Evaluating the Usability of a 3D-Printed Coring Device for Radiologic Pathologic Correlation of Renal Cell Carcinomas

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Abstract

Background: Renal cell carcinomas (RCCs) can be quantitatively assessed using Computed Tomography Textural Analysis (CTTA), which provides information for future treatment methods. The current technique calls for an entire nephrectomy to be performed, removing the tumorous kidney from the patient before the tissue sample is obtained. This paper will introduce a novel biopsy device for extracorporeal kidney biopsies which can then be imaged utilizing CTTA.

Methods: Both the coring device and blade were designed with the intention of minimizing tissue damage, remaining sharp and durable over time, and to be ergonomically sound. Therefore the materials for each were chosen based on their unique properties to achieve this goal. The success of the device was further verified through multiple test methods that included input from accomplished physicians in the field of pathology and radiology.

Results: Tube #7 averaged 4.17 / 5 ± 0.817 while Tube #13 averaged 2.71 / 5 ± 1.12. The p-value of these two designs was less than 0.0001, indicating all findings were statistically significant. Since Tube #7 averaged over 4 /5 in 5 categories, it is deemed successful and this iteration of the tube will be used in further testing.

Conclusions: In conclusion, this study confirms the efficacy of the 3D printed coring device for conducting successful biopsies on resected tumors, particularly in the context of radiologic pathologic correlation of renal cell carcinomas. The device has been validated through rigorous testing, demonstrating its ability to minimize tissue damage, ensure reproducibility, and provide ergonomic satisfaction.

Keywords: Renal cell carcinoma, Computed tomography textural analysis, Coring Biopsy

Introduction

In the United States, there are approximately 65,000 new cases and almost 15,000 deaths from renal cell carcinoma (RCC) each year [1]. Not only is it common, but RCC is highly variable with there being more than 50 different types of renal cell carcinomas, clear cell renal cell carcinoma (ccRCC) being the most common. These cell types are classified into four different categories based on their size, shape, and staining. Grades I-II are low and grades III-IV are high. High-grade tumors have increased invasive capacities and possibility of metastasis, and have a poorer prognosis [2].

Although tumor size, grade, and RCC subtype has provided important prognostic information in the past, there is a distinct need for further RCC research as there is currently no cure for advanced RCC that has spread beyond the kidney [3]. Due to the aggressive nature of advanced RCC, it is crucial that the diagnosis process is as efficient as possible. Surgical intervention is the most common approach to treating RCC, especially when detected during early stage progression via Computed Tomography (CT) imaging. A nephrectomy of the diseased kidneys is performed and samples of the tumor are then biopsied from the resected kidney [4].

Computed tomography texture analysis (CTTA) is used to quantitatively analyze tumor heterogeneity via pixel distribution, location, and relationships [5]. It correlates quantifiable data with histological images for further analysis. This imaging technique is especially useful in diagnosing and estimating prognosis of RCC. It is a promising technology for the management of cancer metastases and predicting treatment response [6]. Due to the complex spatial heterogeneity and histologically diverse nature of renal tumors, producing an accurate image analysis is challenging for physicians. These characteristics pose complications when performing biopsies on larger tumors because of the various types of cells dispersed throughout the mass [7]. CT texture analysis allows for slice-by-slice imaging of the tumor, which may help differentiate between different types of renal cell cancers, therefore improving individualized treatment and contributing to a better prognosis [8]. With no current competing designs on the market, this device will be the first of its kind to help correlate histological findings with quantifiable data.

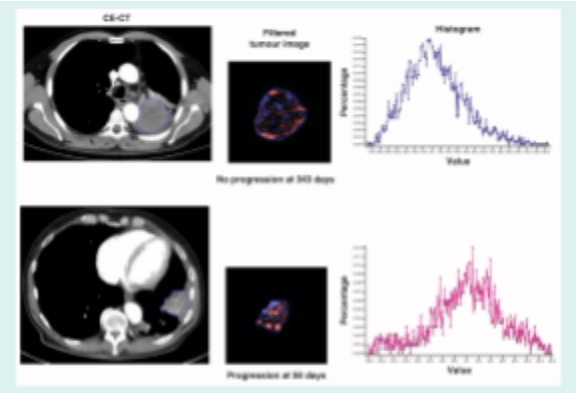

Figure 1: *Example of how CTTA can correlate quantifiable data with histological images [8].*

The current method to resect a biopsy sample for CTTA analysis involves using a Delrin coring device and screw-attached blade. However, this blade is much too dull and too thick to successfully obtain a sample without causing extensive tissue trauma. The tissue damage caused to the tumor sample and remaining kidney tissue renders the sample unimageable and therefore cannot be used for radiologic-pathologic correlation between the specimen and CT images. Furthermore the current coring device design falls apart when force is applied while cutting into the kidney tissue. Together, the components of the current analysis method are not optimal for CTTA analysis and therefore considered unusable. Our proposed device consists of a thinner blade and coring tube that will not cause external tissue damage and will stay together while in use. This is necessary as the non uniform gene types prevalent in renal cell carcinomas require the device to pass through multiple different tissue layers with great force.

The human kidney is a highly complex organ with many working parts. When testing the functional integrity of the biopsy device, it is important that the device has the ability to penetrate through the various layers of kidney tissue, in addition to the tissue composition of the tumor. As illustrated in Figure 2, the kidney is surrounded by perirenal adipose tissue, or perirenal fat, which protects the kidney and renal blood vessels from external damage or forces [9]. It is also encompassed by Gerota's Fascia, which is a thin connective tissue made of collagen that anchors the kidneys to the posterior abdominal wall [10]. The kidney itself is composed of a renal capsule as its outermost layer. The following layer is referred to as the cortex, then the medulla. Inside the medullary spaces are renal pyramids, referred to as papilla, that contain loops of Henle of each renal tubule and their associated collecting ducts that all play a role in the blood filtration system. The innermost structure is the renal pelvis, which stores urine and passes it down to the ureters [11]. The ability of the biopsy device to effectively penetrate the multiple layers of kidney tissue is crucial to its performance. The device must be able to penetrate the fibrous tumor tissue as well without causing excessive tissue damage while collecting viable biopsy samples.

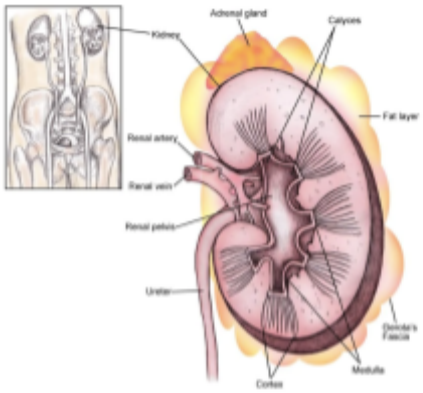

***Figure 2**: Human renal anatomy [9].*

In this paper, we introduce a RCC biopsy device for CTTA assessment, to aid in better correlation between biopsy site and computed tomography (CT) imaging. This imaging and biopsy device combination approach aims to improve prognosis upon patients with RCC by improving treatment efficacy through individualized tumor assessment. This functional biopsy device - consisting of a detachable blade and patient specific 3D printed sample collection tube - collects a 10 mm diameter tumor sample from a resected kidney, while causing minimal tissue damage to preserve the integrity of the surrounding specimen tissue for further analysis. Once the biopsy device is inserted into the specimen, the device and kidney are imaged by CT to correlate the biopsy samples with the exact locations they were resected from within the specimen. The results from these biopsies will be implemented into the existing network of knowledge regarding renal cell carcinomas, in order for health care professionals to better understand the disease and work towards more promising, patient specific treatment options.

Methods

Design Components

The device is made up of a trephine stainless steel blade, a resin coring tube, and a PLA plunger (Figure 3).

Figure 3: *Final assembly consisting of blade, coring tube, and plunger.*

Firstly, the blade has a .7 mm wall thickness and slight taper at the end, allowing for seamless incision into the sample. It also features a .9 cm length non-tapered section that is easily press-to-fit into the coring tube. This allows the blade to stay connected to the tube during resection, but can also be removed with a small amount of force by the physician.

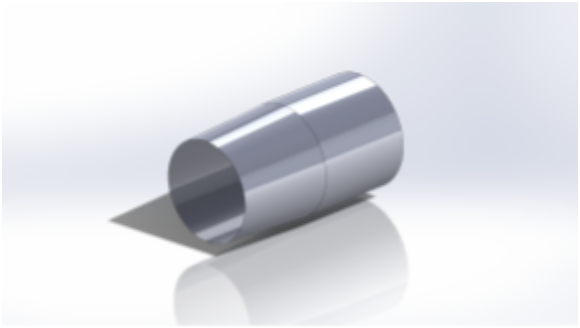

Figure 4: *SolidWorks model of "Punch Biopsy" blade design.*

The coring tube is 10 cm long with an inner diameter of 11 mm and an outer diameter of 15 mm. It features a "male" half with pegs and "female" half with holes. The holes have a 0.1 mm tolerance gap with the pegs for a secure fit, while still allowing the user to easily open and close it. The design also features an internal lip to prevent the blade from slipping into the tube during the procedure.

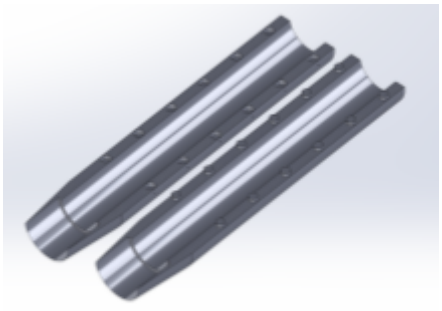

Figure 5: *SolidWorks model of "Lego" coring device.*

The prototype also features a plunger that is 15 cm in length and has a 10.25mm diameter to comfortably fit within the coring tube. The plunger serves as a sample removal object to maintain sterilization during the procedure. It also features a thumb support for ergonomic stability and comfort when removing the sample from the coring tube.

Figure 6: *SolidWorks model of plunger device.*

Materials

The team's coring tube was 3D printed in FormLabs BioMed Clear Medical Resin. This is a rigid, USP Class VI certified biocompatible material, with an ultimate tensile strength of 52 MPa and Young's Modulus of 2080 MPa post-cure [12]. This resin is in compliance with ISO 10993-1:2018, ISO 7405:2018, and ISO 18562-1:2017, ensuring that the device is

biocompatible and “performs with an appropriate host response in a specific situation.” [13].

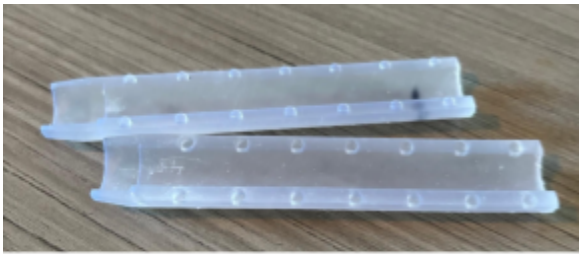

Figure 7: *Image of 3D printed coring device opened to allow tissue to be removed.*

The plunger cylinder is a single use device made from that is 3D printed in white PLA plastic on a Bambu Lab X1 Carbon printer.

The coring blade was purchased from Microsurgical Technologies and is made of DIN EN 1.4408 grade stainless steel, commonly known as 316 stainless steel. This rigid material was chosen as it is an austenitic stainless steel with high levels of chromium and nickel that allow for corrosion resistance [14]. The material also contains up to 2.5% molybdenum content which provides high corrosion resistance to non-oxidising acids and chlorine-containing materials [14]. Furthermore, the blade displays exemplary mechanical properties with a yield tensile strength of 290 MPA and a Rockwell hardness of 95 [15]. Finally, the material is autoclavable and therefore reusable for multiple procedures. This allows 316 stainless steel to be utilized in many medical applications.

Qualification of Manufactured Blade

Previously, the team had designed, manually fabricated, and tested a circular blade from 316 stainless steel tubing. From the results from fall of 2023, found in Appendix C, the team qualified the blade design as successful in both minimizing tissue damage and sustaining multiple cycles of uses. However, due to trouble replicating the design manually and inconsistency in dimensions, the team has decided to move forward with a pre-made blade from Microsurgical Technologies. The team performed a qualification of the new pre-made blade in Appendix J.

Fabrication Process of Coring Device

The coring tube was printed at a 30° orientation to the build plate. The Formlabs file can be seen in Figure 8**.** Additional supports will be added to enhance support in the area directly below the slits to prevent any deformation during the printing process.

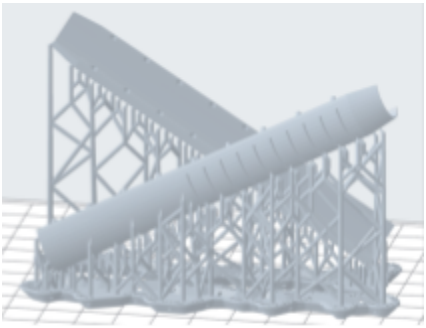

Figure 8: *Formlabs 30° orientation from build plate.*

The coring tube will also go through a unique post-processing parameters to prevent any bowing or deformation from occuring due to a rapid change in temperature. First, the coring device is washed in an Isopropyl Alcohol (IPA) bath for 15 minutes and then it is dried by fan for 20 minutes, per manufacturing guidelines for FormLabs Biomed Clear Resin [16]. The manufacturing guide recommends curing

prints for 15 minutes at 60° C in the Form Cure device [16]. Instead, the coring tube will be cured by being left in direct sunlight for 2-3 hours to slowly UV cure.

Study Populations

An ergonomic and performance study will be conducted on 3 previously resected human kidney samples that vary from 1-3 weeks post procedure. Another study will be conducted to measure tissue damage from the site of incision on 4 pig kidneys with attached perirenal fat that were harvested between 0-1 weeks prior.

Assessment of Ergonomics

A likert study that is focused on performance and ergonomics will be conducted by Dr. Meghan Lubner, Dr. Hu Rong, and Dr. Daniel Shapiro. Each member of the study has experience in pathology and radiology which will allow them to accurately score the device. All members will cut into the human kidney using the blade-coring device assembly. Once the blade is through the entire kidney, they will remove the blade and resect the tissue sample, opening it to observe the tissue and note any damage. They will complete 4 more cuts and then fill out the survey giving their feedback on the tension and accuracy of the device. This survey will be rated on a 1-5 scale, where 1 stands for strongly disagree and 5 stands for strongly agree. The goal of this survey is that the device is overall rated an average of 4 out of 5 in all of the scoring criterias. If the device has an average of 4 out of 5, that means the device is successful.

Assessment of Tissue Damage

Furthermore, another study will be conducted to measure tissue damage from the site of incision on 4 pig kidneys with attached perirenal fat. This test does not require any medical or technical knowledge, therefore it will be conducted by the same member of the team each time. This study will yield 40 data points, 10 from each kidney. The team member will cut the kidney in a similar fashion to that described above, and after each cut will observe any tissue damage radiating from the incision site. All damage will be measured using a caliper and recorded using photos. Any patterns or notable areas of damage will be cited.

Statistical Analysis

The statistical analysis of the performance survey data aimed to identify significant trends and relationships within the collected dataset. To assess the difference in performance between Tube #7 (.7 mm thick) and Tube #13 (.5 mm thick), a two-sample t-test was employed. This test allowed for the determination of whether the observed disparity in average performance scores between the two tubes was statistically significant.

Additionally, graphical representations, such as box plots, were generated to visually depict the distribution of performance survey scores for each category and tube configuration. These plots provided a comprehensive overview of the data distribution, highlighting any outliers or trends.

All statistical analyses were performed using MATLAB, with significance levels set at $p < 0.05$ to determine statistical significance. The results of the statistical analysis were interpreted to provide meaningful insights into the performance surveys of the two evaluated biopsy devices.

Results

The performance survey assessed two distinct configurations of blades with tubes, Tube #7 and Tube #13. Tube #7 demonstrated an average performance score of 4.17 ± 0.817 surpassing the passing criteria in 5 out of the 6 evaluated categories (Figure 9). In contrast, Tube #13 had an average score of 2.71 ± 1.12 where it only passed 1 out of the 6 categories assessed (Figure 10). Tube #7 excelled particularly in smooth opening and closing functionality, while Tube #13 showed strength in preventing observable tissue damage. Additionally, an increase in tube thickness correlated with improved performance in several categories, including satisfied cut, tube integrity, ergonomics, and user confidence in device operation.

The difference in average performance scores between Tube #7 and Tube #13 was statistically significant, as determined by a two-sample t-test with a two-tailed p-value of less than 0.0001. For raw data of the ergonomic survey, see to Appendix C.

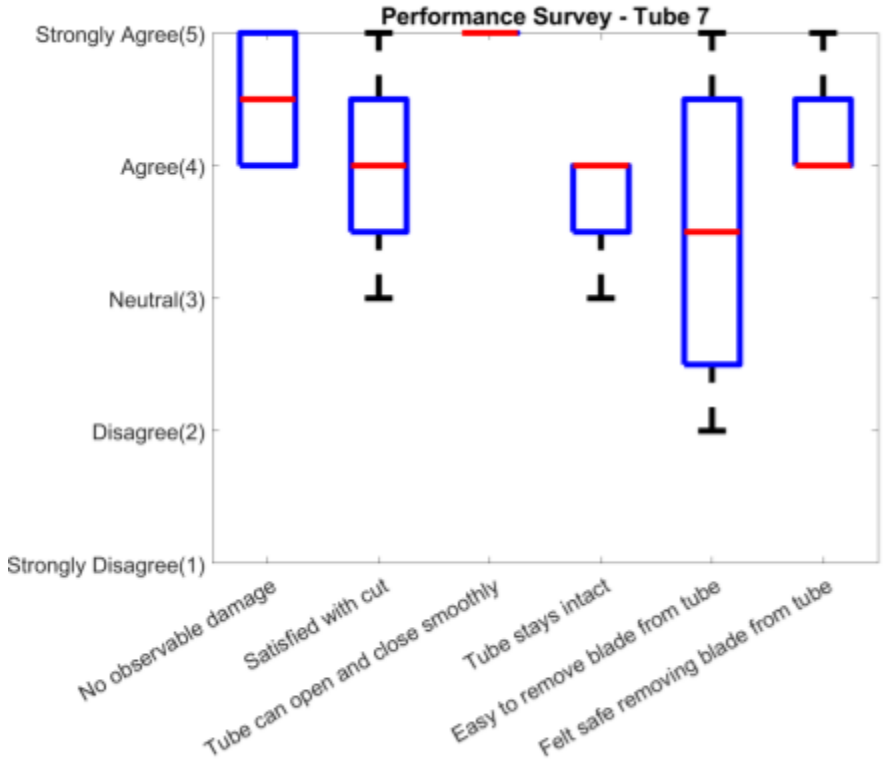

Figure 9: *Box plot of the performance survey results done with coring tube prototype #7.*

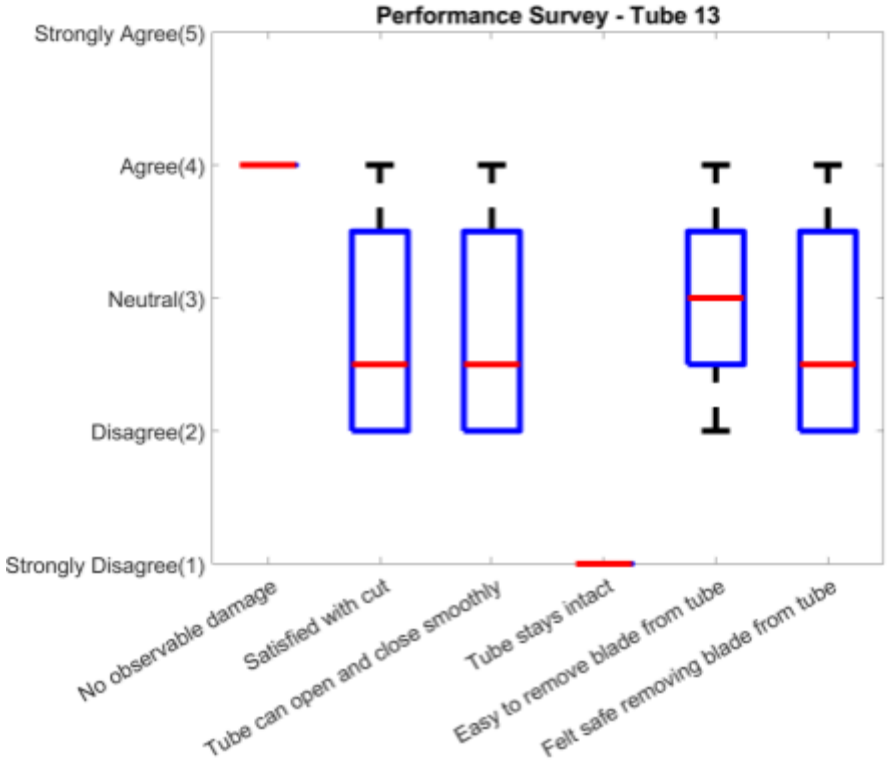

Figure 10: *Box plot of the performance survey results done with coring tube prototype #13.*

Discussion

The results relay the importance of ergonomic comfort and security when designing a biomedical device. Tube #7's success in meeting passing criteria in the majority of categories, highlights the significance of using a thicker tube to ensure stability and a smooth functionality. In contrast, Tube #13's limited success suggests the need for further refinement to meet desired performance standards.

The ergonomic surveys revealed that an increase in coring tube thickness positively affected device performance in multiple categories, showing that Tube #7 is deemed successful. These findings contribute to advancing the design of an easily reproducible biopsy device suitable for clinical settings. This tube iteration will be used in further testing in future research upon IRB approval.

In conclusion, Tube #7 demonstrates great potential to be used as an effective biopsy tool in future procedures. Its ability to easily cut through tissue with minimal drag while staying intact meets all the requirements brought forth by the client. The device can also easily adjust for every tumor size though easily altering the length dimension in the SolidWorks model. These advances in designing a properly functioning biopsy device that can be easily reproducible by a clinical team show promising steps toward becoming a widely used method of analyzing renal cell carcinomas in a clinical setting with the aim to improve patient outcomes.

Ethical and safety considerations

Using human kidneys for testing may implicate ethical considerations. The human kidneys used during biopsy tests performed by physicians to conduct ergonomic performance surveys were kidneys that were no longer clinically needed and soon to be discarded. The human kidneys were professionally evaluated and tested thoroughly by physicians at the UW Department of Radiology before biopsy device testing was performed.

A primary safety concern of the biopsy device is the sterilization process. In order for the blade to be reusable, it must be able to withstand autoclave sanitization between biopsies. An autoclave uses high pressure and high heat steam to kill bacteria and viruses on the blade [17]. The material of the blade, 316 stainless steel, purchased for the biopsy device can withstand such conditions.

Conclusion

To conclude, our results indicate that the fabricated biopsy device can be utilized to resect kidney samples with renal cell carcinoma. Furthermore, the prototype not only demonstrated rigidity, but created minimal tissue damage so that the physician can adequately perform radiologic pathologic correlation for further research and improved diagnosis of renal cell carcinoma.

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Appendix

Appendix A: Product Design Specification

Function :

The goal of this project is to develop a blade and coring device for tumor resection. The blade should be able to effectively resect a cross-section from an ex-vivo kidney tumor without causing damage to the overall tissue sample. Currently, the resection device used is too blunt and thick to effectively extract tissue without causing surrounding areas to be damaged and un-imageable on CT. The coring device should stay intact during the biopsy while also easily revealing the sample inside for analysis. By creating a new blade and coring tube designs, the pathologist can preserve the extracted tumor during the biopsy. In maintaining the integrity of the tumor, the pathologist will be able to accurately correlate CT image markings and findings with their location in the patient sample.

Client requirements:

- Timeline: All final deliverables must be completed by December 13th, 2023
- A device is needed to allow for radiologic-pathologic correlation of resected renal cell carcinoma
- The device must accommodate ex vivo tumors of large size, approximately 20 x 7 x 7 cm
- Tissue samples should be cleanly cored without damaging the integrity of the tissue
- The device should be easily sterilized and cleaned between uses
- The device should be reusable and long-lasting
- The blade must be easily detachable from the cylindrical corer
- The team has a budget of $500 for one device

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirement*s: The coring blade must be able to resect a single tissue sample from the kidney, roughly 7-10mm in size in order to fit on a microscope slide. The cut must be sharp enough to minimize the trauma to the surrounding tissue. The blade must be reusable and therefore must be able to withstand sterilization in an autoclave at 121 degrees Celsius. The blade must be easily detachable in order to be removed before imaging. The sample collection coring tube must preserve the integrity of the biopsied tissue, minimizing tissue trauma on the samples. The tube must also minimize drag and surrounding tissue trauma, meaning it must have a smooth finish. It must also stay closed during the biopsy collection process but be easy to open to retrieve the biopsy samples.

b. *Safety*: To ensure the safety of the pathologist, the blade should be round and smooth on the sides while remaining sharp at the point of incision. A cover will be made to cover the blade when not in use to protect the pathologist.

c. *Accuracy and Reliability*: The device must be effective enough so that it takes only one cut to insert into the tumor. The extent of trauma to the surrounding tissue should be no more than 3mm in diameter.

d. *Life in Service*: The blade portion of the coring device should be reusable and able to perform at least 40 resections of tissue samples without becoming dull. Therefore, it should compare to the hardness of sterile surgical blades which are outlined in BS 2982:1992 and BS EN ISO 7153 Part 1 [1]. The coring tube is a single use device that is 3D printed using FormLabs BioMed Clear resin on a case to case basis, therefore has a one case life in service.

e. *Shelf Life*: The blade must have a minimum shelf life of 50 years [2]. When not being used, the device should be stored in sealed packaging in dry, room-temperature conditions (<50% humidity, 27 ℃) [3]. The coring device must adhere to the FDA 1991 shelf life regulations for medical devices [4].

f. *Operating Environment*: The coring device should only be used in a clinical pathology lab. This laboratory should be compliant with the ISO 15189 standard [5]. This standard outlines quality and competence standards for medical laboratories. It's designed for labs to develop their management systems, assess their competency, and gain recognition from users, regulators, and accreditation bodies.

g. *Ergonomics*: The blade and coring tube should be comfortable and easy for the pathologist to use. Therefore, it will be lightweight (< .453 kg), have no rough edges, and be balanced so that it only takes one attempt to successfully collect a sample in less than 5 minutes [6].

h. *Size*: The coring device must produce samples that can be accurately observed on microscope slides. Therefore, the diameter of the circular blade must be between 7 to 10 mm according to Dr. Jason Abel. The core blade must resect a tumor that is 10 cm in depth. The tissue collection tube varies between patients based on the dimensions of the kidney and tumor. The diameter of the tube must be the same as the blade, 10 mm, to properly harvest tissue samples.

i. *Weight*: The design should be as simple as possible, minimizing unnecessary bulkiness. The coring aspect of the device should be less than .453 kg to not put any strain on the pathologist's hands when collecting a sample.

j. *Materials*: The blade of the coring aspect should be made of surgical-grade stainless steel that is hardened to the Rockwell C hardness of about 46-53 [7]. The material of the blade must be able to withstand high temperatures in order to be sterilized in an autoclave. The material of the coring tube should be biocompatible so that it does not interfere with the surrounding tissue integrity.

k. *Aesthetics, Appearance, and Finish*: The device should be smooth and simple. There are no appearance or finish specifications required by the client.

2. Production Characteristics

a. *Quantity*: There is only a requirement for one device, however considering the possibility of mass production, the number of devices may need to meet market demands. The coring tube is 3D printed within the client's facility based on patient specific data.

b. *Target Product Cost*: The target product cost for this device is $500. It will be paid for via UW Health research funds.

3. Miscellaneous

a. *Standards and Specifications*: The device would need to adhere to the ISO 13485:2016 regulation which outlines requirements for regulatory purposes of medical devices. Regarding the blade for a tumor resection coring device, this standard specifies that a technical support device must consistently meet customer and applicable regulatory requirements [7]. In addition, the device must follow ISO 15189:2022 so that it meets the quality and competence requirements to be used in a medical laboratory [6]. Because the blade may need to be detachable, the device should also adhere to ISO 7740:2018 which states the dimensions and features needed to be a detachable blade used in a laboratory [8]. Lastly, the model would also need to follow the FDA's Code of Federal Regulations Title 21, Volume 8 which outlines the requirements for medical devices [9].

b. *Customer*: Dr. Meg Lubner is a professor (CHS) in the Abdominal Imaging Section at the University of Wisconsin School of Medicine and Public Health. She is asking for a blade that would be compatible with the tumor resection coring device that was

fabricated by the previous group. Dr. Daniel Shapiro and Dr. Jason Aebl will act as alternate contacts for this project as well. Both doctors have specialties in minimally invasive surgery and urologic oncology, giving the team specialized knowledge about RCC.

c. *Patient-related concerns*: The device will not interact directly with the patient, only with the kidney tumor after it has been fully surgically removed. However, it is crucial that the coring device takes an accurate and interpretable biopsy of the tumor. Minimizing the tissue trauma caused to the kidney tumor when taking a core biopsy is critical to conclude an accurate diagnosis and to collect data from the procedure.

d. *Competition:* Currently, there is a lack of available devices in the market designed for core biopsies of kidney tumors. The existing method involves excising square sections around markers within the tumor. However, this approach falls short of providing comprehensive insights into the depth of specific areas of interest. A device sharing a similar underlying principle already present in the market is the punch biopsy tool employed for skin graft procedures. In a punch biopsy, a circular-tipped cutting instrument is utilized to extract deeper layers of skin for diagnostic purposes [10]. This tool is rotated into the skin and then withdrawn to generate a columnar biopsy of the skin's deeper layers. However, these devices cannot be used to create a core biopsy of a kidney tumor because they do not cut deep enough.

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Appendix B: Blade Design Matrix from previous semester

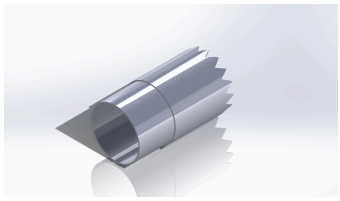
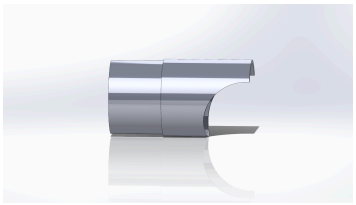
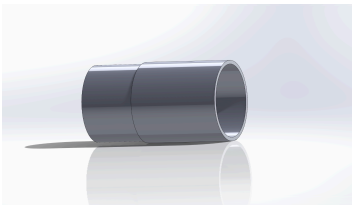
Criteria	Pineapple Corer		Recorder Blade		Punch Biopsy Blade	
						
Precision (30)	2/5	12	4/5	24	5/5	30
Durability (20)	2/5	8	3/5	12	5/5	20
Feasibility (20)	3/5	12	3/5	12	4/5	16
Ease of Use (20)	5/5	20	4/5	16	4/5	16
Cost (10)	3/5	6	4/5	8	4/5	8
Score (100)	58		72		90	

Table 1. Design Matrix for Renal Cell Carcinoma Blade

Scoring Criteria:

Precision (30%)- Precision is a measurement of how much external tissue trauma the blade creates around the sample site. The trauma should not radiate more than 3mm in any direction off the circumference of the sample. Higher scores were assigned to designs that would cause the least amount of damage to surrounding tissue while lower scores indicate more predicted trauma.

Durability (20%)- Durability relates to how long the blade will last over the course of its lifetime. The blade must be able to effectively resect 50 samples, and be able to withstand an autoclave without losing its sharpness. Low scores were given the designs thought to dull quicker.

Feasibility (20%)- Fabrication of prototypes should not be difficult. Ideally, the prototypes should be created with resources easily accessible and not require too much finesse to

manufacture. High scores are given to prototypes with more readily available resources and less complex fabrication processes.

Ease of use (20%)- Ease of use correlates to the ergonomics of the design, how easily it can detach from the core, how much pressure/strength the client needs to apply to the device, and a low procedure time (< 5 minutes). Higher scores indicate more of these requirements met than designs with lower scores.

Cost (10%) - The overall cost of fabricating the design holder prototype should be no more than $100. The team was given an overall budget of $500 but do not expect to exceed $100 for one individual prototype. Low scores indicate an expensive fabrication process , while high scores are more cost-effective designs.

Overall, the design that won was the Skin Biopsy Design as it scored the highest in four out of five categories: precision, durability, feasibility, and cost. This design creates the least amount of external tissue damage due to the simplicity of the blade. The rigged “teeth” on the pineapple corer and the non-uniform circle of the slated blade will cause uneven cuts and can tear the tissue more. The simplicity of the blade allows for it to remain sharper than the other blades. It also is an overall more simplistic design with less detailed components than the competing designs, therefore it won durability and feasibility as well. Since all three designs will most likely be made of stainless steel, all designs scored similar in the cost category. Overall, the pineapple corer design is too rough for human tissue and the slanted blade is a more complex model of the skin biopsy design.

Appendix C: Raw Data

Chicken Breast Blade Thickness Data Fall ‘23:

	Blade #1	Blade #2	Blade #3	Blade #4	[mm]
Initial	0.18	0.16	0.22	0.04	
5 cuts	0.18	0.16	0.21	0.04	
10 cuts	0.17	0.15	0.21	0.04	
15 cuts	0.17	0.15	0.21	0.04	
20 cuts	0.17	0.14	0.21	0.04	
25 cuts	0.17	0.14	0.21	0.04	
30 cuts	0.17	0.14	0.21	0.03	
35 cuts	0.16	0.14	0.21	0.03	
40 cuts	0.16	0.13	0.21	0.03	
	Blade #1	Blade #2	Blade #3	Blade #4	
Total Change	0.02	0.03	0.01	0.01	

Ergonomic Survey Data Fall ‘23:

	Blade 1	Blade 1	Blade 2	Blade 2	Blade 3	Blade 3	Blade 4	Blade 4
Min Pressure	4.00	4.00	4.00	4.00	3.00	2.00	3.00	2.00
Low # Cuts	4.00	4.00	3.00	3.00	4.00	3.00	3.00	2.00
Limited Tension	3.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
Sharpness Maintained	4.00	3.00	3.00	3.00	4.00	2.00	3.00	2.00
No observable Damage	4.00	4.00	3.00	3.00	4.00	4.00	3.00	1.00
Satisfied with Cut	4.00	4.00	4.00	3.00	4.00	4.00	3.00	3.00

Ergonomic Survey Data Spring ‘24:

Tube #	Tube 7	Tube 7	Tube 7	Tube 7	Tube 13	Tube 13	Tube 13	Tube 13
Min Pressure	5.00	5.00	5.00	5.00	2.00	2.00	2.00	3.00
Low # Cuts	5.00	5.00	5.00	5.00	2.00	3.00	2.00	3.00
Limited Tension	4.00	4.00	5.00	4.00	2.00	2.00	2.00	2.00
Sharpness Maintained	5.00	5.00	4.00	4.00	2.00	3.00	3.00	3.00
No observable Damage	3.00	4.00	5.00	4.00	4.00	4.00	4.00	4.00
Satisfied with Cut	5.00	5.00	5.00	5.00	2.00	4.00	3.00	2.00
Coring tube feasibility	5.00	5.00	5.00	5.00	4.00	2.00	3.00	2.00
Coring stays intact	4.00	4.00	3.00	4.00	1.00	1.00	1.00	1.00
Removing blade from coring tube is easy	2.00	5.00	4.00	3.00	4.00	2.00	3.00	3.00
Felt safe removing blade from tube	4.00	4.00	5.00	4.00	4.00	2.00	2.00	3.00

Appendix D: Maintenance Instructions

GENERAL INSTRUCTIONS FOR CARE, HANDLING AND REPROCESSING OF 3D PRINTED CORING BIOPSY DEVICE	
Intended Use:	A reusable blade and disposable coring device intended to take coring biopsies of resected kidneys.
How Supplied:	Blades are supplied non-sterile and must be cleaned, sterilized, and inspected prior to each use.
Warnings:	• These devices are designed for use by appropriately trained, qualified and competent personnel. • When reprocessing medical devices always follow local Health & Safety procedures. Always follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. • Avoid the use of mineral acids and harsh, abrasive agents. • Some sensitive materials can be damaged by higher alkaline solutions (pH >10). • The use of the device for tasks other than those for which they are intended may result in failure or damage/breakage. • Correct cleaning, handling and sterilization will ensure that the device

GENERAL INSTRUCTIONS FOR CARE, HANDLING AND REPROCESSING OF 3D PRINTED CORING BIOPSY DEVICE

Intended Use:	A reusable blade and disposable coring device intended to take coring biopsies of resected kidneys.
	performs as intended and extends its useful life. ● Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals. ● Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated devices. ● Manual cleaning is not advised if an automatic washer/disinfector is available
Care and Handling: The following information is provided to give general guidance on how the circular biopsy blade may be processed to prepare them for use. Equipment, operators, cleaning agents and procedures all have a contribution to the efficacy of the processing and the healthcare facility should ensure that the blade is safe for use at all times.	
Pre-Cleaning:	Do not allow blood and/or bodily fluids to dry on the instruments. Reprocess as soon as reasonably practicable following use. If they cannot be reprocessed immediately, use an enzymatic cleaner to help prevent any soiling from drying. Remove any gross contaminants with a steady stream of lukewarm water (below 110°F/43°C.) Rinse each instrument thoroughly, do not use saline or chlorinated solutions.
Cleaning:	Whenever possible, the automated method should be used as it is a more reproducible process and therefore more reliable. ● Avoid mechanical damage during transportation to the process area. ● Transport to the processing area as soon as possible. ● Do not soak the blade in hot water, alcohol, disinfectants, or antiseptics to avoid coagulation of blood or other body fluids. ● Do not use steel wool, wire brushes, pipe cleaners or other abrasive cleaners. ● Only specifically formulated cleaning agents (detergents). Enzymatic agents with both bacterial and fungicidal properties are preferred for manual cleaning. **Equipment Required:** ● Double Sink System (Not used for hand washing) dedicated for blade cleaning. ● Soft Bristle Brush. ● Personal Protective Equipment (PPE) as recommended by the cleaning agent supplier. **Procedure:** ● Ensure the water temperature does not exceed 35°C. In the first sink,

GENERAL INSTRUCTIONS FOR CARE, HANDLING AND REPROCESSING OF 3D PRINTED CORING BIOPSY DEVICE

Intended Use:	A reusable blade and disposable coring device intended to take coring biopsies of resected kidneys.
	keeping the blade submerged, using a soft autoclavable brush, apply cleaning solution to all surfaces of the blade until all soiling has been removed. ● In the second sink, rinse instruments thoroughly with soft, high-purity water controlled for bacterial endotoxins. ● Dry the blade. ● Visually inspect all areas of the blade for any remaining soiling and if necessary, repeat the steps above.
Disinfection:	● After cleaning, immerse the biopsy blade in a high-level disinfectant solution recommended for medical instruments. ● Follow the manufacturer's instructions regarding the concentration of the disinfectant solution and the required immersion time. ● Ensure complete submersion of the blade to disinfect all surfaces thoroughly. ● After disinfection, rinse the blade under running water to remove any residual disinfectant solution.
Sterilization:	● Sterilization must follow a washer/disinfector process. ● Ensure proper packaging of the blade before placing it in the autoclave to prevent contamination during sterilization. ● The recommended sterilization parameters are a minimum of three minutes at a minimum temperature of 134°C. ● The three minutes is for exposure, it does not include ramp up times or dry cycle times needed. Allow the blade to cool down completely before handling or storing. ● Always follow the instructions of the machine manufacturer. **Note: The final responsibility for validation of sterilization techniques and equipment lies directly with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations**
Inspection:	● Visual inspection under good lighting of all parts of the blade should be performed to check for visible soiling, damage or wear. ● Particular attention should be paid to the edge of the blade: ○ Closely inspect for any signs of damage, corrosion, or dullness. ○ If any abnormalities are detected during inspection, do not use the blade and consult with the appropriate personnel for further evaluation or replacement.
Packaging:	Blades are to be packed following local protocol in accordance with relevant standards.

GENERAL INSTRUCTIONS FOR CARE, HANDLING AND REPROCESSING OF 3D PRINTED CORING BIOPSY DEVICE

Intended Use:	A reusable blade and disposable coring device intended to take coring biopsies of resected kidneys.
Storage:	• The shelf life is dependent on the sterile barrier employed, storage, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by the healthcare facility • Store the biopsy blade in a clean and dry environment to prevent contamination. • Avoid storing the blade near sources of moisture or heat, as these can promote corrosion or degradation. • Use designated storage containers or trays to keep the blade organized and protected when not in use. • Ensure biopsy is stored with its cap properly by adhering to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030)
References:	• BS EN ISO 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices. • HTM 01-01 Management & decontamination of surgical instruments (medical devices) used in acute care. • BS EN ISO 15883: Parts 1 & 2: Washer-disinfectors • OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030)

Appendix E: User Manual
Instructions for Use

Device Description
This device is a handheld renal cell carcinoma biopsy device which is used to obtain core biopsy samples from soft tissue and tumors of the kidney. This device has a detachable blade head that can be reused between test specimens and a patient specific 3D printed collection tube that is fully disposable after use.

Device Preparation
1. Prior to using the biopsy device, ensure that the reusable blade has been sterilized by autoclave and that its protective packaging has not been damaged to avoid cross contamination. If it does appears that the blade has not been sterilized properly, do not use the device
2. Ensure that the collection tube has been printed correctly and that the outer and inner diameter appear smooth to avoid tissue damage. If the 3D printed collection tube does not meet these standards, do not use the device and request a replacement tube
3. Carefully remove the blade from its protective packaging and push the exposed area into the collection tube
4. Once the blade and the collection tube have pressed to fit, remove the blade cap to expose the working blade
5. Refer to the safety precautions manual for steps on how to handle exposed sharp objects

Performing the Biopsy
1. Identify the target area
2. Prepare the biopsy site as required
3. Place the outer edge of the biopsy blade on the tissue and begin pushing down in circular motions
4. Continue pressing into the tissue until the biopsy device has pierced through the thickness of the tissue
5. Remove the blade from the other side of the resected tissue sample and place into a sterile container to be autoclaved
6. Image the collection tube in the specimen as needed
7. Remove the collection tube from the specimen
8. Carefully open the collection tube from either end to retrieve tissue samples
9. Retrieve tissue samples from the tube for testing
10. Repeat steps 1-9 for any other biopsy sites on the same specimen
11. After collection, dispose of the collection tube to biohazardous waste

Appendix F: Safety Manual for Biopsy Blade and Coring Tube

Introduction

This safety manual provides guidelines for the safe handling, maintenance, and disposal of reusable biopsy blades in healthcare settings. Adhering to these procedures helps minimize the risk of injuries and ensures compliance with relevant standards and codes.

1. Handling

1.1. Engineering Controls: Employers must provide safety-engineered biopsy devices to minimize the risk of injuries. Use devices with built-in safety features, such as retractable blades or protective caps.

1.2. Personal Protective Equipment (PPE): Wear appropriate PPE, including gloves and eye protection, when handling biopsy blades to protect against cuts and splashes.

1.3. Training: All personnel handling biopsy blades must receive training on safe handling practices, including proper grip techniques and the use of safety features.

2. Maintenance

2.1. Cleaning: Clean biopsy blades promptly after each use following maintenance instructions provided.

2.2. Disinfection: Disinfect blades using a high-level disinfectant approved for medical devices. Follow maintenance instructions provided for concentration and contact time.

2.3. Sterilization: After cleaning and disinfection, sterilize the biopsy blades using autoclaving or another appropriate sterilization method. Ensure proper packaging to maintain sterility, following maintenance instructions

3. Storage

3.1. Sharps Containers: Store biopsy blades in puncture-resistant sharps containers when not in use. Containers must meet OSHA standards for sharps disposal (29 CFR 1910.1030).

3.2. Labeling: Properly label storage containers to indicate the contents and any necessary handling precautions.

4. Disposal

4.1. Sharps Disposal: Dispose of biopsy blades in designated sharps containers once blade is deemed unusable. Do not recap or manipulate blades by hand to avoid needlestick injuries.

4.2. Biohazard Waste: Treat used biopsy blades as biohazardous waste and dispose of them according to local regulations and guidelines (e.g., EPA regulations).

5. Compliance with Standards and Codes

5.1. OSHA Standards: Adhere to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) for the safe handling of sharps and bloodborne pathogens.

5.2. CDC Guidelines: Follow CDC guidelines for infection control in healthcare settings, including recommendations for the safe use and handling of medical devices.

5.3. Manufacturer's Instructions: Always follow the maintenance and service instructions for the proper use, cleaning, and maintenance of reusable biopsy blades.

Conclusion

By following the guidelines outlined in this safety manual, healthcare facilities can ensure the safe handling, maintenance, and disposal of reusable biopsy blades, reducing the risk of injuries and promoting a safe working environment. Compliance with relevant standards and codes is essential to maintaining workplace safety and protecting healthcare workers and patients from harm.

Appendix G: Tissue Damage Testing Protocol

Materials:

- 8 pig kidneys
- Final prototype of the blades
- Ethanol
- Scissors
- Caliper
- Gloves
- A large, square, polystyrene dish
- Paper towels

Procedure:

1. Prepare the area by layering the polystyrene dish with multiple paper towels
2. Put on gloves
3. Using the scissors, cut open the packages of pig kidneys and drain the liquid
4. Place the pig kidneys in the polystyrene dish, making sure no pig kidneys overlap
5. Cut the pig kidneys by holding the blade in your hand with your thumb pointing down and rotating your wrist
    a. You can rotate your wrist multiple times to cut all the way through the chicken breast, but do not take the blade out and put in back in the chicken to make the cut
6. Once the blade is through the entire chicken, lift the blade up and remove the specimen from the inside
7. Using the calipers, measure the amount of tissue damage the cut created and record this distance in millimeters
    a. This is the distance from the edge of the circle of the intended to the furthest sign of tissue trauma, either a tear in the chicken or a larger than 10mm diameter circle
    b. If no visual damage is seen, record this observation
8. Repeat steps 5-7 for a total of 40 cuts
9. Bag all of the pig kidneys, packaging, and paper towels and dispose of in a black trash bag to be placed trash outside of ECB
10. Using ethanol, wipe down the table, polystyrene dish, scissors, and all blades
11. Put back all materials once dry

Appendix H: Performance Survey Testing Protocol

Materials:

- Pencil
- Final prototype of blades
- Scissors
- Caliper
- A large, square, polystyrene dish
- Gloves
- Paper towels
- Ethanol

Procedure:

1. Prepare the area by layering the polystyrene dish with multiple paper towels
2. Put on gloves
3. Using the scissors cut open the packages of pig kidneys and drain any liquid
4. Place the pig kidney in the polystyrene dish
5. Have the client cut into the pig kidney using one blade
6. Once the blade is through the entire pig kidney, lift up the blade and remove the tissue specimen
7. Have the client note the integrity of the tissue specimen and the overall pig kidney
8. Ask the client the questions of the performance survey and write down their answers
9. If there is noticeable tissue damage, use the calipers to measure how much damage there is in millimeters
10. Repeat steps 5-9 with 3 other clients
11. Place all pig kidney waste, paper towels, and gloves in a bag and dispose of in the trash
12. Using the ethanol, wipe down the calipers, scissors, blades, polystyrene dish, and table
13. Put all materials back where they belong

Appendix I: Performance Survey

Name:

Blade #:

1. Cutting the tissue required minimal pressure using the blade.

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

2. It took a limited number of attempts to cut the kidney (<2).

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

3. I did not feel any tension in my wrist or hand when using the blade.

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

4. The blade quality did not decrease over time.

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

5. The blade did not cause any observable tissue damage.

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

6. I am satisfied with the cut of the blade.

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

7. The coring tube opens and closes easily.

   (1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

8. The coring tube stays intact when I need it to.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

9. The tissue sample in the coring tube did not experience any damage.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

10. Removing the blade from the coring tube after a procedure was easy.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

11. I felt safe removing the blade from the coring tube.

(1) Strongly Disagree (2) Disagree (3) Neutral (4) Agree (5) Strongly Agree

12. If there was any tissue damage, how widespread was the damage from the cut? Please give an answer in mm.

13. Please provide any other feedback on blade design

Appendix J: Qualification of Microsurgical Technologies Blade

The team qualified the new pre-made blade as a sufficient replacement to the manually created blades, on the basis of 3 criteria: material properties, dimensions, and reproducibility. Firstly, the Microsurgical Technologies blade is made from German standard EN 1.4408 steel, that corresponds to the American Society for Testing and Materials (ASTM) A 269 standard 316 Stainless Steel the team used for manual fabrication [1]. The materials share 98% of their average alloy composition and display comparable material and mechanical properties [2]. The Microsurgical Technologies blade employs slightly better material composition with up to 4% more chromium content to aid in rust resistance [2]. Both materials also have similar fatigue strengths of 170 MPA and acceptable elongation % before break, with the manufactured blade surpassing the manual with 34% elongation at break [2].

Secondly, the team compared the dimensions of the premade blade to the manual one. The manual blade was fabricated out of 6ft long annealed AISI 316 Stainless Steel tubing with an 15.875mm Outer Diameter (OD) x 14.859mm Inner Diameter (ID) and included a .508 mm wall thickness [3]. The manual blades also utilized a 15 ° taper at the end for easy incision. Similarly, the manufactured blade was dimensioned 11.40 mm OD x 10mm ID, with a slightly thicker wall of .7mm.

In total, the team evaluated these comparisons and determined that the manufactured blade was extremely comparable in properties and function to the manually created blades. This along with the added reproducibility of the manufactured blade, direct the team to move forward with the pre-purchased blade from Microsurgical Technologies.

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