SABCS
SAN ANTONIO BREAST CANCER SYMPOSIUM
December 8-11, 2020
Virtual Symposium
San Antonio, TX U.S.A.

A Novel Technology for Uniform Post-Lumpectomy Radio-frequency Ablation for Margin Extension and Local Control Tested in IRB-approved Pilot Mastectomy Study

Tyler R. Wanke[1,2], Thomas Kurth[2], Alyssa Bailey[2], Zach Rzeszutek[2], Luis Blanco Jr. MD[3], Kevin Bethke 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 breast cavities has been shown to extend the surgical margin to reduce the need for re-operations and to provide local control without radiation therapy in many Breast Conservation Surgery (BCS) patients. However, all studies to-date have had to use adapted RfA needle electrodes designed for inoperable solid liver/kidney tumor ablation as no devices had been specifically developed for breast lumpectomy application. 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 and deliver uniform post-lumpectomy cavity ablation for margin extension and local control. We aimed to evaluate the SIRA device's ablation performance in human breasts of patients undergoing prophylactic mastectomy. The device settings and ablation dose (i.e., power and duration) were previously optimized within this same model 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 multiple patients.

Methods: This study was approved by the Northwestern University IRB. Immediately following the prophylactic mastectomy, simulated lumpectomies 3-4cm in diameter were removed from the breast specimen by a surgeon. The SIRA device was then inserted and secured in place within the cavity with suture by the surgeon. Once secured, the ablation procedure was performed using the optimized modelled ablation dose (80W for 22min). Following each procedure, 18 representative tissue blocks were taken around each ablation cavity, H&E slides were made, and the resulting ablation zones were analyzed histologically by a board-certified pathologist, including the percent fat per slide.

Results: In the 10 procedures performed, a mean ablation depth across all margins of 8mm (SD = 1.3mm) was achieved. The standard deviation within each individual procedure ranges between 0.3mm and 2.8mm, indicating the ablation is relatively uniform around the cavity. 70% of the patients had calculated BIRADs scores of either Heterogeneously Dense or Extremely Dense.

Conclusions: The results of this study confirmed the feasibility of the SIRA device to create consistent and effective uniform ablations to targeted depth of ~1cm around a lumpectomy cavity in fresh human breasts undergoing mastectomy. The prophylactic mastectomy model allows for analysis of the SIRA in freshly excised *ex vivo* tissue to provide nearly identical electrical conductivity, thermal conductive, and mechanical stress-strain properties as *in vivo* breast tissue. Future studies will provide more statistical clarity on the effect of breast density on ablation depth. Most patients in the study had Heterogeneously Dense or Extremely Dense breasts, which was expected due to the nature of the younger patients receiving prophylactic mastectomy; however, the performance here was consistent across densities and supplemented with a parallel study in older, fattier breasts in a cadaveric model. Ultimately, these data show proof-of-concept for the SIRA device to provide margin extension and local control, which may ultimately reduce the need for reoperations and for adjunctive radiation in select BCS patients.