Multi-investigator Pilot Study of Post-Lumpectomy Radio-frequency Ablation for Margin Extension and Local Control in Mastectomy Model

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Background: Radio-frequency ablation (RfA) of post-lumpectomy surgical site has been used to extend the surgical margin and is a promising approach to reduce the need for re-operations and help provide local control without radiation therapy in many Breast Conservation Surgery (BCS) patients. The SIRA™ device (Innoblative Designs Inc., Chicago, IL) is a first-in-class Saline-coupled Intra-cavitary RfA device specifically designed to fit the post-lumpectomy breast cavity to deliver ancillary uniform ablation. In this study, we aimed to evaluate the SIRA device's ablation performance in breasts of patients undergoing prophylactic mastectomy (PM). The PM model allows for analysis of the device ablation in freshly excised *ex vivo* tissue to provide nearly identical electrical conductivity, thermal conductive, and mechanical stress-strain properties as *in vivo* breast tissue. The device settings (i.e., power and duration) were previously optimized within this same model by one surgeon to target a ~1cm ablation depth, where residual cancer cells are most likely to be located. The study was designed to evaluate the repeatability and uniformity of the optimized settings across different breast densities and multiple surgeons.

Methods: Immediately following PM, simulated lumpectomies 3-4cm in diameter were removed from the breast specimen. The SIRA device was then inserted and secured in place within the cavity by a suture. The ablation was then performed using the optimized ablation dose (80W for 22min) with simultaneous administration of saline. Following each ablation,18 representative tissue blocks were taken around each ablation cavity, the tissue was fixed, H&E slides were made, and the resulting ablation zones were analyzed histologically by a board-certified pathologist. Ablation depth was analyzed by surgeon, by margin, and also by breast density scores (BI-RADS) in two groups (Fatty / Scattered Fibroglandular vs. Heterogeneously / Extremely Dense). Fixation-induced shrinkage of each sample was measured and used to correct the final depth of ablation.

Results: In the 22 procedures performed, the average age was 47 years (range 25-69 years). Fifteen patients had Heterogeneous or Extremely Dense breasts and seven patients had Fatty or Scattered Fibroglandular breasts. A mean ablation depth across all margins of 1.0cm (SD = 0.2cm) was achieved with uniformity across each margin (Figure 1). No difference in ablation depths was observed between surgeons (p=0.76, 17 procedures performed by surgeon 1 and 5 procedures performed by surgeon 2). No correlation was seen between the ablation depth and BI-RADS score (p=0.68).

Conclusions: The results of this study support reliability of the SIRA device to create consistent and effective uniform ablations to targeted depth of 1cm around a lumpectomy cavity in fresh human breasts. This study specifically shows device ablation reliability across multiple surgeons with differing techniques. It also shows consistency in ablation depth across differing breast densities with limited settings. Ultimately, these data support the feasibility of the SIRA device to provide an additional zone of ablative treatment around the surgical site to assist in controlled margin extension and local control, which may reduce the need for reoperations and for adjunctive radiation in select BCS patients.

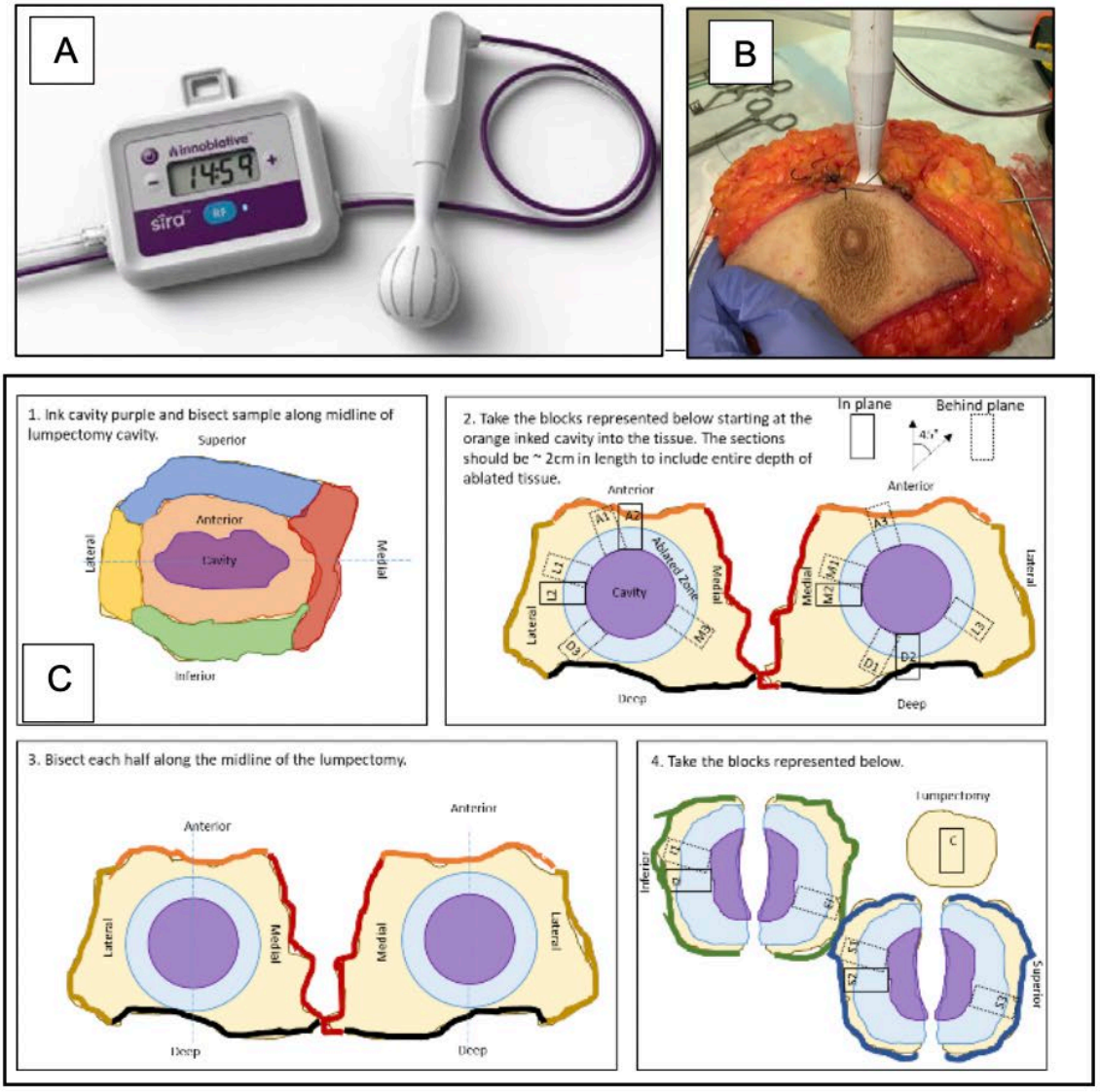

Figure 1. (A) SIRA RFA Electrosurgical Device, (B) device in place in PM, (C) histology sampling methodology, (D) histogram of mean ablation depth across all post-lumpectomy margins.