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

Tyler Wanke MD [1,2], Thomas Kurth [2], Alyssa Bailey [2], Bob Rioux [2], Luis Blanco MD [3], Kevin Bethke MD, Swati Kulkarni MD [4].
[1] Northwestern University Feinberg School of Medicine, Chicago, IL, [2] Innoblative Designs, Inc., Chicago, IL, [3] Northwestern University Feinberg School of Medicine, Department of Pathology, Chicago, IL, [4] Northwestern University Feinberg School of Medicine, Department of Surgery, Chicago, IL

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. (Fig. 1) 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.

Figure 1 – Innoblative SIRA™ Device

Methods

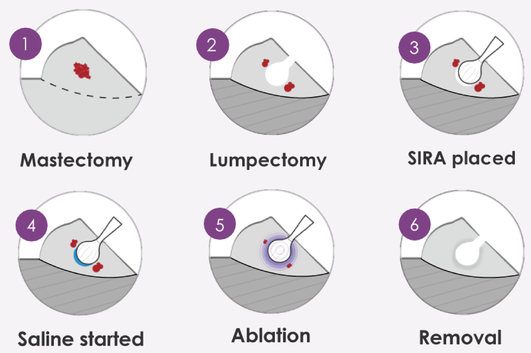
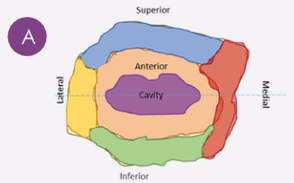
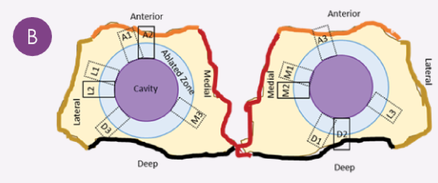


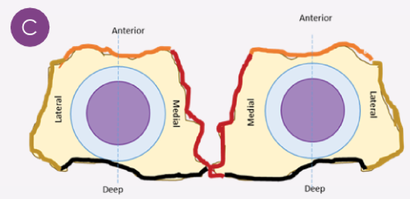
Figure 2 - Surgeon steps:
1. Prophylactic mastectomy performed by board certified surgeon
2. Lumpectomy created (3-4cm diameter)
3. SIRA placed in lumpectomy cavity and sutured in place
4. Saline drip started (30mL/hr) for irrigation, cooling, and coupling
5. Ablation (80 watts for 22 minutes)
6. SIRA removal



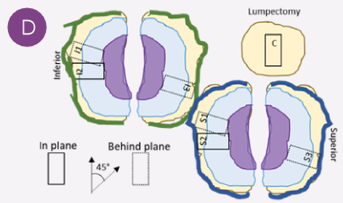
A) The 6 margins of the mastectomy specimen (anterior, deep, lateral, medial, superior, inferior) and cavity are inked



B) The specimen is bisected and tissue blocks (represented by rectangles above) are taken for histology; sections are ~ 2cm in length to include ablation zone



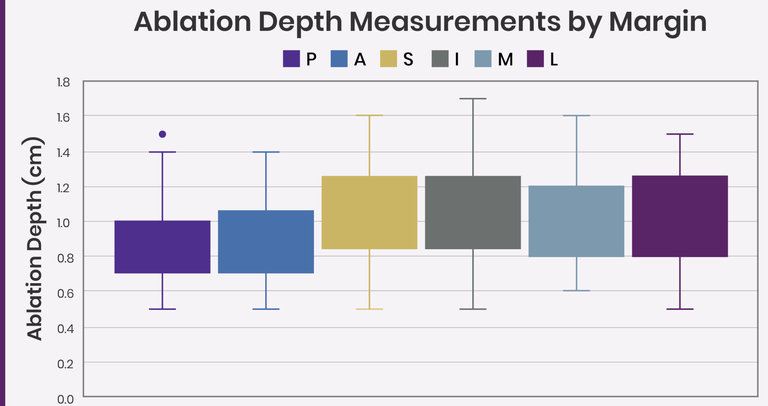
C) Bisect each specimen half along the midline



D) The tissue blocks above are further collected

Figure 3 - Histology preparations: 18 representative tissue blocks were taken around each ablation cavity (as in A-D above), H&E slides were made, and resulting ablation zones were analyzed histologically by a board-certified pathologist

Results



Ablation Depths Around Lumpectomy Cavity in Mastctomy Tissue (accounting for tissue shrinkage)
Posterior (P), Anterior (A), Superior (S), Inferior (I), Medial (M), and Lateral (L)

Figure 4 – Mean ablation depths by margin in 22 procedures with mean ablation depth across all margins of 1.0cm (SD = 0.2cm) with uniformity across each margin. No difference in ablation depth was observed between surgeons (p=0.76) or 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.

The SIRA device is investigational for use in BCS and is not yet available for sale in the United States.

innoblative

Northwestern University

THE AMERICAN SOCIETY OF BREAST SURGEONS
24TH ANNUAL MEETING
Boston, Massachusetts • • • April 26-30, 2023