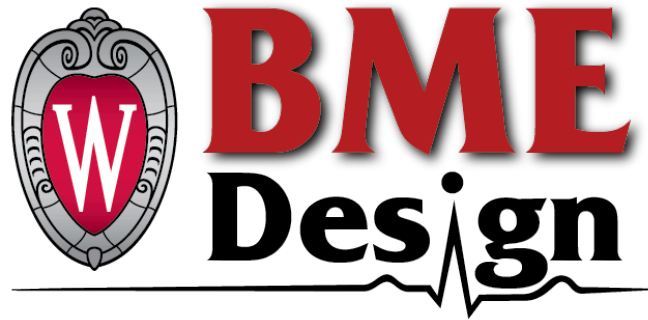


Preliminary Design Report



Print-A-Punch

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Abstract

Biaxial tensile testing allows scientists to explore the mechanics of tissue although there is no current device to allow for symmetric cruciform shape tissue cutting. When tissue samples are cut asymmetrically, it allows shear forces to interfere with the axial stress results [2]. Current products allow for the cost effective symmetric cutting of dumbbell shaped samples for uniaxial testing, however there are limited products for cruciform shaped cutting [4]. The client is asking for an inexpensive device that uses disposable razor blades or biopsy punches to symmetrically cut a circular tissue sample into a cruciform shape. After analyzing multiple preliminary designs based on important design criteria, one design was chosen due to its feasibility of fabrication, simplicity of use, and accuracy of sample produced. The selected design consists of a jig that allows a biopsy punch to be positioned in four guide holes then pressed downwards to cut off the four corners of the sample. Once a satisfactory prototype is produced, the device will be tested on multiple tissue samples. The dimensions of the tissue products will then be measured and analyzed to ensure symmetry within a small margin of error. The final product could then be scaled up to fit a variety of sample sizes and biopsy punches to allow for adjustability of the product for additional use.

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I. Introduction

The Print-A Punch project is centered on the need for a punch that is able to cut out a symmetrical crucifix shape tissue samples. This device must consistently cut symmetrical samples, be sterilizable for lab use, and available at a relatively low cost. This product is developed for the clients' Dr. Colleen Witzenburg and Mr. Daniel Pearce usage in a cardiovascular lab. However, this product should be public domain to be used by any researcher or research facility. This product allows for symmetrical samples to be made, in turn allowing for more accurate testing results from tissue comparison due to having fewer discrepancies between the samples.

This device is necessary to provide more accurate samples, aiding in research and testing. Although this sample is made to be utilized in a cardiovascular lab, there are also a variety of potential uses. With a relatively easy method of fabrication, users need only to 3D print the jig in accordance to the correct size biopsy punches. This jig ensures that the crucifix shaped samples are symmetric, allowing more accurate testing results as the measure of skewness predicted often do not quantify the symmetry correctly [1]. While asymmetric samples can be used to compare testing results, they do not produce adequately accurate results. Additionally, asymmetric cruciforms lead to undesirable high shear forces [2].

There are no current patents out for crucifix biopsy jigs, although there are regulations for biopsy punches that must be followed when creating the punch. Specifically, the strain ratio $\rho = \epsilon_2/\epsilon_1$ must be upheld along the direction that the punch imposes on the test specimen, with the "fixed p-value ...between 0 and 1 according to the geometrical configuration of the device [3]. Current competing designs on the market include the Print-A-Punch dog bone shape and the Novel Tissue cutting apparatus. The Print-A-Punch dog bone shape was created by a group of UW Madison students in 2023, utilizing 3D printed components with screws and razor blades to create a hand held punch that cuts out a dog-bone shaped tissue sample. This device bends two razor blades in order to form the correct tissue sample shape. This technology facilitates the broad adoption of standard test methods that improve the quality and reproducibility of tensile tests in soft biological tissue.

Researchers can freely download a set of STL files from this study to build their own Print-A-Punch device [4]. Next, the novel tissue cutting apparatus is a design for a similar cutting process. This device cuts perpendicularly across the desired tissue samples, using 3 linear actuators, 2 load cells, and tissue holding fixture in. Blades are sterilized after each cut. The device works by utilizing 2 actuators controlling lateral movement, with the third controlling the cutting motion [5]. While this device is not directly competing with the Print-A-Punch biaxial device, it is important to analyze and document for reference.

This project's problem statement was to create a device that would allow for uniform, consistent cruciform shaped samples to be created. Current processes often result in asymmetric samples, leading to inaccurate results due to the need to compare two types of samples. This asymmetry is due to high shear strain forces during testing. These forces lead to inaccurate material property measurements that affect patient-specific models. The clients are requesting a new cutting process that will allow them to produce more uniform and accurate samples for cardiovascular tissue testing. This device should maintain these properties consistently no matter the type of cardiovascular tissue or tissue thickness. By ensuring uniformity in the cruciform samples, the system will reduce errors in material property computation, improving the accuracy of mechanical behavior estimations for soft tissues. This approach will serve as a cost-effective alternative to custom steel punches, using 3D printing to enhance accessibility and reproducibility in tissue testing procedures [6].

II. Background

The product's primary function is to cut through cardiovascular tissue; however, the device will be accessible on public domain such that other labs may create their own punch for their own applications. As this prototype will be used for biaxial testing, research was conducted on the effects of impact the sample undergoes during testing. This concluded that a variety of factors such as sample thickness, cross-sectional area, lateral contraction quantification, starting reference configuration, strain determination method, and time all have significant impact. These factors can impact the reconstruction of the mechanical behavior of a sample and the

homogeneity of the stress field under tensile loading [7]. Furthermore, the asymmetry due to shear strain on samples is important to account for, as these shear strains complicate assumptions in planar biaxial testing and affect stress calculations and parameter estimations in modeling. Sample shape asymmetry results in a larger, more homogeneous high shear strain region, potentially improving estimates of shear and axial coupling moduli [2].

The main focus of the design is to achieve accuracy and to lower shear forces through symmetry as asymmetric cruciforms lead to undesirable high shear forces [2]. Specific shear strains of 4-12N are required to puncture heart tissue, and a constant application of 2-4N is required for continual cutting [5]. In regards to the biaxial testing that the client is doing with these specimens, there are a few key points that were taken into consideration for this prototype. One of these requirements is that the plastic used to create the prototype abides by ASTM: 638 [8] as these are the plastics that will not degrade tissue itself, nor under sterilization, making PLA ideal to be used in a lab environment. Furthermore, the biaxial tensile tests that the client conducts are primarily performed in a research and development manner, to investigate stress values at the intersection point of the specimen [9]. Biaxial testing on cardiovascular tissue uses simultaneous forces in two principal directions, allowing for analysis of strain-rate, creep, stress-relaxation, and force-controlled metrics. Strain-rate testing determines time-dependent behaviors of tissue. Creep testing shows how tissue displacement creeps to maintain peak membrane tension, while stress-relaxation testing shows tissue stress reduces from peak membrane tension. Finally, force-controlled testing reveals material's anisotropy and nonlinear stress-strain response, and has the five loading ratios: 1:1, 0.75:1, 1:0.75, 0.5:1, and 1:0.5 [10].

Client Daniel Pearce is a PhD Candidate currently studying the effects of heart attacks on heart tissue, working under Dr. Colleen Witzenburg, the principal investigator of the cardiovascular biomechanics laboratory. Pearce is comparing tissue samples from induced heart attacks to healthy heart samples in order to see the effects that a heart attack has on the cardiovascular tissue's mechanical properties.

The main product design specifications for the project entails a focus on accuracy, ease of use, and low cost. The punch must be capable of cutting a minimum of 3 samples before swapping blades is necessary, and be able to replicate the intended punch pattern on every attempt. Overall length and width of printed punches should have an error less than 5% [6] . For ease of use, the prototype must be able to cut through multiple types of tissue with relative ease, without requiring excessive force to operate. The device must be simple enough to be easily replicated by other researchers for laboratory use. The device must also require minimal setup time. Print-A-Punch should be able to withstand chemical sterilization, meaning that it must not corrode when in contact with ethanol or PBS solution. For this reason, either PLA, resin, or nylon was considered for 3D printing due to their chemically resistant properties [11]. Fabrication requires few criteria, only that the punch must be simple to print on most 3D printers with a fast fabrication time of under 5 hours, with a reasonable price per gram of filament/resin.

III. Preliminary Designs

Design 1: Razor 1-Step

Design one utilizes a large stamping mechanism with attached razor blades for cutting samples to the predetermined geometry. The design requires 4 bolts with wingnuts (not pictured) that screw into the frame of the punch, forcing the razors into the U-shaped geometry required for the cruciform. The razor 1-step is a singular punch, depicted with a before and after cut in Figure 1 below.

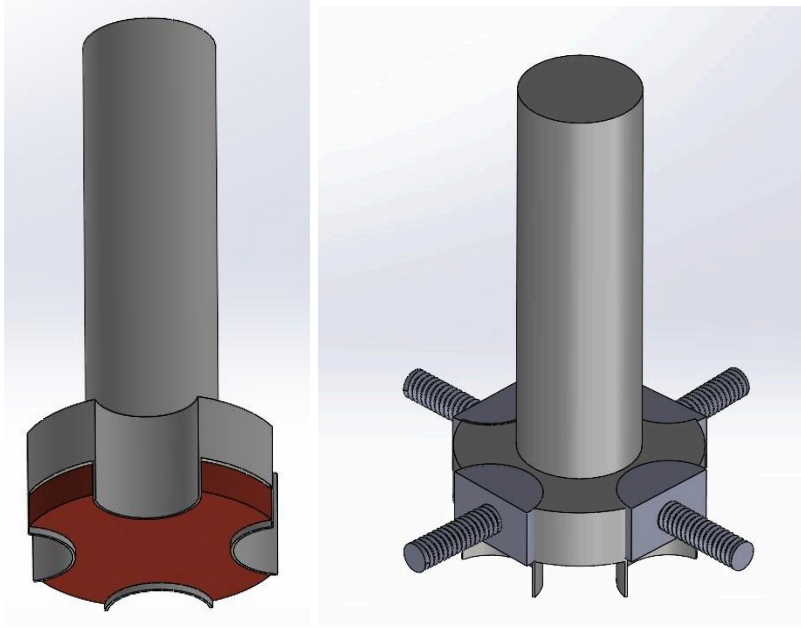


Figure 1: Razor 1-Step CAD model with and without shaping bolts

In using the razor 1-step, the user would first secure the four blades in place by tightening the wingnuts on the shaping bolts. After the wingnuts were sufficiently tightened, the user would then position the punch over the tissue sample, and plunge down in a stamping motion with approximately 4-12N of force [5], to sufficiently cut the apertures from the sample. If required, the user would then use a rolling motion of the wrist to ensure a complete cut of the tissue sample.

One of the benefits of this design consideration is ease of forming. The razor blades in this design would be much easier to shape than that of the other design considerations involving razor blades, due to the wingnuts tightening onto bolts. This element allows for better time management, safety, and overall efficiency of the design. Another benefit of the razor 1-step is a low production cost, as the 3D printed PLA handle is a cheap, versatile option that is easily accessible for most seeking to use such a device [12]. Finally, fewer razor blades would be needed for this design, as bending razor blades to less extreme angles puts less strain on the metal, reducing the factor known as metal fatigue [13].

There are also several constraints of this model to consider. Razor blades may not be the most feasible option for cutting, as successfully bending them could prove to be a challenge. Additionally, if the user desires a perfectly circular sample, this design would be enough to alone cut the tissue, and a second punch would be needed. Finally, the razor 1-step does not address the issue of the fastening the sample during the cut, as the design does not have any feature to prevent the sample from sliding or shifting on the cutting station.

Design 2: Razor 2-Step

Design two again uses a stamp-press method, where the user presses down onto the tissue sample to make a cut. As pictured below in Figure 2, the two components contain separate geometries of razor blades for making two separate cuts, as well as a framing jig as shown in the bottom of Figure 3.

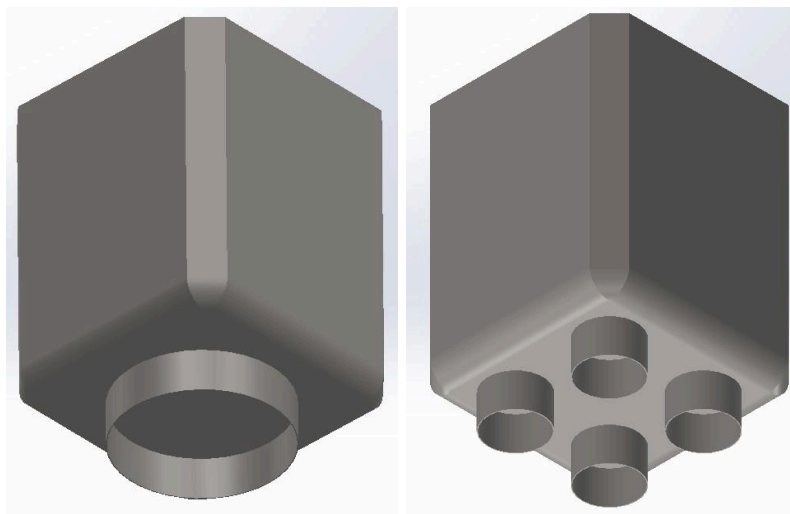


Figure 2: Razor 2-Step CAD model stamps

In using the razor 2-step, the user would first insert the pre-bent blades into the grooves of the PLA plastic handle. The user would then center the tissue sample in the framing box, and while using one hand to secure the frame, the other would stamp downwards with the circular cutter in the same fashion as the razor 1-step, cutting through the tissue sample of interest. The user would next repeat the action with the four-point punch, removing the sections from the cruciform.

There are several benefits to this design. Firstly, this design offers a high level of both precision and accuracy, as the pre-set geometry guarantees that the same cut will be made time and time again. This feature is a key component for the scope of this project, as the main goal is to ensure symmetry and consistency in the samples. Another benefit of this design is time efficiency, as only 2 swift punches are required to prepare the tissue sample for biaxial testing. Finally, the use of a framing jig allows for increased safety, as it ensures that the user's fingers will not be within the danger zone of the blades.

However, several constraints detract from the feasibility of this design option. Bending razor blades to such a precise geometry is not taken into account in this design, which could prove to be a considerable challenge without proper machinery. This in turn would increase the already proportionally high production costs, and paired with the need for several blades per cut, this design is much less viable. Finally, this model lacks a method to secure the sample to the cutting station when inside the jig, potentially resulting in misalignments and therefore asymmetries in the tissue sample. These factors were taken into consideration during design evaluations and ultimately steered the team away from this design.

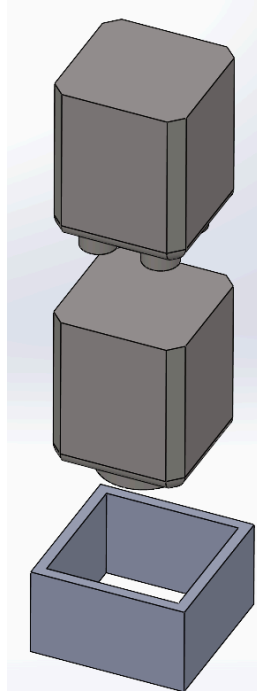


Figure 3: CAD assembly of Razor 2-Step with stamps and frame

Design 3: Biopsy Jig

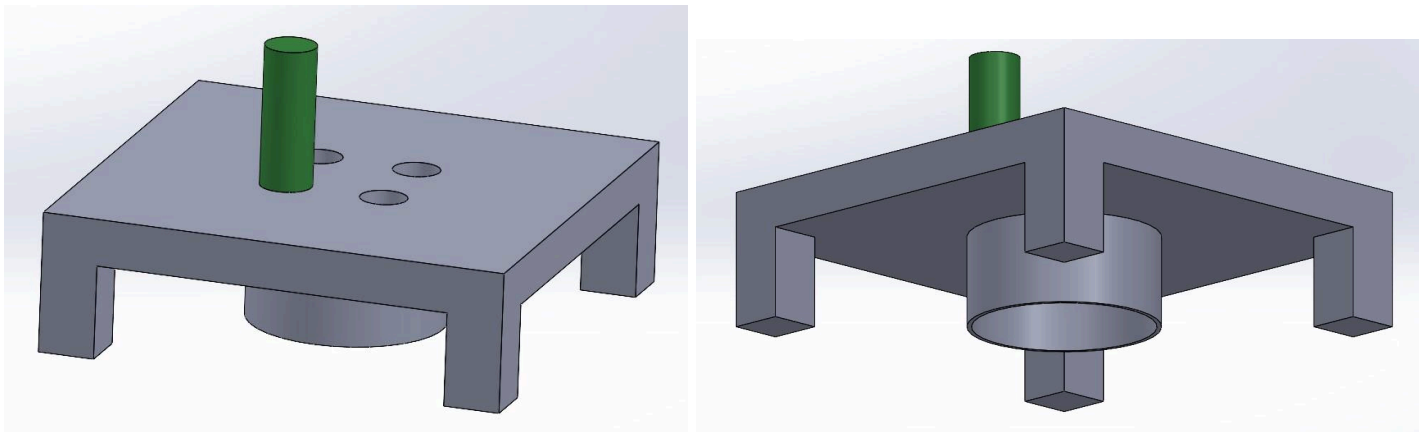


Figure 4: Biopsy Jig CAD model, demonstrating biopsy punch (green) through symmetric holes

Design three takes a new approach to the cutting of tissue samples. Rather than utilizing bent razor blades to make cuts in the sample, the biopsy jig has four symmetric holes meant for aligning a biopsy punch with the four apertures of the sample. The user would first align the tissue sample within the cylindrical holder in the middle, securing the sample to the cutting station. The user would then unpackage a biopsy punch

coordinating with the diameter of the jig's holes, and press the punch vertically downwards into the sample. From that point, the user utilizes standard biopsy punch techniques (twisting, rolling, etc.) to remove the excess material from the cruciform. After all four punches have been made, the user removes the jig, where they may then use a separate razorblade to do any necessary trimming or cleanup.

The biopsy jig design has several advantages over the other designs considered. Firstly, this design eliminates the need for bending any razor blades to high-stress geometries. This factor alone convinced the group of its viability. Additionally, this design allows the user to secure the sample down to the cutting station, ensuring that the sample will not slide or squish during the cutting process, leading to any asymmetries. The pre-cut holes in the jig also certify that the tissue samples will be symmetric and consistent. Finally, this design features great reproducibility, as it is a very simple 3D print job, as well as very easy to understand and assemble.

Several constraints must be considered for this design. Most notable of these is the high maintenance cost of the design. While the two other designs had a much higher initial fabrication cost, the biopsy jig's need for biopsy punches causes an increase in long-term cost [14]. This constraint was justified based on the client's current method involving approximately one punch per tissue sample. Another constraint of this design is time efficiency, as it is less efficient than other designs considered for this application, which were able to make all four necessary cuts in one to two motions.

IV. Preliminary Design Evaluation

Design Matrix

Criteria (weight)	Razor 1-Step		Razor 2-Step		Biopsy Punch Jig	
	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Reproducibility (30)	3/5	18	4/5	24	5/5	30
Cost (20)	4/5	15	3.5/5	14	1/5	4
Ease of Use (20)	4/5	15	4.5/5	18	5/5	20
Reusability (15)	3/5	9	3/5	9	2.5/5	7.5
Ease of Fabrication (10)	4/5	8	2/5	4	5/5	10
Safety (5)	1/5	1	4/5	4	5/5	5
	Sum	66/100	Sum	73/100	Sum	76.5/100

* Scores are out of 5

** Weighted Score = Weight * (Score / 5)

Design Criteria

Reproducibility: Reproducibility entails how accurate each sample will be when tested across multiple trials.

Mechanism of cutting, ability to apply uniform pressure, and ease of the cut were the three factors evaluated for this criteria.

Cost: Cost refers to the price of materials needed for each design. This category considers the upfront costs of 3D printer material or resin casting, and regular maintenance cost, such as the routine purchase of fresh razor blades or biopsy punches.

Ease of use: Ease of use refers to the process of preparing and executing the cut. This criteria covers bending razors, positioning tissue samples, inserting the biopsy punch, etc. Ease of use also includes the punch itself, whether the device requires manual force, or if another tool such as a hammer is required. Devices that require the user to calibrate the press or otherwise complicate preparation would score lower on this criteria.

Reusability: Reusability evaluates the lifespan of the razor or biopsy punch. Reusability also involves the lifespan of the device before a new one must be produced. As one goal of this project was to create a device that can be used for prolonged periods, this criteria was particularly important to meet this requirement.

Ease of Fabrication: Ease of fabrication is a measure of difficulty to produce and assemble the product prior to use. Overly complicated designs also score lower in this criteria. Designs that are difficult to fabricate could lead to accuracy and safety concerns.

Safety: Safety is a measure of the general safety of both assembly and use. Safety considers the potential hazards that could arise from handling sharp objects like razors or biopsy punches, particularly if they are not properly secured or if the design exposes the user to them. Devices that minimize the risk of harm or offer protection from sources of harm will score higher on this criterion.

Design 1: Razor 1-Step

Reproducibility: The design scored a 3% in this category because it features only a single cutting shape, but relies on the user to make an accurate cut with little to guide them. The design does not have any system to secure the tissue for cutting, such as a jig or a frame. In addition, the force applied by the user is not guided, meaning that the user could apply force differently between different cuts.

Cost: This design scored the highest out of the designs, a 4%, because it features inexpensive, easily accessible parts. Firstly, the body is made with a 3D printed frame, which is relatively inexpensive in comparison to other materials. Additionally, the design uses disposable razor blades to make cuts. This design scored higher than the other designs because it features the least amount of pieces to print and uses the least amount of razor blades.

Ease of use: This design received a 4/5 because it is straight-forward with few steps. Users are only required to secure the razor blades into place, tighten the screws to shape the blades, and then apply pressure to the tissue with the cutting-face. This design scored lower in this category than other designs, as it relies on the user's judgment for placement of the cut.

Reusability: This design received a 3/5 for reusability. The design scored moderately in this category because it uses disposable razor blades. Using disposable razor blades allows the frame itself to be reused indefinitely, though the razor blades themselves cannot be used for more than 3-5 cuts, meaning the user must deconstruct and replace the razor blades often, making it difficult to cut multiple samples.

Ease of Fabrication: This design received a 4/5 for ease of fabrication. The design scored highly in this category because it uses a 3D printed body. After fabrication of the body, a user only has to place the razor blades into designated slots and tighten the wingnuts. This design lost a point as it still requires the razor blades to be bent.

Safety: This design received a 3/5 for safety. This design scored lowly in safety because it relies on the user to avoid sharp razor blades. This design works with exposed blades, and an open cutting face serves as a potential hazard. The design is also relatively small, with minimal grip surface area.

Design 2: Razor 2-Step

Reproducibility: This design received a 4/5 because while it features two separate cuts, it has a frame to guide the user to align both cuts. This design secures the sample inside its frame, and then uses both cutting faces that fit into the frame to make the necessary cuts. The rigid structure of this design allows for more reproducible results. Additionally, the force applied by the user is guided in a single direction, increasing reproducibility.

Cost: This design received a 3.5/5 for cost. Like the razor 1-step design, this design is primarily made of inexpensive, disposable parts that contribute to its low cost. The body is constructed from a 3D-printed frame, which is more cost-effective compared to other materials. Additionally, it incorporates disposable razor blades for cutting, offering a lower cost alternative to traditional blades. This design scored slightly lower than the razor 1-step, as it features more parts to construct, and uses more razor blades per cut.

Ease of use: This design received a 4.5/5 because while it has more steps than the other designs, it features a frame that makes the cut easier for the user to perform. Users are only required to arrange the razor blades, shape the blades, align the first cutting-face with the frame, and then repeat for the 2nd cut. This design is higher in this category because the frame guides the user towards a well aligned cut.

Reusability: This design received a 3% for reusability. The design tied with the razor 1-step for the highest score in this category, because it shares similar parts. Its use of disposable razor blades allows the body to be reused for many cuts. While this allows the frame to be reused indefinitely, the blades themselves cannot be reused for many cuts. As a result, users will need to frequently disassemble and replace the blades, making it challenging to cut multiple samples efficiently.

Ease of Fabrication: This design received a 2% because it has multiple parts to fabricate, and requires the razor blades to be bent into a perfect circular shape. The design features three different 3D printed pieces that combine to make the body. Then, razor blades must be bent into the desired shape before cutting the sample. This design requires the blades to be formed into a perfect circular shape, which would be difficult to accomplish.

Safety: This design received a 4/5 for safety. This design scored highly in safety because it has a more secure design that protects the users. Though this design works with exposed razor blades, the cutting frame used to align the cuts provides an extra layer of safety. This design still loses a point for safety, because it still requires the user to handle blades during construction, while avoiding the multiple cutting faces.

Design 3: Biopsy Punch Jig

Reproducibility: This design received the highest score as it uses biopsy punches along with a jig that secures the sample in place. Securing the sample in place allows for a more controlled cut, leading to more accurate results. The biopsy punches themselves cut out perfect holes in the sample. Additionally, this design minimizes possible mistakes made by the user, requiring them to only place the biopsy punch in the slot and press down.

Cost: This design received a 1/5 for cost. This design scored the lowest out of the designs because it uses more expensive biopsy punches rather than the alternative of inexpensive razor blades. Like razor blades, the biopsy punches must be replaced after 3-5 cuts, making the price differential more stark. Though the body would be resin-cast, the price discrepancy between resin and PLA is minimal. More importantly, the recurring costs of the biopsy punches make it much more expensive to use than the alternatives that use razor blades.

Ease of use: This design also received the highest score for its ease of use. The design scored the highest out of the designs, as it has the fewest steps for assembly and simplifies the cutting process. All that is required for use is to secure the sample in the jig, then use a biopsy punch to make cuts through the 4 holes. This design scores highly because it does not rely on the user to decide where to place the cuts, and instead guides them to the correct geometry.

Reusability: This design received a 2.5/5 for reusability. The design scored moderately in this category as it uses replaceable biopsy punches for cutting. Using biopsy punches allows the frame itself to be reused indefinitely, while replacing the biopsy punch whenever it dulls. This scored slightly lower than the designs featuring disposable razor blades, as the biopsy punches are more difficult to replace.

Ease of Fabrication: This design received the highest score as it has only one part to fabricate, along with purchasable biopsy punches. This scored higher than the other designs because it does not have multiple parts and does not require the manipulation of razor blades into specific shapes. By utilizing purchased biopsy punches, the user can cut circles out of the sample without a difficult assembly process.

Safety: This design scored the highest in safety due to the use of biopsy punches, as opposed to razors. Additionally, this design does not require the user to manipulate the biopsy punch in any way, decreasing the interaction with objects. Finally, the design features a secure rig that locks the sample into place, and protects the user from the cutting surface of the biopsy punches.

Proposed Final Design

The proposed final design will be the biopsy jig that features four symmetrically placed holes to guide a biopsy punch. The jig will feature a cylindrical holder on the bottom to clamp the sample to the cutting station to prevent the sample misaligning. The user will place the tissue within the holder, then utilize a biopsy punch with a matching diameter to the jig's holes. By pressing and twisting the punch vertically into the sample, the user can efficiently extract material from specific areas, creating uniform tissue sections. After completing the cuts, any additional trimming or clean-up can be performed with a separate razor blade as needed. This straightforward design supports consistent sample preparation with minimal components. Additionally, this

design is scalable, needing only one dimension to be changed within the CAD files to adjust the hole diameter for a different biopsy punch.

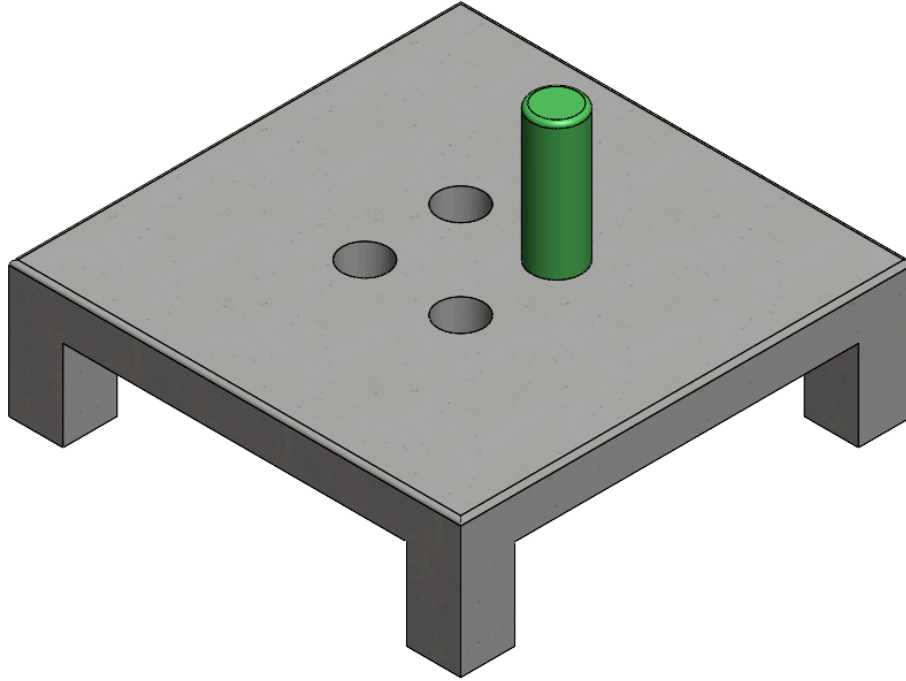


Figure 5: Proposed final design - Biopsy Jig

V. Fabrication/Development Process

Materials

The materials required for the fabrication of the biopsy jig are easily obtainable and relatively inexpensive. The entire unit will be created in one piece using resin printing. Using resin cured printing is preferred in this instance over standard extrusion based 3D printing because resin prints can be made using completely transparent material. This is optimal to allow for the user to better center the punch guide over

desired tissue sections. Along with the printed jig, the design will require the use of biopsy punches to cut circular sections 90° apart. Biopsy punches are the best tool for this design because they don't require any difficult or time intensive set up. The punches are ready immediately after opening. Resin printing at the design innovation center at Wendt costs \$0.42 per gram [12]. This is comparably more expensive than PLA and other plastics but it is worth the cost to improve functionality. Biopsy punches cost approximately \$2.75 per punch when ordered in bulk [15]. Once the punch is printed, the maintenance cost for this design is comparable to traditional techniques, but results will improve.

Fabrication Plan

Fabrication will take place at the design innovation space at Wendt. Resin printing, formally called stereolithography (SLA), will be used to create the final prototype. SLA is a technique that utilizes a light source to cure resin layer by layer. This technique has an extreme high degree of precision which is necessary due to the small dimensions of the design. In order to print, an STL file derived from the CAD design will be used. During the printing process, this design will require supporting material which post print will be trimmed off. After the design is printed and trimmed it will be ready to use with biopsy punches. SLA prints typically take 2-4 hours to complete making it minimally time intensive [16]. A final drawing of the biopsy punch jig is referenced in the appendix. Overall, this prototype will have a relatively easy fabrication process.

VI. Results

Testing and Results

Comprehensive testing of tissue samples cut both by hand and via the print-a-punch will be a crucial aspect to display the overall success of the punch. Symmetry is the most crucial aspect referenced in the PDS and thus will be the initial main focus. To compare symmetry in both methods of cutting, images will be taken and run through image analysis that outlines the sample and quantifies the level of symmetry. The metric for quantification is the percent overlap of opposing arms of the cruciform. Perfect overlap, 100% overlap, will have opposing arms exactly aligned about a horizontal or vertical line. Unsymmetric samples will have opposing arms that do not directly align with one another, ultimately leading to overlap below 100%. After several samples of each method are measured and a percentage overlap is obtained, a two sample t-test will be conducted to compare results. A significance level of 0.05 will be used to determine if methods are statistically different or not. This initial testing will create a baseline to determine if the jig yields more symmetric samples. In order to further test the product, mechanical stress testing will be performed on tissue cut from both methods. This will allow for the comparison of shear forces generated during bi-axial testing. Again, similar statistical analysis will be performed to determine if there is a significant difference in shear forces of each cutting method. Reasonable post analysis expectations are that the biopsy punch jig will perform better than the freehand cutting method. This is a likely assumption because the biopsy punch jig has guide holes that will ensure holes are punched in a uniform manner.

Sources of error are present in all data, in this instance human error is of the biggest concern as both cutting methods are performed by hand. To minimize the human error introduced during the cutting process, a standard operating procedure will be created. This will provide detailed instructions as to how to make the cuts using the jig and freehand method. Additionally, the sample size of each test condition will be 5 or greater to supply

several data points to be used in the analysis process. This too, will minimize the consequence of error present during data collection.

VII. Discussion

The testing results of this device will determine if it can be used generally in biaxial tensile tissue testing. In order for the device to be broadly used, the tissue products must be guaranteed for accuracy and precision on every cut for various tissue types. Tests related to the accuracy of the dimensions of the cut must be conducted to ensure this accuracy while testing on various tissue types will expand the universality of the product. If these tests produce results such as asymmetric tissue samples, changes must be made regarding the design of the product or instructions for usage. Once determined that the dimensions after the cut are accurate, biaxial testing can be performed with validation that shear stresses will be minimized and normal stresses can be effectively calculated. Secondly, by successfully testing the device on various types of tissues, the possibility of biaxial tensile testing on different tissue samples opens up. Given that there are accurate results for the first stage of testing, it is anticipated that results for other types of tissue will also be successful as long as the biopsy punch can cut cleanly through that material.

Another factor to consider is the adjustability or universalness of the product to different size samples with different size removal parts. Starting with a 25mm circular sample, a 10mm biopsy punch should be used to remove the outside corners while a 15mm circular sample requires a 5mm biopsy punch. The goal of the product is to first perfect the latter example while in the future the product could be easily scaled up by this Print-A-Punch group or other customers could scale it up using the CAD files published along with the final paper of this project.

Lastly, cost and simplicity of use must be heavily considered in order to produce a device that not only the current client can operate from instructions, but that any scientist cutting cruciform samples can utilize to make accurate and symmetric samples. This product must be cheap enough to 3D print that these scientists can take advantage of the device without having to worry about cost.

VIII. Conclusion

While there are methods to cut tissue samples for uniaxial tensile testing, there are not currently any cost effective techniques to produce symmetric cruciform shaped tissue samples for biaxial testing. Current methods involve using razor blades and biopsy punches to cut these cruciform shape samples by hand, giving rise to structural asymmetry. A device that uses industrial razor blades or biopsy punches to accurately trim down a sample to a symmetrical cruciform shape would increase the accuracy of the axial stresses thus, increase the understanding of tissue mechanics. After collecting background information and conducting research, the team generated a final design that would appropriately satisfy the requirements of the client, presenting a reusable, reproducible, and cost effective jig for cutting tissue samples for biaxial testing. The team will prototype this design using AutoCAD software before 3D printing for testing. After examining the accuracy results of the testing, modifications will be made where necessary and dimensional analysis will be performed to ensure consistent successful results. At this stage, the device can then be adjusted for multiple sizes and distributed more widely through a paper and CAD files for public utilization.

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X. Appendix

A. Preliminary Design Specifications

Function:

The Print-A-Punch device will serve as a clamping mechanism to secure razor blades in a precise configuration to cut cruciform-shaped soft tissue samples for biaxial testing. The clamping system will enable the consistent cutting of soft tissues, which addresses the challenge of asymmetry that the lab currently has with their biopsy punches. This asymmetry is mainly due to high shear strain and shear forces during testing. These forces lead to inaccurate material property measurements that affect patient-specific models. By ensuring uniformity in the cruciform samples, the system will reduce errors in material property computation, improving the accuracy of mechanical behavior estimations for soft tissues. This approach will serve as a cost-effective alternative to custom steel punches, using 3D printing to enhance accessibility and reproducibility in tissue testing procedures.

Client requirements:

- Device should be reusable
- Device should be able to cut a consistent shape and size of soft tissue sample
- Device must be compatible with generic Stanley-brand razor blades
- Device should be fabricated from stainless steel hardware
- Device must be able to cut through various thicknesses of tissue samples
- Budget of \$250

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements:

- i. Prototype must be able to cut through multiple types of tissue with relative ease, without require excessive force to operate
- ii. Prototype must be able to be replicated by other researchers for laboratory use

b. Safety:

- i. During assembly of punch, blades must be covered or hidden to prevent injury to user
- ii. Device usage must be easy to learn since it is universally available

- iii. Device should pose minimal risk to user during operation
- c. *Accuracy and Reliability:*
 - i. The punch must be capable of cutting a minimum of 3 samples before swapping blades is necessary
 - ii. Body of punch must have an indefinite lifetime
 - iii. Punch must be able to replicate the intended punch pattern on every attempt
 - iv. Overall length and width of printed punches should have an error less than 5% [1]
- d. *Life in Service:*
 - i. Punch must last indefinitely with the ability to replace blades when dulled
- e. *Shelf Life:*
 - i. Punch must not require any unusual storage conditions
 - ii. Punch must be able to withstand a large amount of external pressure from a mallet or a press
- f. *Operating Environment:*
 - i. Punch must be able to be used on demand with little setup time
 - ii. Punch must be able to be used in a laboratory environment
 - iii. Punch should be able to withstand sterilization
- g. *Ergonomics:*
 - i. Punch must be simple to 3D print on most 3D printers
 - ii. Punch must be easy to assemble
 - iii. Blades must be easy to bend during replacement
 - iv. Punch should include a fast fabrication time of under 5 hours
 - v. Razors should be able to be replaced safely in under 5 minutes
- h. *Weight:*
 - i. The device will be lightweight in order to be easily transported and shifted when working with small tissue samples
- i. *Materials:*
 - i. Main device structure will be 3D printed
 - ii. Must not corrode when in contact with tissue storage solution
 - iii. PETG or Nylon can be used for 3D printing due to its chemically resistant properties [4]
 - iv. Stainless steel hardware should be used to avoid corrosion
 - v. Stainless steel razor blades will be used to cut tissue samples

- vi. Materials must be easy to acquire
 - j. *Aesthetics, Appearance, and Finish:*
 - i. No color or finish preference
 - ii. Punch must be appropriate for general laboratory spaces
2. Production Characteristics
- a. *Quantity:*
 - i. Punch should be scalable to a variety of different size products for punching different dimension samples.
 - ii. CAD files and production instructions should be published in the final report for the public domain.
 - b. *Target Product Cost:*
 - i. Each product should be reasonably cheap to produce (under \$10 per device)
3. Miscellaneous
- a. *Standards and Specifications:*
 - i. Product's plastic body should comply with ASTM D638-02a, which specifies tensile testing procedures for plastics, ensuring they meet industry requirements in laboratory use [2].
 - ii. Device should comply with ASTM D412-06a, as it relates to creation of soft tissue models for biaxial testing, ensuring accurate and reproducible measurements of tensile properties [3].
 - b. *Customer:*
 - i. Punch is catered toward tissue testing labs and is not intended to be sold for a profit
 - ii. Individual punches are to be created at owners expense
 - c. *Patient-related concerns:*
 - i. Not in the scope of this project
 - d. *Competition:*
 - i. Print-A-Punch for Uniaxial Testing: Comparable design that uses a dumbbell-shaped punch intended for uniaxial tensile testing, as opposed to biaxial testing [1].

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B. Expense Sheet

Materials and expenses

Item	Description	Manufac-turer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
3D printed Material	Used for 3D printing jig prototypes	NA	NA	Makers pace	NA	10/14		\$1.50	\$15.00	3D printed material
									\$0.00	
Category 2										
									\$0.00	
									\$0.00	
								TOTAL:	\$0.00	

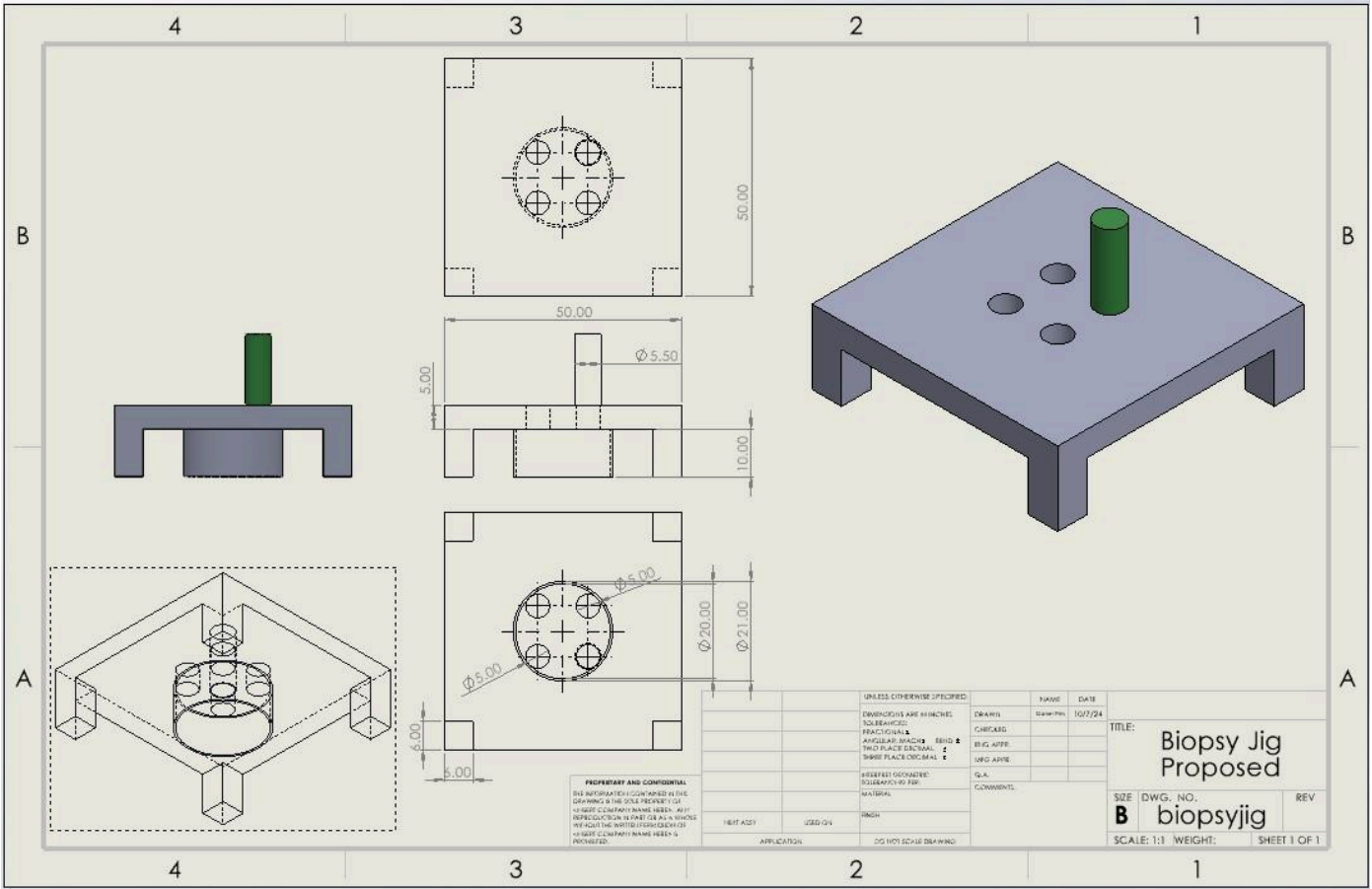


Figure 6: Drawing of final prototype including dimensions