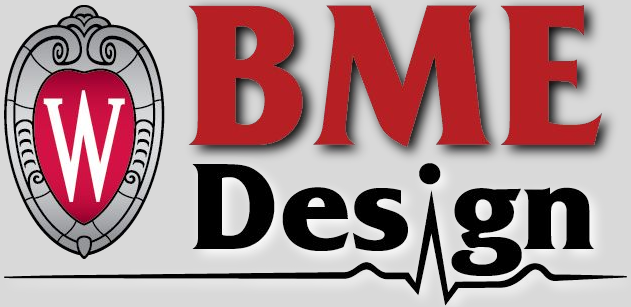
Radiologic Pathologic Correlation in Renal Cell Carcinoma



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Emily Wheat (BWIG), Olivia Jaekle (BPAG), Aleks Skutnik (BSAC)
Advisor: Dr. Tracy Puccinelli
Client: Dr. Meghan Lubner
February 9, 2024

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Client and Design Constraints

- Dr. Meghan Lubner
  - Professor of Radiology - Abdominal imaging
- Constraints:
  - MRI and CT compatible device
  - Detachable stainless steel blade
  - Resect 10mm diameter tissue sample
  - Create minimal tissue trauma

Problem Statement

- Most common type of kidney cancer
- From the body biopsies are too risky
  - Entire kidney removed
- Spatial heterogeneity complicates imaging
- Coring biopsy device
  - Stainless steel blade
  - Formlabs coring tube

Fig 1: Image of shape and placement of a renal cell carcinoma on the kidney [1].

Design Impact

- Each year in the US there is:
  - ~ 65,000 new cases of RCC
  - ~ 15,000 deaths from RCC [2]
- Long-term survival relies on surgical intervention and detection
- CTTA can aid in:
  - Individualized treatment
  - Better prognosis
- Currently no competing designs on the market

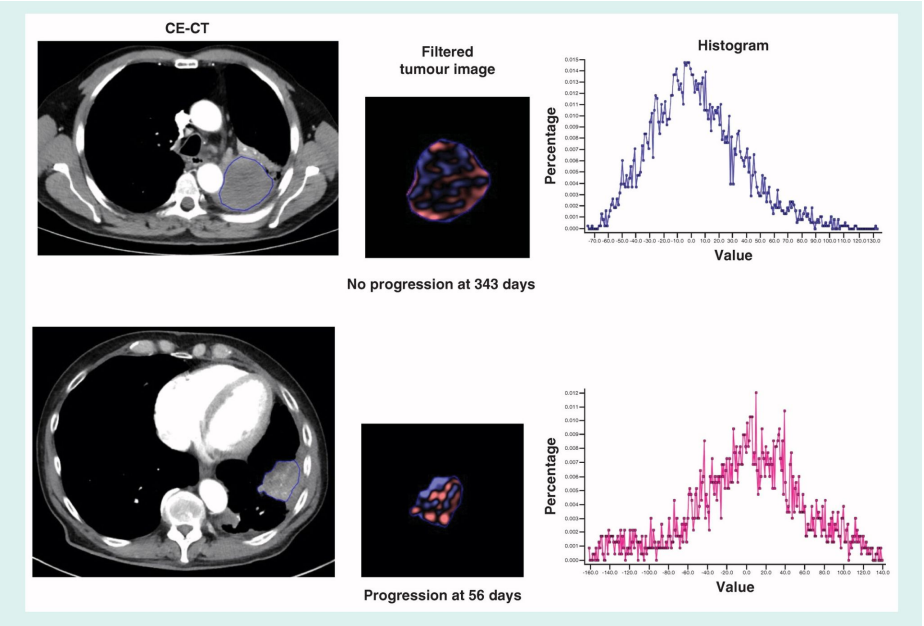

Fig 2: Example of how CTTA can correlate quantifiable data with histological images [3].

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Prior Work

- **“Punch Biopsy” Blade:** 316 stainless steel circular blade
  - Thinned wall and tapered end for seamless cut into tissue
- **“Lego Design” Coring Device:** 3D printed coring handle
  - Peg and hole clasp to open and reveal tumor
- **Testing:** Functionality of prototype on varying mediums
  - Durability
  - Tissue Preservation
  - Ergonomics

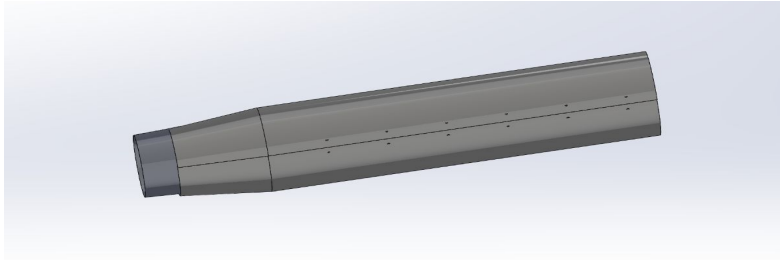

Fig 3: Solidworks assembly of final prototype including the blade and coring device.

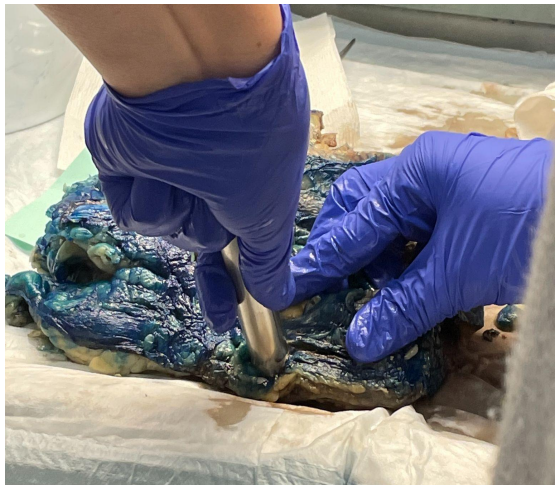

Fig 4: Tissue damage test performed on human kidney specimen by client.

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Prior Work

Table 1: *Test results from fall semester.*

Data Analysis & Results		
Durability	**Tissue Preservation**	**Ergonomics**
• **< .05mm** change in blade thickness	• **< 3mm radial tissue damage** observed • "Stair Stepping"	• **2 ergonomic categories failed** (avg < 3)

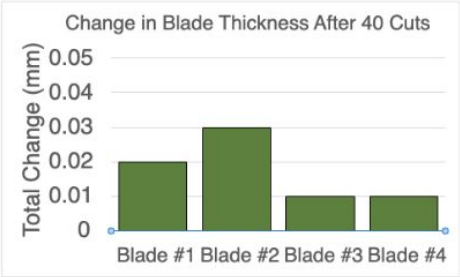
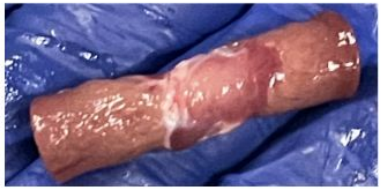
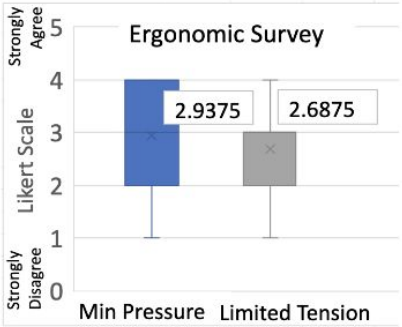

		

Fig 5: Change in blade thickness over 40 cuts.	Fig 6: Image of "Stair Stepping" damage on resected tissue caused by Blade #3.	Fig 7: Image of two categories from the team's Ergonomic Survey.
Passed	Passed	Failed

Lessons Learned

- Kidney tissue is difficult to model
- Successful design engineering of coring device
- Hard to recreate manual blade design

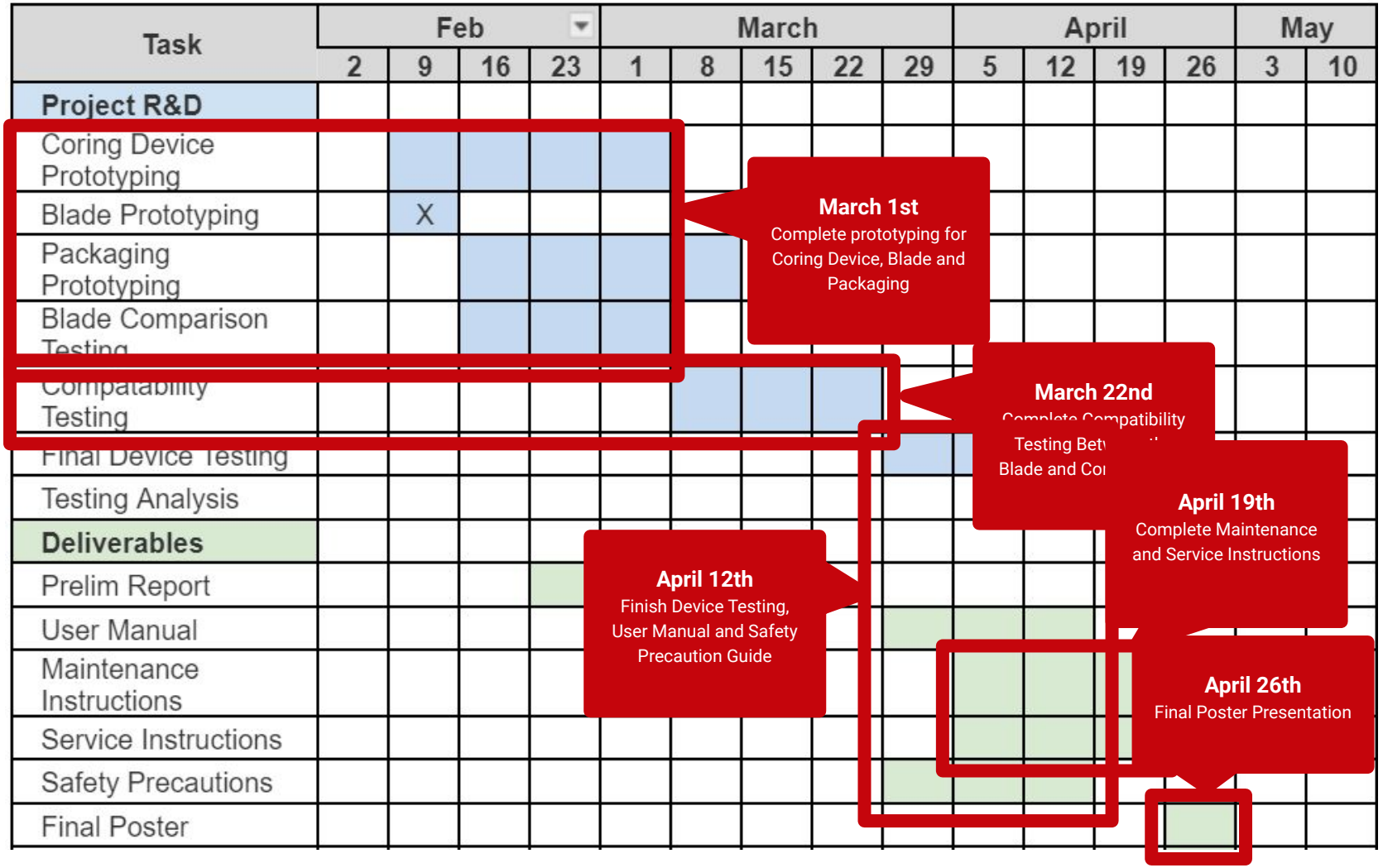
Standardizing Manufacturing

- Manual blades varied in thickness from .04mm < x < .22mm
- Sharp edges internally tore tissue
- Moving forward with a pre-fabricated trephine blade
    - desired thickness, diameter, material

Fig 8: Surgical trephine blade used on corneal tissue [4].

Spring Semester Timeline

Task	Jan	Feb				March					April				May	
	26	2	9	16	23	1	8	15	22	29	5	12	19	26	3	10
Project R&D																
Empathize	X	X	X													
Background…	X	X														
Coring Device Prototyping																
Blade Prototyping			X													
Packaging Prototyping																
Blade Comparison Testing																
Compatability Testing																
Final Device Testing																
Testing Analysis																
Deliverables																
Progress Reports		X	X													
Prelim presentation		X	X													
Prelim Report																
User Manual																
Maintenance Instructions																
Service Instructions																
Safety Precautions																
Final Poster																


Task
Feb
March
April
May
2
9
16
23
1
8
15
22
29
5
12
19
26
3
10
Project R&D
Coring Device Prototyping
Blade Prototyping
X
Packaging Prototyping
Blade Comparison Testing
Compatability Testing
Final Device Testing
Testing Analysis
Deliverables
Prelim Report
User Manual
Maintenance Instructions
Service Instructions
Safety Precautions
Final Poster
March 1st
Complete prototyping for Coring Device, Blade and Packaging
March 22nd
Complete Compatibility Testing Bet
Blade and Co
April 19th
Complete Maintenance and Service Instructions
April 12th
Finish Device Testing, User Manual and Safety Precaution Guide
April 26th
Final Poster Presentation

Final Prototype Requirements

- Packaging
  - Sterile packaging around device
  - Safety cap created by silicone molding
- Documentation
  - Service instructions for physician
  - User manual, maintenance instructions, safety warning and precautions for sharp components
- Budget: $500
- Fabrication improvements
  - Combining blade and coring tube into one unit
  - Standardization of blade manufacturing
- Further testing
  - Functionality of overall device

Estimated Cost of Production

Cost per procedure = $35.1

Table 2: *Cost to produce one viable final device*

Item	Description	Manufacturer	Quantity	Cost	Life in Service (# of procedures)
Trephine Blade	AM0570S 100- 10mm d	MicroSurgical	1	92.7	100
Formlabs Biomed clear resin	Lego Clip Coring Design	Makerspace	64mL	23.06	1
PLA	Silicone Blade Cap Mold	Makerspace	25g	2	100
Silicone Sealant	Silicone Sealant, All Purpose Silicone, 10 oz, Cartridge, Clear	Zoro	1	6.79	100
Pre-Klenz Transport Gel	Cleaning supplies for reusable surgical instruments	Steris	1	Provided	NA
Sterilization Pouch	10'' x 15'' sterilization pouches for packaging	Net32	200	24.94	200

Thank you!

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References

[1] K. M. O'Rourke, "Renal cell carcinoma: 5 things to know," Medscape, https://www.medscape.com/viewarticle/920324?form=fpf (accessed Oct. 4, 2023).

[2] Center for Devices and Radiological Health, "Shelf life of Medical Devices," U.S. Food and Drug Administration, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-life-medical-devices (accessed Dec. 13, 2023).

[3] R. Ladwa et al., "Future medicine | home," Future Medicine, https://www.futuremedicine.com/ (accessed Feb. 8, 2024).

[4] Ambler Surgical, https://amblersurgical.com/33-0550-corneal-trephine-blade-long-16-0mm-length-5-50mm-diameter-packaged-individually-sterile-disposable-box-of-1 (accessed Feb. 8, 2024).