Improving the Precision of Small Human Tissue Biopsy Processing

Preliminary Report

Biomedical Engineering Design 400

Department of Biomedical Engineering

University of Wisconsin-Madison

October 8, 2025

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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. In addition to this, the device has the added functionality of halving the cylindrical samples after culturing for improved sample imaging workflow. Prototype fabrication plans have been created, and testing protocols will be further developed through the prototyping process to assess the overall success of the prototype. By the close of the semester, a final prototype will be presented to UW-Madison faculty, Dr. Angela Gibson, Bailey Donahue, and peers.

Table of Contents

Introduction

Motivation

Every year in the US, there are around one million burn-related injuries, about 50,0000 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.

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

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].

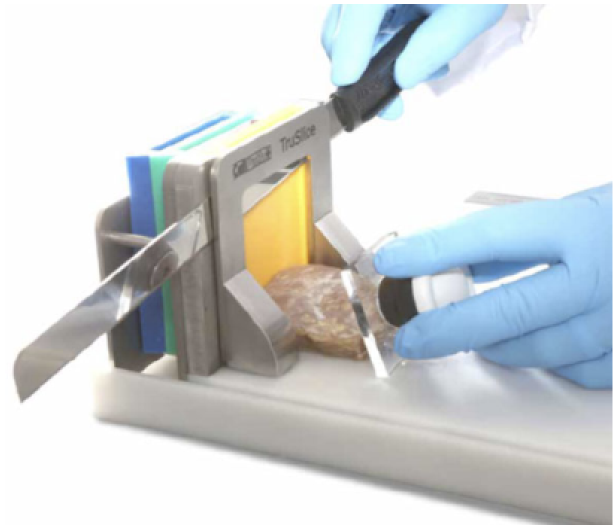


Figure 2: TedPella, Inc. TruSlice Specimen Cut-Up Grossing System $1878.75 [6]

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].

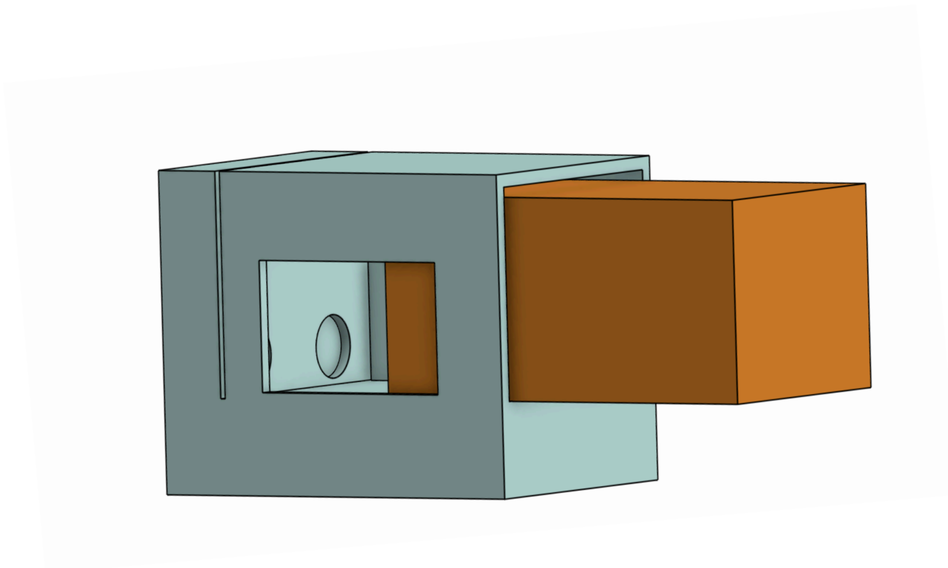


Figure 3: OnShape CAD drawing of client initial prototype [Bailey Donahue]

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.

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. Additionally, this process of creating samples is not standardized, resulting in samples of varying sizes with jagged edges, which limits the efficiency 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

Relevant Physiology and Biology

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.

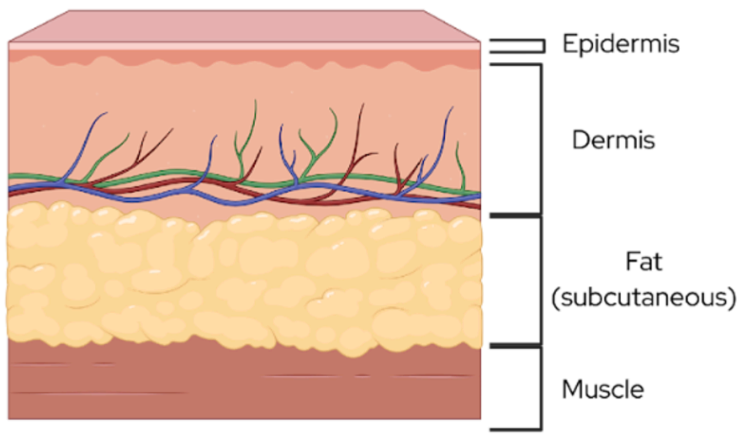


Figure 4: Major layers of the skin – epidermis, dermis, subcutaneous fat (hypodermis). [Bailey Donahue]

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 length 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.

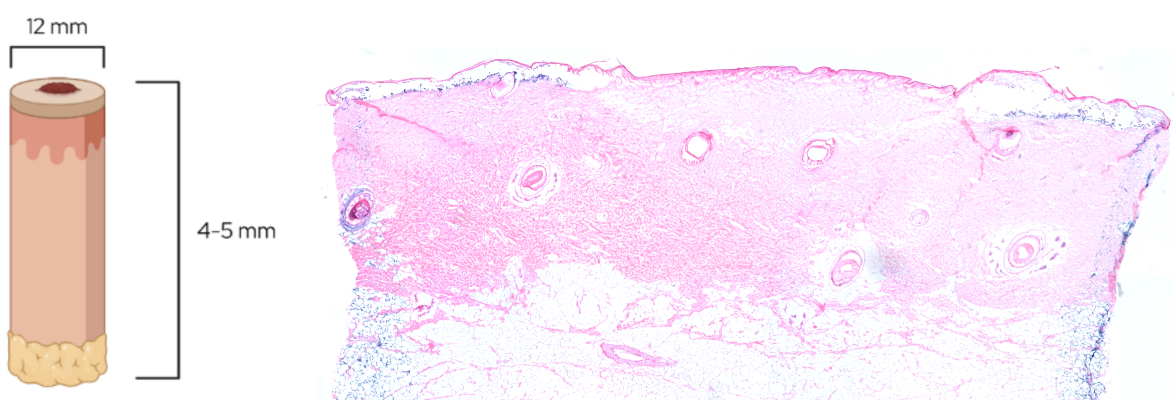


Figure 5: LDH stained pig skin sample *without* additional fat removal; lack of stain indicating poor viability [Bailey Donahue]

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.

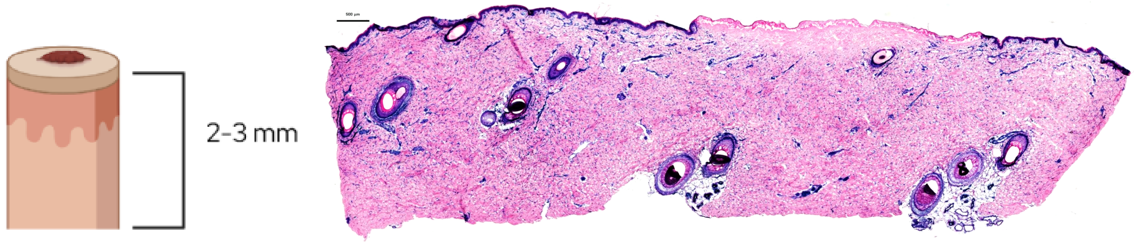


Figure 6: LDH stained pig skin sample *with* additional fat removal; blue LDH stain indicating viability [Bailey Donahue]

Seen in *Figure 6*, the sample with the removal of additional fat 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, 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 Madison - Wisconsin 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^{o}. 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. 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.

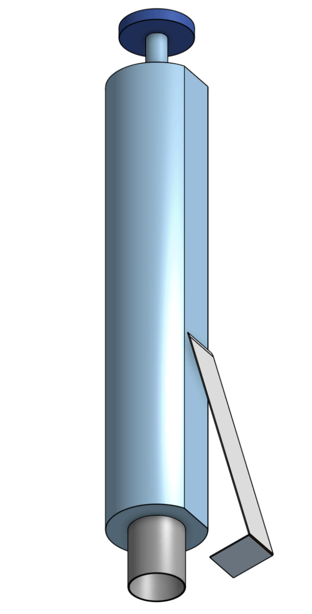


Figure 7: Biopsy Punch Design [Sarah Raubinstine]

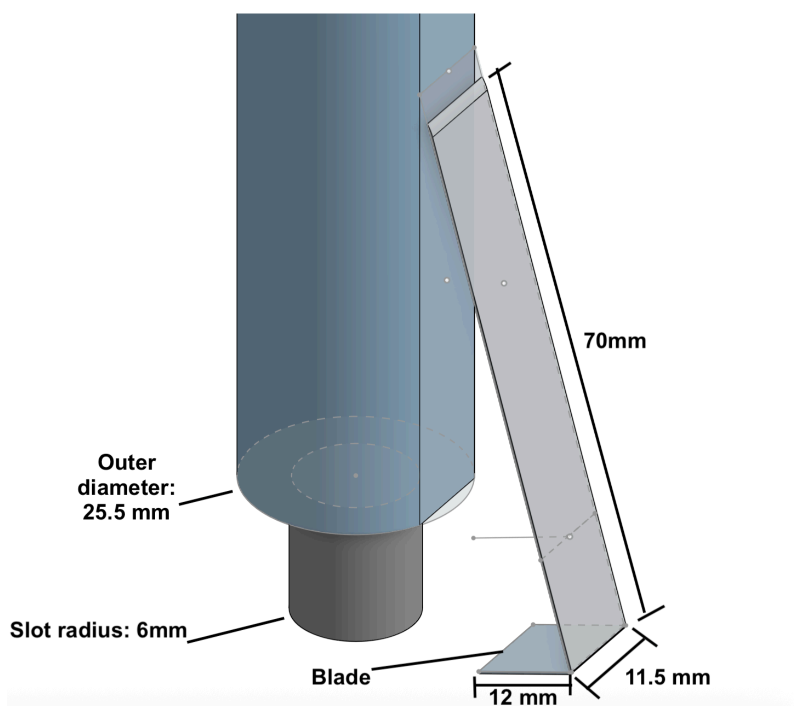


Figure 8: Biopsy Punch Design with dimensions [Sarah Raubinstine]

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 10*. This allows the user to access and wipe down the center of the device that may accumulate debris over time.

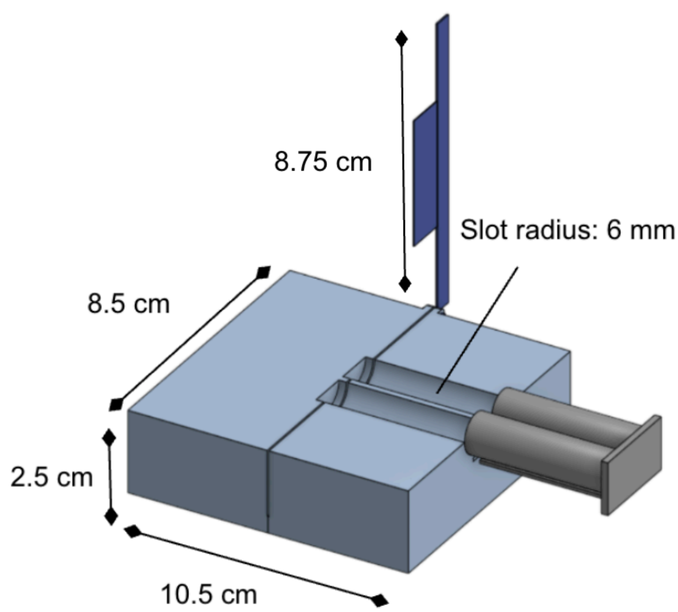


Figure 9: Paper Cutter Design with dimensions [Gianna Inga]

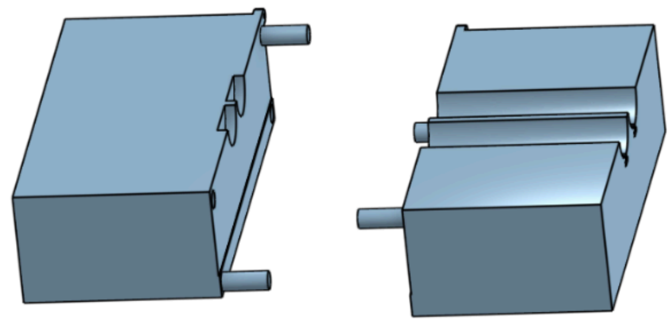


Figure 10: Paper Cutter Design Base Assembly [Gianna Inga]

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.

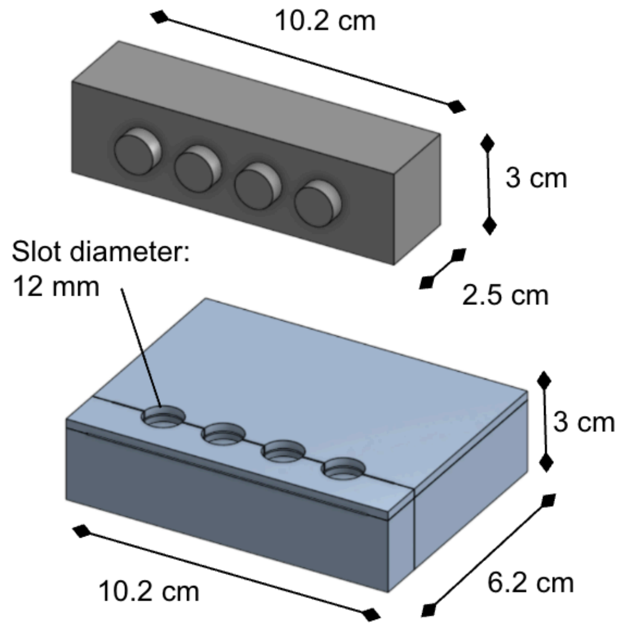


Figure 11: Biopsy Press Design and dimensions [Ella Lang]

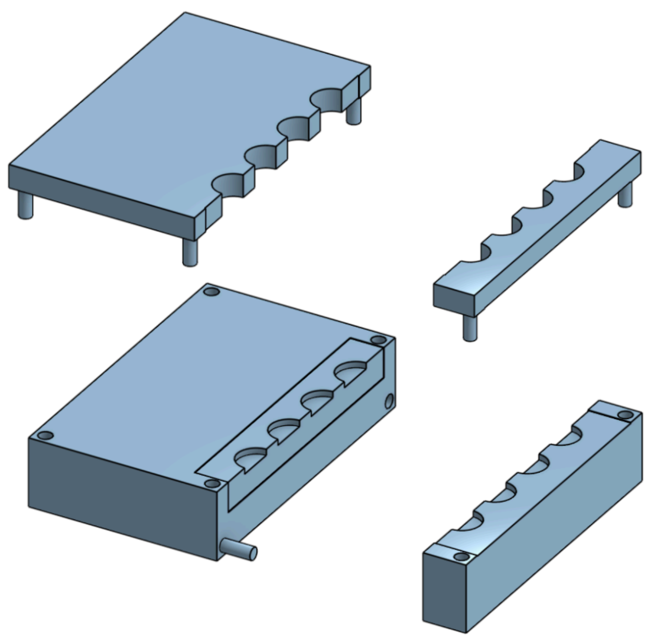
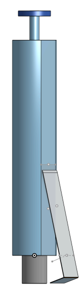
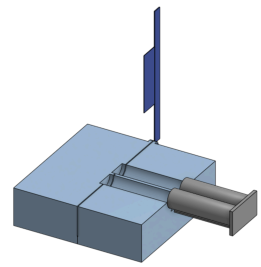
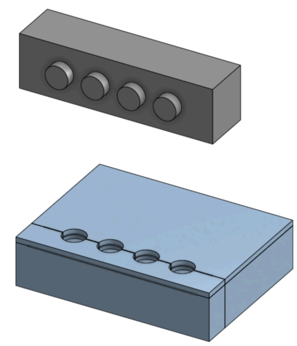


Figure 12: Biopsy Press Design Base Assembly [Gianna Inga]

Table 1: Tissue Processing Tool 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.

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 is 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].

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 will incorporate the dimensions and be compatible with one of the blades.

Methods

The Biopsy Press will be fabricated through 3D printing using finalized CAD models designed for precision and safety. All components, including the base, press housing, and cutting tracks, will be printed in PLA or PMMA, or Nylon 12 to ensure durability and sterilizability. Blade slots and alignment features will be integrated into the model to maintain perpendicular cutting and consistent thickness. Blade mounting hardware will also be fabricated using stainless-steel fasteners to ensure corrosion resistance and easy disassembly for cleaning. The sample chamber will be arranged with removable silicone pads to prevent tissue slipping during pressing and facilitate cleaning between uses. There will be minor adjustments made as needed to optimize fit and functionality before further validation with samples.

Proposed Final Design

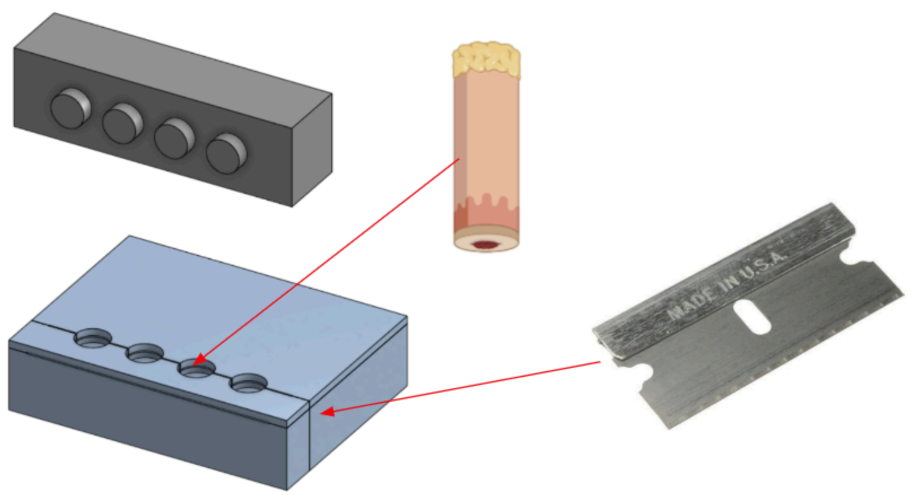


Figure 13: Proposed Final Design – The Biopsy Press Design

The proposed final design consists of two major components: a base that contains the samples within the cylindrical slots and a press that sits atop the base and compresses the samples in place (*Figure 13*). All connector parts and holes consistently share a diameter of 4 mm to allow for a tight connection during the assembly. The design will be printed in PLA during the prototyping process, but the final prototype is anticipated to be printed in nylon or BioMed clear resin, which is readily available in the UW Makerspace [11]. The core base of this device is assembled from four different parts, which attach at the cut tracks (*Figure 13*). After the cylindrically-punched tissue samples are placed fat-side up into the slots, the user will apply the press to hold the biopsies in place. The user will then insert a razor blade into the horizontal cut-line and slide it through the device to shear the ~2mm portion of fat off the tissue samples. The device has a built-in wall, which will stop the razor blade from moving further and potentially causing injury to the user. Additionally, there is a vertical cut-line perpendicular to the primary horizontal cut track. In a similar fashion to slicing the fat off the samples, the user can run the blade down the biopsies to half the tissues, in order to perform imaging techniques. Moreover, since this design is modeled on a CAD software (OnShape), the user is able to customize the amount of slots for the samples to increase performance metrics for research studies. All considered materials (PLA, PMMA, nylon, BioMed resin) are advantageous to use due to its sterilizability and accessibility [12]. One final consideration is the translucence of the material; the user will need to be able to visualize the point where the blade is slicing the samples in order to maximize cut accuracy/precision.

Testing and Results

A comprehensive testing protocol will be developed to ensure that the final design functions as intended, as well as adheres to ISO standards and quality requirements posed from the client. In order to test the efficacy of the device coupled with the razor blade, the client's porcine skin models will first be utilized to determine how well the design performs in certain areas, such as cut accuracy, ease of use, maintenance, and security of biopsies. After iterating on the design to ensure it accommodates all of the requirements, the team will then move into cadaver specimens to measure efficiency at different variations of skin density, elasticity, and viscoelasticity [14].

Additionally, the team will review the mechanical aspects of the device, such as wear resistance and strength, through geometric dimensioning and tolerancing (GD&T), FEA analysis, and a universal testing machine (MTS). Through CAD platforms like SolidWorks and OnShape, control of geometric characteristics and manufacturable parts to validate and standardize the assembly will be assessed [15]. Using the same software, an in-depth FEA analysis will be conducted to predict performance in laboratory or clinical environments through simulation to prevent potential areas of failure [16]. Lastly, simulating a typical compressive force used in biopsy cutting against the device will verify strength and life in service in cycles [17].

The practical use of this device will be qualitatively analyzed through the client's porcine skin models that undergo trauma at the surface level via the contact-burn device. Through usability and feedback surveys, the team will iterate on the device to further meet client specifications. For variability purposes, different clinicians and researchers will be subjected to usability surveys to ensure uniformity across tissue biopsy processing methods.

Discussion

The Biopsy design aims to address the client's requirements for consistency and efficiency in removing subcutaneous fat from porcine burn biopsy samples. The finalized design that consists of a press and base system with horizontal and vertical cutting tracks, enables controlled, reproducible tissue sectioning while minimizing variability and tissue damage that is common in the manual scalpel method. The integrated blade stops and enclosed geometry safety and user control. The customizable number of cylindrical slots also allow variations in scales for high-throughput research applications. Compared to existing tissue slicing systems such as the TedPella matrices or TruSlice, the Biopsy Press is more adaptable to small, cylindrical biopsy samples with lower cost advantage and suitable for repetitive laboratory procedures.

Ethical considerations are considered in every stage of the design. By ensuring reputable cuts and reducing experimental variability, the Biopsy Press reduces the total number of porcine samples required for testing which supports the ethical principle of animal research. Furthermore, enclosed cutting design reduces user exposure to sharp edges and biological materials that aligns with laboratory safety standards [18]. The use of sterilizable materials such as PLA, nylon, and BioMed resin further supports the biosafety compliance while maintaining reusability.

Since this report precedes the fabrication and testing phases, the results discussed at this point are only based on preliminary CAD evaluations and design rationale. The upcoming fabrication and testing phases as mentioned in Testing and Results section will involve use of MTS mechanical testing, finite element analysis (FEA), and porcine skin trials that will validate the structural strength, cut precision, and ergonomic performance. Some sources of error may include variations of user force application, material deformation of the holder under numerous sterilization processes, and tolerance mismatches between the sample slots and biopsy sizes.

Anticipated design revisions will address press alignment, ease of disassembly for sterilization and optimization of material transparency to improve blade visibility during the biopsy procedure.

Conclusion

The Biopsy Press was selected as the final design due to its strong balance of safety, accuracy, and manufacturability. The device fulfils the primary objective of enabling perpendicular, repeatable cuts of 12-mm biopsy samples down to 2-3 mm thickness while also maintaining stable security and visibility for samples. Its enclosed composition not only improves cut consistency but also protects users from direct contact with blade. Overall, the benchtop assembly and use of replaceable, standardized blades make it both practical and cost effective for Gibson Lab. With the collected results, further design adjustments will prioritize improving cleaning accessibility, durability, and ergonomic handling. In the future, the Biopsy Press may be refined into a sophisticated system capable of cutting multiple biopsies simultaneously or applicable for other tissue models used in wound healing studies. Through continued testing and iteration, this design aims to significantly improve precision and reproducibility in biopsy procedure.

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Appendix

Appendix A: Material Expense Spreadsheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Prototype Prints										
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
								TOTAL:	$5.00	

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 ≥ 121℃, 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 22-26 ℃ and ≤ 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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