Coring Biopsy Device for Radiologic Pathologic Correlation in Renal Cell Carcinoma

Team Members: Ellie Steger, Erin Schlegel, Emily Wheat, Olivia Jaekle, Aleks Skutnik

Client: Dr. Meghan Lubner (UW Department of Radiology),

Dr. Jason Abel and Dr. Daniel Shapiro (UW Department of Urology)

Advisor: Dr. Tracy Puccinelli

BME 400, Fall 2023

College of Engineering
UNIVERSITY OF WISCONSIN–MADISON

Problem Statement

RCC Complications

- RCC exhibits unique spatial heterogeneity which complicates visual analysis

Figure 1: *Clear cell renal cell carcinoma [1].*

Treatment Analysis

- Computer Tomography Textural Analysis is a method allowing slice-by-slice tumor analysis [2]
- Correlates tumor slices with histological findings
- Tumor samples and remaining kidney tissue need to remain intact to produce quality images
- Current device causes too much damage, quality images cannot be produced
- Aim to develop a functional device that will cause <3mm tissue damage from improved imaging analysis

Design Specifications

Blade:

- Reusable (detachable)
- Sterilizable in autoclave
- Resect 10mm tumor sample
- Minimal tissue damage
- Remain sharp over time

Coring Tube:

- Tight seal with the blade
- 10-25mm diameter
- Stays together when in use
- Minimal tissue damage
- $500 budget

Background Information

- Most common type of kidney cancer with 400,000 new cases annually [3]

Current method:

- Patients kidney imaged and 3D printed box is produced
- Coring device used to collect sample from the kidney in the box
- Engraved slits are used to correlate slices with location in tumor

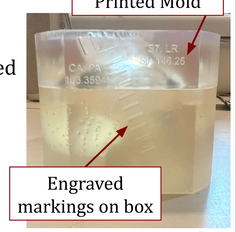

Figure 2: *3D printed acrylic box with engraved markers that holds patients kidney.*

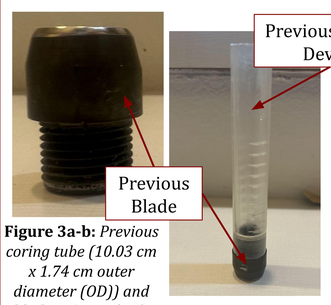

Figure 3a-b: *Previous coring tube (10.03 cm x 1.74 cm outer diameter (OD)) and blade 1.59 cm (OD).*

Existing Device

- Blade too thick and dull
  - Causes extensive tissue trauma
  - Unusable
- Coring tube falls apart
  - Tumor sample not secure

Acknowledgements

The team would like to thank Dr. Meghan Lubner and Dr. Tracy Puccinelli for their guidance. Special appreciation goes to Dr. Rong Hu, Jeff Rappe, and Jesse Darley from the TEAM Lab for their collaboration in the fabrication and testing process.

Final Design

Figure 4: *Stainless steel "Punch Biopsy" blade made in UW TEAM Lab.*

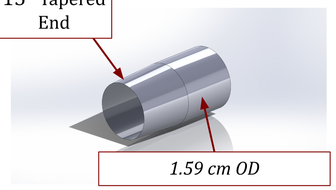

Figure 5: *SolidWorks model of "Punch Biopsy" blade design.*

"Punch Biopsy Design" Blade:

- 316 stainless steel tubing
- 0.51 mm wall thickness
- 15 ° taper using circular saw and dremel rotary tool
- Autoclavable
- Resistant to corrosion

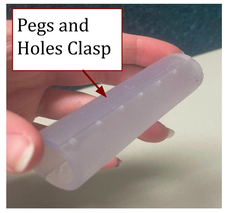

Figure 6: *Final "Lego" design, 3D printed in FormLabs BioMed Clear Resin.*

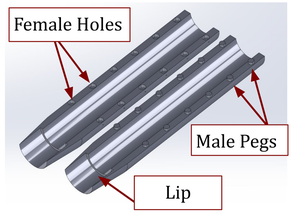

Figure 7: *SolidWorks model of "Lego" corer device.*

"Lego Design" Coring Device:

- Peg and hole fit with .1mm tolerance gap
- Durable design that easily opens to remove sample after resection
- Taper to minimise tissue drag
- Lip to stop blade

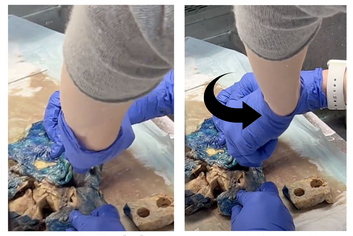

Figure 8: *Pathologist uses a twisting motion with device to resect tumor sample.*

Application of Device:

- Blade and coring device assembled
- Pathologist twists assembly into tumor
- Cut is made, blade detaches, and tissue is CT imaged
- Sample removed from corer for further CT textural analysis

Testing

Blade Integrity Test

- The blades were used to perform test biopsies using chicken breasts to mimic human organ tissue
  - Blade thickness was measured after every five cuts
  - 40 cuts in total were performed for each blade prototype
  - Each tester filled out corresponding blade survey

Tissue Damage Test

- The team visually inspected the tissue surrounding the area of biopsy and noted any observable tissue damage

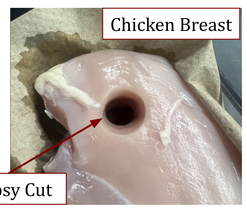

Figure 9: *Test biopsy on a chicken breast showing minimal surrounding tissue trauma.*

Figure 10: *Image of staircase damage within internal tissue caused by Blade #3.*

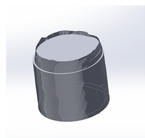

Figure 11: *Image of Blade #1 3D scan before and after Autoclave.*

Figure 12: *Test biopsy on a human kidney sample performed by the client.*

Autoclave Test

- Blade prototypes were placed in an autoclave to test the ability of the material to withstand autoclave conditions
- Blade prototypes were 3D scanned before and after autoclave to capture deformities

Performance Survey

- Rated the blade prototypes after performing test biopsies on a human kidney sample and pig kidney samples
  - Data sets n=4
  - Categories include: tissue damage, amount of applied pressure needed to perform the biopsy, discomfort levels, and blade quality

Results

Blade Integrity Test

- Average change of 0.0175 mm with a range from **0.01 - 0.03 mm**
- P Value: **4.423e-32**
- F value: **1058.6**

Tissue Damage Test

- No observable tissue damage was found

Autoclave Test

- **0.001% difference** in thickness after autoclave
- Each blade deemed autoclavable; no change in appearance

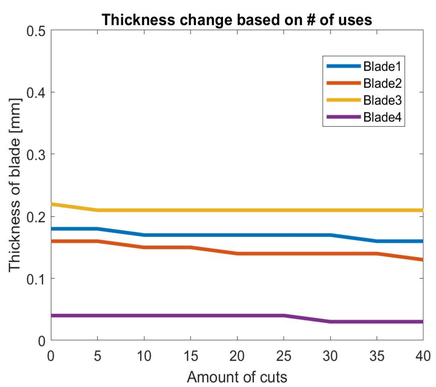

Figure 13: *Plot of 4 different blade's thickness in increments of 5 cuts (40 total).*

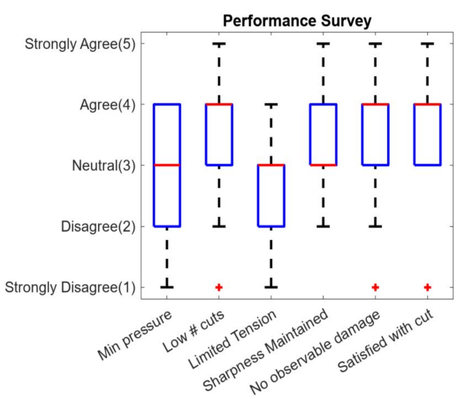

Figure 14: *Box plot of the performance survey results.*

Performance Survey

- Blades total average for survey, **3.19 +/- 1.053**
- Blade 1 excelled in minimal pressure, constant blade quality, and no observable external tissue damage
- All blades were found to cause internal "staircase" damage

Discussion

3 out of 4 tests performed on the device were deemed **successful:**

- **Blade Integrity Test:**
  - Criteria: < 0.05 mm change in blade thickness
  - Result: All blades had a <0 .03 mm change
- **Tissue Damage Test:**
  - Criteria: <3 mm of localized tissue damage
  - Result: No quantifiable damage
- **Autoclave Test**
  - Criteria: <0 .01% change in blade thickness before and after autoclaving
  - Result: All changed in blade thickness is negligible
- **Performance Survey**
  - Criteria: Average score of 4/5 in all categories
  - Result: 3 out of 6 categories averaged a 3/5

Future Work

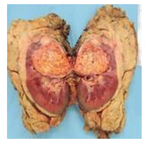

Figure 15: *Resected kidney with RCC surrounded by the layer of perirenal fat [4].*

Testing

- Mimic fat layer surrounding the resected kidney
  - Constructing phantom
  - SolidWorks modeling

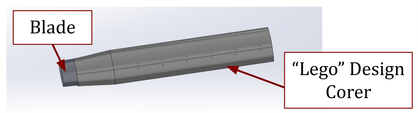

Figure 16: *SolidWorks model of final assembly with coring device and attached blade: L 11cm*

- Press-to-fit blade and corer tube attachment
  - Stability during coring and blade removal for imaging

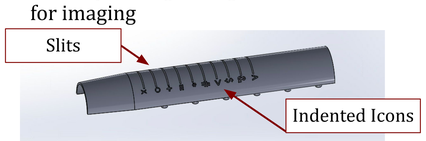

Figure 17: *SolidWorks model of the tube with icon markers: 10 slits 1.5cm each, 0.5cm apart with accompanying icons.*

Magnetic Resonance Compatibility

- Icon Markers on Sample Tube

Ergonomics and Safety

- Silicone Thumb Cap
- Blade Cover

Manufacturing Capabilities

- Blade Width Consistency

References

[1] M. T. Niknejad, "Clear cell renal cell carcinoma: Radiology reference article," Radiopaedia, https://radiopaedia.org/articles/clear-cell-renal-cell-carcinoma (accessed Dec. 7, 2023).

[2]Y. Deng et al., "CT texture analysis in the differentiation of major renal cell carcinoma subtypes and correlation with Fuhrman grade," European Radiology, vol. 29, no. 12, pp. 6922–6929, May 2019. doi:10.1007/s00330-019-06260-2

[3]C. C. medical professional, "Renal cell carcinoma: Symptoms, treatment & prognosis," Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/24906-renal-cell-carcinoma (accessed Oct. 10, 2023).

[4] M. M, "Kidney cancer," Flickr, h4tps://www.flickr.com/photos/58937697@N00/309704909 (accessed Dec. 4, 2023).