Initial Results of a Multi-center Trial Utilizing Xoft Axxent Electronic Brachytherapy to Deliver Intraoperative Radiation Therapy in the Treatment of Early-stage Breast Cancer

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**INTRODUCTION**

- Post-operative whole breast radiation therapy (WBRT) has been shown to decrease local cancer recurrence rates by 30%, as well as to improve overall survival compared to surgery alone. However, delivered over a period of 6 to 7 weeks, WBRT can become a burdensome undertaking due to required commitment of time and resources, thus necessitating many women to either elect mastectomy or omit post-operative radiation altogether.
- Accelerated partial breast irradiation (APBI) has emerged as a valid alternative to WBRT to overcome this burden. Taking it one step further, intraoperative radiation therapy (IORT) delivers radiation at the time of surgery, not only simplifying the treatment logistics, but also delivering radiation therapy before any remaining cancer cells have had a chance to multiply.
- Xoft Axxent (XB) is a form of balloon-based (APBI) that uses an electronic source to deliver kilovoltage radiation. The mobile nature of the XB controller as well as the limited shielding requirements make XB a logical modality to be utilized for IORT.
- We report the initial results of the first trial to utilize XB to deliver IORT in the treatment of early-stage breast cancer.

**METHODS**

- **Objective:** We report the initial results of the first trial to utilize XB to deliver IORT in the treatment of early-stage breast cancer.
- **Patients:** 12 patients ≥45 years of age with early-stage breast cancer, tumors ≤3 cm, tumors with infiltrating ductal or DCIS histology, and uninvolved lymph nodes by frozen section at the time of surgery. All patients had an ultrasound performed at the time of surgery to verify a minimum 1-cm of balloon-to-skin distance and evaluate the conformance of the balloon to the surrounding breast tissue.
- **Treatment:** A pliable lead shield was placed inside the lumpectomy cavity on top of the pectoralis muscle in order to protect the underlying muscle, rib, heart, and lung from irradiation. Pre-loaded radiation plans for balloon inflation sizes of 40cc, 50cc, 60cc, and 70 cc were utilized. The radiation prescription dose was 20 Gy delivered to the balloon surface (9-10 Gy at a depth of 1 cm).
- **Materials:** The XB system consists of the disposable X-ray source, the balloon applicator, and the controller unit.
- **Endpoints:** Successful delivery of the prescribed radiation dose and treatment-related adverse events.

**RESULTS**

- The mean time to deliver the radiation was 22 minutes (range 17 – 27 minutes).
- The total procedure time including lumpectomy, sentinel lymph node biopsy, balloon catheter placement, XB controller calibration, radiation treatment, and closing was a mean time of 1 hour and 42 minutes (range 1 hour 22 minutes – 2 hours 15 minutes).
- The mean balloon-to-skin distance by ultrasound for the 12 patients was 1.5 cm (range 1.0 cm – 1.9 cm).
- All margins of excision were negative on final pathology.

**Figure 1.** Retention-type sutures were used to buttress the overlying subcutaneous tissue and increase the balloon-to-skin distance and circumferential tissue apposition

**Figure 2.** Essential surgical staff remained in the OR during delivery of radiation

- **Cosmesis**
  - At a median follow-up of 15 months, overall cosmesis was rated as excellent in 10 of 12 patients and good in the remaining 2 patients.

- **Safety**
  - Three patients reported mild breast pain, 3 patients developed mild erythema of the skin, 1 patient developed Grade 2 fibrosis, and 2 patients developed Grade 1 fibrosis.
  - To date, there have been no incidences of infection, fat necrosis, desquamation, or rib fracture.
  - To date, no patient has developed a recurrence.

**CONCLUSION**

- IORT utilizing XB is feasible and can be accomplished in a total procedure time of approximately 2 hours.
- At short follow-up, XB IORT appears to be well tolerated.
- IORT utilizing XB is emerging as a novel, patient- and physician-friendly alternative to post-surgical WBRT and APBI in a selected group of patients with early-stage breast cancer.
- Further research on XB and other methods of IORT is needed to establish clinical efficacy and safety for patients with early-stage breast cancer.