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. Rong Hu and Dr. Daniel Shapiro (UW Department of Urology)

Advisor: Prof. Tracy Jane Puccinelli

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College of Engineering
University of Wisconsin–Madison

Problem Statement

RCC Complications

- RCC exhibits unique spatial heterogeneity which complicates visual analysis
- Most common type of kidney cancer with 400,000 new cases annually [2]

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

Current Methods

Treatment Analysis

- Computer Tomography Textural Analysis is a method allowing slice-by-slice tumor analysis [3]
- Correlates tumor slices with histological findings
- Tumor samples and remaining kidney tissue need to remain intact to produce quality images

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

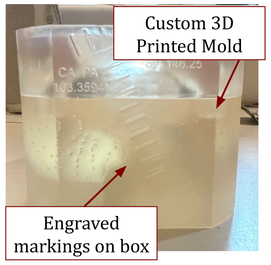

Figure 2: *3D printed acrylic box that holds patients kidney.*

Design Specifications

Coring Tube:

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

Plunger:

- Must fit the coring tube and blade diameters
- Minimal tissue damage
- Disposable

Existing Device

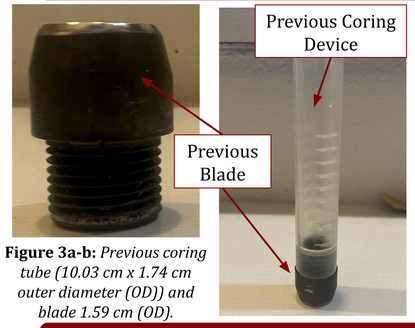

Figure 3a-b: *Previous coring tube (10.03 cm x 1.74 cm outer diameter (OD)) and blade 1.59 cm (OD).*

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

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Final Design

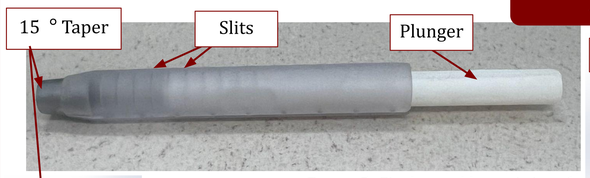

Figure 5: *Final assembly consisting of blade, coring device, and plunger.*

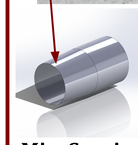

Figure 4: *SolidWorks model of MicroSurgical Blade.*

MiroSurgical Blade:

- 316 stainless steel
- 18-20% Chromium content
- 0.7 mm wall thickness
- Resistant to corrosion
- Autoclavable
- 15 ° taper

"Lego Design" Coring Device:

- Peg and hole fit with .1mm tolerance gap
- Durable design that easily opens to remove sample after resection
- Taper to minimize tissue drag
- Lip to stop blade
- Slits for imaging depth
- 15 mm Outer Diameter (OD) x 11 mm Inner Diameter (ID)

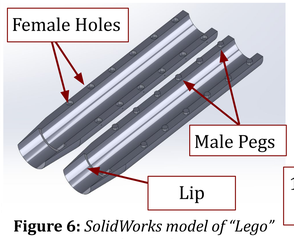

Figure 6: *SolidWorks model of "Lego" coring device.*

Plunger:

- 3D printed in PLA on Bambu Lab X1 Carbon printer
- Adjustable length
- Thumb support for application

Figure 7: *SolidWorks model of plunger device.*

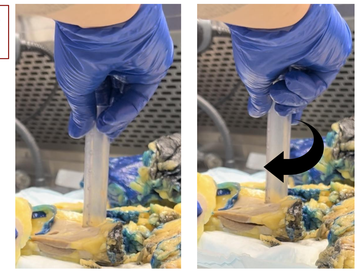

Figure 8: *Pathologist uses a twisting motion with device to resect tumor sample.*

Application of Device:

1. Blade and coring device assembled
2. Pathologist twists assembly into tumor
3. Cut is made, blade detaches, and tissue is imaged on CT
4. Sample removed from corer for further CT textural analysis

Testing

Figure 9: *Test biopsy on a human kidney sample performed by the client.*

Performance Survey

- Client rated two coring device prototypes after performing test biopsies on a human kidney sample
  - Data sets n=5 per device
  - Categories include: tissue damage, cut satisfaction, tube ergonomics, tube durability, blade and tube compatibility, and confidence in using device

Optimization of 3D Printing

- Printing Orientation relative to the build plate
  - 0°, 30°, 60°
- Post-Processing Methods
  - 15 minutes at 60° C, 15 minutes at 45° C twice, 2 hours in direct sunlight

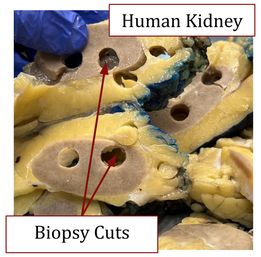

Figure 10: *Test biopsy results after extracting samples to observe tissue damage.*

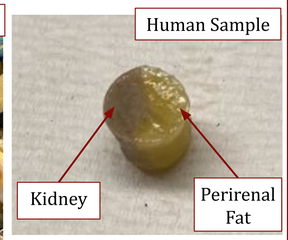

Figure 11: *Test biopsy sample showing seamless extraction of two tissue types.*

Results/Discussion

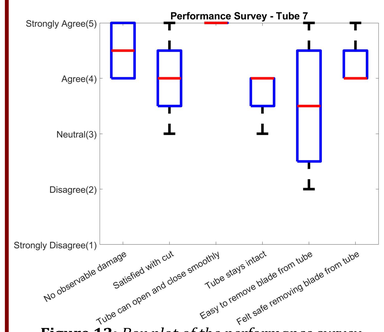

Figure 12: *Box plot of the performance survey results done with coring tube prototype #7.*

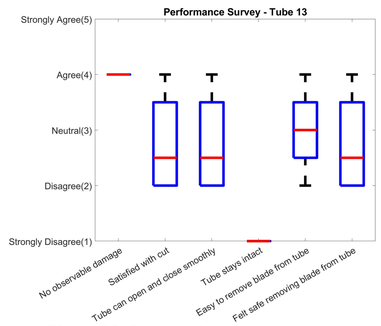

Figure 13: *Box plot of the performance survey results done with coring tube prototype #13.*

Performance Survey

- Blade with Tube #7 averaged **4.17 +/- 0.817**
- Blade with Tube #13 averaged **2.71 +/- 1.12**
- Highest scoring category for Tube #7: **Tube can open and close smoothly**
- Highest scoring category for Tube #13: **No observable tissue damage**
- With increase in thickness the following categories also increased in performance: **satisfied cut, tube staying intact, tube ergonomics, and confidence in using device**

Figure 14: *Close up of Tube #13 showing the gap created when too much force from blade.*

- **Discussion**
  - Passing Criteria: Average score of 4 out of 5 over all categories
  - Tube #13 Results: 1 out of 6 categories passed criteria
  - Tube #7 Results: 5 out of 6 categories passed criteria
  - Tube #7 deemed **successful**

3D Printing Optimization

Table 1: *Table categorizing the rigidness of the print at different angles to the build plate.*

Tube Angle	1	2	3
0°	Fail	Fail	Fail
30°	Success	Success	Success
60°	Fail	Success	Fail

- At 0° the tube was not well supported and fell into the resin pool
- At 60° the tube severely deformed in the area below the slits
- **Discussion**
  - Print at a 30° angle with enhanced supports directly below slits to prevent deformation

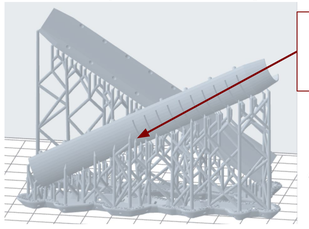

Figure 15: *Formlabs 30° orientation from build plate.*

Post-Processing Parameters

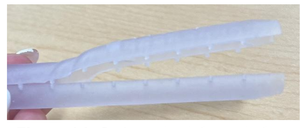

Figure 16: *Coring tube deformed after being UV cured at 60 C for 15 minutes.*

Figure 17: *Coring tube slightly deformed after being UV cured twice at 45 °C for 15 minutes.*

- **Discussion**
  1. Wash the tube in isopropyl alcohol (IPA) bath for 15 minutes
  2. Dry under a fan for 20 minutes
  3. Leave the tube in direct sunlight for 2-3 hours
     - Do not use FormCure

Future Work

Institutional Review Board (IRB)

- Approval to test device on freshly resected kidneys

Coring Tube Closure Mechanism

- Rubber cap at the bottom of the coring tube
  - Coring tube made longer for cap not to impede the tissue sample inside the tube

Figure 18: *Example of silicone rubber end cap to go on coring device* [5].

References

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