Obtaining tumor free specimen margins is critical for most breast surgical oncology procedures. Frozen sections are slow and not feasible for many procedures. Tools are needed for accurate, real time identification of residual tumor during cancer surgery. We assessed the LUM Imaging System, a cathepsin-activatable fluorescent dye, LUM015 for distinguishing tumor from normal tissue in a variety of tumor types.

**Methods**

I. **Breast**: (Figure 2)
- The LUM Imaging System can distinguish tumor from normal tissue in a wide variety of breast specimens.
- The LUM Imaging System correctly predicted residual tumor in 8 of 8 patients with positive surgical margins.
- Toxicology studies and clinical production of LUM015 was federally funded from the NCI and NIH, under NCI’s Experimental New Drug (IND).
- Specimen were imaged ex vivo; areas of high signal were compared with standard histopathology.
- In vivo and ex vivo areas of fluorescent signal were compared with standard histopathology.
- Gi Feasibility Study performed at the Massachusetts General Hospital (MGH)
  - Injection with LUM015 at 1.0 mg/kg 42 hours prior to surgery
  - Breast lumpectomy cavity walls were imaged in vivo and breast specimens examined ex vivo
  - In vivo areas of high signal were identified and excised
  - In vivo and ex vivo areas of fluorescent signal were compared with standard histopathology
- III. **GI Feasibility Study** performed at MGH
  - Injection with LUM015 at 0.5, 1.0, and 1.5 mg/kg 42 hours prior to resection
  - Esophageal, colorectal, and cervical cancers were imaged with the LUM system ex vivo

**RESULTS**

I. **Breast Feasibility Study** performed at the Massachusetts General Hospital (MGH)
- Dose (0.5, 1.0, 1.5 mg/kg LUM015) and time point study
- Specimen were imaged ex vivo; areas of high signal were compared to standard histopathology
- Breast Feasibility Study performed at the Massachusetts General Hospital (MGH)
  - Injection with LUM015 at 1.0 mg/kg 42 hours prior to surgery
  - Breast lumpectomy cavity walls were imaged in vivo and breast specimens examined ex vivo
  - In vivo areas of high signal were identified and excised
  - In vivo and ex vivo areas of fluorescent signal were compared with standard histopathology
- II. **GI Feasibility Study** performed at MGH
  - Injection with LUM015 at 0.5, 1.0 and 1.5 mg/kg 42 hours prior to resection
  - Esophageal, colorectal, and cervical cancers were imaged with the LUM system ex vivo

**CONCLUSIONS**

The LUM Imaging System can distinguish tumor from normal tissue in a wide variety of carcinomas and sarcomas.

The 2.6 cm diameter field and image acquisition in 1 second allows rapid assessment of a large specimen or in vivo surgical bed.

Further clinical trials are underway to assess the ability of the LUM Imaging System to reduce positive margin rates in breast cancer lumpectomies compared with standard surgery (NCT03321929).

Additional studies are underway to assess the performance of the LUM Imaging System in a variety of GI tumor types (NCT02584244).

**REFERENCES**


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