Designing Tools for Greater Confidence in Lung Biopsy

Background: Lung Cancer Biopsy Procedures

Problem Statement

The Boston Scientific SCOPE Team researched bronchoscopy tools and procedures and worked with physicians to develop areas of opportunity for Boston Scientific's pulmonary development team. Boston Scientific asked the team to investigate the problem space of **pulmonary lesion identification and diagnosis** and develop a solution space.

- Lung cancer accounts for 14% of cancer diagnoses and 28% of cancer deaths[1]

- **Early detection increases 5-year survival rate to 52%, but only 15% of lung cancer cases are detected at an early stage**[1] [2]

- New screening techniques **detect lung cancer at an earlier stage**, potentially increasing survival rates

- Even with new screening techniques, **current tool designs are insufficient for accurate diagnosis**
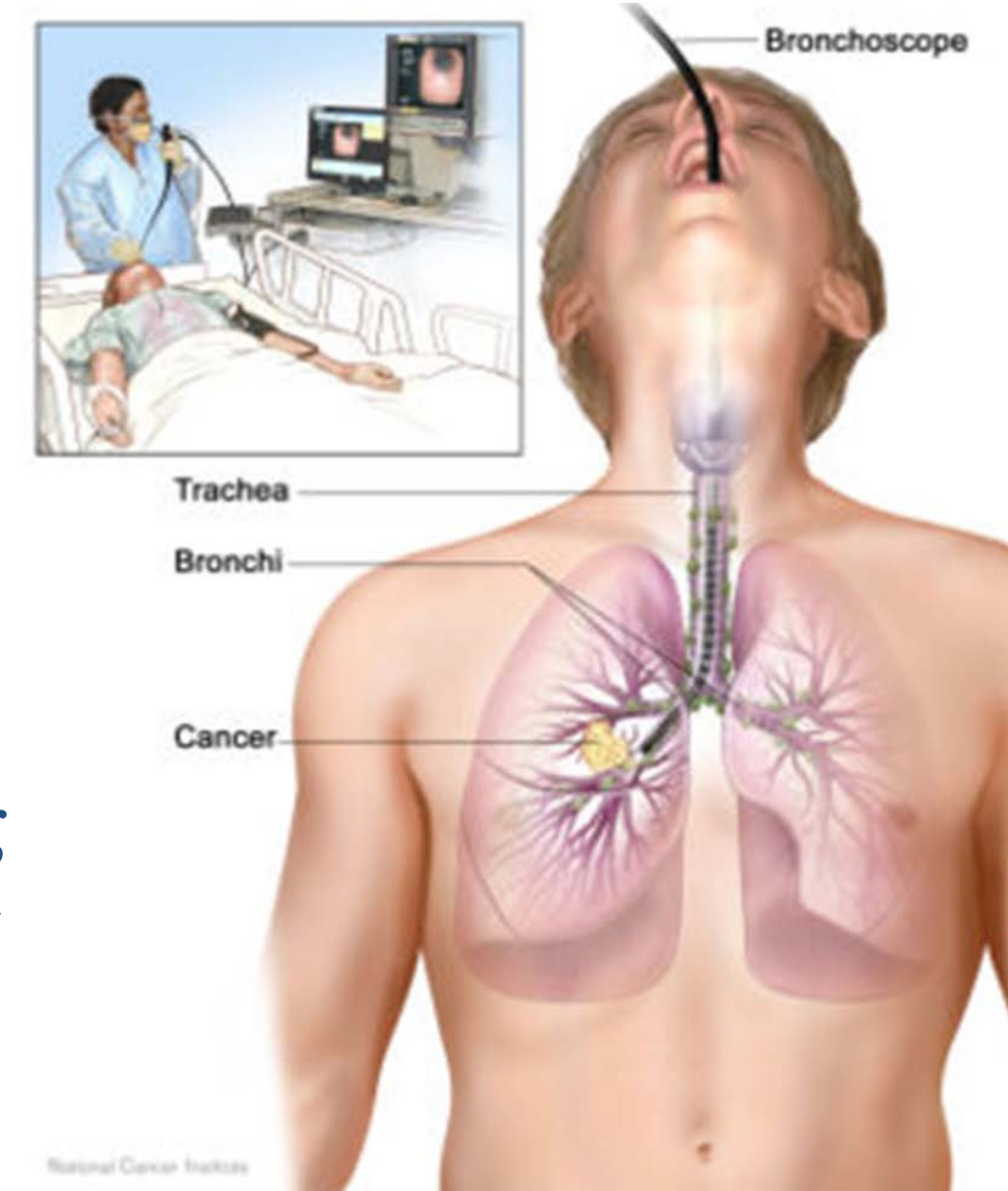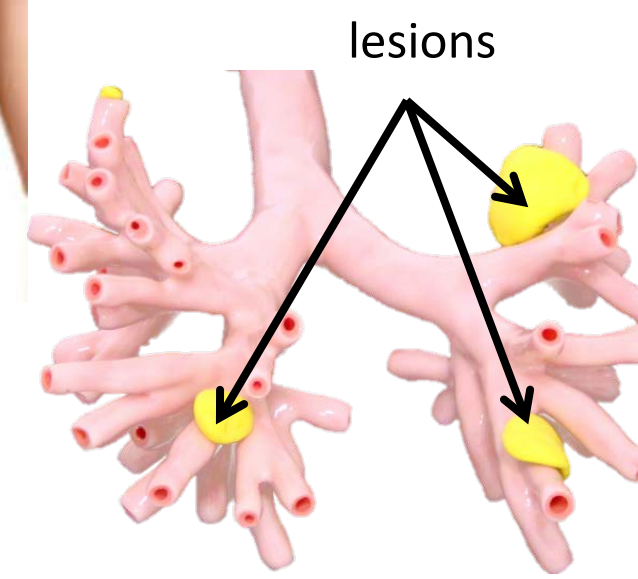
Figure 2: Image of bronchoscopy procedure[3]

lesions

Pre-Bronchoscopy: Patients at risk are screened for suspicious lesions (dense tissue), which **may be cancer, benign, or an infection.**
Bronchoscopy: A bronchoscope is fed manually down the patient's throat. Navigational technologies help locate lesions:
- Video feed on bronchoscope
- Fluoroscopy
- Endobronchial Ultrasound

Multiple samples are taken using forceps, needles, or brushes.
Post-Bronchoscopy: A cytologist confirms if the sample is cancerous.

Physician Concerns
- Tool manipulation in bronchioles
- Obscured bronchoscope vision from bodily fluids
- Excessive sampling due to uncertainty of sampling accuracy
- Inadequate sampling volume

Giving Physicians Confidence That They Are Sampling the Correct Tissue

Areas of opportunity in instrument design for greater physician confidence:
- precision in manipulation
- higher volume sampling
- **higher accuracy in tissue recognition - Boston Scientific's suggested focus**

Figure 3: Biopsy tool accidentally sampling from lung tissue instead of lesion (yellow).

The team researched 5 tissue properties that could be measured and came up with 5 requirements to ensure successful tissue differentiation. The team selected the tissue property that best met the requirements to distinguish between healthy and lesion tissue.

Criteria [Weighting: 0.0-1.0]:	A	B	C	D	E
In body confirmation [1.0]	4	4	4	4	4.5
Clear distinction in healthy and lesion tissue values [1.0]	5	3.5	3	4	4
Integration with existing biopsy tool [0.8]	5	4	4	3	3.5
No false positives from other tissue and fluids [0.6]	4.5	3	2.5	4	4
Confirmation before sampling [0.5]	4.5	3	4	4	2
Weighted totals:	17.95	14.00	13.70	14.80	14.70

Tissue Property:

Tool Design
The SCOPE Team presented one tool design with a probe measuring property A to Boston Scientific with preliminary validation tests, full system models, and comments on market research, patentability, manufacturability, and scaling.

References:
[1] American Cancer Society, "Cancer Facts and Figures 2012," 2012. [Online]. Available: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-031941.pdf. [Accessed Apr 2013].
[2] American Lung Association, "Lung Cancer Fact Sheet," 2013. [Online] Available: http://www.lung.org/lung-disease /lung-cancer/resources/facts-figures/lung-cancer-fact-sheet.html#1. [Accessed May 2013].
[3] Bronchoscopy.com, "About bronchoscopy". [Online]. Available: http://www.bronchoscopy.com/. [Accessed Apr 2013].