

Real-time, intraoperative detection of residual breast cancer in lumpectomy cavity margins using the LUM Imaging System: Results of a feasibility study

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BACKGROUND

- Tumor-free margins are critical for local control in breast conserving surgery
- 20-40% of lumpectomy patients have positive margins that require surgical re-excision
- Tools are needed to identify residual cancer in the tumor cavity intraoperatively
- We assessed LUM015 (protease-activated dye) and the LUM2.6 Imaging System for intraoperative detection of residual tumor in the tumor cavity of breast cancer patients

METHODS

- Breast cancer lumpectomy patients were injected with 1.0 mg/kg LUM015 4±2 hours prior to surgery
- Standard lumpectomy was performed
- All lumpectomy cavity surfaces were imaged with the hand-held probe
- Areas of high-fluorescence were detected, analyzed and excised. Lumicell images and standard histopathology were compared (Figure 3)
- 2.6 cm diameter image acquisition, analysis and display required only ~1 second

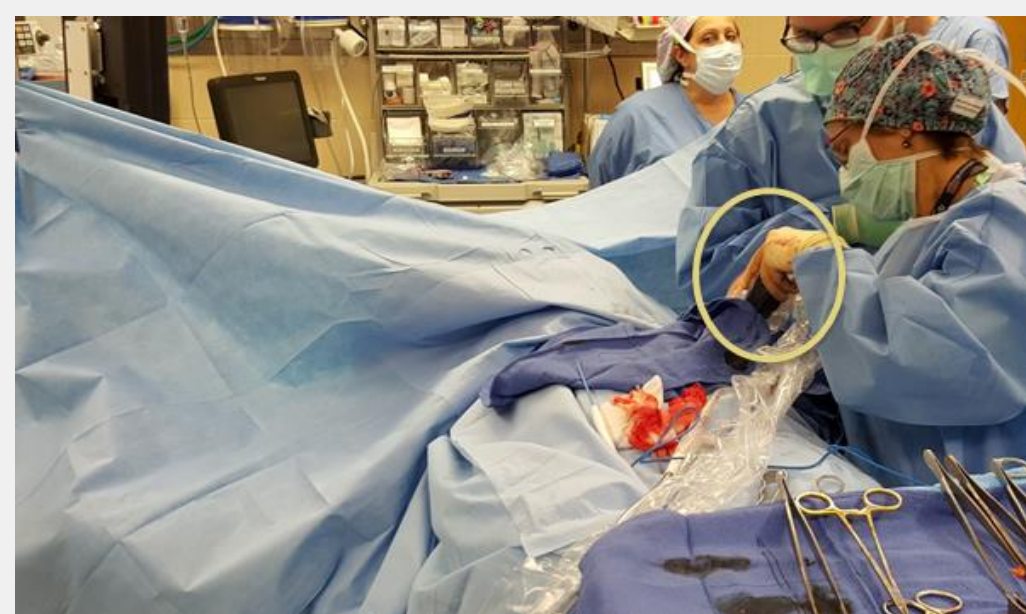


Figure 1: LUM Imaging System in use

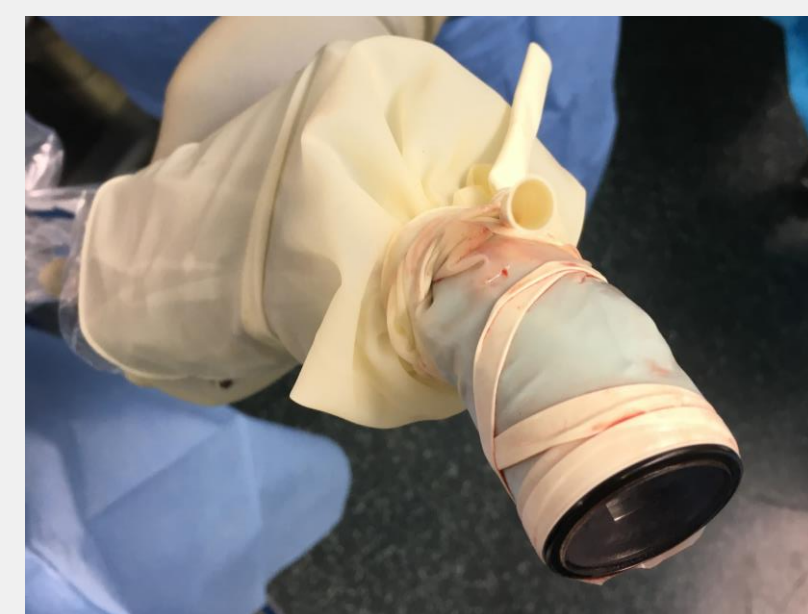


Figure 2: LUM optical head with sterile barrier

RESULTS

- Invasive ductal, invasive lobular, and ductal carcinoma in situ lesions were visualized
- Tumors were visualized in pre- and post-menopausal women
- 569 cavity margin surface images were evaluated
 - 100% sensitivity
 - 73% specificity
- Signal was observed in some benign tissue (~15%) including:
 - Macrophages associated with healing biopsy sites
 - Fibrocystic changes with usual ductal hyperplasia and cysts
- 8 of 45 patients had positive margins by standard histopathology, corresponding LUM intraoperative readings are shown in Table 2
- 1 adverse event: extravasation of LUM015 during IV injection
 - Blue staining of the forearm that resolved in ~3 months

CONCLUSIONS

- No positive margins containing invasive cancer or DCIS were missed by the LUM Imaging System**
- Taking Lumicell guided margins prevented re-excision surgeries
- A multi-center Phase III/Pivotal clinical trial of this approach is funded and will start shortly

ACKNOWLEDGEMENTS

- Toxicology studies and clinical production of LUM015 was federally funded from the NCI and NIH, under NCI's Experimental Therapeutics Program (www.next.cancer.gov)
- This study was supported by NCI grant 1R21CA173762-01 – PI Barbara L. Smith, MD, PhD
- Lumicell provided training for the LUM System and conducted the imaging data analysis
- We gratefully acknowledge nursing support provided by the MGH Translational Clinical Research Center.

Table 1

Patient Demographics (n=45)	
Median age (years)	60 (44-79)
Invasive carcinoma	79%
Ductal Carcinoma in situ (DCIS) only	21%
Mean tumor size (cm)	1.2 (0.06-3.5)

Figure 3: LUM Imaging compared to Standard Histopathology

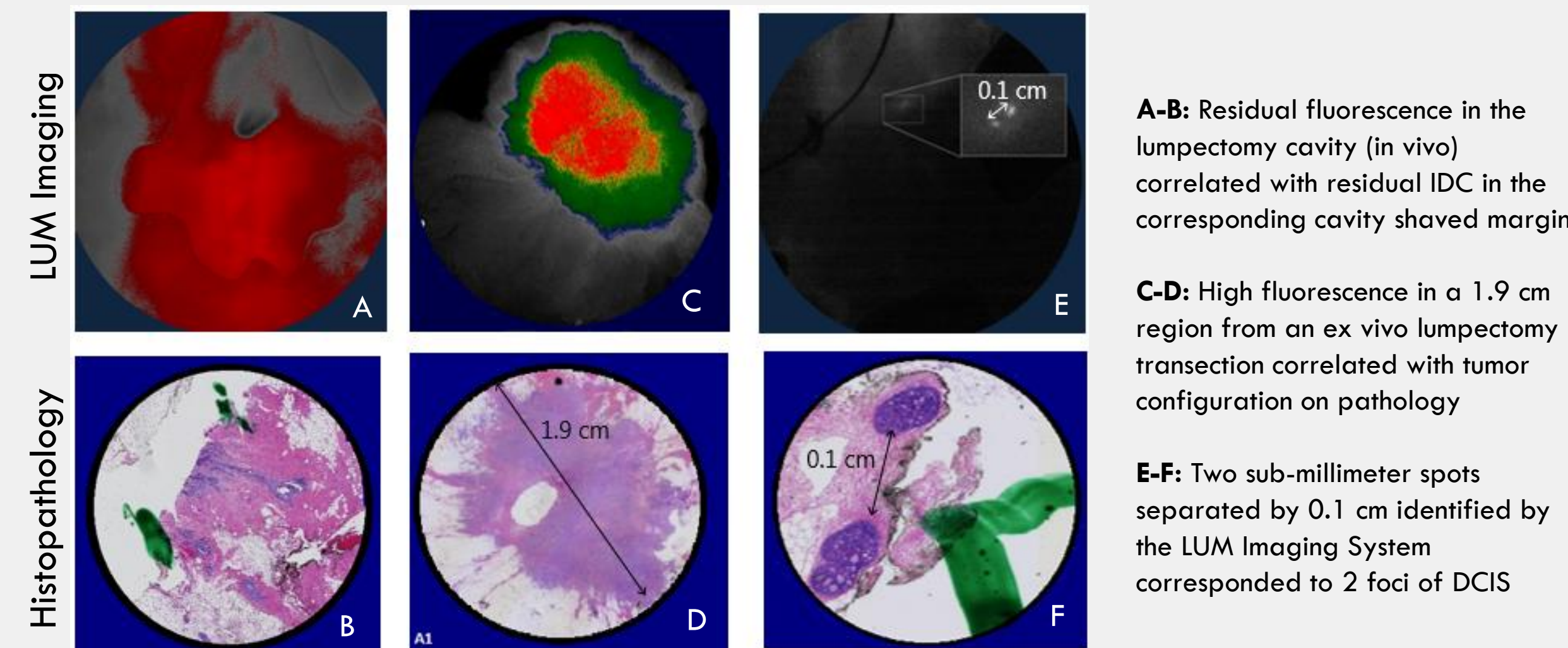


Table 2

Positive margin histopathology reading	LUM Imaging result of cavity beyond margin	Action taken	Tumor found in resected tissue	Result
DCIS <2mm from ink	+	LUM guided shave	+	A
DCIS <2mm from ink	+	LUM guided shave	-	A
DCIS <2mm from ink	+	Re-excision	+	B
IDC on ink	+	Re-excision	+	B
ILC on ink	+	Re-excision	+	B
DCIS <2mm from ink	+	Re-excision	-	B
IDC on ink	-	Re-excision	-	C
DCIS <2mm from ink	-	Re-excision	-	C

RESULT - A: Re-excision prevented – B: Surgeon declined to take additional Lumicell guided margin – C: No tumor found in second surgery, LUM Imaging System predicted negative margin