Impact of pegulicianine fluorescence guided surgery (pFGS) on radiotherapy decisions and long-term outcomes in patients undergoing breast conserving surgery

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DECEMBER 9-12, 2025
HENRY B. GONZALEZ CONVENTION CENTER • SAN ANTONIO, TX
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Introduction

- Breast cancer often recurs near the original tumor; thus, complete removal during breast conserving surgery (BCS) is crucial. LumiSystem, whose components have been FDA-approved, allows real-time detection and excision of residual cancer, a procedure termed pegulicianine fluorescence guided surgery (pFGS).
- Two prospective clinical trials[1,2] have evaluated pFGS enrolled stage 0-3 breast cancer patients, where cavity margin specimens were taken at sites of pegulicianine fluorescence. pFGS guided the removal of residual cancer in 7.6% of patients[1].
- The proposed study hypothesizes that removal of residual cancer not identified during the initial BCS can reduce 5-year local recurrence rates and that pFGS-guided excisions will provide appropriate margin gains or remove residual disease, altering radiotherapy planning. **This data will assess the long-term benefits of pFGS in improving surgical outcomes and informing radiotherapy decisions.**



Figure 1: LumiSystem is the combination of two FDA approved products: LUMISIGHT™ (pegulicianine) and Lumicell™ Direct Visualization System (DVS)

Methods

Study Design: Prospectively-designed, retrospective, observational chart review. Follow-up analysis of up to **640 breast cancer patients** enrolled in the prior pFGS parent trials (**NCT03686215** and **NCT03321929**). This study targets to obtain follow up data from at least 490 eligible participants.

Co-Primary Objectives:

1) Evaluate the median 5-year local recurrence free survival rate in participants who received the pFGS intervention.

2) Evaluate the impact on radiotherapy treatments in participants who received the pFGS intervention.

Analysis: The median follow-up period will be calculated as the time from index lumpectomy to last healthcare provider encounter. The **5-year median local recurrence rates** and the 95% confidence interval (CI) will be calculated using **Kaplan-Meier methods** for time to event endpoints. A breast cancer radiation oncologist will determine the recommended radiotherapy treatment prior to pFGS use which will be compared to actual treatments received.

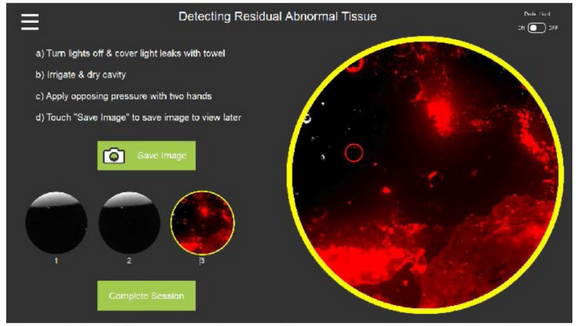


Figure 2: LumiSystem test image of lumpectomy cavity to identify suspicious tissue indicated by red signal

Study Design

Completed pFGS Trials

NCT03686215	NCT03321929
n=234	*n=406*

Retrospective Chart Review

Adjuvant therapy treatments and compliance | *Breast cancer recurrence information* | *5-year median follow-up*

Data Abstraction and Analysis Methods

Systematic retrospective chart reviews with rigorous quality control measures | *Centralized BC radiation oncologist and BC surgeon evaluation of study endpoint data*

Comparator Data

Peer-reviewed literature on similar breast cancer populations

Figure 4: Study Design Overview

Study Progress

This study aims to determine the impact of pegulicianine fluorescence-guided surgery in breast-conserving treatment by assessing the impact to radiotherapy treatment decisions and the long-term patient outcomes. By enabling precise intraoperative detection of residual disease, pFGS may reduce local recurrence rates and inform more personalized, evidence-based radiotherapy decisions. If confirmed, **these findings could support broader adoption of pFGS to optimize surgical and adjuvant care for patients with 0-3-stage breast cancer.**

Data collection is **90% complete** with **4%** of the population determined to be **lost to follow up** (LTF).

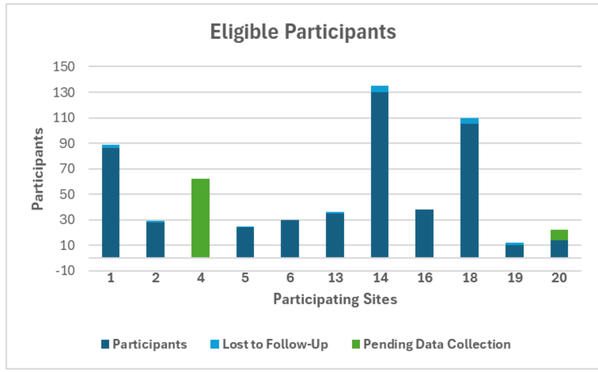


Figure 5: Study Progress Metrics

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1. Smith *NEJM Evid* 2023;2(7) DOI: 10.1056/EVIDoa2200333
2. Hwang JAMA Surg 2022;157:573-580

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Abstract Number: 510
Presentation Number: PS5-07-13

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