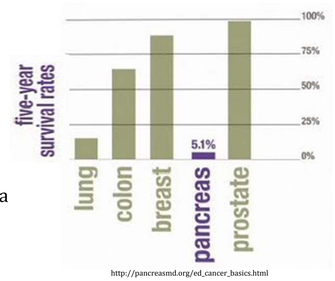
Endoscopic Ultrasound-Guided Fine Needle Aspiration: Improving Diagnosis

Allison Coté, Roland Liu, Gabriela Pérez Villalobos, Jessica Rucker, Jennifer Simonovich, Sam Sun
Faculty Advisor: Alisha Sarang-Sieminski
Boston Scientific Liaison: Shawn Ryan

Cancers of the GI Tract

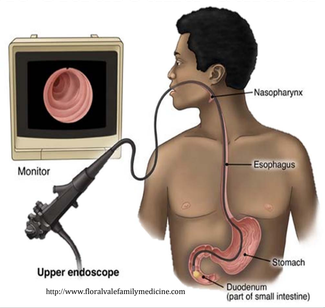
- Though cancers along the gastrointestinal (GI) tract account for 25% of cancer-related deaths annually, they remain difficult to diagnose and have a very low five-year survival rate. [1]
- This is especially true for pancreatic cancer, which has a 5% five-year survival rate. [2]



http://pancreasmd.org/ed_cancer_basics.html

Endoscopic Ultrasound-Guided Fine Needle Aspiration

- Used for diagnosing cancer along the GI tract
- Minimally invasive and faster recovery time [3]
- Low associated risk: < 2% complication rate [3]



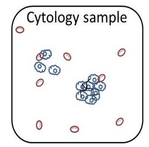
http://www.floralvalefamilymedicine.com

EUS-FNA Procedure:

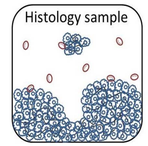
1. Thread endoscope down the throat
2. Use camera on endoscope to identify region of interest
3. View biopsy site in ultrasound image
4. Thread needle through endoscope
5. Insert needle into biopsy site
6. Collect sample
7. Expel and analyze sample

View EUS-FNA procedure, as performed by Dr. Shyam Varadarajulu, University of Alabama at Birmingham here

Types of Samples



Cytology: Cell-based sample acquired through vacuum aspiration. Represent 85% of all current EUS-FNA procedures.



Histology: Tissue-based sample acquired through biopsy core. Represent 15% of all current EUS-FNA procedures. Used for stiff tumor tissues that does not give aspirate sample.

Project Motivation

In March 2011, Boston Scientific released their first EUS-FNA needle. There are currently two Boston Scientific needles on the market. With successes in the aspirate needle aspect of the market, Boston Scientific would like to introduce a core needle. To this end, the Olin SCOPE team has been asked to address three aspects of the project.

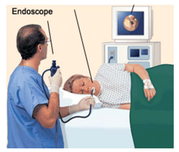
Project Goals

1. Identify important EUS-FNA needle parameters
2. Determine appropriate tissue substitute
3. Assess Boston Scientific EUS-FNA needles

Identifying Important Needle Parameters

In order to develop a shared understanding of what a good sample is and what the issues with current sampling techniques are, we interviewed the main physicians who perform EUS-FNA.

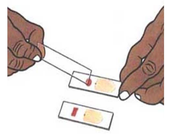
Endosonographers



- Perform the EUS procedure and acquire EUS-FNA samples
- Control the endoscope and visualize biopsy site

"What [the endosonographers]want to get at is a product that eliminates operator variability, maximizes yield, is safe, and is easy to interpret."
- Endosonographer, Massachusetts General Hospital, Boston, MA

Pathologists



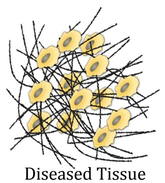
- Use bodily tissues to diagnosis disease
- Analyze EUS-FNA sample through imaging and tissue staining

"We don't touch the needle or the endoscope – [the endosonographers] will put a drop of specimen on one or two of our slides."
- Cytopathologist, Brigham Woman's Hospital, Boston, MA

Based on user interviews, we determined that sample consistency, average sample size, removal feasibility, and needle tip strength were the four most important parameters for a successful EUS-FNA needle.

Determining Appropriate Tissue Substitute

Healthy Tissue



Diseased Tissue

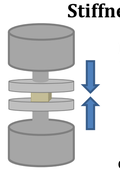
In healthy tissue, cells are suspended in a three-dimensional extracellular matrix. In diseased tissue, the extracellular matrix increases in fiber concentration, resulting in a stiffer, more fibrous tissue.

An ideal tissue substitute would mimic diseased tissue and provide similar results to clinical tests. The team investigated several different potential tissue substitutes:

1. Excised organs
2. Polyurethanes
3. Hydrogels
4. Synthetic Polymers A and B

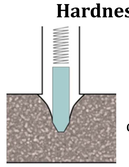
And assessed potential tissue substitute on four parameters.

Stiffness



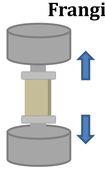
Determined by the ratio stress to strain during elastic deformation

Hardness



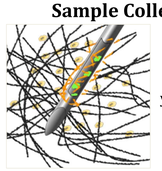
Measure of local material deformation

Frangibility



How easily a material gives up a sample once punctured

Sample Collection



Whether a material yields a core or aspirate sample

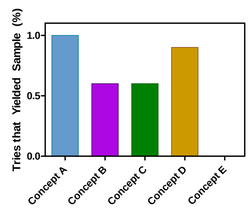
Conclusion: Based on performance in these tests, we recommend to Boston Scientific that they use **Synthetic Polymer B** as a tissue substitute for needle testing. .

Assessing Boston Scientific EUS-FNA Needles

Boston Scientific developed five new core needle designs and asked the Olin College SCOPE team to assess them at the pre-technology stage.

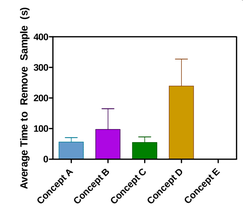
Sample Consistency

Purpose: To determine if needles consistently provide samples



Removal Feasibility

Purpose: To determine the ease of removal for each needle design



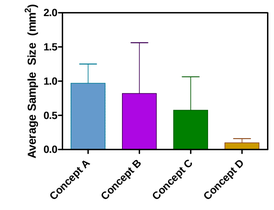
Degree of Importance

	Sample Consistency	Average Sample Size	Removal Feasibility	Needle Tip Strength
Design A	+ +	+	+ +	-
Design B	-	+	+	+
Design C	-	+	+ +	-
Design D	++	-	- -	+ +
Design E	- -	N/A	N/A	+ +

Conclusion: Based on this analysis, we recommend that Boston Scientific move forward with **Design A**

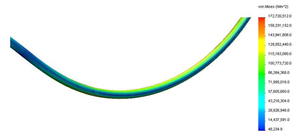
Average Sample Size

Purpose: To determine the average size of core sample acquired by



Needle Tip Strength

Purpose: To identify any mechanical weaknesses in each needle design



References

1. National Home Office: American Cancer Society. "Cancer Facts & Figures 2010" Atlanta, 2010.
2. Minna, JD; Schiller JH (2008). *Harrison's Principles of Internal Medicine (17th ed.)*. McGraw-Hill. pp. 551–562.
3. Ho CK, Kleeff J, Friess H, Buchler MW. "Complications of pancreatic surgery." HPB. 2005.
4. "The Pancreas Center." *Columbia University Department of Surgery.* http://pancreasmd.org/ed_cancer_basics.html.
5. "Upper GI Endoscopy." *Floral Vale Family Medicine.* http://www.floralvalefamilymedicine.com.

Acknowledgements

A big thank you goes to our liaison, Shawn Ryan, for his endless effort helping the team understand the project, collaborating with us every week to guide our testing and decision process, and introducing us to other members of the Boston Scientific team. Thank you to Farah Khan and Andrew Whitney for continued technical and research support, providing us with literature and testing materials, and guiding us through Boston Scientific's campus. Thank you to Cole Lafferty for explaining and supplying us with data pertaining to the marketing side of developing needles. Thank you to John Hutchins for project support. Thank you to the DePuy Mitek SCOPE team, Alex Morrow, and Rakesh Pandey for their continual feedback on our technical and project process.