2016 San Antonio Breast Cancer Symposium

Publication Number: P1-10-19

Title: Two-year follow-up results of a multi-center trial of intra-operative electronic brachytherapy during breast conservation surgery for early stage breast cancer

Syed AMN, Chang H, Schwartzberg BS S, Bremmer AK K, Boylan S, Lopez-Penalver C, Vito CA A, Davis M, Dooley WC C, Chakravarthy AB B, Croomer C, Proulx GM M, Golder SL L, Ivanov O, Fernandez KL L, Farha M, Gonzalez V, Wengler C, Bhatnagar A, Neuner G, Kopkash K, Rahman S, Corn C, Costa P, Ellenhorn J and Cox C. Todd Cancer Institute / Long Beach Memorial Medical Center, Long Beach, CA; David Geffen School of Medicine at UCLA / Revlon/UCLA Breast Center, Los Angeles, CA; Sarah Cancer Research Institute/Rose Medical Center, Denver, CO; BREASTLINK, Murietta, CA; Sentara Northern Virginia, Woodbridge, VA; Doctors Hospital, Miami, FL; City of Hope National Medical Center, Duarte, CA; Swedish Medical Center, Englewood, CO; Oklahoma University, Oklahoma City, OK; Vanderbilt University, Nashville, TN; Staten Island University Hospital, Staten Island, NY; Exeter Hospital, Exeter, NH; Shannon Cannon Cancer Center at Parkridge Medical Center, Chattanooga, TN; Florida Hospital, Orlando, FL; MEDSTAR Health (Franklin Square), Baltimore, MD; MEDSTAR Health (Union Memorial), Baltimore, MD; University of Arizona, Tuscon, AZ; Martin Health System, Stuart, FL; Cancer Treatment Services, Casa Grande, AZ; Greater Baltimore Medical Center, Baltimore, MD; Rush University Medical Center, Chicago, IL; Diablo Vallen Oncology Hematology Medical Group, Pleasant Hill, CA; Phoenix Baptist Hospital, Phoenix, AZ; PORTO, Senhora Da Hora, Portugal; Tower Outpatient Surgery Center, Los Angeles, CA and University of South Florida, Tampa, FL.

Body: Objective
To assess the safety and efficacy of single-fraction, intra-operative radiation therapy (IORT) delivered with the Xoft® Axxent® Electronic Brachytherapy System® (eBx®) immediately following surgical resection for treatment of early stage breast cancer.
Methods
This phase 4, open-label, single-arm, prospective, non-randomized trial is still enrolling participants and is currently being conducted at 26 hospitals in the USA (25) and Portugal (1). 878 participants with biopsy-proven ductal carcinoma in situ (DCIS) or invasive ductal carcinoma who met the inclusion criteria underwent lumpectomy followed by single-fraction IORT to the lumpectomy cavity. Briefly, a small, presterilized lead shield piece was placed on the chest wall to reduce the dose to the ribs, and then a balloon applicator, suitable to the surgical bed, was placed in the lumpectomy cavity and inflated with saline (30-75 cc); skin was temporarily closed over the balloon and ultrasound was used to confirm a balloon surface-to-skin distance ≥ 1.0 cm. The Xoft System was used to deliver the 20 Gy dose at the balloon applicator surface. The balloon was deflated, lead shield and balloon removed and the surgical site sutured. The prespecified primary outcome of this 10-year follow-up study is recurrence of ipsilateral breast tumor at 5 years. Prespecified secondary outcomes include 10-year recurrence and cosmesis (Harvard Scale). Trial Registry: ClinicalTrials.gov; Identifier: NCT01644669.
Findings
Of the 878 participants treated, 877 participants received the prescribed 20 Gy dose with a mean radiation treatment time of 594.5 seconds, whereas one participant received 14 Gy due to a source failure. 569 participants have reached 18-month (333), 2-year (199), and 3-year (37) follow-up. The mean age at enrollment was 65 years (range 41-90). 219 participants had DCIS and 658 had invasive ductal carcinoma. The DCIS nuclear grade was high (N=79), intermediate (N=100), or low (N=40). Invasive cancers were Grade 1 (N=282), 2 (N=282), or 3 (N=94). 664 participants had T1 lesions, 56 had T2 lesions, and 3 were unknown. The mean tumor size was 12.33 ± 10.5 mm. Cosmesis was excellent to good in 90% of participants who reached 2-year follow-up. To date, 155 reported adverse events were Grade 2 or higher. The most frequent side effects were breast pain, seroma, induration, and erythema. There were nine deaths, none of which were breast cancer related, four ipsilateral breast recurrences, and three new contralateral breast cancers.
Conclusions
Early results from this multi-center trial demonstrate that IORT using the Xoft Axxent eBx System at the time of breast conservation surgery continues to be a promising treatment option for early stage breast cancer. The short course of radiation therapy for select patients has excellent to good cosmetic results and a low rate of high-grade adverse events and recurrences.
Funding
Funded by Xoft, Inc., a subsidiary of iCAD, Inc.

Acknowledgement
Medical writing support from Dr. Theresa E. Singleton, Singleton Science, LLC.