining indicating viability [Bailey Donahue]

Seen in *Figure 5*, the sample without any additional fat removal has no blue staining on the epidermal layer, indicating that there are no viable cells able to contribute to wound healing. Without a viable sample, no information about wound behavior can be gained after culturing and imaging the sample. Additionally, with the complete lack of sample viability, the actual burn wound area is difficult to distinguish on the epidermis.

Alternately, the sample with the removal of additional fat in *Figure 5* does have blue staining on the epidermal surface and throughout the dermis of the sample. This indicates that this sample is still viable and wound healing activity is able to be observed along with the pink burn area clearly distinguishable from the viable tissue on either side. The lab has found that cutting samples down to 2-3 mm reliably removes all of the remaining fat on the dermis and dramatically increases sample viability.

Client Information

Angela Gibson is the client of this project. She is a practicing surgeon, specializing in trauma and burn wound healing. She obtained her MD and PhD from the University of Wisconsin-Madison and continues to practice and conduct research through UW Health. She also serves as an associate professor in the Department of Surgery in the UW School of Medicine and Public Health. Within Dr. Gibson's RENEW research lab, she explores skin alternatives, wound healing, burn healing, and the microenvironments of such wounds [7].

Design Specifications

To adequately solve the problem brought forth by the client, the device needs to meet functional, financial, and sanitary requirements. To accommodate the biopsy samples, the product must be able to secure 1-3, 12mm diameter and approximately 5 mm tall cylindrical pig skin punches. The device must also allow the samples to be cut 2 mm in distance parallel to the epidermis with a variation of .2 mm and 2°. When in use, the device must be stationary on the lab benchtop, and portable for storage when not. Thus, the design's weight must, at maximum, be .25 kg. The blade utilized in the design must be easily replaceable as the durability of pig skin dulls the component and will lead to non-uniform cuts that may further damage the sample. The

blade must also be compatible with the supplies the lab already has in house: single edge razor blades, #10 and 11 surgical blades. Blade components must also have grippable handles that are intuitive and limit potential harm to the user. The body of the device, which is every component but the blade, will need to last a year in service or approximately 1000 cutting cycles before replacement. However, for replacement, the device should be easily fabricated, and ideally 3D printable as the client has access to that fabrication resource. The total budget set forth by the client and thus maximum spending is \$500; however, to be competitive in the market, the device should be \$10-150, depending on the blade quality [8][9]. Finally, the device must be cleanable to dispose of any residual bacteria, tissue, and media fluid that it may encounter in use. Thus, the body of the device should be able to withstand standard autoclave conditions, UV, and 70% ethanol. In terms of storage and non-use, the device should be corrosion and degradation resistant within lab environment conditions: 20-25 °C, 20-80 % relative humidity [10].

Preliminary Designs and Evaluation

Tissue Processing Tool Designs

1. Biopsy Punch

This design features a 3D-printed cylindrical pen-like case with a plunger at the top as seen in *Figures 6-7*. Upon pressing down the plunger, a cylindrical 12 mm diameter biopsy punch blade is extruded from the opposite end. The biopsy punch blade will cut through a tissue slab to a depth of 3 mm. The user then spreads away the tissue around the biopsy site using two fingers. The side blade can then be pushed inward to cleave the sample from the tissue slab, producing a cylindrical sample with a height of 3 mm and a diameter of 12 mm. This design can prepare one sample at a time while reducing user-sample interaction and improving ergonomics. Additionally, the functionality is intuitive due to the pen-like design.

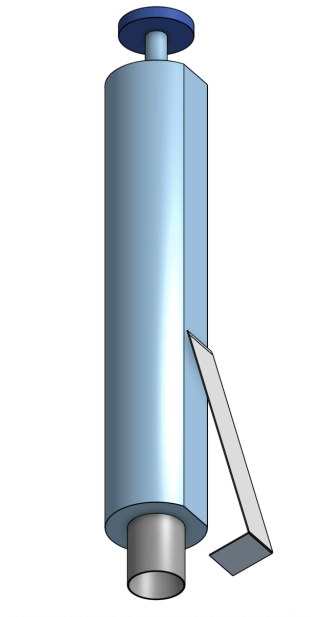


Figure 6: Biopsy Punch Design [Sarah Raubenstine]

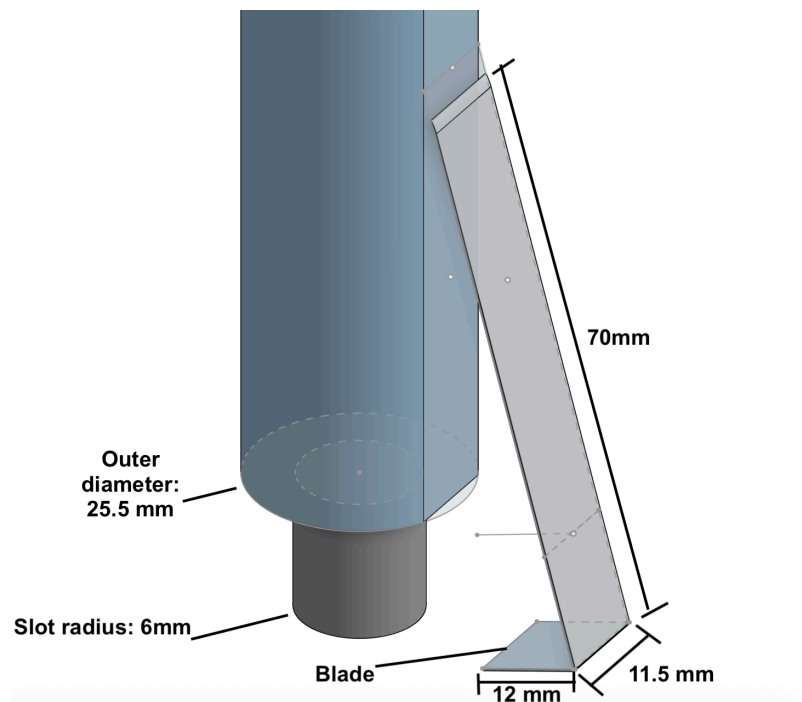


Figure 7: Biopsy Punch Design with dimensions [Sarah Raubenstine]

2. Paper Cutter

This design features sample slots, a hinged blade, and a mechanism to apply pressure while cutting. The cylindrical samples, which will have been preliminarily cut with a biopsy punch, will be placed in the slots with the surface tissue facing into the device. Before cutting, the pressure applicator tool can be pushed up against the cylindrical samples, compacting the samples and holding them in place. The user can then swing down the hinge blade onto the samples, cutting them to a height of 3 mm.

The blade will be a standard razor blade, and can be replaced via a snap-in mechanism. It will be integrated into a handle that the user grabs onto to swing the blade up and down. These aspects increase safety by reducing blade handling and making it easy to replace. Additionally, to increase the sterilizability of the device, the base snaps apart at the cut line of the blade, as shown in *Figure 9*. This allows the user to access and wipe down the center of the device that may accumulate debris over time.

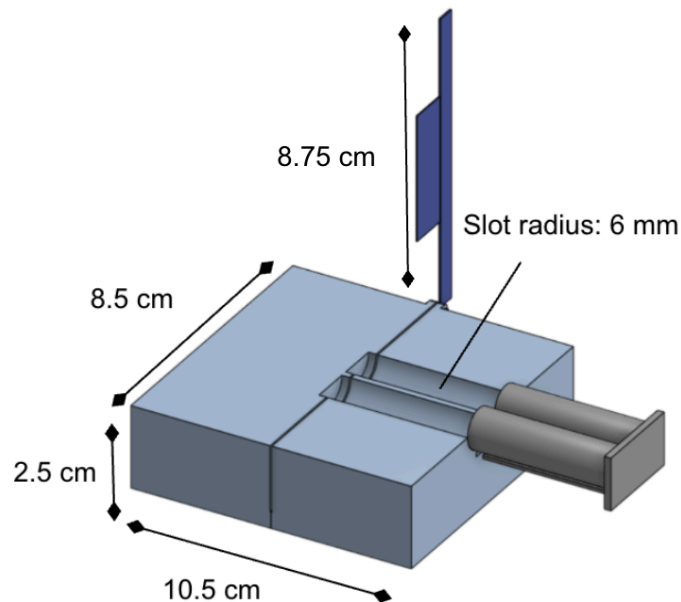


Figure 8: Paper Cutter Design with dimensions [Gianna Inga]

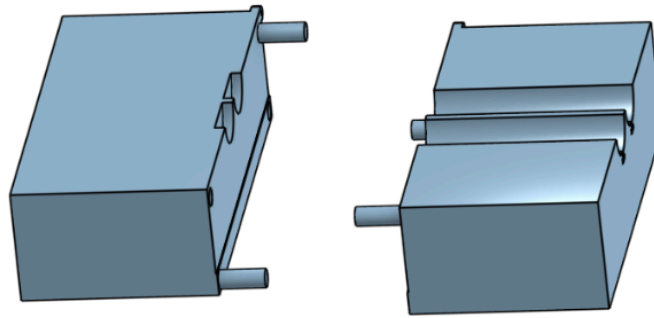


Figure 9: Paper Cutter Design Base Assembly [Gianna Inga]

3. Biopsy Press

This design features a base that holds the samples, multiple cut tracks, and a press that holds samples in place. The base of this device is part of an assembly, which comes apart into four separate pieces at each cut-line. This allows for ease of sterilization, as the multiple tracks will accumulate debris over time. To use the device, the biopsy punch pre-cut cylindrical tissue samples are placed surface side down into the sample slots. The user then aligns the press block with the sample cutouts, applying slight pressure to hold the samples in place. Using the cut track on the side face of the base, the user inserts a razor blade and slides it along the track until reaching the opposite wall. The user can then remove the razor blade and samples.

Another feature of this design is the cut track that runs through the top of the base. The user can insert the samples, surface side down, and insert a razor blade into the top track. After pushing the blade along the track, the user can remove the samples and the razor blade. This process halves the samples, which is ideal for imaging. Both cut tracks ensure that the blade is entirely enclosed until the user removes it from the track.

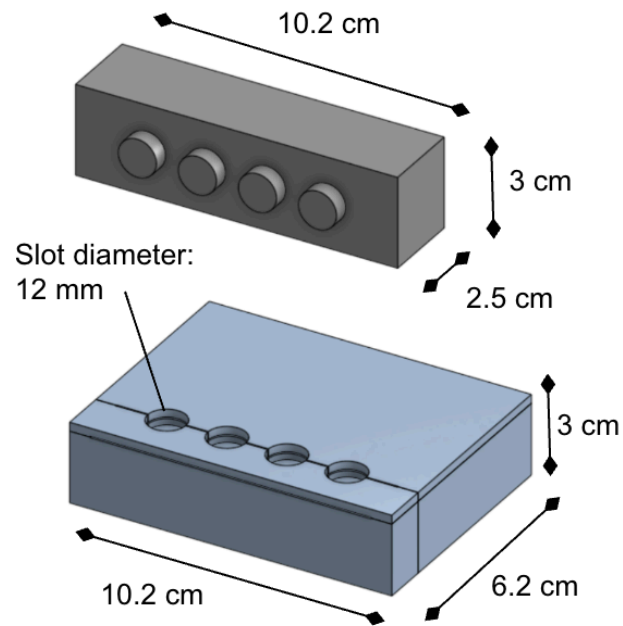


Figure 10: Biopsy Press Design and dimensions [Ella Lang]

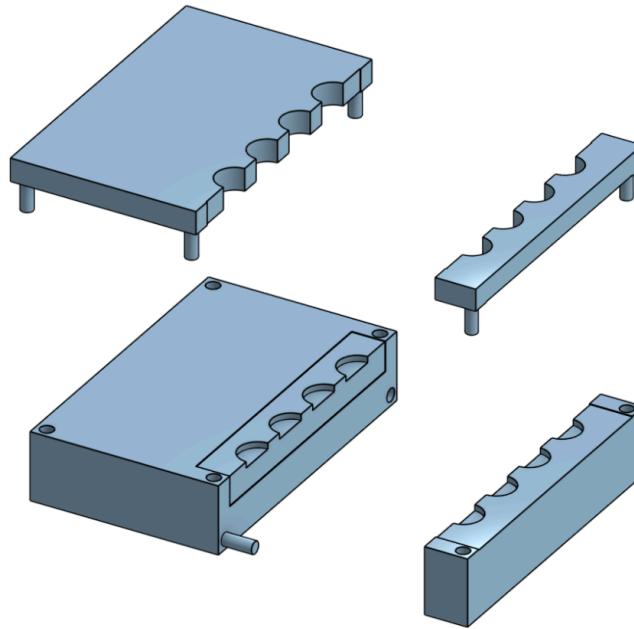
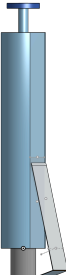
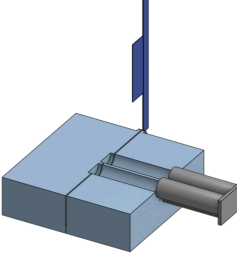
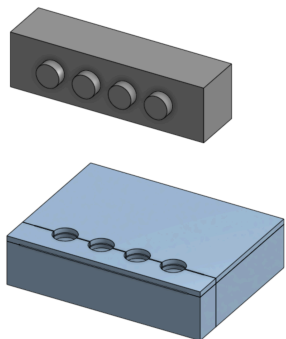


Figure 11: Biopsy Press Design Base Assembly [Gianna Inga]

Design Matrix

Table 1. Tissue Slicing Device Decision Matrix

Criteria:	 Biopsy Punch		 Paper Cutter		 Biopsy Press	
Ease of Use (30)	5/5	30	4/5	24	4/5	24
Cut Accuracy & Precision (25)	2/5	10	5/5	25	5/5	25
Maintenance (15)	3/5	9	4/5	12	3/5	9
Security of Biopsy (15)	3/5	9	4/5	12	5/5	15
Ease of Fabrication (10)	3/5	6	4/5	8	5/5	10
Safety for User (5)	4/5	4	4/5	4	5/5	5
Total	68		85		88	

Criteria Descriptions and Justifications:

Ease of Use: This criterion evaluates how well the end-user will be able to utilize the design throughout the setup and procedure. The device should provide a more straightforward method of trimming the remaining fat off of the biopsy sample, when compared to the current technique of using a pair of tweezers and a blade to shear the tissue.

Cut Accuracy & Precision: This criterion evaluates how well the device will reliably slice through a biopsy sample. Biopsy samples must be consistently cut down to the defined two millimeter thickness with a clean and straight cut along the biopsy cross-section. The accuracy and precision of this cut are a major component of the device's purpose, essential to sample uniformity and therefore experimental outcome.

Maintenance: This criterion evaluates how effectively the design can be cleaned and sterilized between uses to prevent the contamination of samples. Since the device will continuously interact with biological materials, it must also withstand exposure to common sterilization techniques such as autoclaving, chemical disinfectants, or UV treatment without causing degradation. A design that minimizes openings, moving parts, or materials highly resistant to sterilization will score higher. Ensuring sterilizability is crucial for both experimental validity and user safety to minimize any potential risks of biohazards before and after usage of the design.

Security of Biopsy: This criterion evaluates how well the sample is held in place during tissue preparation, set-up, and cutting. The Tissue Processing Tool must stabilize the cylindrical tissue sample in order to produce cleaner cut results and reduce user-tissue involvement. This criterion ensures that the device chosen contributes to the hands-off goal of the device.

Ease of Fabrication: This criterion evaluates the complexity in the manufacturing of the selected design. Since the preliminary design was modeled using OnShape, a CAD software, a 3D printer will be utilized in fabrication. Additionally, the device must have an area for visibility, either through an opening or through a translucent material to ensure consistent slicing of the biopsy tissue samples. This will allow the user to correctly verify measurements and clean the device for the next use.

Safety for User: This criterion evaluates the measure of minimizing the risk of injury to the user during the setup and use of the design. The device should reduce the possibility of accidental cuts, pinching, or any form of exposure to the sharp blades when compared to the current manual method in use for biopsy research. Safety is particularly important given that repetition of cutting

tasks can increase the likelihood of user error. A safer design should ensure having protective features such as blade shielding and a minimal need for direct manual operation of tissues. Although it has the lowest weight of all criteria, it is still a necessary part for design considerations for basic user safety, which is essential for widespread adoption and reliable use in laboratory environments.

Design Scoring:

Ease of Use: Based on the *Ease of Use* criterion, the Biopsy Punch scored the highest at 5/5. This device is designed to be a handheld tool that simultaneously combines the punching and cutting of the biopsy tissue samples. The Paper Cutter and Biopsy Press both scored a 4/5 due to the dynamic mechanisms involved. In the Paper Cutter, the samples need to be loaded into the cylindrical components before the hinged blade can pivot down to cut fat off. In the Biopsy Press, the user needs to ensure that the samples are correctly aligned with the holes before a blade can be used.

Cut Accuracy & Precision: Using this criterion to evaluate the device designs, both the Paper Cutter and the Biopsy Press scored the highest with a 5/5 for cut reliability. The Paper Cutter design has its blade on a hinge located at a two-millimeter depth, using a guide to hold the samples in place when cutting. This ensures a straight cut consistently at the desired two millimeter sample thickness. Similarly, the Biopsy Press holds the samples down as the user runs the blade down a track at the desired two millimeter depth. This design will also produce flat and consistently sized biopsy samples with minimal room for error. The Biopsy Punch design scored the lowest in this category, receiving a 2/5 for cut accuracy. With this design, the location of the cut is dictated by the user, using the plunger of the biopsy punch to depress the sample to the desired cut location. This leaves plenty of opportunity for inaccuracies and inconsistencies within the biopsy samples.

Maintenance: The Paper Cutter scored the highest with a 4/5. Its flat surfaces and relatively simple plain geometry make it easier to sterilize compared to other design choices. However, some joints may still trap small amounts of biological debris, which made it award a full score. The Biopsy Punch score 3/5, since its cylindrical design and narrow cutting channel make

sterilization more challenging, especially after repeated usage. The Biopsy Press as well scored 3/5, because of its complex composition of multiple slots and press interface, which can introduce small gaps in between that may prevent complete sterilization.

Security of Biopsy: The Biopsy Press scored the highest, receiving a 5/5 . This design has cylindrical slots to insert the tissue into before cutting, and a fitted press that is pressed down into the tissue slots and on top of the tissue while cutting. This mechanism ensures the samples stay compact and in place on all four sides. The Paper Cutter design scored the second highest, receiving a 4/5 . The design presses the samples into a wall, allowing for the samples to stay compact and enclosed on three sides. However, with this application of pressure, the tissue samples could bulge on the unenclosed sides, leading to jagged cut edges. The Biopsy Punch came in last, receiving a 3/5 . This is due to the fact that there is no mechanism for the user to apply force onto the samples while cutting, which could lead to jagged edges or the sample falling out if held vertically.

Ease of Fabrication: The Biopsy Press scored the highest with a 5/5 in the *Ease of Fabrication* category. It involves two rectangular blocks with a slit in one, accompanied by circular divots in the main block to hold the tissue biopsy samples. On the other block, there are four circular extrusions that align perfectly with the divots to further contain the tissue samples. For manufacturing, a 3D printer will be able to fabricate this without additional supports. The Biopsy Punch scored a 3/5 because of the combined mechanism of punching the samples and shearing them. The Paper Cutter scored a 4/5 because the main body can be easily manufactured; however, it will be difficult to attach the hinge to the side with a blade attached.

Safety for User: The Biopsy Press scored the highest with a 5/5. Its enclosed press mechanism reduces the user's direct interaction with the blade and keeps their hands away from the cutting surface, hence making it the safest option out of all the design choices. The Paper Cutter scored slightly lower with 4/5 as its mounted blade provides some protection, but still requires users to position samples close to the cutting trajectory, which introduces a moderate level of risk. The Biopsy Punch also scored 4/5 as its design places the user's hand near the blade, which increases the potential risk for injury compared to the enclosed press system.

Proposed Final Design

The initial final design was chosen based on the above matrices and would consist of two components: a base that contains the four samples within the cylindrical slots and a press that sits atop the base and compresses the samples in place.

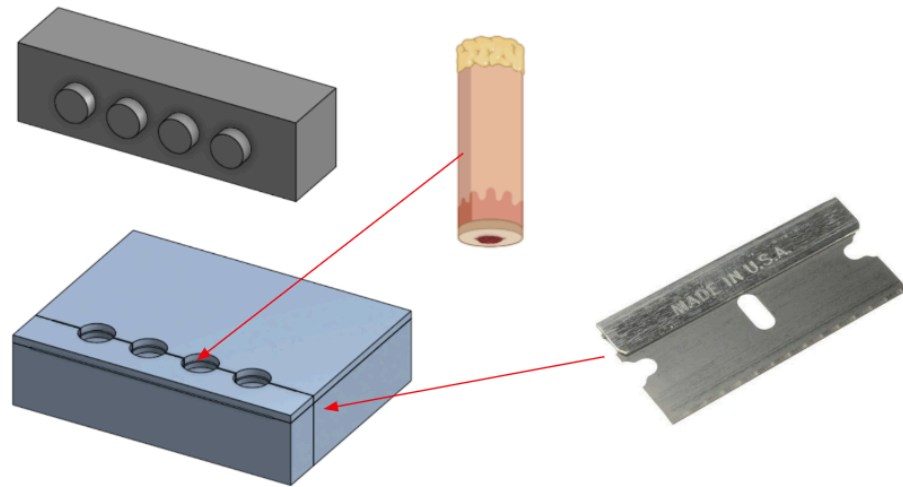


Figure 12: Proposed Final Design – The Biopsy Press Design

During the CAD design process, some initial design choices were implemented, while other design plans pivoted from the design shown in *Figure 12*, such as the pressure applicator design, the implementation of hinged wings, and the addition of a rubber base and razor blade handle. In the initial and final design, male and female internal connector parts were used to allow the device to be easily assembled and disassembled for cleaning and removal of the samples. The dimensions are the pegs and ports consistently share a diameter of 4 mm to allow for a tight connection during the assembly. Additionally, in both designs, cut lines on the front face were implemented into the assembly to allow for a consistent horizontal cut thickness of the cylindrical tissue samples, while a cut line on the top face allows for the cylindrical samples to be halved for imaging. The cut lines are dimensioned to accommodate standard single-edge razor blade dimensions. The initial design iterations were printed in PLA during the prototyping process, but the final prototype was printed in nylon, which are both readily available in the UW Makerspace [11].

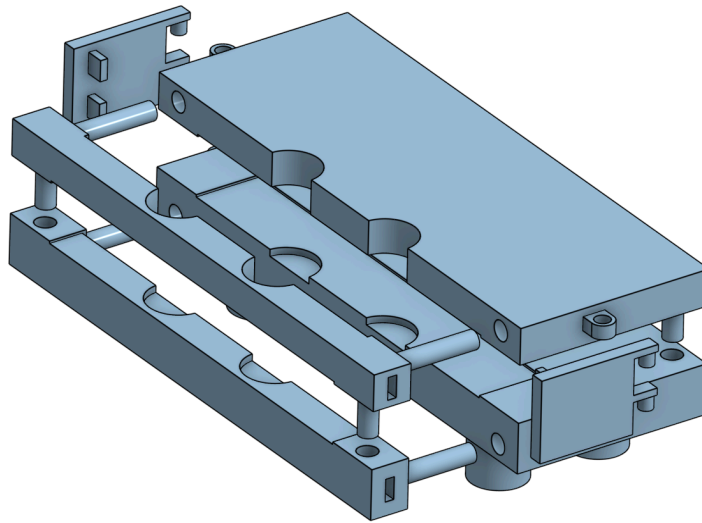


Figure 13: CAD assembly of the final design - base components.

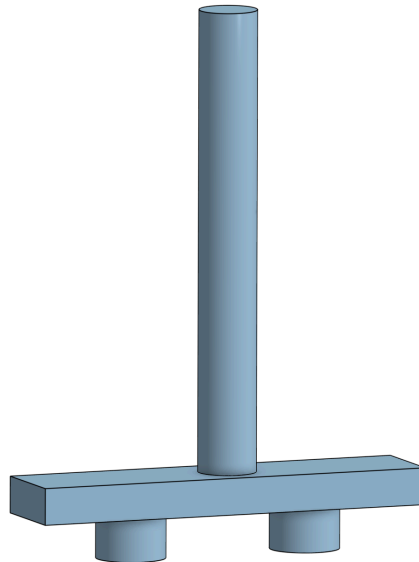


Figure 14: CAD drawing of the pressure applicator.

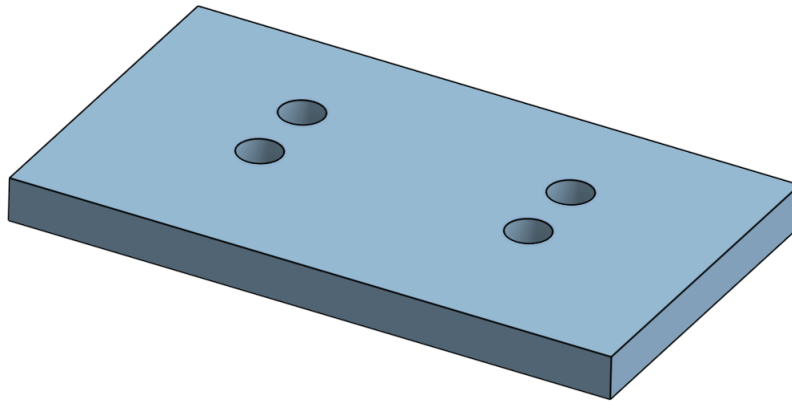


Figure 15: CAD drawing of the neoprene base.

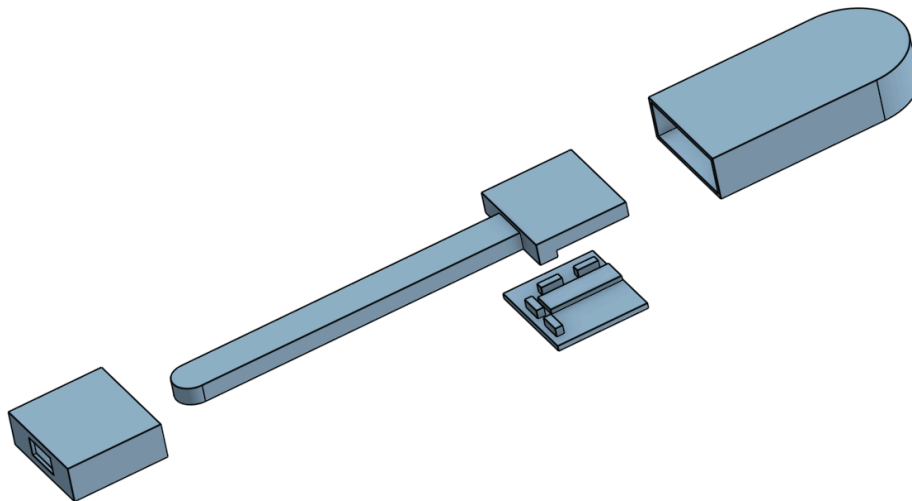


Figure 16: CAD drawing of blade handle components.

In the creation of the final design, two sample slots were implemented instead of four to allow for more accurate pressure application during cutting. The pressure applicator was also modified to have a longer handle that allows the user to maintain a better grip on the applicator during sample cutting (*Figure 14*). The final design incorporates the addition of hinged wings, which securely fasten together the four base components and associated male and female connectors. These wings snap shut and are easily swung open for device disassembly. On the bottom of the device, extruding pegs were added to snap into ports on a neoprene rubber mat (*Figure 15*). The rubber mat was implemented in order to provide greater friction between the

device and the lab bench top, reducing movement of the device during cutting. Lastly, a blade handle was implemented to hold the razor blade securely and allow for controlled cutting, as shown in *Figure 16*. This handle incorporates a slide-on shield that allows the user to cap the blade while not in use, increasing user safety.

Fabrication

Materials

The main requirements for the device materials are that they are sterilizable / cleanable, cheap, and sharp to cut the sample. To achieve this the body of the device will be 3D printed for ease of replacement for the client and fabrication. The ideal 3D printable material was Nylon 12 through the formlabs fuse 1 printer as it is able to withstand the normal sterilization cycle of an autoclave as it has a heat deflection temperature of 171 degrees celsius at .45 MPa [11]. It is also able to be wiped down with 70% ethanol and come into contact with media as it has a low fluid weight gain of .2% for both salt water and isopropyl alcohol when submerged for 24 hours [11]. Nylon 12 is also able to be sterilized by EtO, plasma, chemical, and gamma processes [12]. PLA is also an option for the material as the client has access to an ultimaker printer. Where it falls short of Nylon 12 is because of the fabrication process and material properties. PLA is fabricated by printing layers while Nylon 12 is printed by laser fabrication. Thus, PLA has micro-gooves that can house bacteria, media, and tissue. PLA also cannot be autoclaved as when it is, it causes significant distortions [12]. However, it is able to withstand and be cleaned with EtO and plasma [12]. Throughout the design process, both materials were utilized, but nylon 12 was chosen as the final design while PLA was implemented in prototyping and initial testing.

The blade material will be stainless steel as it is sharp, corrosion resistant, cost effective, and readily available in the market [13]. Currently, in the lab, the client has access to single edge razor blades, #10, and #11 surgical blades. Thus, to minimize spending and utilize the lab's vendors, the design must incorporate the dimensions and be compatible with one of the blades. The client decided to focus the design to be compatible with the single edge razor blade, thus that was the material utilized in the final design.

The neoprene rubber baseplate was additionally implemented through the iteration of design to further improve the stability during cutting by increasing friction between the Biopsy

Press and the fume hood benchtop. A 12.7 mm thick, 50A-60A durometer neoprene sheet was specifically chosen because its hardness range accomplishes the strong surface grip while maintaining durability during repeated loading [14]. Neoprene also withstands repetitive cleaning with 70% ethanol and does not degrade significantly which makes it suitable for long-term usage along with other design components.

Methods

The biopsy press base, blade holder, and sample presser were all fabricated utilizing 3D printing. To do so, they were all first rendered on onshape CAD software.

The base design was constructed with two 13 mm diameter wells, each 10 mm deep to house the sample during cutting. These wells were split by cut tracts both horizontally and vertically to generate the 2mm slice from the epidermis and the diameter for image processing. Cut tracts were 1mm in width, 94 mm in length, and 23 mm in depth to ensure that the blade would not rotate, cut the device, and entirely pass through one sample before interacting with the other one while cutting. The base was also split into 6 parts: 4 to separate the base on the cut lines for cleaning and 2 winged panels on each side to secure the parts together. The 4 main parts interact with each other through female and male cylindrical extrudes and holes while the winged panels can swing on a pivot point and secure into a well on separate parts. This securement design was chosen to increase the lifespan of the device, as snap together parts create a lot of strain on 3D printed parts and can break faster.

The blade handle was designed to secure a single edge razor blade by its center and one side hole. The first part of the handle was constructed by encasing one side of the blade to the center hole and extruding through the holes. This part also had a simple handle design that was based off of a surgical handle to increase ergonomics, which ended up being 102 mm long, 10.5 mm wide, and 5 mm thick with a rounded edge. To encase the other side of the blade, another part was designed to sandwich the blade and further its securement through inverse extrudes and wells. Finally, to avoid a snap design, a shell lock was incorporated, in which a part was designed to encapsulate the sandwich parts and the blade in between it. A cap was also designed to further safety of the device while not in use.

Finally, a sample presser was created to apply pressure on the samples to ensure no movement and a clean cut. Its design was the inverse of the wells in the base design, with 12mm diameter extrudes 10mm in length. The extrudes were connected by a top plate in which a cylindrical handle extruded vertically off of. The handle was 10mm in diameter and 80 mm in length to mimic a standard biopsy punch to increase ergonomics and user comfort.

These parts were printed using both PLA and nylon 12 depending on the goal of the print. To test out prototype iterations and changes PLA was utilized as each print would cost approximately \$2 and take 5 hours. When the design was finalized for testing, it was printed with nylon 12 as the print cost approximately \$25 and took a whole weekend. When printing with different materials however, there is a difference in tolerance needed for the parts to accurately interact with each other without complications like not fitting, excess friction, too loose, etc. PLA interaction tolerance was .2mm while nylon 12 was much smaller at .05mm. When fabricating, the difference was not known and when the final design that worked in PLA was printed in nylon, it was too loose for accurate functionality. Future designing and fabrication will implement these versatile tolerance dimensions when printed between PLA and nylon 12.

After obtaining the initial sheet of neoprene rubber through purchase from Grainger retail store, it was further fabricated using a waterjet cutter provided by Design Innovation Lab to achieve clean, precise geometry. Four circular holes with a diameter of 12.7mm were cut through entirely of the neoprene sheet without tearing or deformation. The corresponding four pegs were also printed as additional, modified parts of the biopsy press base using nylon 12 and PLA material. To assemble the base, the modified neoprene rubber sheet was positioned beneath the device, and each peg was pressed through its matching until fully seated. No adhesive was required since the tight mechanical fit prevented shifting between the two intersections.

Final Prototype

After iterative prototyping, design evaluations, and fabrication of the body, base, applicator, and blade handle, a finalized prototype was produced.

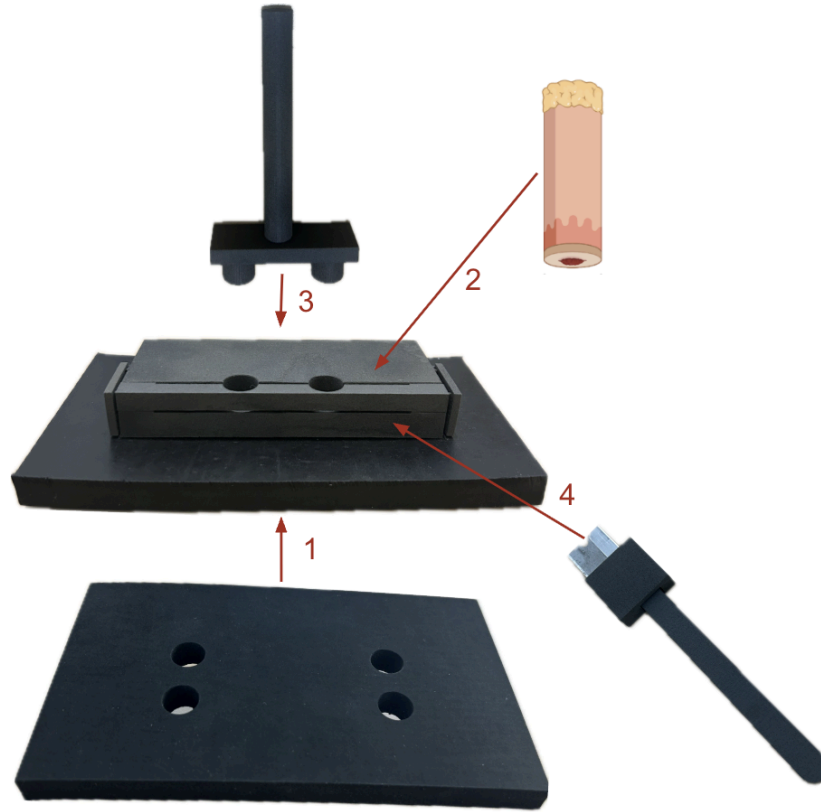


Figure 17: Assembly and use of the final design printed in nylon 12. 1: Attach the rubber base plate to the pegs on the bottom of the device. 2: Insert the cylindrical tissue sample fat side up. 3: Apply pressure to the tissue samples with the applicator. 4: Insert the blade into the horizontal cut line.

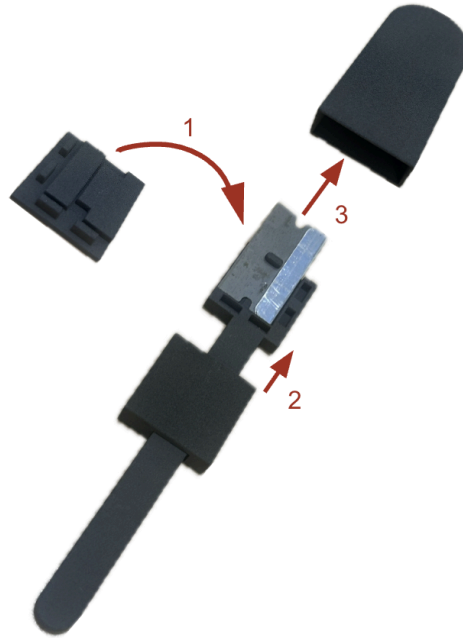


Figure 18: Assembly of the final razor blade handle design. 1: Snap together the handle and square piece. 2: Slide the bottom cover up. 3: Cover the blade with the cap.

To use the final device, the cylindrically-punched tissue samples are placed fat-side up into the slots, and the user applies the applicator to hold the biopsies in place. As shown in *Figure 18*, the user will attach the razor blade to the handle through its center hole, enclose the bottom half of the blade with a snap-in piece, and slide up a cover that sandwiches the blade in place. Next, the razor blade is inserted into the horizontal cut-line and slid through the device to shear the 2mm portion of fat off the tissue samples. The device has built-in walls, which stop the razor blade from exiting the device and potentially causing injury to the user. Additionally, there is a vertical cut-line perpendicular to the primary horizontal cut track. Similarly to slicing the fat off the samples, the user can run the blade down the biopsies to halve the tissue samples, which is needed to perform imaging of the samples. After blade use, the cap can enclose the razor blade while it is still attached to the handle. This final design costs approximately \$20 to 3D print in nylon 12 [11].

Testing and Results

A comprehensive testing protocol was developed to ensure that the final design functions as intended, and adheres to the quality standards posed by the client. In order to test the efficacy of the biopsy press with the blade, a series of tests were performed to determine how well the design executed its functions in areas such as maintenance, cut accuracy, ease of operation, and biopsy sample security. First, a sanitization test was performed with a solution to identify best practices for maintaining and cleaning the biopsy press. Next, medical students and research interns at the UW-Madison SMPH conducted simulated experiments to evaluate the effectiveness of the slicing mechanism of the biopsy press. The medical students were given styrofoam, a material that closely mimics the density of porcine skin. The research interns in the RENEW lab implemented porcine samples to further simulate the studies the clients will participate in. Lastly, an Finite Element Analysis (FEA) test was completed on OnShape to identify potential weak points of the frequently used components.

Based on the results from the usability and feedback surveys, as well as the sanitization test and FEA, the team will implement new ideas and iterate on the device to further meet client specifications. For variability purposes, different students, interns, and researchers will be subjected to usability surveys to ensure uniformity across tissue biopsy processing methods.

Sanitization Testing

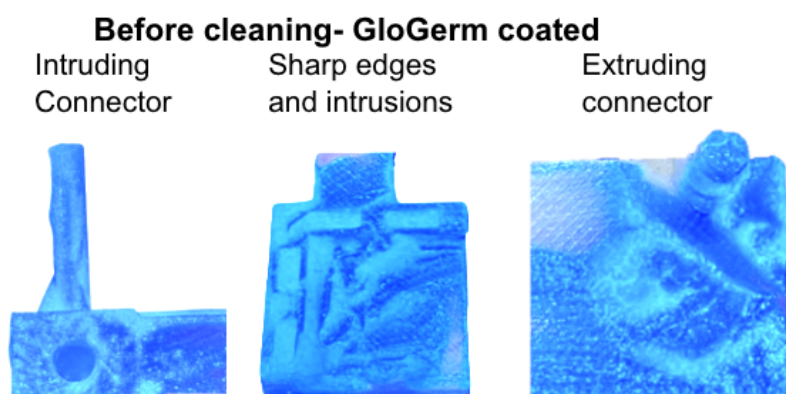


Figure 19: GloGerm coated device components.

To evaluate the buildup of fat that may occur within the device after frequent use, sanitization testing was performed. GloGerm lotion solution was used to mimic the sticky quality of porcine fat, and each face of the device that may come into contact with fat was coated in the GloGerm solution, as shown in *Figure 19*. GloGerm is Ultra Violet light-activated, and when subjected to UV light, can be visually examined [15]. Two cleaning methods were tested to evaluate which was most effective in removing the GloGerm from the device, with images taken immediately following each sanitization method (see *Appendix D*).

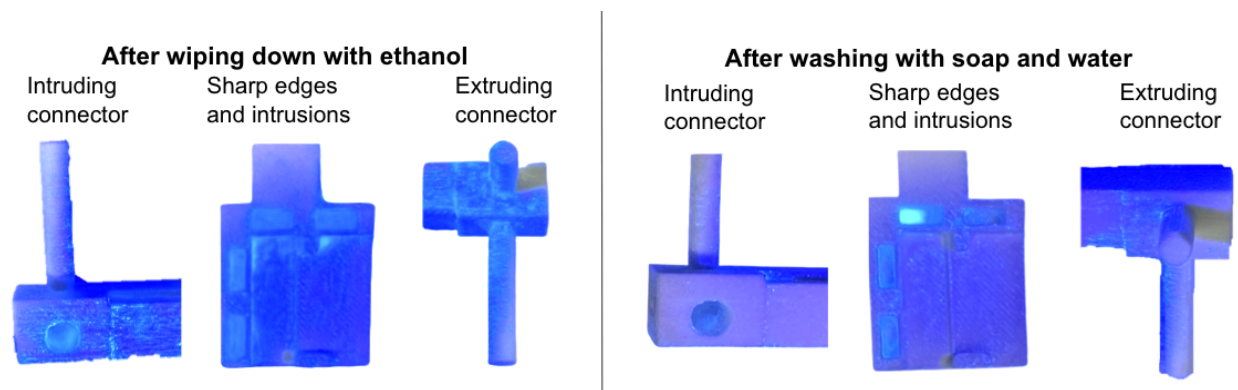


Figure 20: Results of sanitization testing with spray ethanol and soap and water.

The first test evaluated the effectiveness of using spray ethanol and paper towel to remove the GloGerm solution. The results shown in *Figure 20* showed that there was some minor residual solution buildup on flat surfaces, and significant build up within intrusions and sharp edges. The second test looked at cleaning the device with soap and water. This test produced more favorable results, with less flat surface, intrusion and sharp edge build up. Ultimately, it is recommended that the client clean out the device using soap and water after each day of testing.

Usability Survey

Survey testing was conducted to gather user input on the ease of use and functionality of the device. Survey participants were volunteers from a sample of UW-Madison School of Medicine students, all participants having ample experience with lab blades to assure safe and comfortable use of the device. Samples of styrofoam were prepared to simulate pig skin biopsy samples, each sample 12 millimeters in diameter and 5 millimeters in thickness. Participants

were given a briefing (outlined in *Appendix D*) on how to use the device and asked to slice the styrofoam biopsies into 2 millimeter thick, bisected samples, using the biopsy press.

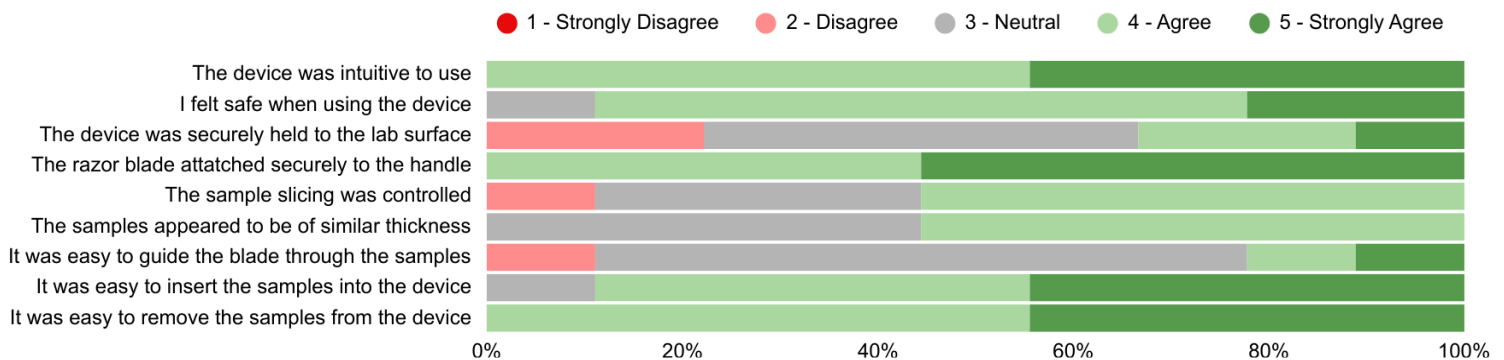


Figure 21: Usability survey responses with each participant rating each question on a scale of 1-5 (a score of 1 indicating strongly disagree and 5 indicating strongly agree).

After completing their task, participants were given a survey evaluating different aspects of the device on a scale from one to five, a score of one indicating strong disagreement and a score of five indicating strong agreement. Ratings were overall positive, as displayed in *Figure 21*. Scores reflected satisfaction with the intuitiveness, safety, and security of the device and felt it was simple to insert and remove the biopsy samples from the press. However, scores also indicated trouble guiding the blade through the samples and keeping the device securely held to the lab surface.

Additionally, participants were asked to give any further commentary or suggestions for improving the device. Participants experienced some difficulty inserting the blade into the horizontal slicing interface and found that the pressure applicator would obstruct the path of slicing, disrupting horizontal cuts. Also, the wide variance in force applied by the pressure applicator was found to cause discrepancies in the final sample sizes. When samples were removed and the device was disassembled, users also felt that the extruded pegs holding the device together were too fragile, snapping off in multiple instances.

After initial survey testing, the device was handed off to the client, who used the device in a lab setting with real pig skin samples, leaving commentary more specific to the device's actual use. In the vertical slicing task, the thin, sticky, samples were pushed into the horizontal slicing path, making it very difficult to vertically slice and remove the samples. This was

attributed to the thickness of the path and the dullness of the razor blade. The client felt the razor blade used for slicing was too thick and dull to easily slice through the samples and led to variability in final sample thickness. The client noted that the inconsistency in force from the pressure applicator also led to discrepancies in final sample thickness with the porcine tissue, similar to the participant feedback from the styrofoam survey testing.

Finite Element Analysis (FEA)

A finite element analysis test was performed to identify potential weak points of the design. Both the surface and pegs of the body of the biopsy press and handle of the razor blade are subjected to varying forces, ranging from grip strength to shearing force required to slice the biopsy samples. A range of force from 10-20 Newtons for the biopsy press body and 1-5 Newtons for the razor blade handle was considered and used in the simulation [16], [17]. A von Mises stress analysis, as compared to a max principal stress analysis, simulation was implemented as nylon exhibits predominantly ductile properties [18].

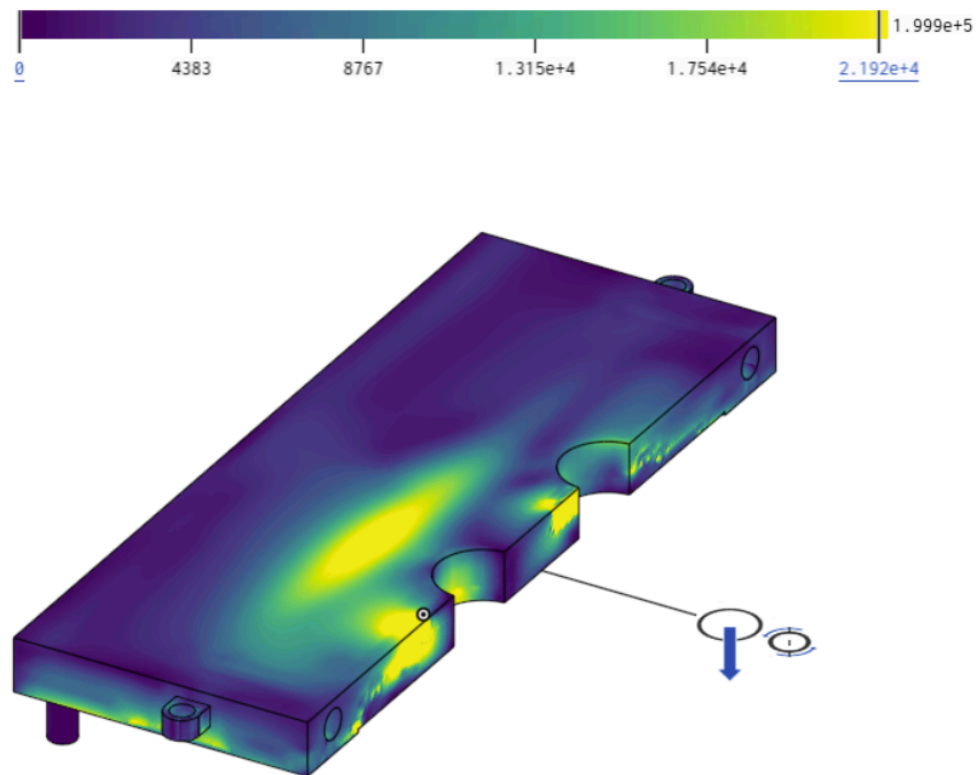


Figure 22: Simulated force exertion results on the lateral pegs and surface of the press.

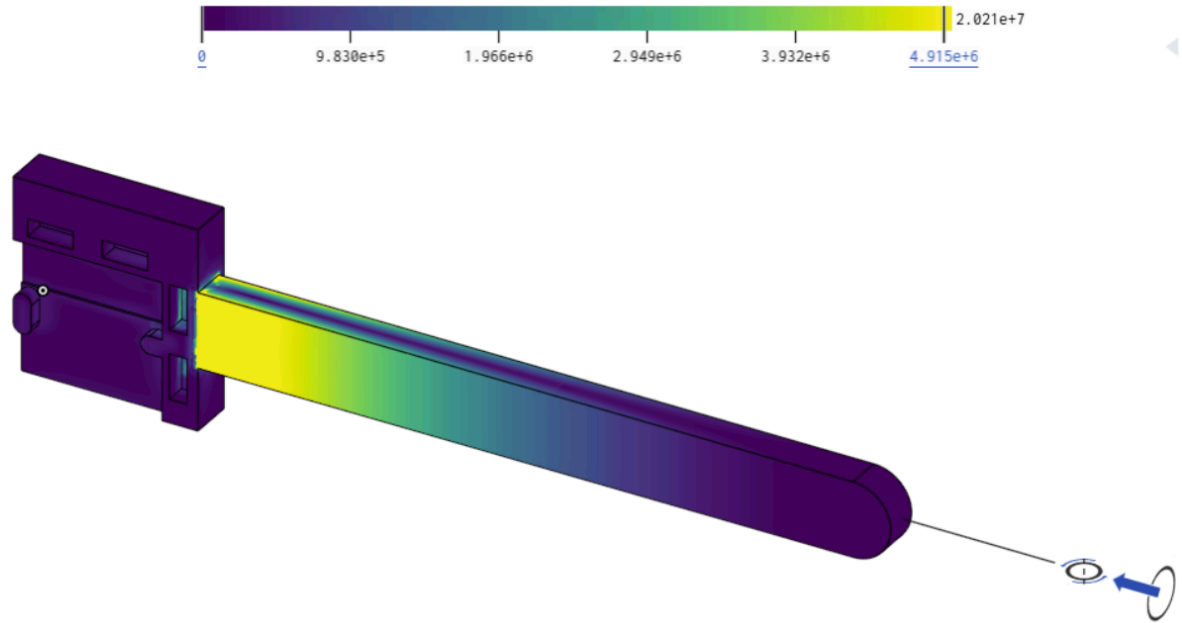


Figure 23: Simulated force exertion results on the handle of the razor blade.

The results from the study are shown in above Figures 22 and 23. A 22 N force was applied to the surface of the biopsy press; this value was slightly above the considered range, accounting for additional impact forces that could potentially be exerted by the user. Despite this force exaggeration, the biopsy press was able to withstand upwards of 22 kPa without the critical risk of deformation, reinforcing its structural integrity. Similarly, a 9 N force was directed at the rear end of the handle, which was able to absorb substantial amounts of force. There was a minimal risk around the point of connection between the handle and the shield, but generally could support up to 5 MPa while providing stability for the user to cut the tissue samples. Overall, both of these components emphasized the device's durability and strength, being able to withstand the user's applied forces, allowing successful processing of tissue biopsy samples.

Discussion

Analysis of images taken during the two trials of the sanitization testing revealed the efficacy of wiping the device down with ethanol in comparison to washing it with soap and water after use. With using only ethanol to wipe down the device, gel residue was very apparent within harsh edges and intrusions, ineffectively cleaning the surfaces of the device. After washing the

device with soap and water, the gel was much more significantly removed from the flat surfaces and edges of the device, though it still remained within the deep instructions of the connective pieces and blade handle. To limit this effect, it is recommended that future iterations of the device avoid harsh edges and such deep connector intrusions to avoid porcine fat buildup in the device and allow for easier cleaning. For the current model, to best sanitize the device, it should be washed with soap and water after use to rid of any fat buildup, followed by a wipedown with ethanol to disinfect the device for future use.

The FEA results reinforced the structural stability of the lateral pegs and main surface of the biopsy press, as well as the handle of the razor blade. While there were no points in the design where critical failure was imminent, the surface of the press and the connection between the razor blade and the shaft absorbed more energy, making it more susceptible to deformation. To address this, a higher infill of chosen material can be 3D printed to increase the overall strength of the device.

Overall, usability testing provided key insights on validating the major functional elements of the design but also prompted targeted improvements. The testers of the final prototype noted that controlled downward force and rigid housing minimized tissue deformation, which aligns with literature emphasizing mechanical stabilization as primary determinant of biopsy thickness consistency. [6] Along with minor feedback including blade insertion difficulty, connector's weakness, applicator's peg height adjustment. Feedback also guided to the next major iteration of the design that mainly dealt with redesigning the cutting system into two separate, dedicated sections, where one is optimized for horizontal cutting and another for vertical cutting instead of having a combined section of both pathways. Separating these mechanisms is expected to improve precision especially in vertical cutting of samples with thickness of 2-3mm after initial horizontal cutting.

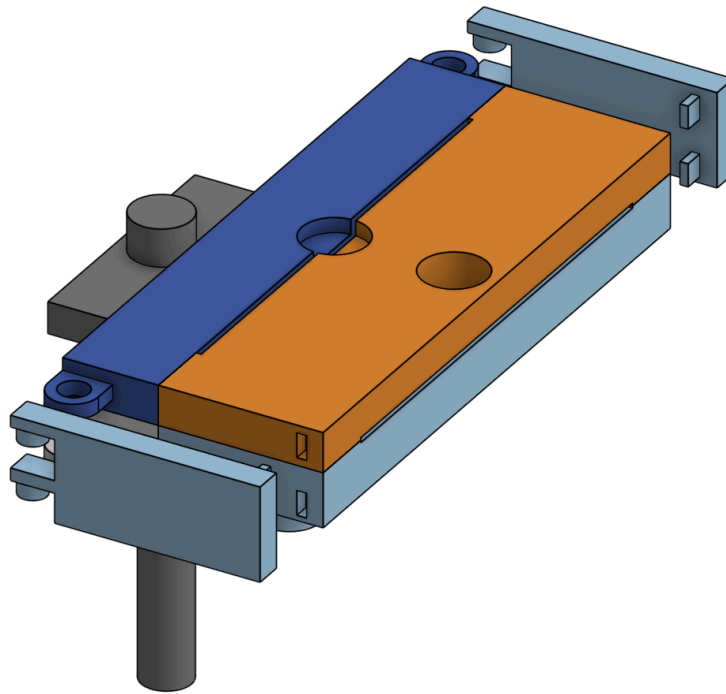


Figure 24: Updated with modifications from the clients on the final design of Biopsy Press

Furthermore, users noted specific challenges with the razor blade itself with difficulty in maintaining fully perpendicular orientation even with the use of the final prototype. This indicates the need to switch from razor blade to a sharper, more effective cutting option. Carrying on with further discussion with client, the decision came to switch to standard #10 or #11 surgical blades that provide superior sharpness, stiffness, and better cutting profile. Therefore, the cutting interface along with blade handle and casing will be further modified to accommodate the dimensions and orientation of those new blades that will be incorporated into the design. The surgical blades will offer better precision when applied to sectioning small cylindrical biopsies.

Conclusion

The Biopsy Press was developed to achieve precision, safety, and consistency in preparing porcine skin biopsies for wound headline studies. This final prototype integrates a guided press system, perpendicular cutting tracks, and a neoprene baseplate that enhances friction and stability when in contact with laboratory surfaces.


Testing outcomes across sanitization trials, usability assessments, and finite element analysis collectively validated the core functionality of the prototype while highlighting areas for refinement. Sanitization testing showed that soap-and-water cleaning removed residue more effectively than ethanol alone, confirming that the device can be reliably cleaned but that deeper connector geometries may trap debris. Usability testing demonstrated that users were able to prepare samples safely and intuitively, with strong agreement on device stability and sample control; however, users also noted challenges with blade insertion, variable pressure application, and the tendency of thin samples to shift during vertical cutting. FEA supported these findings by confirming that the nylon structure withstands expected loading without failure, while identifying localized stress concentrations at the press surface and blade-handle connection that will benefit from future reinforcement. These outcomes from various testings support the prototype's potential for consistent, efficient preparation of 12-mm cylindrical biopsies at controlled thicknesses

While the core mechanisms performed effectively with the finalized prototype, testing also identified areas that require refinement. Blade slot accessibility, tolerance control of the alignment rails, and the performance limitation due to razor blades indicated the need for further design iteration. Upcoming modifications informed by client feedback include transitioning to surgical blades and developing segregated vertical and horizontal sections to improve visibility and enhance cutting accuracy. Future work will expand with more testing with porcine samples, adjustments with internal areas to minimize residues trapped after sanitization, and implementation of a new type of blade. With receiving more feedback while working further with the clients, more sophisticated design components may be included. Examples of such include integrating threaded bolts for providing more security of biopsies' containment inside the device and scaling the system to handle more biopsies simultaneously for high-throughput research. Through continued iterations, the Biopsy Press aims to become a next-staged, advanced

benchtop tool that significantly elevates efficiency and reproducibility in biopsy preparation for the client's research.

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Appendix

Appendix A: Material Expense Spreadsheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	9/26/25	1	\$5.00	\$5.00	N/A
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	10/16/25	1	\$1.20	\$1.20	N/A
Rubber Slab	12 in x 12 in sheet of 50A black rubber	Grainger Vendor	6050-1/2A	Grainger	848EH8	10/31/25	1	\$49.99	\$49.99	https://www.grainger.com/product/Rubber-Sheet-Commercial-Grade-848EH8
Glo Germ Gel - White	Gel used to investigate thoroughness of surface cleaning.	Glo Germ	GEL	Avantor Science Central	470100-620	11/7/25	1	\$25.75	\$25.75	https://www.avantorsciences.com/us/en/product/8875880/glo-germ
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	11/18/25	1	\$1.84	\$1.84	N/A
PLA	3D printed	Makerspace	N/A	UW-Madison	N/A	11/25/25	1	\$1.79	\$1.79	N/A

	polymer through BME design Makerspace budget					5				
Nylon	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	11/28/2 5	1	\$21.00	\$21.00	N/A
Nylon	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	12/3/25	1	\$19.50	\$19.50	N/A
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison		12/10/2 5	1	\$3.08	\$3.08	N/A
								TOTAL:	\$129.15	

Appendix B: Product Design Specification

Function

The purpose of this design is to improve the precision and consistency of processing small tissue biopsies for ex vivo wound healing studies. Current methods rely on manual tools such as surgical scissors or scalpels, which often leave residual fat layers and lead to variations of sample thickness that compromise culture viability. The client, Dr. Angel Gibson, requires a reliable method for reducing porcine tissue biopsies to a uniform thickness of 2 - 3 mm while maintaining perpendicular cuts across the sample. The design must be able to hold 12 mm cylindrical biopsies and allow for precise trimming of the lower fat with ease of usability to ensure that samples remain viable for extended culture. Overall, by standardizing sample preparation, the design is aimed to minimize variability through experiments, improve the desired outcomes, and fasten the workflows for the client in tissue engineering and wound-healing research.

Client Requirements

- ❖ Device must evenly cut cylindrical 12 mm diameter porcine tissue samples to a thickness of 2-3 mm
- ❖ Device must have a fixed blade that can be easily replaced
- ❖ Device must be portable
- ❖ Device must be able to cut cylindrical 12 mm diameter porcine tissue samples vertically down the center
- ❖ Device must be easily sterilizable
- ❖ Device must be able to cut up to 4 samples at a time
- ❖ Device must allow for sample visibility during cutting
- ❖ Device should be easily reproducible

Design Requirements

1. Physical and Operational Characteristics

a. Performance Requirements

- i. The device must remove the lower 2 mm of a 12 mm diameter pig skin biopsy sample in order to increase the sample's viability through fat removal.
- ii. The device must be sterilizable by autoclave, UV radiation, or 70% ethanol between each use.
- iii. The blade of the device must be commonly sourced and easily replaceable in the device.

b. Safety

- i. To best prioritize the safety of the user, the device must follow common laboratory cutting safety measures to limit possible harm to the user. During use, the device must secure on the lab table top without slipping. The blade of the device should be safely contained when not in use and must also be easily removable with minimal effort and contact with the user. The device should limit the user's contact with the blade to minimize the possibility of injury [1].

c. Accuracy and Reliability

- i. The device must be able to cut tissue biopsy samples to a thickness of 2 to 3 mm from epidermis to dermis and allow variation of ± 0.2 mm. Cuts should also remain parallel to the biopsy surface within 2° to avoid tilted spaces that can compromise culture viability. The device system should perform at least 95% repeatability across experiments up to 48 biopsies and maintain cutting precision for a minimum of 200 samples before blade replacement is required.

d. Life in Service

- i. The device should remain functional for at least one year of routine laboratory use under standard sterilization and cleaning purposes. With consideration of up to 48 biopsies per experiment and having around 20 experiments per year, each unit is expected to withstand approximately 1000 biopsy cutting cycles before requiring replacement of core components (not including the blade). For cutting performance, two blades are available: Tissue-Tek Accu-Edge High Profile Blades (PTFE-coated, designed for microtomy/cryotomy) and Standard Razor Blades (Stanley 11-515, high-carbon steel). Accu-Edge blades are optimized for dense tissues like pig skin and are expected to last around 200 cuts per blade according to histology practice. Standard razor blades are less durable and should be expected to last 100 cuts before dullness compromises cutting precision.

e. Shelf Life

- i. Non-disposable components of the device should maintain structural integrity, sterility, and usability when stored under a set range of ambient environments (20-25 °C, 20-80 % relative humidity) [2]. Disposable blades should be able to retain sharpness and sterility for 12 months when sealed and stored unopened. Following the common sterilization methods that includes autoclaving, UV irradiation, alcohol wiping), the device's materials should be able to resist corrosion and degradation. Small metal instruments autoclaved and stored in double-wrapped linen indicate that

they can remain sterile up to 96 weeks while packaging integrity and storage conditions are maintained [3].

f. Operating Environment

- i. The device should be used exclusively for laboratory environments in controlled settings in biosafety cabinets. It should operate under ambient conditions identical to the ones stated in Shell Life criteria. Since sterility is critical for the success of tissue culture, the device should be able to withstand repeated sterilization by autoclaving at $\geq 121^{\circ}\text{C}$, UV radiation in biosafety cabinets, and chemical wipe-downs with isopropanol or ethanol without causing material degradation [2]. All exposed surfaces of the device should resist corrosion, moisture and contamination from biological fluids. Sharp edges should be protected to ensure operator safety during sample handling. For storage, environmental control guidance suggests maintaining $22\text{-}26^{\circ}\text{C}$ and $\leq 60\%$ relative humidity in sterile supply areas to protect both reusable device components and packaged disposable blades [4].

g. Ergonomics

- i. The device should be intuitive to use, with cuts able to be done in swift motions. Tissue samples should be held in place during cutting and be easily removable upon completion to reduce user involvement. All blades should have grippable handles and run on a track to increase user comfort, safety, and sample cut consistency. The device should incorporate a measurement system and clear sides to assist the user in preparing uniform samples without the need for individual measurement. Additionally, the device itself should firmly attach to a surface to reduce slipping upon blade engagement.

h. Size

- i. The size of the device must accommodate the small dimensions of the sample for accurate performance, as well as be large enough to be controlled by the user. It must contain a cylindrical porcine biopsy sample with a diameter of 12 mm and height ranging from 4 to 5 mm. To be easily

used and not overoccupy the lab table area, the device should be within 75-125 mm in length and width. Furthermore, since the client stated that blades dull after 4-5 cut samples, the cutting component must be replaceable and thus the dimensions should allow for market product blades. The most common surgical blade is No. 10 with a blade length of 41.7 mm and thickness of .4 mm [5]. An average single edge razor blade length is 38.1 mm and thickness of .3 mm [6]. Thus, these dimensions should be implemented into the design for the ease of manufacturing and cost.

i. Weight

- i. The device must be transportable for storage and movement around the lab for the user. Thus, the weight maximum of the total design must be .25 kg.

j. Materials

- i. The main requirements the materials need to meet are that it needs to be sterilizable, cheap, and sharp to cut the sample. For the blade, most market surgical products utilize stainless steel as it is sharp and corrosion resistant [7]. As for the rest of the design, since the client has access to a 3D printer, she recommended that it be utilized for ease of fabrication. Thus, Nylon 12 will be used for the design as it can be sterilized in many ways: autoclave, EtO, plasma, chemical, and gamma [8] [9, p. 3]. This is shown by its low fluid weight gain, .2% for both salt water and isopropyl alcohol when submerged for 24 hours, which makes it safe to be wiped down and come in contact with the sample media [10]. It also has a high heat deflection temperature of 171 degrees celsius at .45 MPa which makes the device safe for the autoclave which averages around 134 degrees celsius at .22 MPa [10] [11]. The way nylon is fabricated also makes it the best material to use as it does not contain microgaps that can harbor contaminants and bacteria if not sanitized properly.

2. Production Characteristics

a. Quantity

- i. A single prototype of the design will be created for use in the client's lab. However, the device must be easily manufacturable for possible use on a larger scale in biopsy laboratory research.

b. Target Product Cost

- i. The client has set a maximum budget of \$500, though considering the cost of projected materials the estimated cost is likely to be around \$100. To be potentially market competitive, the device must have a comparable price to existing biopsy punches and blades, ranging from \$10 to \$150 depending on blade quality [12][13].

3. Miscellaneous

a. Standards and Specifications

- i. In addition to the client requirements, there are specific ISO and FDA standards the design needs to adhere to. Generally, surgical scalpels and blades must follow good manufacturing and quality control practices, proper registration and documentation, and need to meet labeling requirements [14]. Moreover, ISO 13402:2025 states the resistance of surgical instruments to corrosion, heat, and autoclaving, which is extremely relevant to the environment the design will be placed in. ISO 7153-1:2016 covers metallic materials for surgical instruments, specifically high-carbon stainless steel [15].

b. Customer

- i. Dr. Angela Gibson, MD, PhD, FACS, based in Madison, Wisconsin, is a surgeon, associate professor, and the Vice Chair of Research at the UW Hospital, and Medical Director of UW Health Wound Healing Services [16]. She specializes in surgically treating trauma and burns and performing surgical critical care. Dr. Gibson's RENEW (Regeneration, Engineering, and Novel Epidermal Wound-healing) Wisconsin Lab focuses on epithelial cell regeneration in burn injuries, the evaluation of skin substitutes, and human tissue model development for wound healing [17].

- ii. Ms. Bailey Donahue, BS, is a Research Technician in the RENEW Wisconsin Lab. Bailey oversees lab operations and helps conduct tissue experiments. She also contributes to the lab's research by investigating wound-healing mechanisms and working on therapies aimed at improving outcomes for burns and other injuries [18].

c. **User / Researcher-related Concerns**

- i. To guarantee viable tissue samples, each tissue biopsy taken needs to ensure complete fat removal such that the remaining thickness is 2-3 mm. All biopsies are contained within a 12 mm diameter and approximately 5 mm thick punch; the design needs to accommodate for this small, cylindrical shape while cutting down the sample to just the epidermis and dermis.

d. **Competition:**

- i. Acu-Punch - Disposable Skin Biopsy Punches [19]: These small, handheld tools cut precise biopsies and come from a complete set of fourteen sharp, sterile sizes, ranging from 1mm to 12mm. Each tool utilizes an ergonomic, ribbed handle for control and comfort. They are individually wrapped in sterile packaging, available in boxes of 10, 20, or 50. These range from \$35.00-\$156.80.
- ii. Sakura Finetek USA - High Profile Microtome Blades [20]: These FDA Class I tools are designed for high profile blade holders and have sharp edges at a 35 degree angle to deliver high quality performance and durability. Each soft tissue blade is coated in a PTFE resin to reduce friction when sectioning, either in microtomy and/or cryotomy. These blades are available in a set of 50 for \$190.65 [21].

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Appendix C: Fabrication Protocol

3D Printing Protocol

Materials:

- Nylon filament spool (D.I. Lab approved material)
- FDM or SLS 3D printer configured for nylon
- STL files for all device components
- Printer bed adhesive or SLS chamber powder (depending on equipment)
- Tweezers or dental pick for debris removal
- Compressed air or soft brush
- Nitrile gloves

Printer Setup Instructions:

1. Upload the STL model files to the print management software.
2. Orient components to minimize support usage and to maintain dimensional accuracy for connector ports and sample wells.
3. Set printing parameters appropriate for nylon (temperature, layer height, infill).
4. Load nylon filament or prepare the SLS powder chamber depending on printer type.
5. Preheat the printer as required for nylon processing.

Printing Instructions:

1. Begin the print and monitor the first 2–3 layers to ensure proper adhesion.
2. Allow the print to run to completion. (D.I. Lab nylon jobs typically require extended print time relative to PLA prints, the duration for us to print nylon took roughly a week)

3. When printing finishes, let the printed parts cool inside the machine to avoid thermal deformation.
4. Remove components from the build plate or powder chamber.

Post-Processing Instructions:

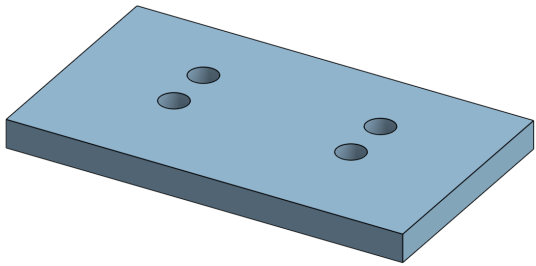
1. Use tweezers or a dental pick to remove nylon dust and residue from infill holes, ports, and internal geometries (as shown in fabrication documentation).
2. Lightly brush off remaining powder and debris using compressed air or a soft brush.
3. Inspect all critical dimensions, including peg connections, sample wells, and slot features, to confirm they match CAD specifications.
4. Place components on a clean surface and prepare for subsequent assembly.

Quality Verification:

1. Dry-fit parts to verify that connector tolerances allow proper assembly.
2. Document any warping, elongation, or dimensional deviations in the fabrication log for use in future iterations.
3. Approve parts for device integration once confirmed dimensionally and structurally sound.

Waterjet Cutting Protocol

This equipment was used to create the neoprene rubber base plate that provides stability and surface grip for the device



CAD Drawing (base plate with neoprene rubber)

Material list:

- Neoprene rubber sheet (0.25–0.5 in thickness)
- Waterjet cutting machine (D.I. Lab)
- CAD or .DXF cut file for base plate
- Clamp fixtures for securing material
- Protective gloves and safety goggles
- Paper towels for drying

Waterjet Cutting Machine Setup instructions:

1. Power on the waterjet machine and complete the standard system calibration.
2. Load the neoprene rubber sheet onto the machine bed.
3. Use clamps to secure all four corners of the neoprene sheet to prevent shifting during cutting.
4. Upload the finalized cut file to the machine interface.
5. Verify toolpath alignment using the machine's preview function.
6. Adjust water pressure and abrasive flow to settings appropriate for dense rubber material.

Cutting Procedure

1. Initiate the cutting process and monitor the progress through the machine enclosure window.
2. Continue observing until the waterjet completes the perimeter and peg-hole cuts for the base plate.
3. Once finished, turn off the machine and wait for the carriage to return to its home position.
4. Remove clamps and lift the neoprene sheet from the bed.
5. Blot excess water from the surface using paper towels.
6. Inspect cut edges to ensure smooth geometry and confirm that peg holes match the intended dimensions.

Post-Fabrication Steps

1. Place the base plate on a clean surface and allow remaining moisture to air dry.
2. Align the base plate with the four pegs on the underside of the device's main base assembly to verify proper fit.
3. Record fitment observations and note any modifications needed for future iterations.

Appendix D: Testing Protocol

Sanitization Protocol

Participants asked to use the device to evaluate sufficient sanitization after use. In place of porcine tissue residue, a biologics-free product, GloGerm, is used for the visualization of cleaning mode effectiveness. GloGerm is UV reactive.

Material list:

- 1 UV flashlight
- 8 oz Lotion-based GloGerm solution
- 1 Small paintbrush
- Paper towel
- Spray bottle of ethanol
- Bottle of dish soap

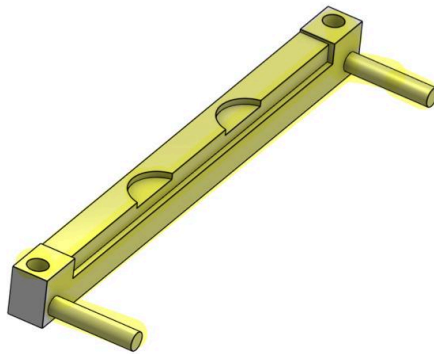
- 1 sponge

Material setup instructions:

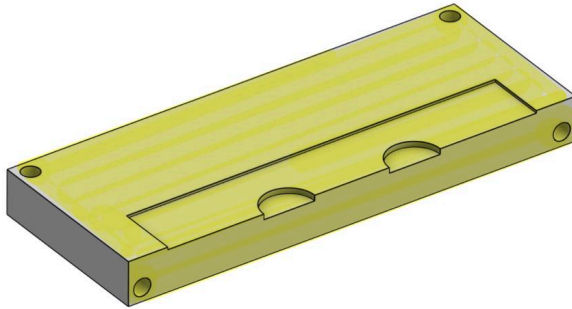
1. Separate the device into four pieces and place the pieces on a paper towel
2. Place a tablespoon of GloGerm solution in a dish
3. Wash and dry the paintbrush

GloGerm application instructions:

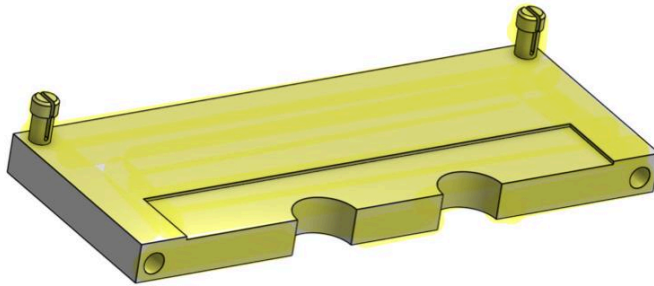
1. Thoroughly coat the tip of the paintbrush with GloGerm solution
2. On the half of the bottom base with extruding and intruding connection components, evenly apply GloGerm to the inner face, top face, sample wells, intruding connection ports and protruding cylindrical connectors. Reapply GloGerm to the paintbrush as needed. See highlighted application area diagram below.



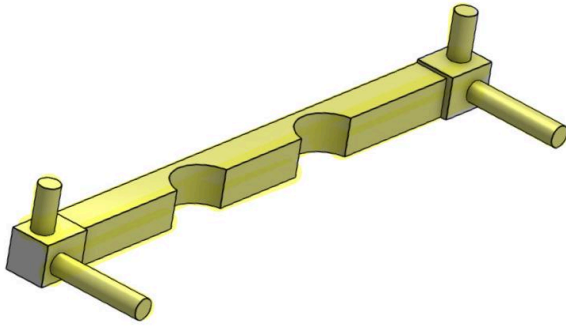
3. Set the prepared base half off the side on a clean paper towel
4. On the half of the bottom base with intruding connector sites, evenly apply GloGerm to the inner face, top face, sample wells, and inside the connection ports. Reapply GloGerm to the paintbrush as needed. See highlighted application area diagram below.



5. Set the prepared base half off the side on a clean paper towel
6. On the top half of device with intruding and extruding connection components, evenly apply GloGerm to the bottom face, inner face, including sample holder walls, extruding connectors and inside of connector ports. Reapply GloGerm to the paintbrush as needed. See highlighted application area diagram below.



7. Set the prepared top half off the side on a clean paper towel
8. On the top half of the device with extruding connectors, evenly apply GloGerm to the bottom face, inner face, including sample holder walls and extruding cylindrical connectors. Reapply GloGerm to the paintbrush as needed. See highlighted application area diagram below.



9. Set the prepared top half off the side on a clean paper towel

Soap and water testing instructions:

1. Prepare device components according to the GloGerm application instructions section
2. For each of the four pieces:
 - a. Run thoroughly under warm sink water for 20 seconds
 - b. Apply dawn dish soap to a sponge and scrub the device component under warm water for 20 seconds
 - c. Pat the component dry with a clean paper towel
 - d. Set the component out to air dry for a minimum of 15 minutes
 - e. Image all orientations of the component using the UV light, ensuring any intruding ports are visible

Ethanol spray testing instructions:

1. Prepare device components according to the GloGerm application instructions section
2. For each of the four pieces:
 - a. Spray all faces, connectors and ports with ethanol
 - b. Use a dry paper towel to wipe down all faces, connectors and ports for 45 seconds
 - c. Set the component out to air dry for 3 minutes
 - d. Image all orientations of the component using the UV light, ensuring any intruding ports are visible

Usability Survey Protocol

Survey participants are University of Wisconsin School of Medicine students with background experience and comfort with lab blades to best mitigate safety risks. Participants volunteered to take part in testing and signed forms of consent.

Participants asked to use the device to slice 12 mm diameter, 5 mm long biopsy samples that have been preprepared out of styrofoam.

Instructions for using device:

1. Insert 12 mm biopsy sample into each indentation on the base of the device (2 samples total)
2. Attach covered razor blade to blade handle
3. Unsheathe razor blade
4. Use compression piece to lightly press down on the biopsy samples, aligning the extrusions with the indentations in the base
5. Insert razor blade into side slot in the base and slice through samples
6. Remove razor blade from device
7. Insert razor blade into top slot in the base and slice through sample cross sections
8. Remove razor blade from handle and dispose of blade in sharps bin
9. Take off top section
10. Remove biopsy samples
11. Visually compare the prepared biopsy samples
12. Reassemble device

Participants will be asked to repeat the sample slicing procedure twice. After completing this task, participants will be asked to fill out a printed survey assessing the performance and functionality of the device. Each question will be answered by assigning a number based on their satisfaction, a rating of 1 indicating strongly disagree and a rating of 5 indicating strongly agree, 3 indicating neutrality.

Survey Questionnaire given to participants as follows:

Please evaluate each of the following statements on a scale of 1-5 based on your agreement, a score of 1 indicating strong disagreement, a score of 3 indicating neutrality, and a score of 5 indicating strong agreement. Your answers to this survey will remain anonymous and the data collected will be presented in aggregate form with no identifying information.

The device was intuitive to use:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

I felt safe when using the device:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

The device was securely held to the table:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

The razor blade attached securely to the handle:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

The sample cutting was controlled:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

The samples appeared to be of similar thickness:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

It was easy to guide the blade through the samples:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

It was easy to insert the samples into the device:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

It was easy to remove the samples from the device:

1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

Any suggestions to improve the device?

FEA Applied Load Protocol

1. Open OnShape, create a new assembly tab by clicking the + in the lower left corner
2. Import the selected parts into the page by clicking Insert.

3. Right click on the imported parts and select Nylon as the material from the OnShape library
4. Select the force simulation icon, in the top right corner, and input the considered forces for each component
5. Select the moment simulation icon, in the top right corner, and input the considered moment for each component
6. Finalize the direction of the applied forces and moments
7. Generate the simulation and wait for the results to load.

Appendix E: IRB Submission Exemption Approval

EXEMPTION GRANTED

NO ACTION REQUIRED:
Exempt review process has been completed.

VIEW APPLICATION

Print Form
 Compare

+ New Change

+ Update Personnel

+ New Reportable Event

ACTIVITIES

Export Application to PDF

Submit Study Closure Report

→ Edit Administrative Access

→ View Study Team Training

→ Register a NetID

Improving the Precision of Small Human Tissue Biopsy Processing

Improving the Precision of Small Human Tissue Biopsy Processing

APPLICATION DETAILS

ID: 2025-1650

PI: Tracy Puccinelli

Reviewing Board: MRR IRB

Staff Reviewer: Monica Esquibel

Reviewer Contact: mesquibel@wisc.edu

MILESTONES

Date Submitted: 11/7/2025

Initial Approval: 11/19/2025

+ MORE DETAILS

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graph LR
    A([Pre-Submission]) --> B([Scientific Review])
    B -- "Modifications Requested" --> A
    B --> C([IRB Staff Pre-Review])
    C -- "Modifications Requested" --> B
    C --> D([IRB Committee Review])
    D -- "Modifications Requested" --> C
    D --> E([Review Complete])
            
```

History	Follow-On Submissions	Reviewer Notes	Correspondence	...
Activity	Author	▼ Activity Date		
Create Pdf Snapshot	Esquibel, Monica	11/19/2025 3:31 PM		