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]

Endoscopic Ultrasound-Guided Fine Needle Aspiration: Improving Diagnosis

Endoscopic Ultrasound-Guided Fine Needle Aspiration

- **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

Types of Samples

- **Cytology:** Cell-based sample acquired through vacuum aspiration. Represents 85% of all current EUS-FNA procedures.
- **Histology:** Tissue-based sample acquired through biopsy core. Represents 15% of all current EUS-FNA procedures. Used for stiff tumor tissues that do not give aspirate sample.

Cancers of the GI Tract

- Endoscopic ultrasound-guided fine needle aspiration

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 areas of the project.

Identifying Important Needles 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.

**Endoscopographers**
- Perform the EUS procedure and acquire EUS-FNA samples
- Control the endoscope and visualize biopsy site
- "What the endoscopographer wants to get at is a product that eliminates operator variability, maximizes yield, is safe, and is easy to use." - Endoscopographer, 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 – it’s endoscopographer who puts a drop of specimen on one or two of our slides." - Cytopathologist, Brigham Women’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

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.

**Degree of Importance**

1. EUS-FNA Sample Size
2. Feasibility
3. Needle Tip Strength
4. Consistency

**Average Sample Size**

1. EUS-FNA Procedure
2. Feasibility
3. Needle Tip Strength

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

**Degree of Importance**

1. Average Sample Size
2. Removal Feasibility
3. Needle Tip Strength

**Average Sample Size**

1. Sample Consistency
2. Average Sample Size
3. Removal Feasibility
4. Needle Tip Strength

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

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

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