

Tissue Oracle

High-resolution tissue scanner



COLUMBIA | ENGINEERING

The Fu Foundation School of Engineering and Applied Science

Tissue Oracle

Fast, High-Resolution, AI-enabled Tissue Scanner



Breast Cancer: Prevalence and Cost



Most common cancer in women in the world: 2M+ diagnosed worldwide/year, 330k diagnosed in US/year



Breast cancer projected to cost the US \$20.5 billion in 2020

2/3

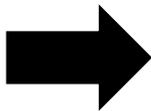
2/3rd patients diagnosed with invasive breast cancer choose to undergo lumpectomy

\$2,000+
specimen

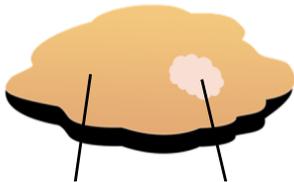
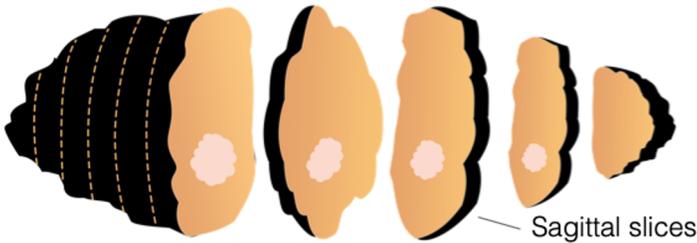
Surgical specimens are costly to process in terms of technical and professional costs

Breast Pathology Overview

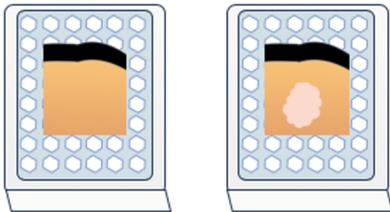
Breast cancer patient undergoes surgery



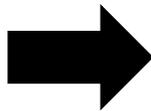
Surgical specimen sent to pathology gross room for processing



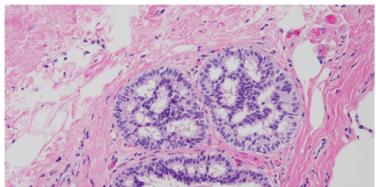
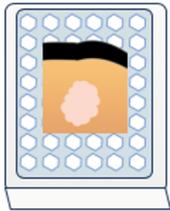
Gross examination of specimen



Cutting of specimen into blocks

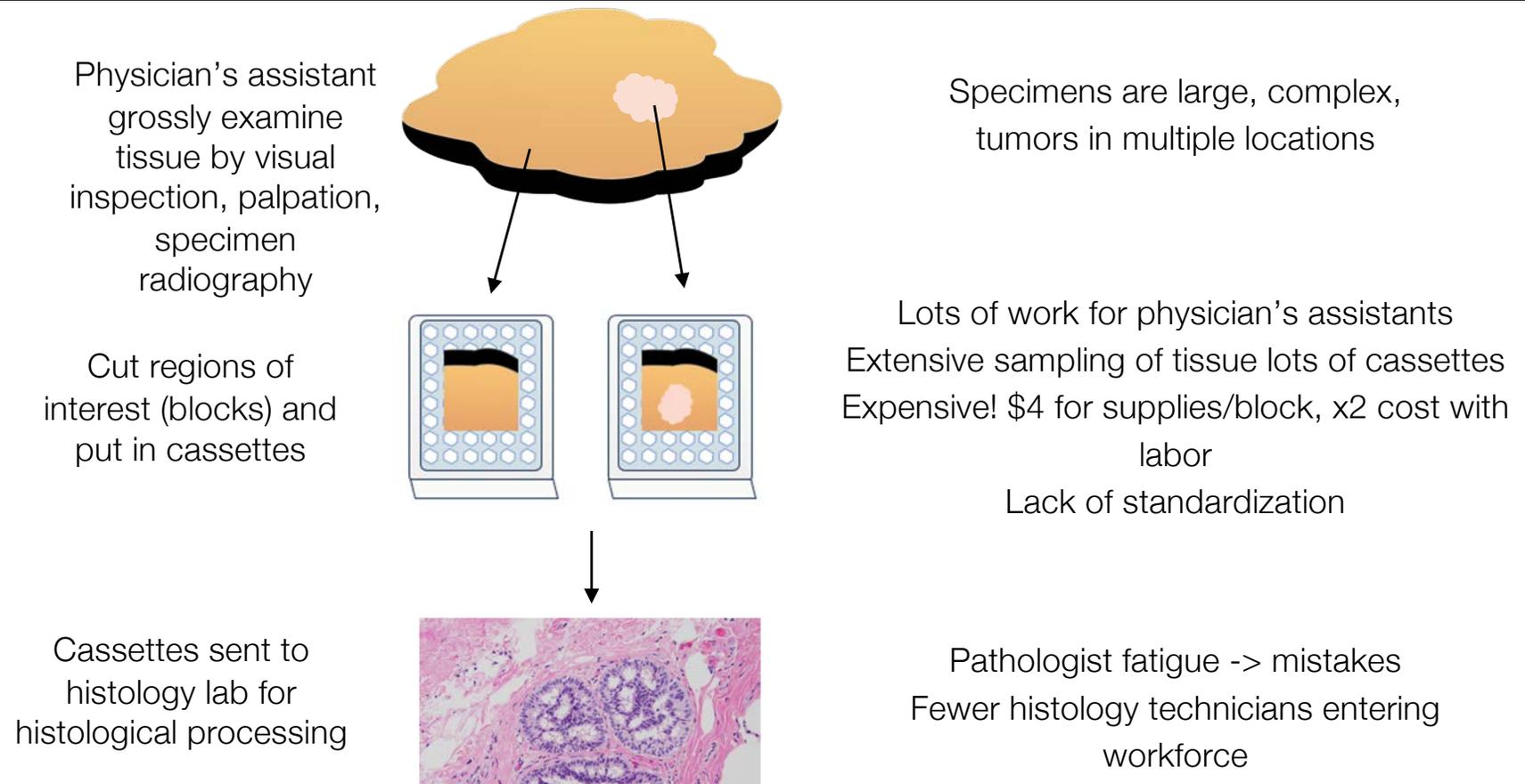


Blocks sent to histology lab to make slides that can be reviewed by pathologist



Blocks processed into histology slides + pathologists review slides

Gross exam \neq microscopic evaluation



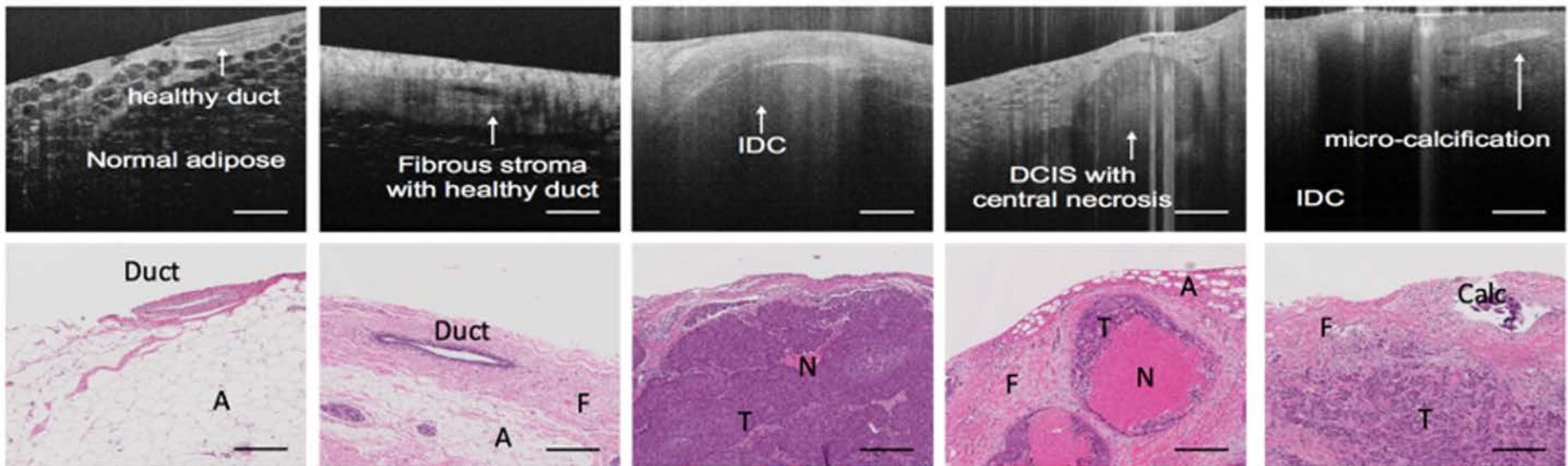
Breast pathologists need a highly accurate technology to identify regions of interest in breast specimens to reduce technical cost of processing, block submission rate, and pathologist review time by 30-50%

Our technology can scan a tissue block in 1.4 minutes followed by real-time AI interpretation

- Our **ultrafast** and **ultrahigh** resolution OCT system has a **large imaging field of view** that can image a tissue block in 1.4 minutes, followed by real-time AI interpretation

AI performance differentiating cancer vs. no cancer

Accuracy	94%
Sensitivity	96%
Specificity	92%



Non-interest



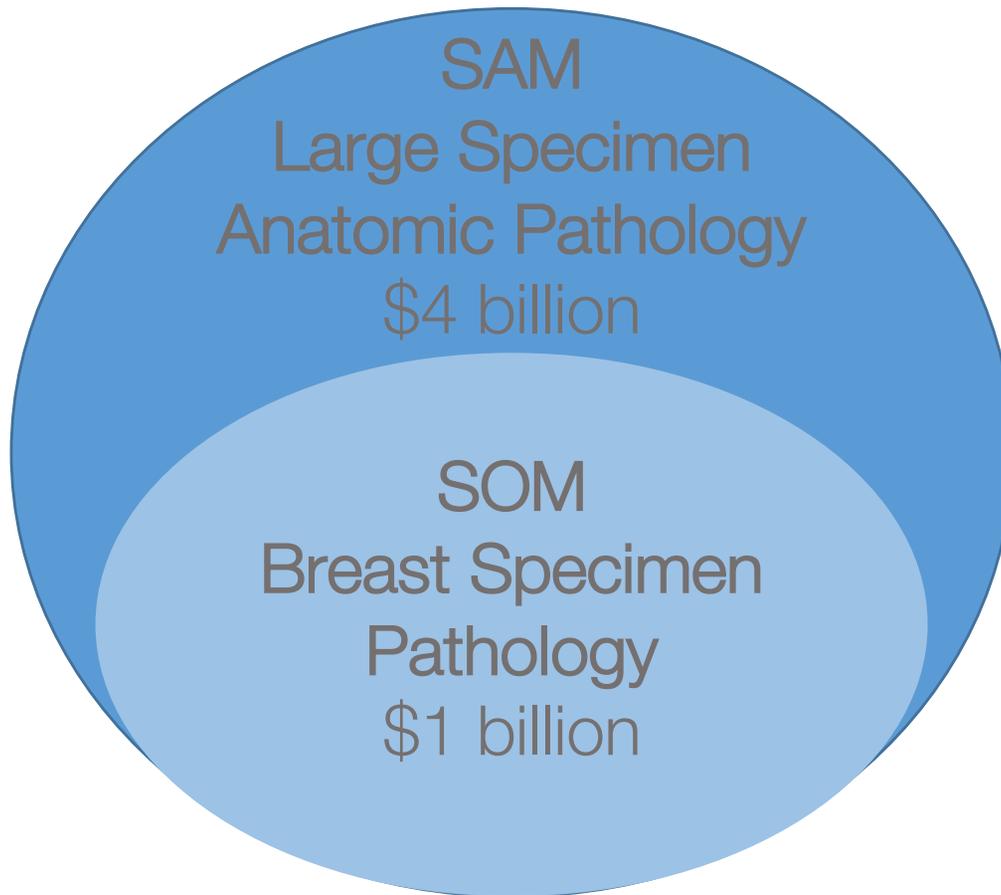
Interest

The Market for Tissue Oracle: Large Specimen Anatomic Pathology

TAM
Anatomic Pathology
\$15.4 billion

Large specimens represent
25% of total surgical
excisions per year

At CUIMC, large surgical
excisions sent for anatomic
pathology in 2018:



Breast	3,100	} 47% of total surgical specimens sent for pathology analysis
Lung	1,400	
Prostate	723	
Other	7,077	
Total	12,300	

Medicare compensation for large breast specimen pathology diagnostics

College of American Pathologists (CAP) Medicare Physician Fee Schedule 2019 for mastectomy and lumpectomy pathology analysis:

Technical cost	\$186.68
Professional cost	+ \$86.85
1 breast specimen	\$273.54
7 specimens/surgery	x7
Pathology cost / patient	\$1,914.78 / patient

290k women diagnosed with breast disease/year * \$2000/patient = **\$580 million/year in USA**
+ many more (at least 3x) with benign breast disease

CUMC alone received at least \$850,000 to process 3,100 large breast specimens in 2018

Value Proposition: Cost Savings + Improved Practice

- 30-50% of blocks submitted for histology analysis are not required for diagnosis
- Benefits of eliminating negative blocks with Tissue Oracle scanner:
 - Save \$250,000 – 500,000 / year at a large hospital
 - Increase efficiency in gross room
 - Improve the use of pathologist time
 - Conserve technical resources
 - Reduce time to diagnosis
 - Improve standardization within and across hospitals

Competition: Actual and Future

- **Now:** No technology is currently used to limit the number of specimen blocks submitted for histology analysis
 - Closest competition is the Faxitron, which identifies surgical clips and calcifications, only
- **Future:** Emerging competition use AI to review histology slides + machines to automate histology lab tasks (ex. cutting of paraffin blocks) but not to limit the number of blocks submitted

What are stakeholders looking for?

Physician's assistants	Lab administration	Pathologists
+ Standardization in their practice + Workload reduction	+ To limit the number of blocks submitted + Fast, easy-to-use device	+ Fewer slides to review + Target diseases where gross evaluation \neq microscopic evaluation

*"There should be a best way to do things that we all can follow, but there's **so much variability across institutions and even within Columbia**"*

-Liana Wong, PA at CUIMC

*"Go after **techniques where gross evaluation is not effective** (breast + prostate + brain)"*

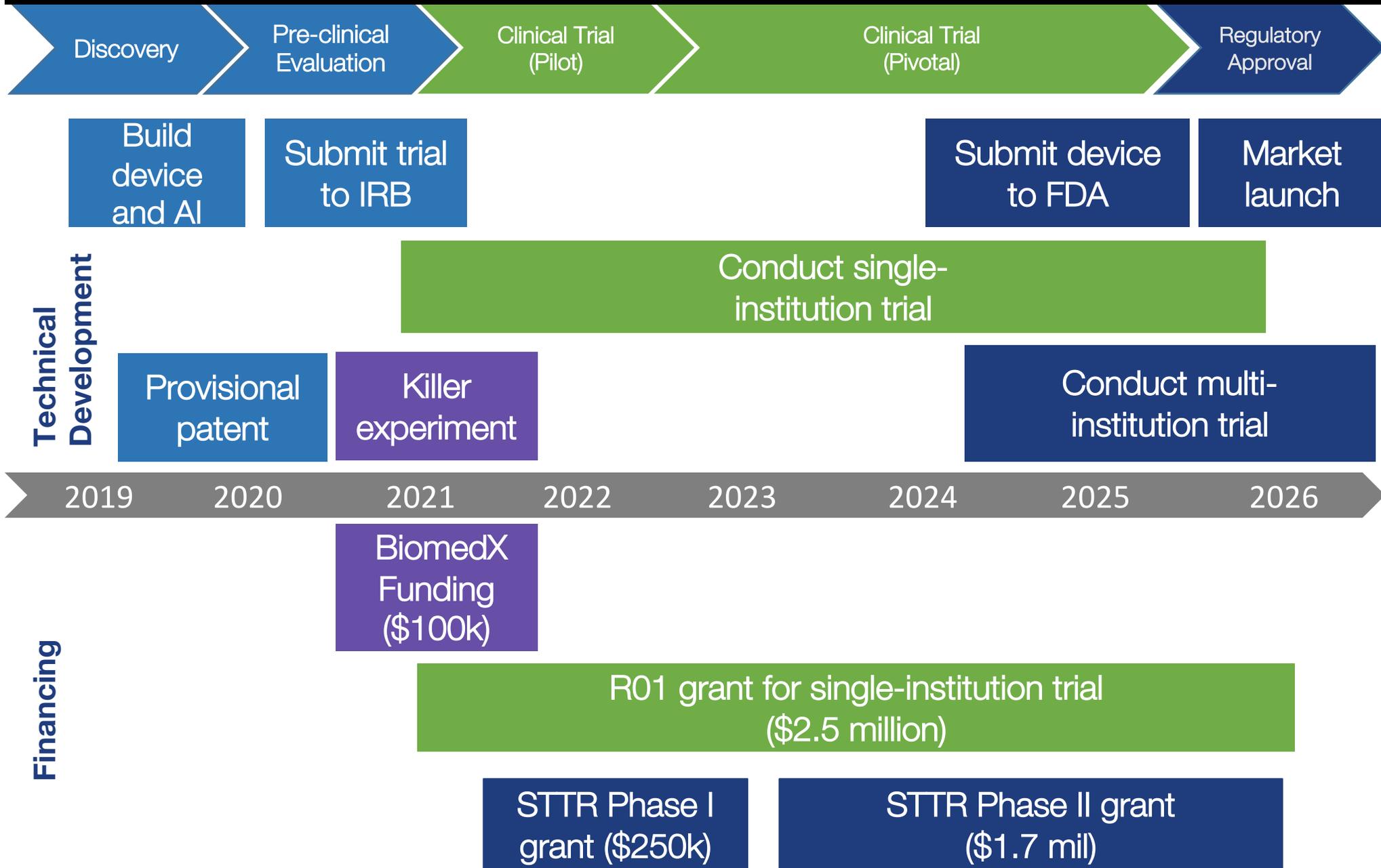
-Glen Markowitz, MD

Vice Chair, Anatomic Pathology CUIMC

*"It would be really helpful to limit the number of blocks, **we often submit the whole thing** (lumpectomy or mastectomy) and that **can lead to 120 blocks.**"*

-Doreen Hebert, Division Administrator, Anatomic Pathology CUIMC

Go to Market Timeline



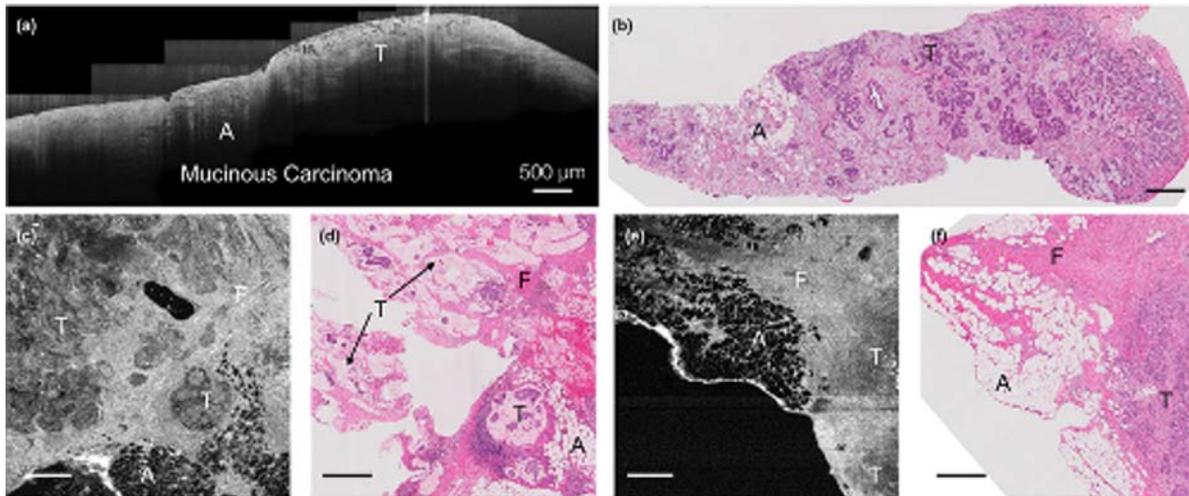
Killer Experiment

Killer Experiment

Prospective single-institution study imaging tissue blocks from 25 patients at CUMC to show that our ultrahigh-resolution, high speed, large field-of-view with AI real time interpretation, novel imaging device (Tissue Oracle) is able to identify tissue blocks of non-interest with greater than 95% accuracy.

Enabling Milestones

1. Optimize image acquisition settings and protocol
2. IRB submission and approval
3. Cassette holder and covers for OCT imaging system



Budget \$99,371

- Personnel support for Physician Assistant and Biomedical Engineer
- Histology processing fees for scanning and de-identification

Intellectual Property Portfolio

Provisional patent application submitted

System, method, computer-accessible medium, and apparatus for ultrahigh-resolution optical coherence tomography for automated detection of diseases

Key Claims:

- Our clinical application in pathology
 - Patenting scanning of blocks, sagittal slices, and core biopsies
 - OCT has previously been used for applications in breast cancer margin assessment
- Our OCT system for its high resolution, high speed, and large field of view
 - Better than state-of-the-art for breast cancer imaging with OCT
- Our AI technique
 - Use of deep learning automated analysis in breast cancer OCT imaging

Regulatory: Device

- Device Classification: Class II (with special controls)
 - Identified risks:
 - Inaccurate or missing results leading to, for example, incorrect diagnosis
- Regulatory Pathway – 510(k)
 - Predicate: Pathology whole slide scanner – has similar risks and mitigation measures, also attempts to automate a human task
 - Special Controls: Data from clinical study to show device has greater than or equal performance to a physician's assistant gross examination
 - Keys: Detailed information demonstrating the performance characteristics of device - ex. intra-system and inter-system precision

The Team



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