Improving the Precision of Small Human Tissue Biopsy Processing

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ABSTRACT

Current laboratory research into novel burn treatments frequently relies on porcine skin models to analyze wound healing behavior and cellular regeneration. For preserving tissue viability during ex vivo culture and imaging, subcutaneous fat must be completely removed from the skin samples. However, the conventional method of removing this fat involves manual holding of the sample with forceps and freehand slicing with a scalpel, which is arduous, inaccurate, and exposes laboratory personnel to ergonomic strain and hazards by sharp blade contact. Existing commercial tissue slicing matrices fail to securely stabilize the small, cylindrical skin punches required for this specific protocol. This study details the design, fabrication, and testing of the Biopy Press, a novel laboratory benchtop device engineered to expedite and standardize the procedure of 12 mm diameter porcine skin biopsies. The device features a layered assembly of a 3D-printed Nylon 12 and machined polycarbonate that incorporates a cylindrical sample well, a customized pressure applicator, and precisely cut tracks to constrain blade trajectory. This enclosed press mechanism eliminates direct contact between the hand to blade, along with consistency in sample thickness of 2mm (±0.2 mm) while effectively removing the fat layer. Mechanical integrity was validated through Finite Element Analysis (FEA) to confirm the assembly withstands operational compressive forces without failure. Sterilization testing demonstrated that the device's flat geometry and material selection allows effective decontamination through standard autoclaving and chemical wiping to follow viability standards required for subsequent Lactate Dehydrogenase (LDH) staining. Lastly, usability testing confirmed high user satisfaction primarily on ease of use, stability, and safety. By providing a consistent, hands-free approach to tissue preparation, the Biopsy Thickness Slicer design substantially minimizes human error and enhances sample reproducibility, therefore supporting the successful outcome of burn wound healing research.

INTRODUCTION

Burn injuries are typically underappreciated in their prevalence, morbidity, and mortality rates, despite being one of the most common sources of injury worldwide, with nearly 11 million annual occurrences [1]. Burn patients can face life-threatening health complications from sepsis, shock, or organ failure, as well as long-lasting physical and psychological impacts on the individual. There is a clear bimodal age distribution of burn injuries, the majority occurring in young children or those of working age, particularly with occupational complications [2]. Burn injury survival rates have been steadily improving thanks to the application of different skin grafting measures over the past decade [3]. However, there is still much to be done towards improving treatment technologies with skin substitutes and autologous skin regeneration.

Current lab-based research into novel burn treatments and therapies analyzes wound healing behavior to better understand skin regeneration processes, aiming to develop clinical advancements for burn injuries and expedite the healing process. In particular, pig skin is often accepted as a valid in vitro model of human skin for translational wound healing research [4]. When a burn is inflicted on the skin, the healing process to regenerate tissue varies based on the severity of the injury. Generally, viable keratinocyte cells surrounding the wound migrate across the area and multiply to restore the uppermost epidermis layer of the skin. The fibroblasts within the dermis layer below rebuild the skin structure by producing collagen, elastin, and fibronectin to scaffold the new tissue [3]. In order for research labs to accurately observe wound healing, these cells must remain viable and able to regenerate in tissue culture. Additional subcutaneous fat remaining on the skin samples forms a hydrophobic layer which interrupts media absorption and affects sample viability and, in turn, experimental validity. Therefore, research labs studying burn injuries require specialized sample processing techniques to remove additional fat from skin samples in order to accurately analyze wound healing behavior.

The current method of subcutaneous fat removal involves securing each sample with forceps and slicing the fat layer off with a scalpel. This method has proven to be both tedious and inaccurate, producing inconsistent sample thicknesses and a jagged, angled sample surface. Additionally, existing tissue slicing devices intended for lab use are not suitable for this particular usage and are very expensive, costing upwards of $3000. Tools like tissue matrices are commonly available and used for precise and consistent slicing of irregularly shaped tissue samples [5]. There are also many tissue slicing apparatus available, used to create thin tissue slices at a set thickness [6]. However, many of these current options require specialized blades for use and are unable to stabilize the small cylindrical skin samples used in burn wound analysis. To streamline the processing of skin biopsy samples, researchers need an accessible device able to securely hold and slice the tissue samples for analysis. Ultimately, the goal of this study is

to design a device that consistently, accurately, and efficiently removes any excess fat from pig skin biopsy samples in order to retain sample viability for burn healing research.

MATERIALS AND DESIGN REQUIREMENTS

The development of a tissue processing tool requires strict adherence to specific clinical, biological, functional, and sanitary specifications to ensure reliable outcomes of small human tissue biopsy processing. The overall design constraints are divided into clinical needs, structural and sterilization requirements, and human factors, which define the successful functionality for the Biopsy Thickness Slicer within a burn-wound research environment.

Biological and Clinical Requirements

The primary clinical objective of the device is to accurately prepare porcine tissue biopsy samples for ex-vivo wound-healing models. After the localized contact burn has been administered, 12 mm diameter biopsies are extracted from porcine skin, creating initial samples with approximately 4 - 5 mm of thickness. To preserve the viability of the epidermis and dermis during subsequent tissue culture, all underlying subcutaneous fat must be completely removed, as the hydrophobic adipocytes create a barrier that prevents the absorption of culture media [7]. The biological requirement for the device is to consistently cut the samples parallel to the epidermis down to a thickness of 2mm (with a tolerance of +/- 0.2 mm), which will successfully remove the fat layer while preserving tissue viability for further studies, as demonstrated by the ex vivo burn-injured skin work of Cuddihy and colleagues [8].

To minimize mechanical distortion and the creation of jagged tissue edges, the device is also aimed to replace the traditional process of holding tissues manually with forceps and slicing to a user-estimated 2 mm using a scalpel. The traditional repetitive manual dissection of small, resistant biological samples poses a significant risk of injury to users handling sharp blades. To lessen these occupational hazards, the device should enclose the blade and create physical distance between the user's hand and the cutting surface.

Structural Requirements

The final prototype must adhere to structural requirements in order to adequately process porcine tissue samples while the user simultaneously applies compressive and grip forces. The body of the Biopsy Thickness Slicer should last a year in service or approximately 1000 cutting cycles before potential replacement. The #11 scalpel blade is securely attached to a custom 3D-printed handle equipped with a slide-on casing that allows the sharp edge of the blade to be safely capped at any point of usage. During

the cutting procedure, the blade motion should be constrained such that unintended lateral movements are eliminated and cut stability is increased, creating smooth edges.

Sterilization Requirements

For ease of sanitization in a lab setting, the device must be autoclavable, able to be hand-washed, and wipeable with a 70% isopropyl alcohol solution. Therefore, the material must withstand 121 degrees Celsius and 15 psi for thirty-minute to one-hour standard autoclave cycles [12]. Commonly used autoclavable polymers include polycarbonate and polypropylene, as these do not break down with frequent autoclave or alcohol sterilization, extending the Biopsy Thickness Slicer lifetime [12], [13].

Materials and device designs that incorporate tight or impermeable closures, as well as sharp edges and deep intrusions, should be avoided in order to reduce tissue-slicing byproduct buildup [12]. In addition, the device should be designed for easy disassembly into individual components. This ensures that all parts can be individually sterilized in an autoclave while allowing internal components to be disinfected using a dish soap or alcohol solution.

Human Factors and Ergonomics Requirements

Repetition of tasks involving manual gripping of biological tissues with forceps while applying downward cutting force with a standard scalpel is a commonly documented ergonomic stressor that can lead to musculoskeletal disorders and Repetitive Strain Injuries (RSIs) in the hands, wrists, and forearms. [14]. To reduce the compressive forces placed during high-volume sample preparation, the device aims to set specialized ergonomic features incorporating a pressure applicator design. This design should mimic a standard clinical biopsy punch and to provide a comfortable, neutral grip for the user to apply. The device should also utilize a layer assembly with defined geometry to increase ease of disassembly for sterilization and stabilize the tissue samples during slicing to minimize the need for uncontrolled movements of the user's dominant hand. To further enhance the ease of use, a base that provides friction with the laboratory benchtop should be incorporated to reduce the need for the user to hold the device down to the surface of the laboratory benchtop with their non-dominant hand during use. This material will provide additional security measures, as it will stop the device from sliding during the tissue slicing procedure.

DESIGN PROCESS AND STRUCTURAL ARCHITECTURE

Final Design Architecture

The final design, the Biopsy Thickness Slicer, incorporates a stacking mechanism that snaps into a rubber base. To cut a cylindrical tissue sample to the desired thickness, the sample is placed within the

horizontal cutting well, skin surface side down, as shown in Figure 1. The #11 scalpel blade is then fully inserted into the horizontal cut line on the side face of the device (Figure 1). To hold the tissue sample in place during slicing, the user grasps the pressure applicator handle and applies slight pressure to the sample within the cutting well (Figure 1). With the other hand grasping the scalpel handle, the user slides the blade through the cut line, pushing the sharp blade aside away from them until it makes contact with the end of the blade track, indicating the sample has been sliced through. To cut the cylindrical tissue sample vertically for imaging, the sample is placed within the vertical cutting well, and the #11 scalpel blade is placed in the vertical cut line, on the top face of the device, as shown in Figure 1. The user then pushes the sharp edge of the blade through the cutline until it makes contact with the end of the blade track, once again, indicating the sample has been fully cut through. Similarly, to halve the sample vertically, the sample is first placed within the vertical cutting well, shown on the top face of the device in Figure 2. The #11 scalpel is then inserted into the vertical cut line, on the top face of the device, with the user pulling it through the cut line to slice the sample.

The assembly on the device relies on an assembly mechanism, allowing for easy access to internal device faces for sanitization and small sample removal. The base with extruding pegs is fabricated using Nylon 12 or PLA, as shown in layer 3 of Figure 4. The clear polycarbonate components are then stacked on the pegs (layers 1 and 2 of Figure 4). Finally, the bottom face of the extruding peg base snaps into holes within the rubber mat (layer 4 of Figure 4). The rubber mat and assembled design can be placed on the workbench.

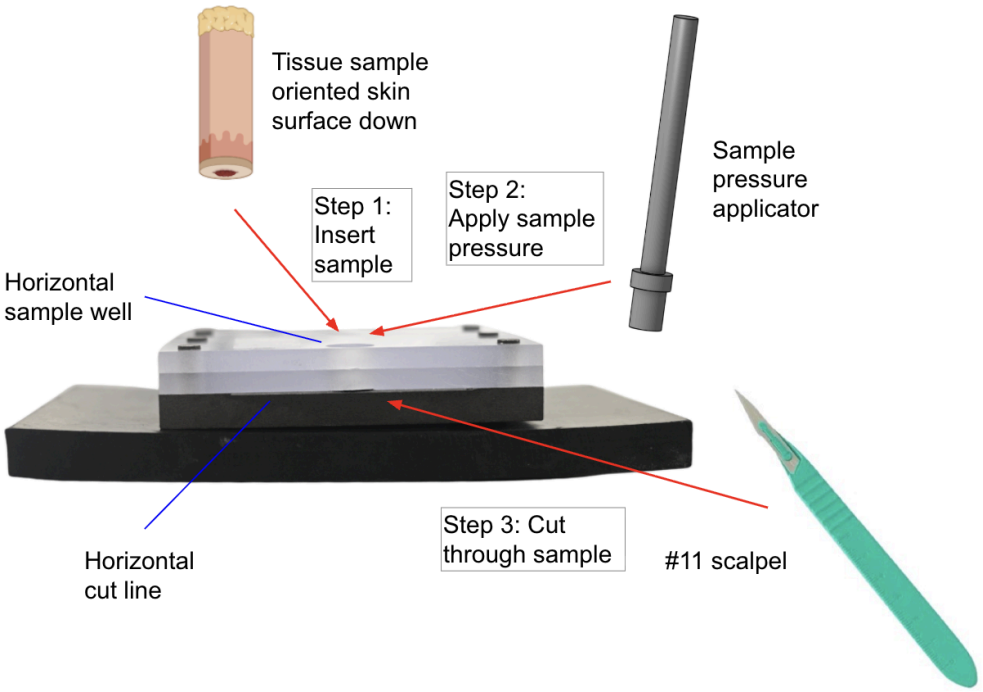

Figure 1: Horizontal sample slicing usage map. Step 1: Insert the sample into the horizontal slicing well. Step 2: Apply pressure to the sample within the sample well. Step 3: Insert the #11 scalpel into the horizontal cutline and slice through the sample.

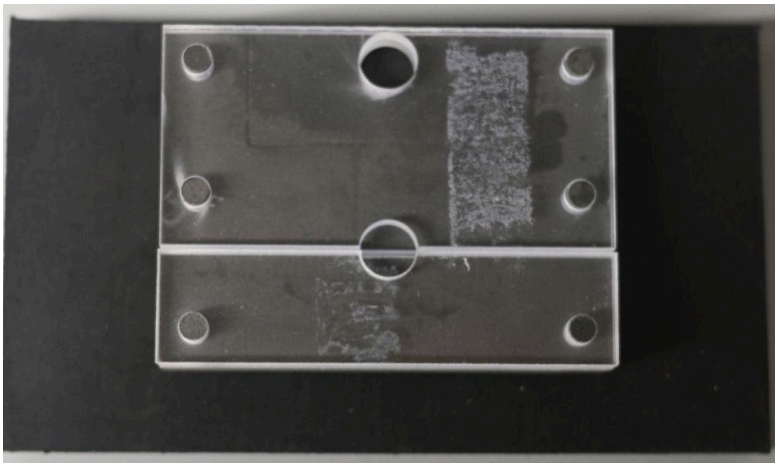

Figure 2: Top view of the Biopsy Thickness Slicer displaying the horizontal sample cutting slot (top hole) and the vertical slicing slot (bottom hole) used to image the biopsies following processing.

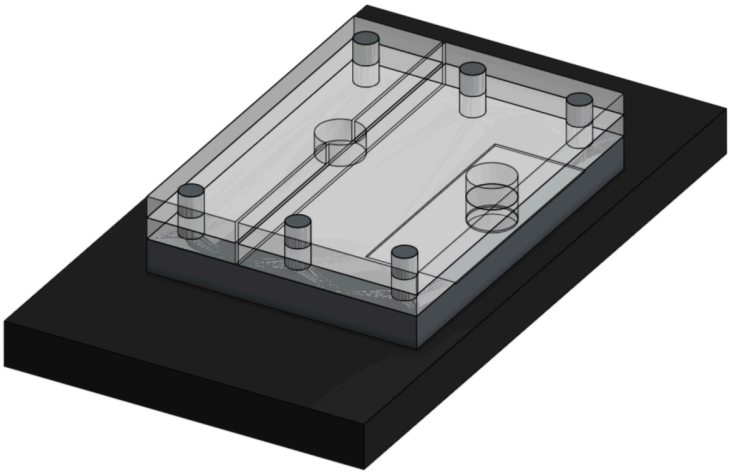

Figure 3: Realistic CAD full assembly of the final design, the Biopsy Thickness Slicer

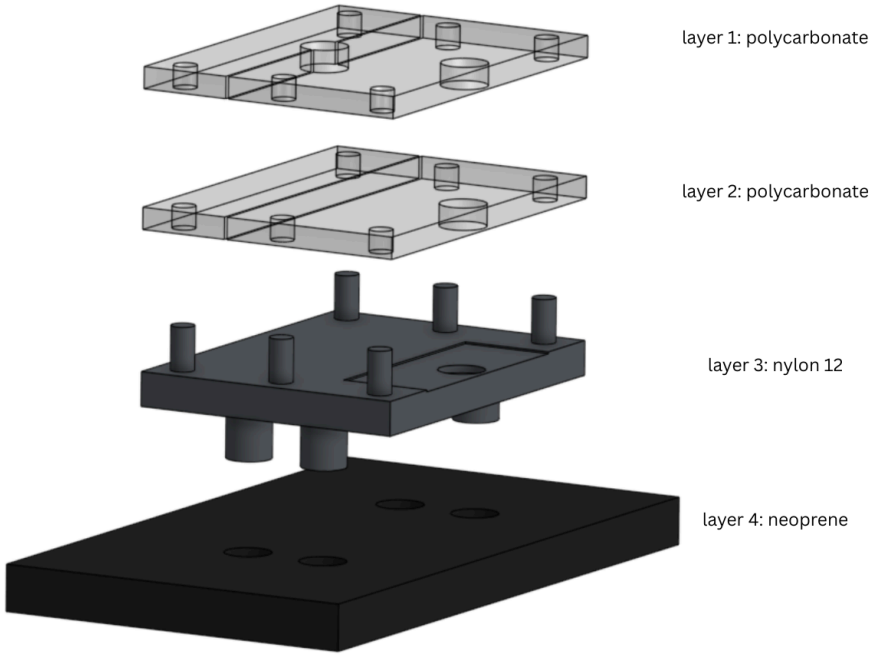

Figure 4: Exploded view of the layered system of the final design, the Biopsy Thickness Slicer

Design Process

Three initial design ideas, observable in Figure 5, were generated and scored on ease of use, cut accuracy, maintenance, biopsy security, ease of fabrication, and safety for the user. The Biopsy Thickness Slicer design, which utilized a vertical well system and horizontal cutting, scored the highest based on these criteria and thus was the design utilized. The design then went through multiple iterations, as shown in Figure 6, with main changes including the number of wells, device size, sample pressure applicator ergonomics, and internal connections. The number of wells was reduced through the iterations, as initial cylindrical samples were not of consistent height, and slicing resulted in uneven pressure application and ultimately, thickness. The device size has varied to allow for a more ergonomic design with increased surface area to ensure user safety and ease of handling, such that the user's hands are not close to the cutting slot. The sample pressure applicator shifted from a block to a rod design so that the user can better control the applicator, and allowing for more distance between the user's hand and the blade. Finally, the most variation occurred in the Nylon 12/PLA base piece connection mechanism, which started off with a long extruding peg and deep insertion holes, similar to LEGO connections (seen in Figure 6 versions a, b, c, d, e, and f); however, although length increased stability, the long pegs were fragile and broke with continuous use. To mitigate this, the pegs were shortened, and hinged doors were incorporated on the

sides of the device to maintain stability (seen in Figure 6 versions c, d, e, and f). The last iteration, the final Biopsy Thickness Slicer, shifted to a layered system as observable in Figure 4, and the stackable component material was switched to polycarbonate for the transparent aspect, allowing the user to view the cylindrical tissue sample while slicing the design intentionally minimizes intrusions, crevices, and sharp edges, while allowing users to disassemble the components as needed to improve overall sterilization efficiency. Protrusions and transitions can create areas where debris, dust, or biological contaminants accumulate, making thorough cleaning more difficult and less reliable [24]. By incorporating smooth surface transitions, the design reduces contamination traps and allows disinfectants to access all surfaces, ensuring more consistent sanitation outcomes.

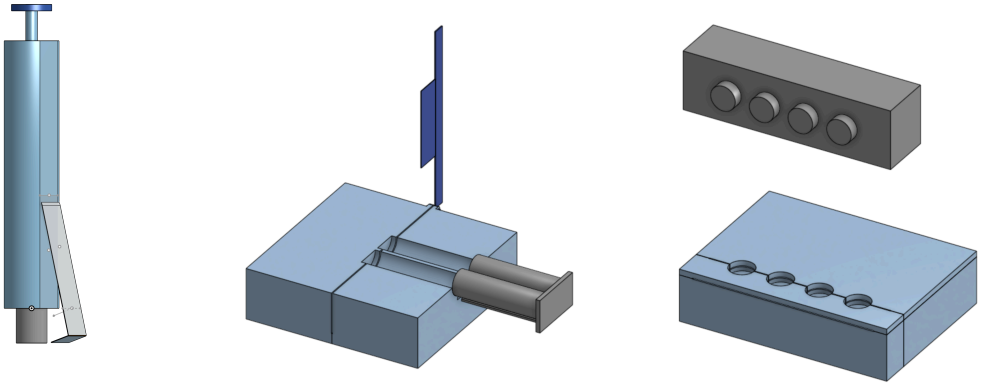

Figure 5: The initial design ideas consisted of the biopsy punch (left), paper cutter (middle), and Biopsy Thickness Slicer (right).

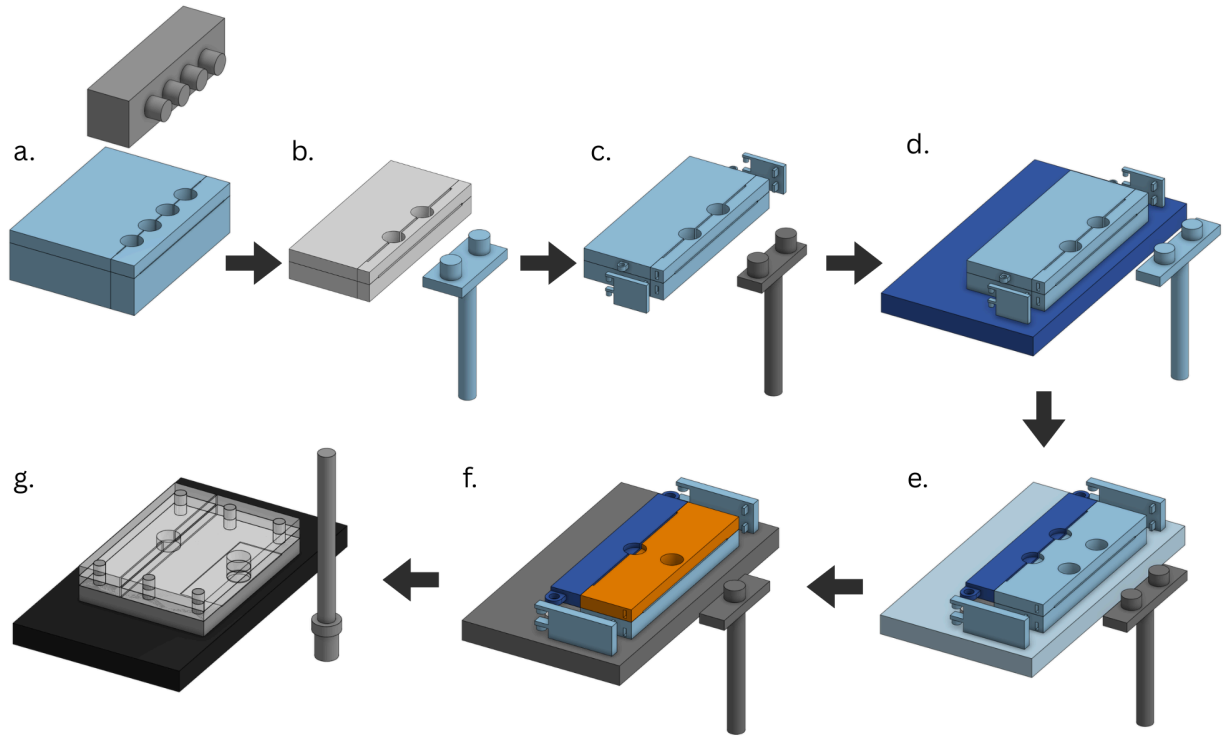

Figure 6: Design iterations of the Biopsy Thickness Slicer, 3D printed out of PLA and nylon 12. Main changes were the number of sample wells, sample presser ergonomics, device size, and part connection.

FABRICATION

Materials

The main requirements for the device materials are that they are sterilizable, affordable, and easy to fabricate, maximizing usability. To achieve this, the body of the device will utilize both polycarbonate and nylon 12. Nylon 12 is a 3D printable material through the Formlabs Fuse 1 printer. It is able to withstand the normal sterilization cycle of an autoclave as it has a heat deflection temperature of 171 °C at .45 MPa [15]. 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 saline and isopropyl alcohol when submerged for 24 hours [15]. Nylon 12 is also able to be sterilized by ethylene oxide (EtO), plasma, chemical, and gamma processes [16]. Polylactic acid (PLA) is also an option for the material if the device is single-use. PLA has micro-grooves that can house bacteria, media, and tissue, and cannot be autoclaved because it would cause significant distortion [16]. However, it is able to withstand and be sterilized with EtO and plasma methods [16]. 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. Polycarbonate is used in the final design stacking mechanism because it is transparent, allowing the user to observe the sample as they cut. It also has a low water absorption of .13% and a maximum temperature of 132 °C (270ºF), which allows autoclaving as a sterilization option [17].

The neoprene rubber baseplate was also implemented through iterative design to further improve stability during cutting by increasing friction between the Biopsy Thickness Slicer and the fume hood benchtop. A 12.7 mm-thick, 50A-60A durometer neoprene sheet was specifically chosen because its hardness range provides strong surface grip while maintaining durability under repeated loading [18]. Neoprene also does not degrade significantly under long-term usage, along with other design components, which makes it suitable for the base support choice.

Methods

The Biopsy Thickness Slicer base layers and sample presser were designed on OnShape CAD software. Layer 3 was 3D printed using a laser to fuse layers of nylon 12 powder together with the SLS Formlabs printer, while the sample presser was printed in PLA [19]. The CAD models for layer 3 and the sample presser are in Figures 8 and 10 respectively.

For layers 1 and 2 in Figure 7, an initial 30.48x30.48x.599 cm polycarbonate sheet purchased through Grainger was cut utilizing a waterjet machine provided by the UW-Madison Design Innovation Lab. The CAD files were formatted into a DXF file and imported into the waterjet. The polycarbonate sheet was clamped to the bed of the waterjet and water was filled until the sheet was completely covered. The machine was then set to cut the design submitted. This same fabrication procedure was utilized for the neoprene rubber, also purchased from Grainger, into the design depicted in Figure 9.

To assemble the device, the layers were pieced together, starting with the neoprene base, then adding the nylon base, and the subsequent polycarbonate layers. No adhesive was required since the tight mechanical fit prevented shifting between the two intersections. The sample presser is only utilized in device usage and does not assemble with the rest of the device.

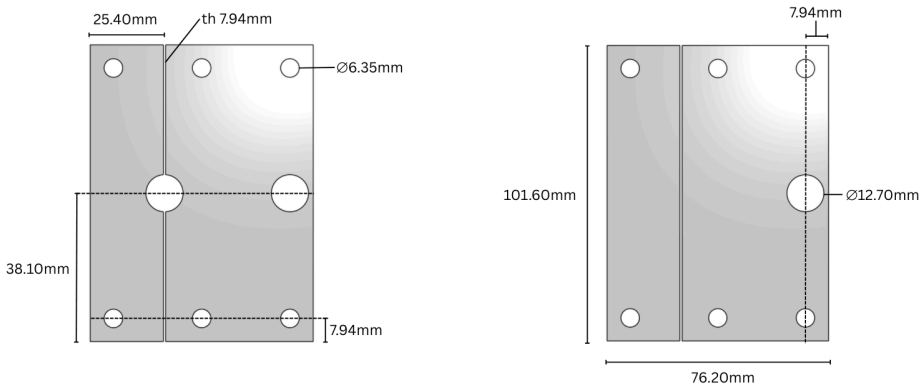

Figure 7: Dimensions of the layer 1 (left) and layer 2 (right), both fabricated with polycarbonate, 6mm thick

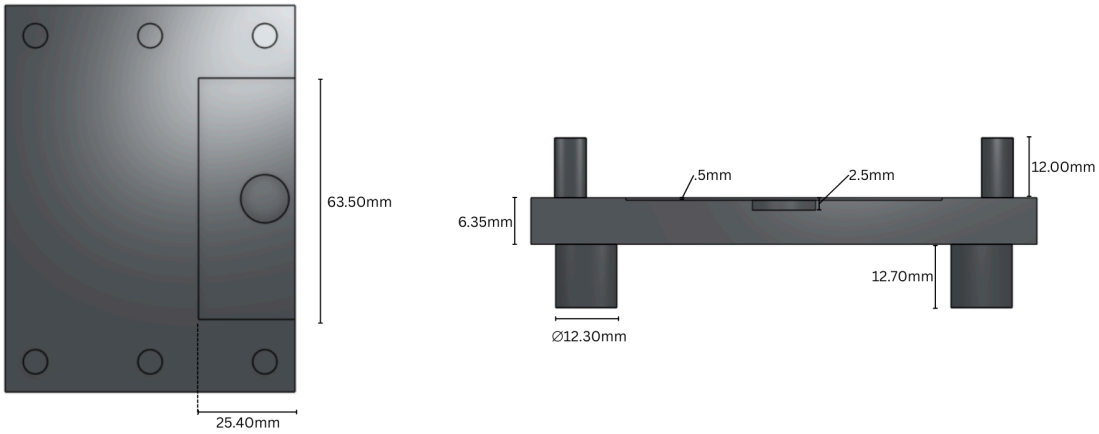

Figure 8: Dimensioned layer 3, fabricated out of PLA and nylon 12

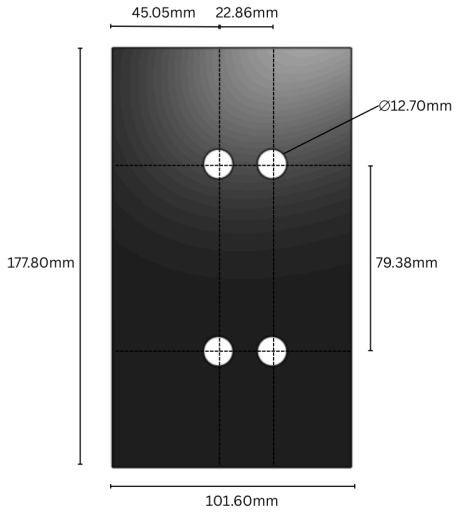

Figure 9: Dimensioned layer 4, neoprene, 12.7mm thick

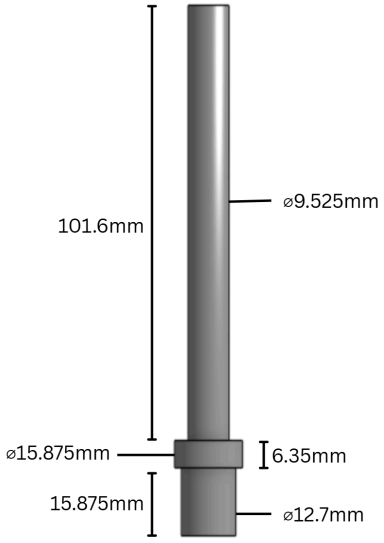

Figure 10: Dimensioned sample presser CAD design, fabricated out of PLA

STRUCTURAL EVALUATION

Finite Element Analysis

To verify the mechanical strength of the Biopsy Thickness Slicer and pressure applicator, a Finite Element Analysis (FEA) test was performed. These parts were selected to be simulated as they are the most susceptible to plastic deformation due to the frequency with which they are used. Through OnShape Simulation, a software that analyzes part, assembly, and structural performance, the components were subjected to varying load conditions in an FEA, as shown in Figures 11 and 12. Fifty newtons were applied to the assembly of the Biopsy Thickness Slicer to further analyze the internal connector pins that are subjected to physical stresses and contact [20]. The pressure applicator undergoes forces due to grip strength, which resulted in an applied force of 22 newtons, derived from literature values and general estimations [21]. Due to the inherently ductile properties of the polycarbonate and PLA used in the final material selection, a von Mises stress analysis was performed to predict the failure criterion [22].

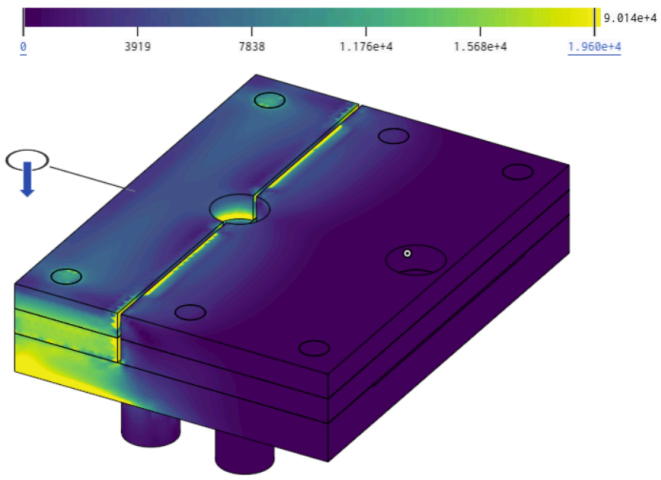

Figure 11: von Mises stress analysis results of the simulated 50 N force application on the PLA layered assembly in Pascals.

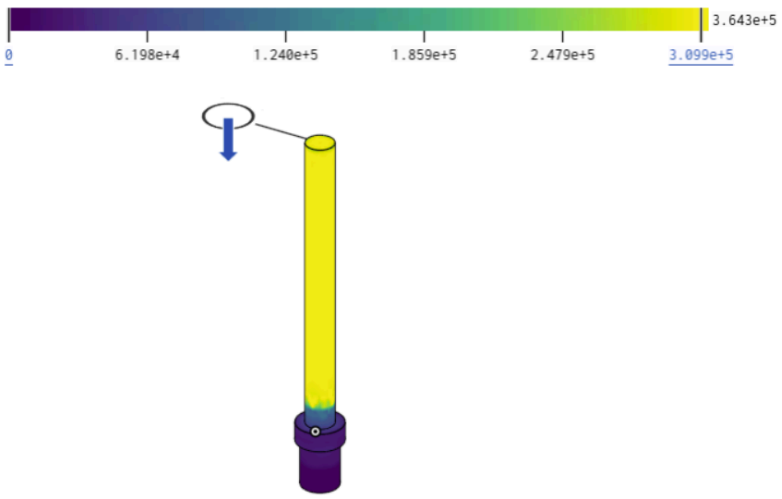

Figure 12: von Mises stress analysis results of the simulated 22 N force application on the PLA pressure applicator in Pascals.

Force Simulation Results

The results validated the mechanical strength of both the assembly and the pressure applicator. The primary assembly demonstrated a maximum tolerable load of 1.96×10^4 Pa, indicating sufficient structural integrity under expected operating conditions. No critical deformation risks were identified. Minor stress concentrations were observed along the lateral walls of the assembly and at the imaging access hole, but these regions remained within acceptable safety margins. The pressure applicator exhibited a substantially higher load capacity, withstanding up to 3.099×10^5 Pa. While this value falls within the cautionary range of the safety assessment, the component maintained functional integrity. Under applied grip forces, the applicator experienced measurable compression and torsional deformation; however, these behaviors are consistent with the expected mechanical response of the design.

STERILIZABILITY ASSESSMENT

Material Compatibility and Geometry Considerations

Polycarbonate and nylon 12 are well-characterized polymers that can withstand autoclave temperatures without melting or failure. However, autoclaving causes strength loss within the bulk material, causing repeated autoclave cycles to shorten the overall lifetime of labware as the material gradually weakens [23]. This is due to polycarbonate's heat deflection temperature, being near the standard autoclave cycle temperature of 121 degrees Celsius, whereas nylon 12's heat deflection

temperature is significantly higher [12], [23]. Polycarbonate and nylon 12 are chemically resistant to common alcohols, like isopropyl alcohol and ethanol, maintaining their integrity under normal cleaning conditions and avoiding degradation of surface properties [23]. Additionally, through the reduction of intrusions and sharp edges, the reduced buildup of slicing byproducts can be achieved.

Protocol

To evaluate the Biopsy Thickness Slicer's ability to withstand autoclaving, an initial visual examination was performed after a standard autoclave cycle. The device was disassembled and marked with autoclave tape, which changes color to indicate that the necessary cycle temperature has been reached [12]. Three thirty-minute cycles at 121 degrees Celsius and a minimum of 15 psi were performed [12]. Upon cycle completion, the components were removed from the autoclave, and the applied tape was visually examined to ensure the temperature requirement was reached. Each component was visually inspected for melting, warping, deformation, or damage, and compared to images of the component prior to testing.

To evaluate surface ethanol sterilization of the device, isopropyl alcohol, dish soap, and UV-reactive GloGerm solution were utilized [25]. The GloGerm solution represents the residue left behind by continual testing with porcine tissue. The device was disassembled into components, and GloGerm was evenly applied to all inner and outer surfaces that come into contact with the tissue samples during cutting. To clean the device, the alcohol was sprayed onto each component, and the component was subsequently wiped down. The second cleaning method required using a sponge and dish soap to thoroughly scrub and rinse each surface. After each cleaning method, each component was examined using UV light for GloGerm buildup. Buildup areas were visually identified and imaged. Buildup areas were analyzed using ImageJ and compared between sterilization methods.

Surface Sterilization Results

The results of the GloGerm surface sterilization analyses indicated that the optimal tissue buildup removal was achieved through washing the components with soap and water. Within the polycarbonate components, the greatest buildup occurred within the peg connection and sample well holes. After sterilization with ethanol, the GloGerm buildup within the peg connection holes was reduced by 38.82%, to an average area of 0.008 in^2. Upon cleaning with soap and water, the buildup within these holes was reduced by 75.88%, with an average area of 0.003 in^2. The same conclusion was reached for the nylon 12 base with extruding pegs. This component had the most GloGerm buildup around the extruding peg bases and within the sample well holes. Cleaning with ethanol yielded an 88.24% reduction in buildup

area around the peg bases, corresponding to an area of 0.002 in^2, while cleaning with soap and water resulted in the removal of all major buildup, or an 100% reduction. These polycarbonate and nylon 12 sterilization results were statistically significant, yielding p-values < 0.05. The standard error remained relatively low for both cleaning methods. For polycarbonate, the reduction percentage estimate could vary by about ± 11% of the mean for both ethanol and soap and water methods. On the other hand, for nylon 12, the reduction percentage estimate could vary by about ± 4% of the mean. These results support that cleaning the components with soap and water is sufficient to remove a majority of the tissue buildup, as shown in Figure 13.

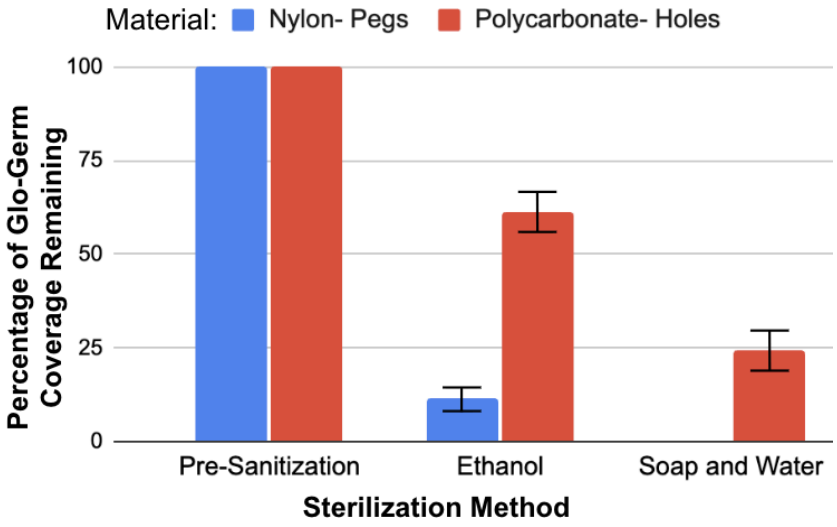

Figure 13: Plot comparing the percentage of GloGerm buildup during sanitization testing with polycarbonate and nylon 12 components. Ethanol and soap and water sanitization methods were performed on all components. Nylon 12 extruding peg bases and polycarbonate peg hole intrusions were analyzed.

Autoclave Assessment Results

An autoclave sterilization assessment was performed to evaluate the thermal tolerance of the device's polymer materials. Both the nylon and polycarbonate components were subjected to a standard temperature and pressure autoclave cycle to determine if their structural integrity would be compromised. Post-cycle visual inspection showed no evidence of warping, degradation, or cracking in either material, as shown below in Figure 14. The nylon component exhibited temporary swelling; this was expected as this material displays a moisture absorption behavior under elevated temperatures. The piece returned to its original dimensions upon drying, indicating that the swelling did not result in permanent deformation.

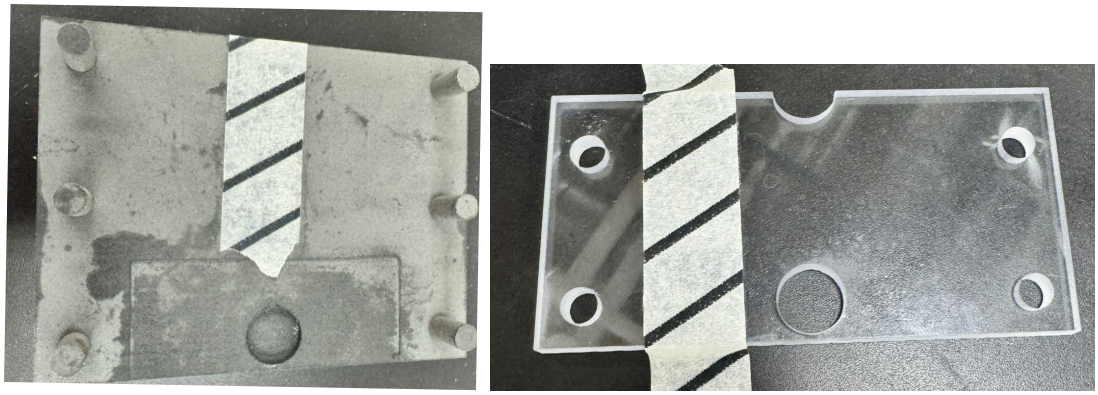

Figure 14: The nylon and polycarbonate components after the completed autoclave cycle, not displaying any mechanical damage such as warping, cracking, or degradation.

Considerations of this sterilization method include the cumulative effects of repeated cycles, which may degrade the nylon faster or induce brittleness in the polycarbonate. Future design considerations could evaluate other sterilization-resistant materials or apply coatings to the surface to extend its lifespan.

USABILITY ASSESSMENT

Protocol

To evaluate the usability of the Biopsy Thickness Slicer for standardized preparation of cylindrical biopsy samples, a structured user evaluation was performed that follows the usability definition in ISO 9241-11, which specifies usability in terms of effectiveness, efficiency, and satisfaction (user comfort/maneuverability) [26]. The user evaluation study conducted a simulated tissue-processing task to reduce variability and safety risk while preserving the main objectives of the device usage, which involves guided trajectory cutting, sample stabilization, and blade management before and after the slicing procedure. Participants were volunteers with tissue-slicing experience within a lab setting. Prior to testing, each participant received a short safety briefing and device demonstration that aligned with the usability survey protocol distributed in a physical copy. This includes safe handling and disposal of blades in approved sharps containers. Test samples were prepared from artificial skin commercially available for suturing practices to mimic soft-tissue handling and cutting behavior during evaluation [27].

The device was placed on a flat laboratory benchtop with the neoprene base installed. Each participant performed a standardized task sequence using the Biopsy Thickness Slicer. First, a 12 mm cylindrical sample was placed into the base well, a #11 scalpel blade was installed into the blade handle,

and the blade was secured with a sliding case. Next, the pressure applicator was inserted, and light compression was applied to stabilize the samples while a horizontal trimming cut was performed by advancing the blade through the side track to the mechanical stop. The cut sample was then transported using forceps to another base well, and a vertical bisection cut was then performed by advancing the blade through the top vertical track. After the cutting procedure, the blade was resheathed/removed, the device was disassembled, samples were removed, and visually inspected for thickness consistency and cut quality. The whole procedure was repeated five times per participant for adaptability effects and short-term repeatability of the device usage.

After completion of both trials, participants filled out usability questionnaire focused on the functionality and accuracy of the device using a 5-point Likert scale (1= strongly disagree to 5 = strongly agree) to rate perceived safety, stability on the benchtop, blade attachment security, control of cutting, ease of inserting/removing samples, ease of guiding the blade, and perceived consistency of final sample thickness. At the end, an open-response prompt was also included to gain more insights into user preferences and design feedback.

Results

Usability testing sessions were repeated throughout the design process. Batches of survey data were collected using design iterations 6-10. For the initial design iteration tested, user ratings indicated mild dissatisfaction with how securely the device was held to the table surface, the control of the sample cutting, and the ease of guiding the blade through the samples. After iterative prototyping, implementing user feedback and satisfaction scores, the final design iteration that was tested yielded much higher user satisfaction as shown below in Figure 15. All participants evaluated satisfaction statements with either general or strong agreement.

Participant feedback was centered around sample thickness and consistency. Comments indicated changes needed to be made to the depth of the sample wells in order to get accurate sample thickness. Sample well depth and base material were adjusted between design iterations and testing sessions to evaluate prototype iterations. Reductions in sample well depths resulted in higher satisfaction scores, making more consistently cut samples. Material changes resulted in minor changes in satisfaction scores, with the nylon base having slightly lower satisfaction levels than the PLA base. Users experienced mild difficulty with the rougher texture of the nylon model, having trouble guiding the blade across the base with higher levels of friction.

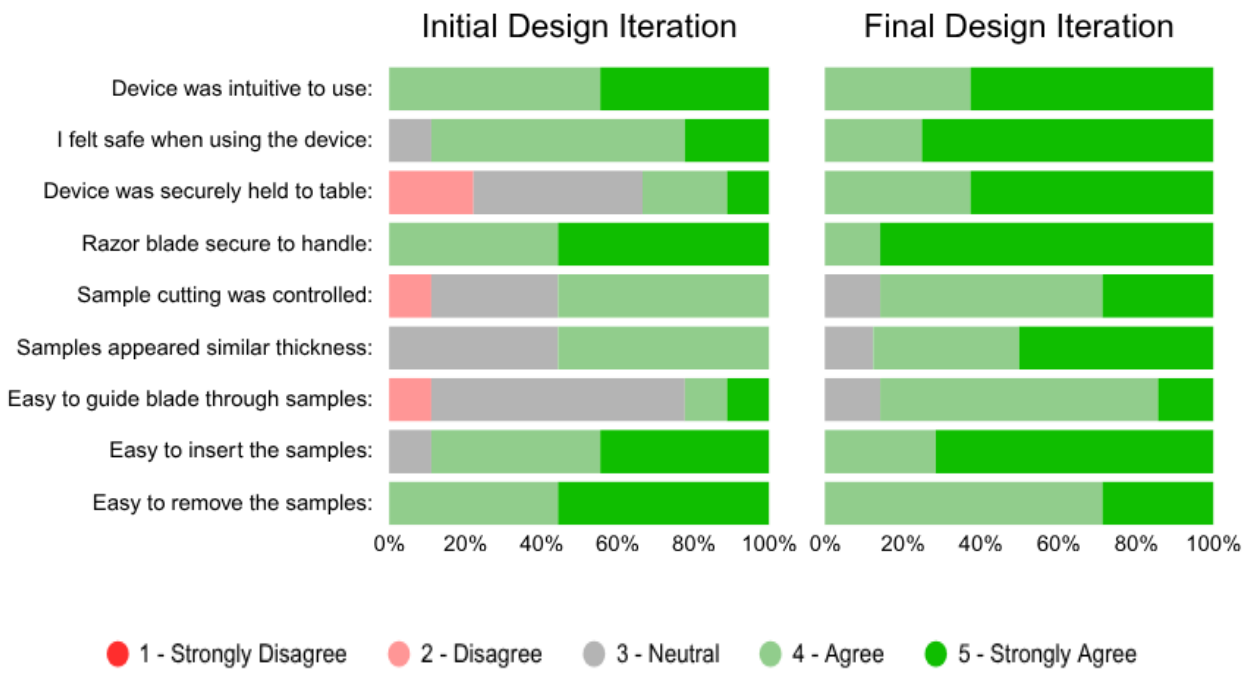

Figure 15: Comparison of usability survey scores for the initially evaluated design iteration and the final design iteration evaluated. Design components evaluated on a scale of 1-5, 1 indicating Strongly Disagree and 5 indicating Strongly Agree. An overall increase in user satisfaction scores can be deduced from the survey result comparison.

SAMPLE THICKNESS ASSESSMENT

A thickness consistency assessment was performed to evaluate the uniformity of processed biopsy samples produced by the Biopsy Thickness Slicer. The iterations varied in material choice – nylon or PLA – and decreasing well depths. This determined how material properties and different geometric constraints influenced final sample thickness. Following slicing, the thickness of each sample was measured with calipers to quantify the variability across the trials. In all conditions, the device produced samples within the expected range of thickness. Material changes resulted in minor consistency changes; nylon exhibited more variability compared to PLA, as shown in Figure 16. Well-depth size, as expected, impacted the thickness as deeper wells produced thicker samples. Iterations 7,8, and 9 involved the PLA base, whereas Iteration 10 had the nylon base. The well depth decreased over the four iterations. Overall, the design can create reproducible sample thicknesses with different materials and geometric tolerances.

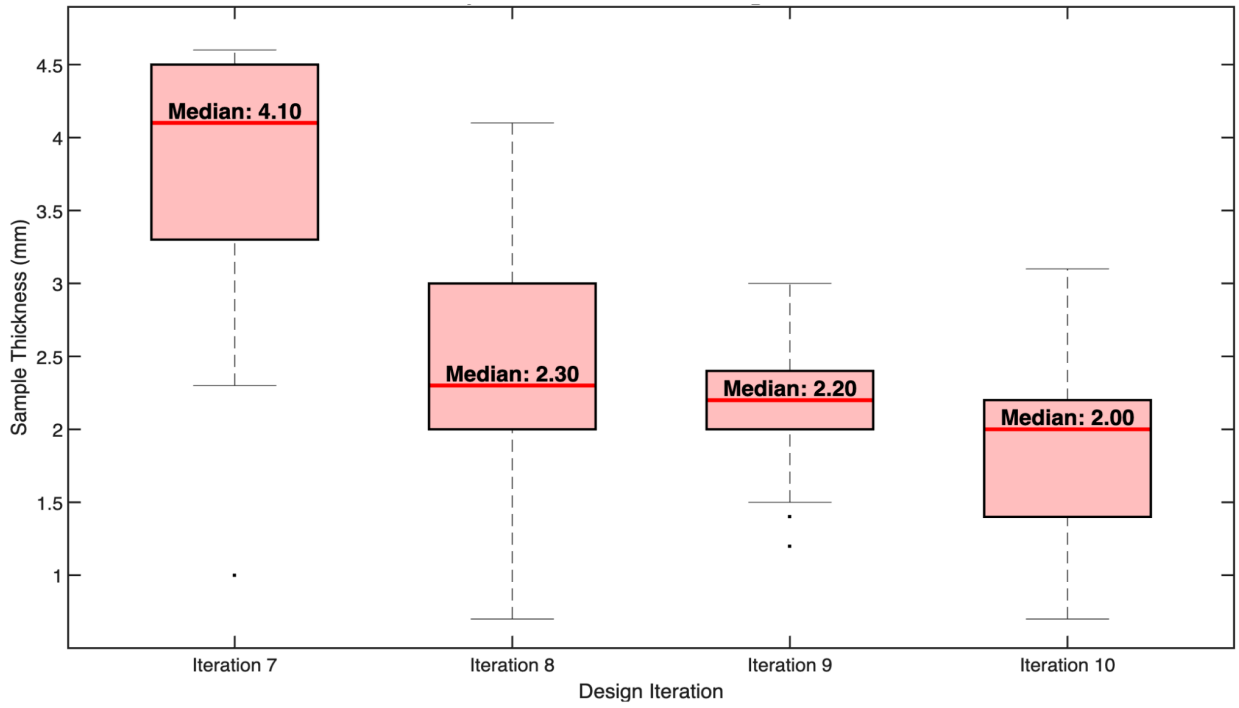

Figure 16: Plot of median sample thicknesses throughout design and material iterations. The material that displays the least variability is PLA in iteration 9.

DISCUSSION

The evaluation of the Biopsy Thickness Slicer demonstrates that the device improves consistency and usability in small tissue biopsy processing while identifying key areas for refinement. Performance trends observed across iterative designs indicate that modifications contributed to improved thickness control, with results converging toward the 2.0 mm target in thickness with reduced variability. This progression reflects the effectiveness of incorporating repeated usability feedback into the design process, especially for optimizing blade guidance and sample stabilization. However, remaining variability suggests that user-dependent factors, such as applied force and blade handling, continue to influence cutting outcomes with slight variations.

Mechanical analysis supports the structural feasibility of the design under expected operating conditions. FEA shows that both the primary assembly and pressure applicator operate within acceptable stress limits when subjected to representative loading conditions. Although localized stress concentrations were observed, they remained below material failure thresholds. These findings indicate adequate

short-term structural performance. However, the potential for long-term material fatigue at connection interfaces leads to further consideration, particularly for repeated usage.

Sterilization testing confirmed compatibility with standard laboratory cleaning protocols and highlighted the importance of geometry in contamination removal. The device's accessible surfaces enabled effective reduction of simulated biological residue with the soap-and-water cleaning technique, outperforming ethanol-based methods. Despite this, material responses to autoclaving introduced limitations, including dimensional changes in nylon components. Such changes may affect assembly tolerances and functional precision over time, which indicates that material stability under repeated sterilization cycles remains a constraint.

User evaluation results further contextualize device performance by emphasizing both strengths and weaknesses in practical use. Participants in usability testing reported favorable outcomes in safety, stability, and overall ease of operation that align with design intent to reduce direct blade interaction and improve ergonomic handling. At the same time, feedback defined challenges related to blade insertion, consistency of applied pressure, and stability within the blade-guiding mechanism. These factors are directly linked to operation reliability and highlight the need for further refinement of user-device interaction.

The findings collectively indicate that while the device improves upon conventional manual techniques, its performance is influenced by both mechanical design and user interaction. Variability in cutting outcomes, material limitations under sterilization, and usability constraints suggest that further optimization is required to achieve a fully standardized device for slicing operations. Future design efforts should prioritize improving control of blade motion and force application, enhanced material durability, and narrower component tolerances. Furthermore, expanded validation with larger sample sizes and a diverse population of users are necessary to establish reproducibility of the device across broader laboratory settings.

CONCLUSIONS

The Biopsy Thickness Slicer device was fabricated to standardize and effectively process porcine tissue samples to contribute to revolutionary burn wound healing research. The design achieves precision, safety, and consistency while providing the user with a simplistic experience. The final prototype integrates a guided press system, removable layers connected by internal pins, a pressure applicator, a

surgical blade handle, and a neoprene rubber baseplate to enhance friction and stability when in contact with laboratory benchtop surfaces.

Outcomes from the areas of testing in sterilization, usability assessments, and mechanical analysis collectively validated the core functionality of the prototype while highlighting areas for improvement. Sterilization testing demonstrated that the device can be maintained well with soap and water, and that an autoclave is effective for nylon and polycarbonate under non-excessive usage. The usability assessments confirmed user confidence throughout the device usage, emphasizing areas of blade and sample security. Lastly, the FEA supported these findings by highlighting the structural integrity by demonstrating how much stress it can withstand before potentially deforming. Overall, the design exemplified its ability to accommodate a 5 mm tall, 12 mm diameter cylindrical porcine skin sample and consistently eliminate the layer of fat, improving the viability of the sample.

The final prototype demonstrated reliable performance across its primary mechanical functions; however, testing also indicated several areas requiring further refinement. Specifically, the nylon components would benefit from the application of an epoxy coating to reduce surface intrusions and improve post-sterilization cleanability. The blade-guiding mechanism could benefit from a redesign to enable smoother, more controlled translation during slicing. In addition, the internal connectors should be strengthened, as their constant contact during operation presents a risk of fatigue or fracture over repeated use. Through continued iterations, the Biopsy Thickness Slicer aims to become a novel and advanced laboratory benchtop tool used to significantly elevate efficiency and reproducibility in biopsy preparation for research and clinical purposes.

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APPENDIX

A. Product Design Specifications (PDS)

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

Physical and Operational Characteristics

Performance Requirements

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.

The device must be sterilizable by autoclave, UV radiation, or 70% ethanol between each use.

The blade of the device must be commonly sourced and easily replaceable in the device.

Safety

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].

Accuracy and Reliability

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 100 samples before blade replacement is required.

Life in Service

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.

Shelf Life

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].

Operating Environment

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].

Ergonomics

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.

Size

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 100 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.

Weight

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.

Materials

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.

Production Characteristics

Quantity

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.

Target Product Cost

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].

Miscellaneous

Standards and Specifications

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].

Customer

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].

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].

User / Researcher-related Concerns

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.

Competition:

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.

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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B. Testing Protocols

a. Sterilization

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. Autoclave compatibility will also be visually evaluated to ensure the device does not begin to degrade.

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
Autoclave tape

Material setup instructions for the GloGerm application:
Place a tablespoon of GloGerm solution in a dish
Wash and dry the paintbrush
Prepare multiple dry paper towels

GloGerm application instructions:
Completely disassemble the Biopsy Press device
Thoroughly coat the tip of the paintbrush with GloGerm solution. Repeat as often as necessary throughout the remaining steps
For each piece, thoroughly coat each face enclosed within the device when assembled with the GloGerm solution
Once coated, set each piece on a clean, dry paper towel
For each piece with extruding pegs, thoroughly coat the entire peg with the GloGerm solution
Once coated, set each piece on a clean, dry paper towel
For each piece with intruding connectors for peg insertion, coat the entire intrusion with the GloGerm solution
Once coated, set each piece on a clean, dry paper towel

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

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

Autoclave testing instructions:
Completely disassemble the Biopsy Press device
Apply autoclave tape to three separate components
The components selected can be at random
Image all components, with and without autoclave tape
Place all components in the autoclave, ensuring about an inch of space between components
Run the autoclave for 30 minutes
Ensure a minimum temperature of 121 degrees Celsius is reached
Ensure a minimum pressure of 15 psi is reached
Upon completion of the autoclave cycle, let the parts cool for 10 minutes
Put on heat-resistant gloves and lab goggles
Remove the components from the autoclave
Examine the tape on the three components and ensure the tape has turned black, indicating the autoclave reached adequate sterilization temperature
If the tape has not turned a dark color, return to step 1 and run the autoclave for a longer period
Visually inspect each component for melting, warping, deformation, or damage
Image all components, noting any damage found in step 8

b. Usability Assessment

Survey participants selected from individuals outside the design group with previous experience using lab blades to mitigate safety risks associated with blade usage. Participants will sign forms of consent and be briefed on how to safely use the device and associated blades.

Participants asked to use the device to slice 12 mm diameter, 5 mm long biopsy samples.

Instructions for using device:

Insert 12 mm biopsy sample into each indentation on the base of the device (2 samples total)
Attach covered razor blade to blade handle
Unsheath razor blade
Use compression piece to lightly press down on the biopsy samples, aligning the extrusions with the indentations in the base
Insert razor blade into side slot in the base and slice through samples
Remove razor blade from device
Insert razor blade into top slot in the base and slice through sample cross sections

Remove razor blade from handle and dispose of blade in sharps bin
Take off top section
Remove biopsy samples
Visually compare the prepared biopsy samples
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 shown on the following page.

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?

c. Finite Element Analysis (FEA)

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 PC for the first three layers and Nylon as the bottom layer for the material selection 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. Apply the force to the internal connectors, the face of the biopsy press, and the shaft of the blade handle.
7. Finalize the direction of the applied forces and moments
8. Generate the simulation and wait for the results to load.

C. Fabrication Protocol

a. Polycarbonate Layers

i. the onshape CAD file top orientation was utilized to turn into needed DXF files for the waterjet
ii. the DXF files were transported on a flash drive and uploaded to the waterjet computer
iii. the polycarbonate sheet was fastened with clamps to the bed of the waterjet
iv. water was added to the machine until it cover the surface of the polycarbonate
v. the nozzle was lowered to the polycarbonate surface
vi. the splash shield was lowered
vii. the waterjet cutting was started
viii. after cutting, the polycarbonate pieces were removed and cleaned

b. Base

i. Extrude a 3x4" (76.2x101.6mm) sketch by .368" (9.3472mm)
ii. Sketch a .25" (6.35mm) diameter circle .3125" (79.375mm) square to the top right corner (along the 3" (76.2mm) side)
iii. Linear pattern the circle twice with 1.1875" (30.1625mm) between each circle
iv. Mirror the circles to the bottom 3" (76.2) side
v. Extrude all the circles by .472" (11.99mm)
vi. Subtract extrude a .5" (12.7mm) diameter circle on the midline of the 4" side (101.6mm), .3125" (7.9375mm) from the edge by 2.3mm
vii. Subtract extrude 1x2.5" (25.4x63.5mm) centered on the midline of the 4" (101.6mm) side, flush to the edge with step 6, by .5mm
viii. On the bottom surface, sketch a .4843" (12.3mm) diameter circle .45" (11.43mm) to the side and 1.5625" (39.69mm) to the top from the center
ix. Mirror the circle across the midline of the 3" (76.2mm) side
x. mirror the 2 circles across the midline of the 4" (101.6mm) side
xi. Extrude the circles by .5" (12.7mm)

c. Sample Presser

i. Extrude a .5" (12.7mm) diameter circle by .625" (15.875mm)
ii. Extrude a .625" (15.875mm) diameter circle centered on step 1 by .25" (6.35mm)
iii. Extrude a .375" (9.525mm) diameter circle centered on step 2 by 4" (101.6mm)

D. Final Report - Fall 2025

Improving the Precision of Small Human Tissue Biopsy Processing

Final Report

Biomedical Engineering Design 400

Department of Biomedical Engineering

University of Wisconsin-Madison

December 10, 2025

Team Members:

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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.

Table of Contents

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].

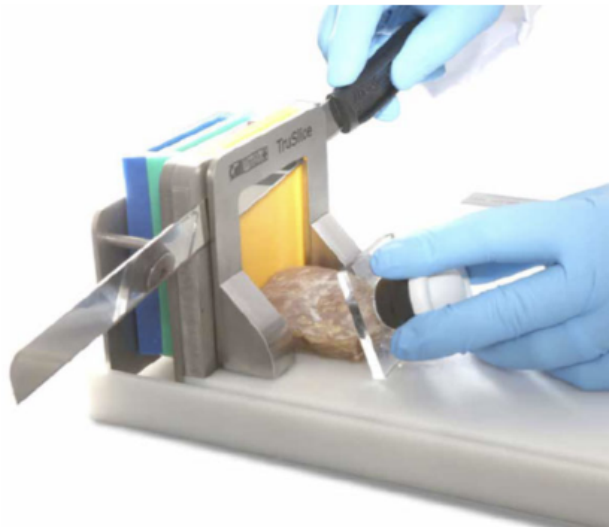


Figure 2: TedPella, Inc. TruSlice Specimen Cut-Up Grossing System $1878.75 [6]

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.

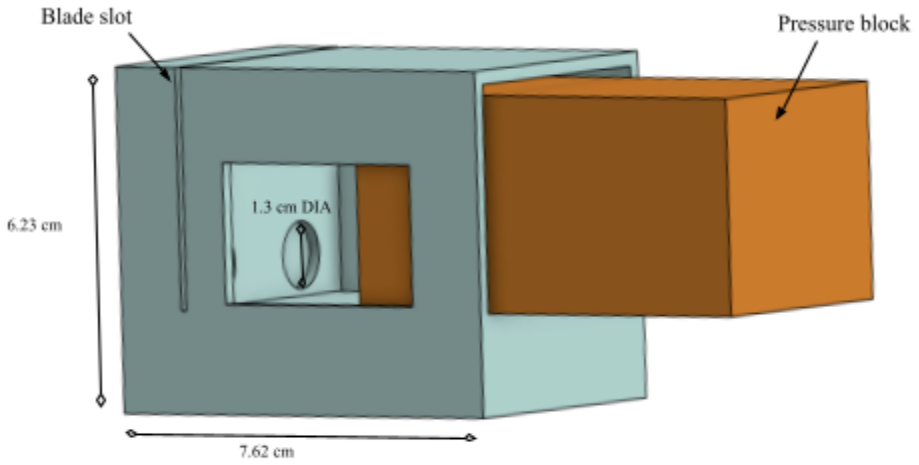


Figure 3: OnShape CAD drawing of client initial prototype [Bailey Donahue]

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.

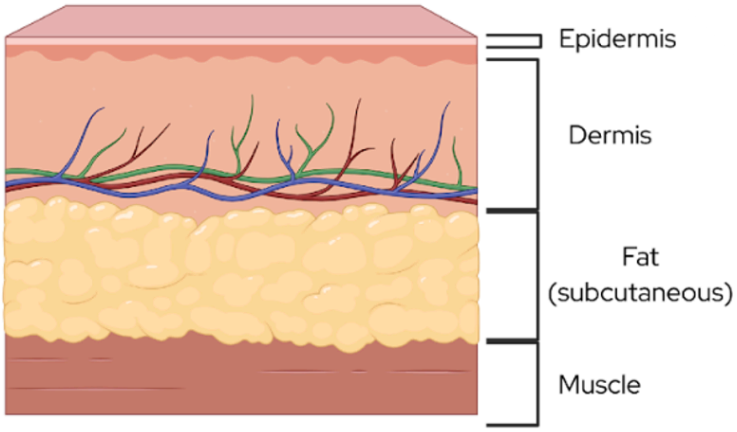


Figure 4: Major layers of the skin – epidermis, dermis, subcutaneous fat (hypodermis). [Bailey Donahue]

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.

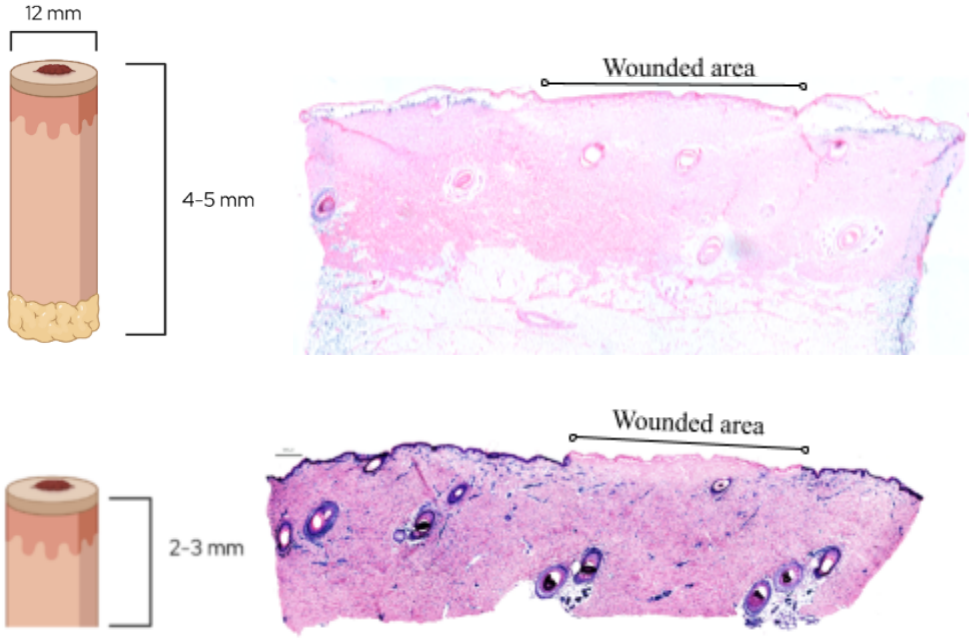


Figure 5: LDH stained pig skin samples without additional fat removal (top image) and with additional fat removal (bottom image); blue staining indicating viability [Bailey Donahue]

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^{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 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.

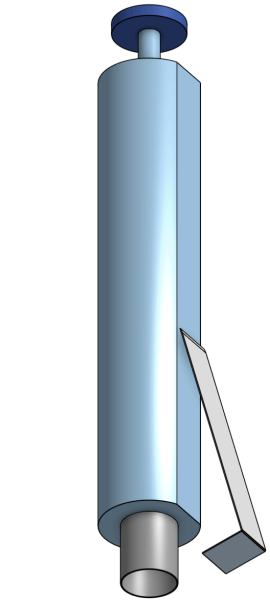


Figure 6: Biopsy Punch Design [Sarah Raubenstine]

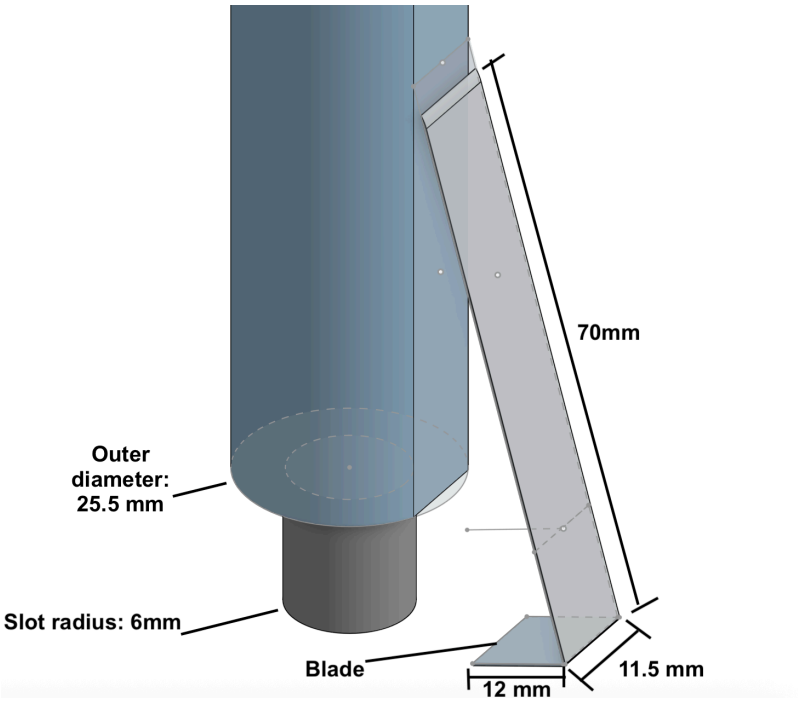


Figure 7: Biopsy Punch Design with dimensions [Sarah Raubenstine]

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.

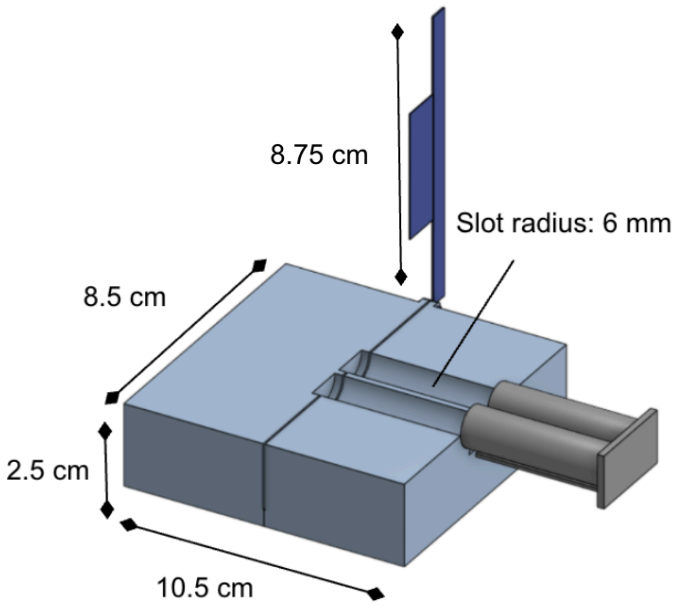


Figure 8: Paper Cutter Design with dimensions [Gianna Inga]

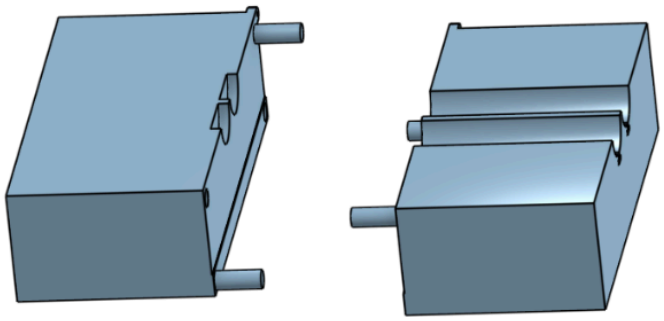


Figure 9: Paper Cutter Design Base Assembly [Gianna Inga]

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.

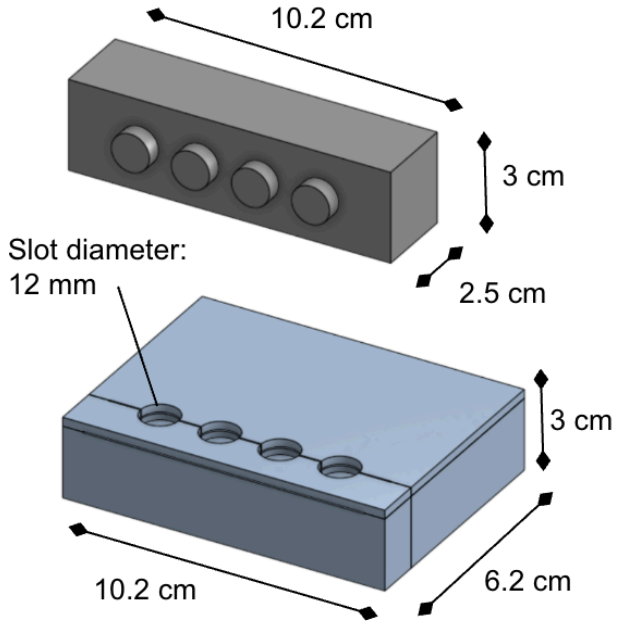


Figure 10: Biopsy Press Design and dimensions [Ella Lang]

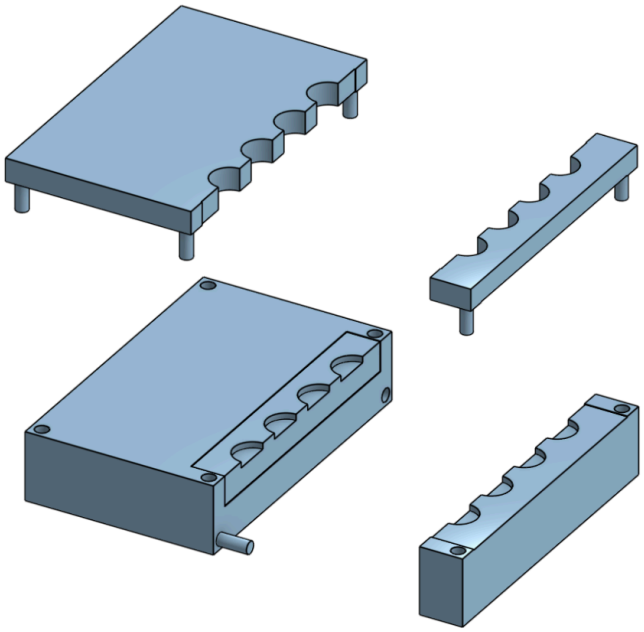
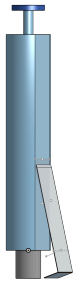
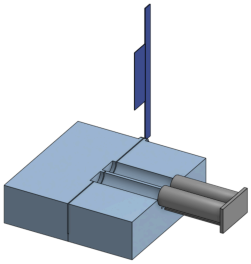
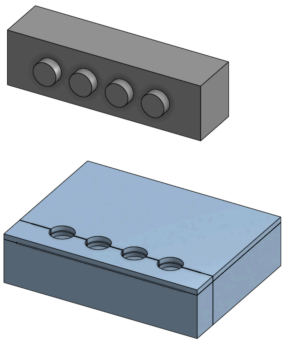


Figure 11: Biopsy Press Design Base Assembly [Gianna Inga]

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. 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 (*Figure 13*). 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].

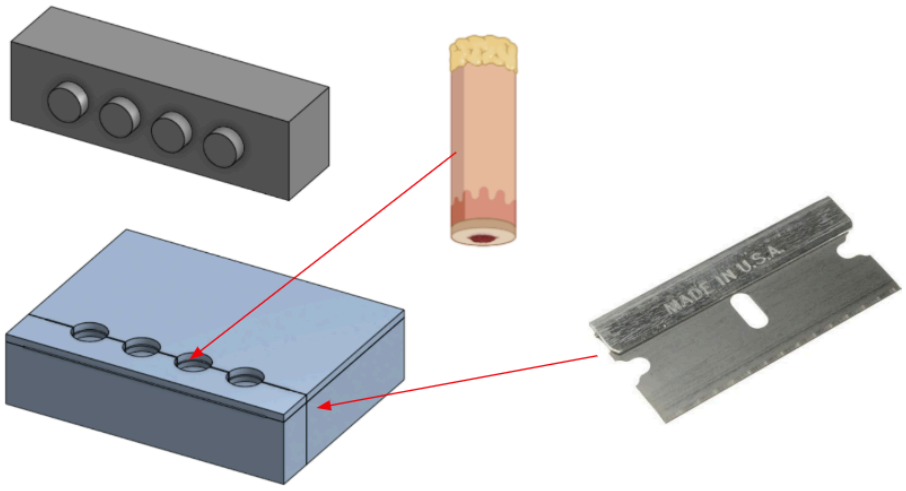


Figure 12: Proposed Final Design – The Biopsy Press Design

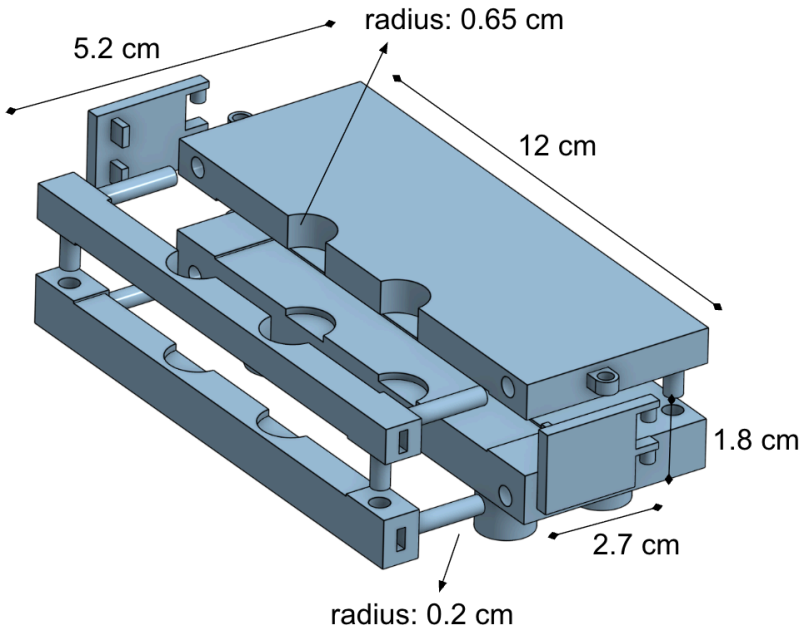


Figure 13: CAD assembly of the final design with dimensions - base components.

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.

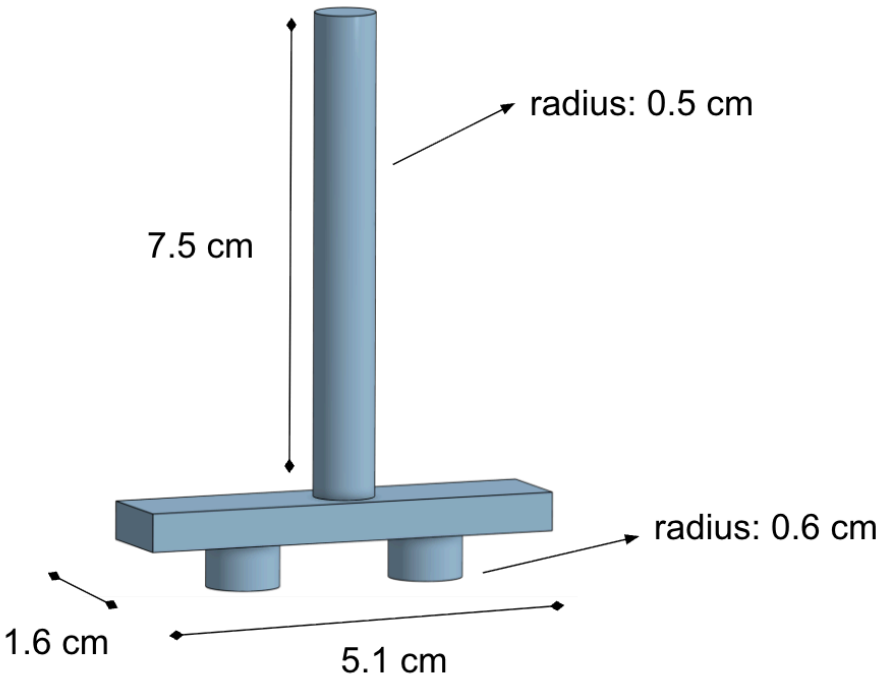


Figure 14: CAD drawing of the pressure applicator.

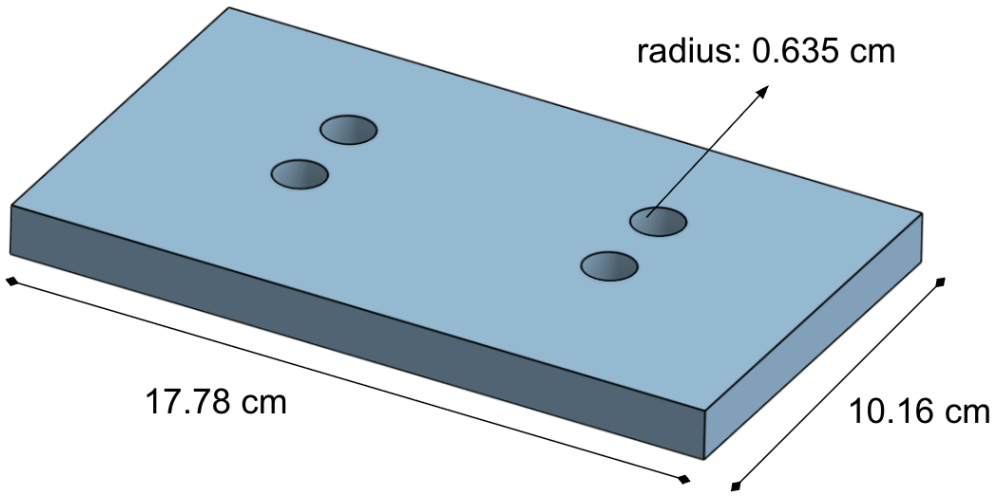


Figure 15: CAD drawing of the neoprene base.

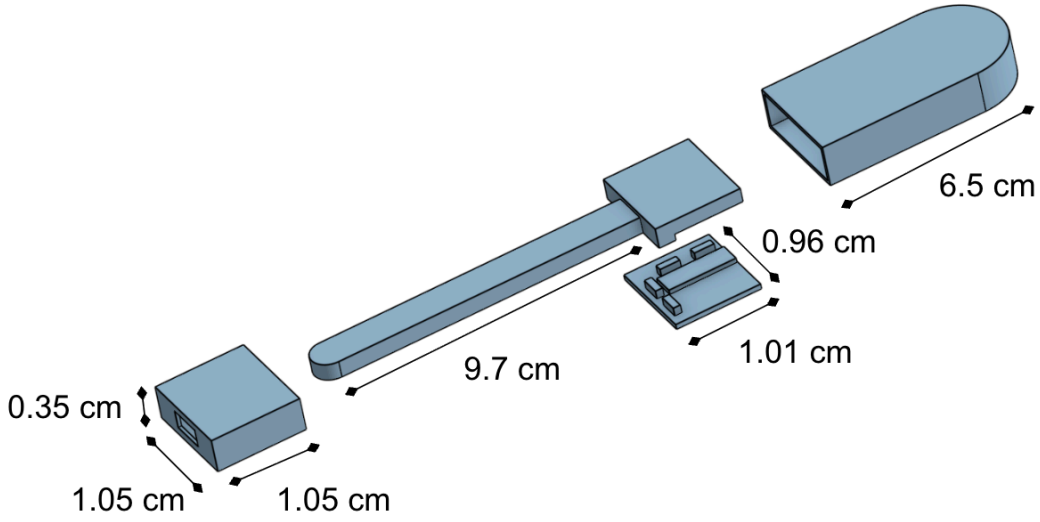


Figure 16: CAD drawing of blade handle components.

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 does not degrade significantly long-term usage along with other design components which makes it suitable for the base support choice.

Methods

The biopsy press base, blade holder, and sample presser were all fabricated utilizing 3D printing. First they were 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.

During the development phrase, additive manufacturing materials were selected based on specific prototyping objectives. Polylactic Acid (PLA) was utilized for rapid iterative design validation due to its cost-effectiveness (lower than $2 per unit) and short print duration (approximately 5 hours). Nylon 12 was used for the final test-ready prototypes for its superior mechanical properties and durability despite the higher cost ($25 per unit) and extended print duration (approximately 48 hours). While PLA components had a tolerance of 0.2 mm to accommodate thermal expansion and layer adhesion inconsistencies, Nylon 12 parts demonstrated significantly higher precision that required a tighter tolerance of 0.05 mm.

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. 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].

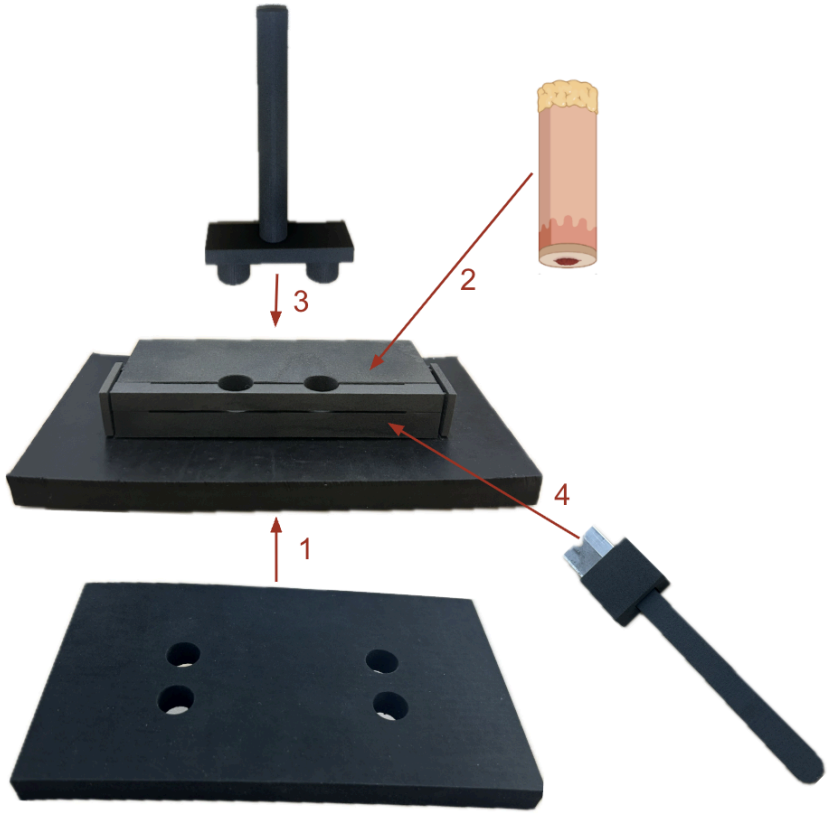


Figure 17: Assembly and use of the final design printed in nylon 12. 1: Attach the rubber base plate to the pegs on the bottom of the device. 2: Insert the cylindrical tissue sample fat side up. 3:

Apply pressure the the tissue samples with the applicator. 4: Insert the blade into the horizontal cut line.

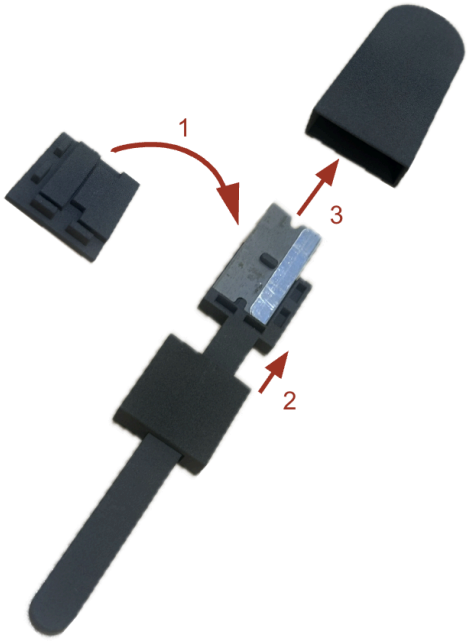


Figure 18: Assembly of the final razor blade handle design. 1: Snap together the handle and square piece. 2: Slide the bottom cover up. 3: Cover the blade with the cap.

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

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*).

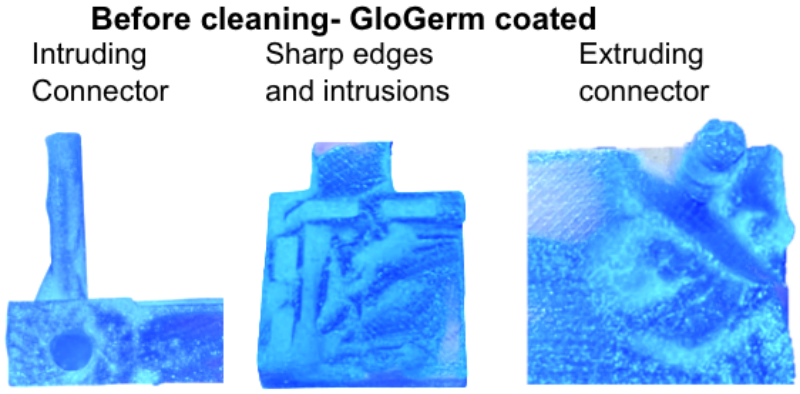


Figure 19: GloGerm coated device components. The leftmost image has an extruding peg and an intrusion. The middle component is part of the blade handle, with intrusions. The rightmost image is part of the base design with an extruding connector.

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.

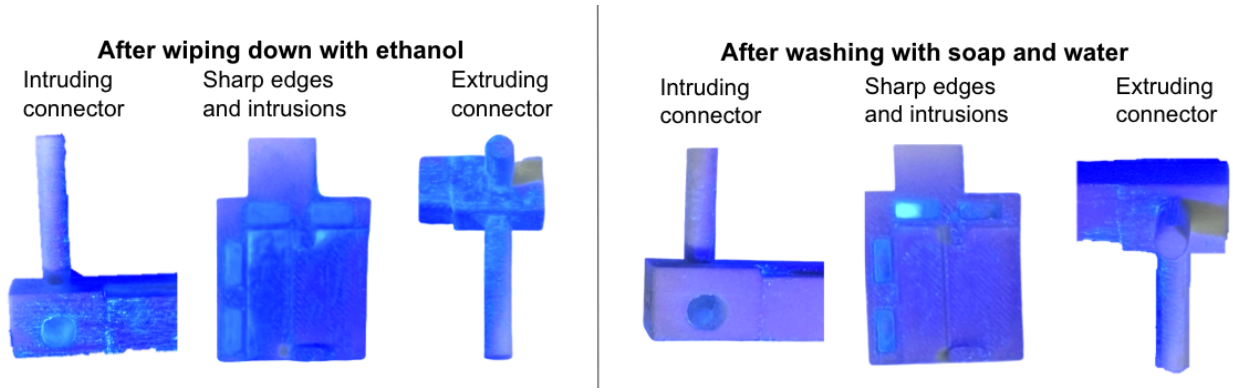


Figure 20: Results of sanitization testing with spray ethanol and soap and water.

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.

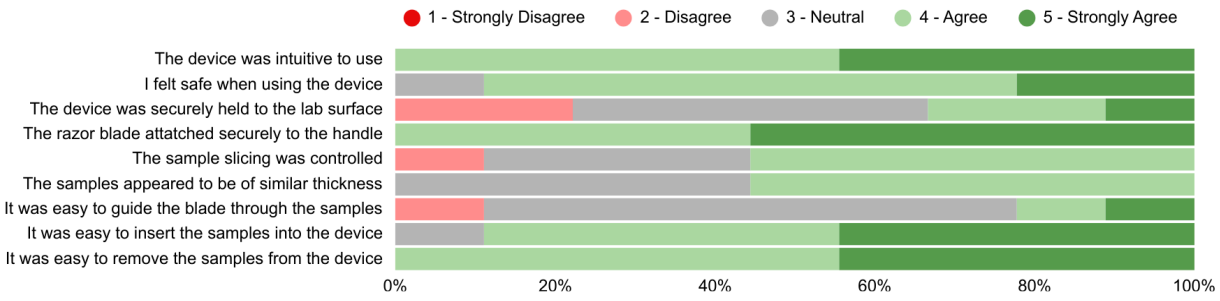


Figure 21: Usability survey responses with each participant rating each question on a scale of 1-5 (a score of 1 indicating strongly disagree and 5 indicating strongly agree).

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. Through literature analysis of estimated grip strength, 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].

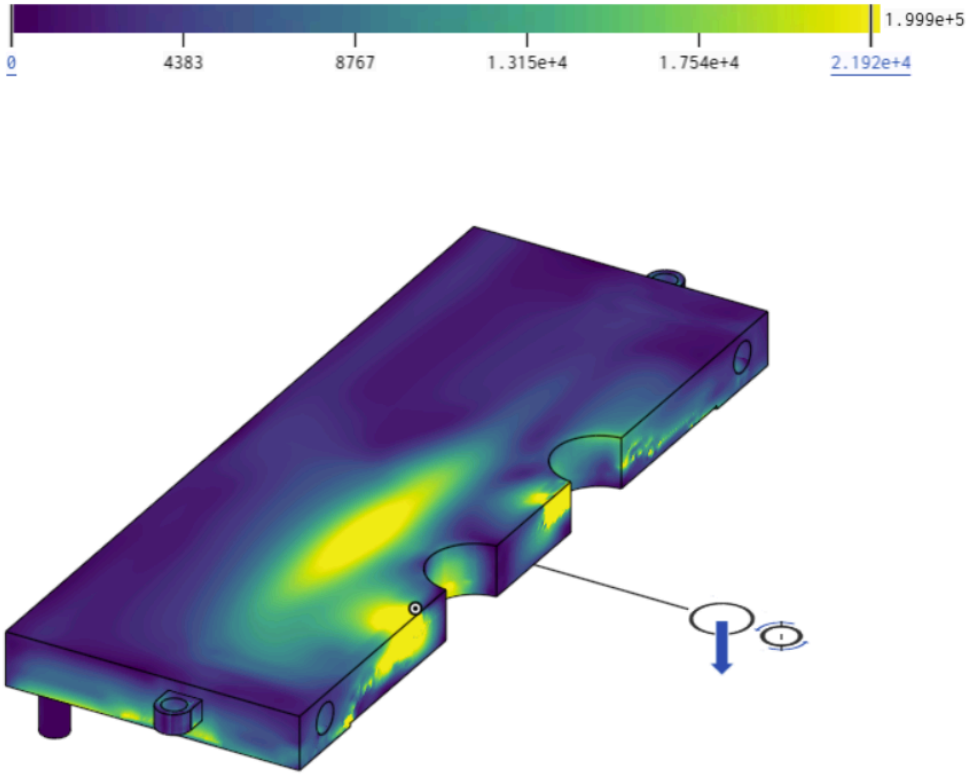


Figure 22: Simulated force exertion results on the lateral pegs and surface of the press.

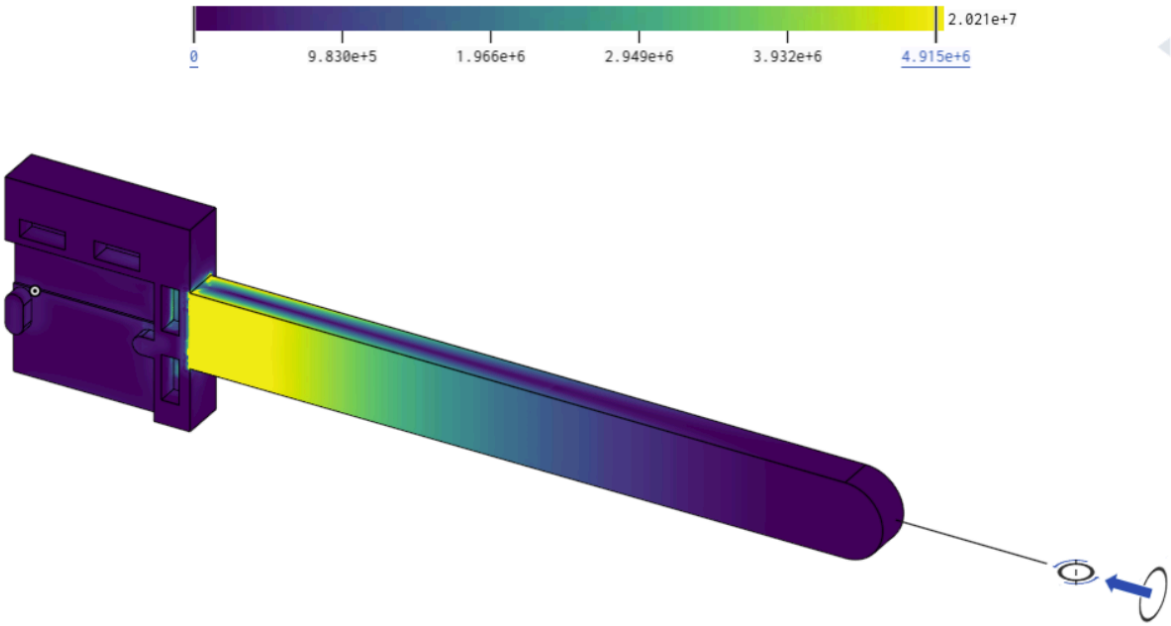


Figure 23: Simulated force exertion results on the handle of the razor blade.

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 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.

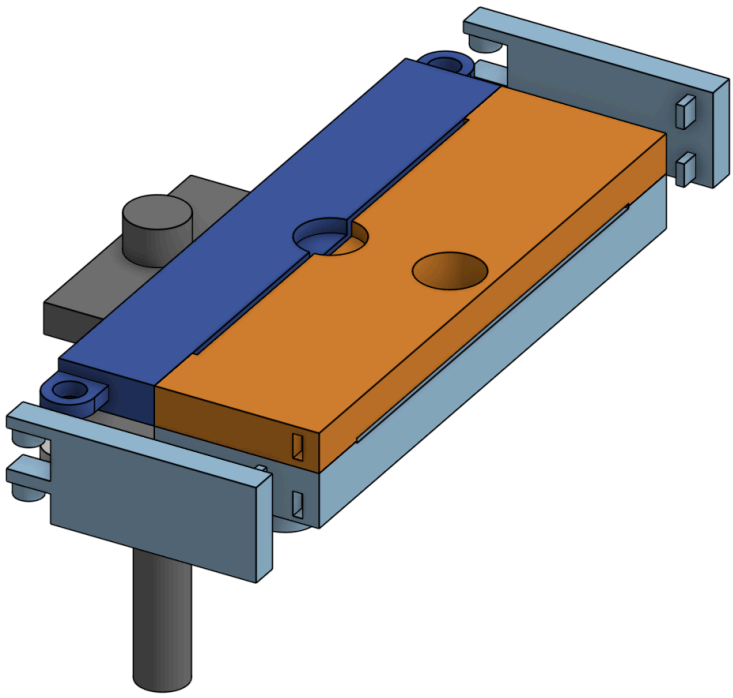


Figure 24: Updated with modifications from the clients on the final design of Biopsy Press

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 healing 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	11/25/2	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	11/28/25	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	N/A	12/10/25	1	$3.08	$3.08	N/A
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	2/10/26	1	$2.81	$2.81	N/A
BME Clear Resin	3D printed polymer through Makerspace design budget	Makerspace	N/A	UW-Madison	N/A	2/18/26	1	$11.42	$11.42	N/A
0.236 in PC	Polycarbonate Sheet: 0.236 in Thick, 12 in x 12 in, Colorless, Clear, 9,500 psi Tensile Strength	N/A	PS-PC-SR-189	Grainger	1ETY6	2/20/26	1	$21.20	$21.20	https://www.grainger.com/product/Polycarbonate-Sheet-0-236-1ETY6
0.118 in PC	Polycarbonate Sheet: 0.118 in Thick, 12 in x 12 in, Colorless, Clear, 9,500 psi Tensile Strength	N/A	PS-PC-SR-181	Grainger	1ETY4	2/20/26	1	$14.36	$14.36	https://www.grainger.com/product/Polycarbonat

										e-Sheet-0-118-1ETY4
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	3/4/26	1	$1.12	$1.12	N/A
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	3/11/26	1	$2.06	$2.06	N/A
Nylon	3D printed polymer through the BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	3/19/26		$8.00	$8.00	N/A
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	4/15/26	1	1.12	1.12	N/A
PLA	3D printed polymer through BME design Makerspace budget	Makerspace	N/A	UW-Madison	N/A	4/20/26	1	$1.61	$1.61	N/A
								TOTAL:	$192.85	

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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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:

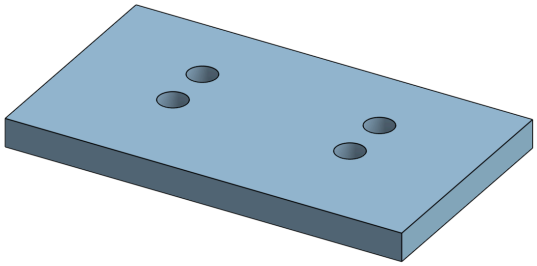
1. Dry-fit parts to verify that connector tolerances allow proper assembly.

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. Autoclave compatibility will also be visually evaluated to ensure the device does not begin to degrade.

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
- Autoclave tape

Material setup instructions for the GloGerm application:

1. Place a tablespoon of GloGerm solution in a dish
2. Wash and dry the paintbrush
3. Prepare multiple dry paper towels

GloGerm application instructions:

1. Completely disassemble the Biopsy Press device
2. Thoroughly coat the tip of the paintbrush with GloGerm solution. Repeat as often as necessary throughout the remaining steps
3. For each piece, thoroughly coat each face enclosed within the device when assembled with the GloGerm solution
    a. Once coated, set each piece on a clean, dry paper towel
4. For each piece with extruding pegs, thoroughly coat the entire peg with the GloGerm solution
    a. Once coated, set each piece on a clean, dry paper towel
5. For each piece with intruding connectors for peg insertion, coat the entire intrusion with the GloGerm solution
    a. Once coated, set each piece on a clean, dry 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

Autoclave testing instructions:

1. Completely disassemble the Biopsy Press device
2. Wash each component with soap and water. Let dry for 5 minutes.
3. Apply autoclave tape to three separate components
    a. The components selected can be at random

4. Image all components, with and without autoclave tape
5. Place all components in the autoclave, ensuring about an inch of space between components
6. Run the autoclave for 30 minutes
    a. Ensure a minimum temperature of 121 degrees Celsius is reached
    b. Ensure a minimum pressure of 15 psi is reached
7. Upon completion of the autoclave cycle, let the parts cool for 10 minutes
8. Put on heat-resistant gloves and lab goggles
9. Remove the components from the autoclave
10. Examine the tape on the three components and ensure the tape has turned black, indicating the autoclave reached adequate sterilization temperature
    a. If the tape has not turned a dark color, return to step 1 and run the autoclave for a longer period
11. Visually inspect each component for melting, warping, deformation, or damage
12. Image all components, noting any damage found in step 8

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. Unsheath 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:

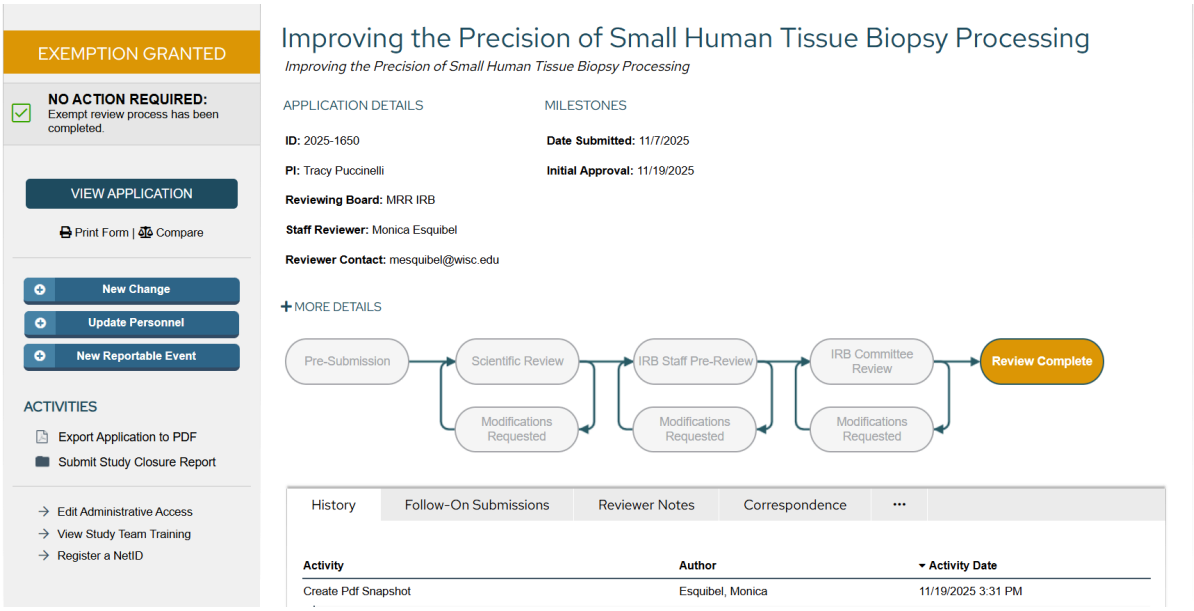
1 - Strongly Disagree 2 - Disagree 3 - Neutral 4 - Agree 5 - Strongly Agree

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

Pre-Submission → Scientific Review → IRB Staff Pre-Review → IRB Committee Review → Review Complete
Modifications Requested (Scientific Review)
Modifications Requested (IRB Staff Pre-Review)
Modifications Requested (IRB Committee Review)

History | Follow-On Submissions | Reviewer Notes | Correspondence | ...

Activity	Author	Activity Date
Create Pdf Snapshot	Esquibel, Monica	11/19/2025 3:31 PM