Xoft® Axxent® Electronic Brachytherapy:

A New Method of Delivering Partial Breast Irradiation

by Adam Dickler, MD

In Brief
Xoft® Axxent® Electronic Brachytherapy is a novel method of balloon-based accelerated partial breast irradiation that uses an electronic X-ray source rather than a radioisotope. In an FDA post-market study, 10 institutions across the country evaluated the performance and safety of the Xoft device in the treatment of patients with resected, early-stage breast cancer. This technology has the potential to make accelerated partial breast irradiation more available to patients and to increase the number of settings where the treatment can be offered.

Standard breast conserving therapy consists of a lumpectomy followed by whole breast external beam radiation therapy (EBRT). Unfortunately, more than 40 percent of women who are eligible for breast conserving therapy are still undergoing a mastectomy.[1] Also, the number of women who are receiving breast conserving surgery without undergoing EBRT is steadily increasing.[2] The 6-7 week course of EBRT is considered to be the most significant barrier for many patients who may be candidates for breast conserving therapy.

Accelerated Partial Breast Irradiation

To overcome the barriers presented by EBRT, many centers have adopted accelerated partial breast irradiation (APBI). APBI involves the treatment of the lumpectomy bed plus a 1-2 cm margin of breast tissue. This treatment is in contrast to standard EBRT, which involves radiation treatment to the whole breast. The primary advantage of APBI is that the radiation dose can be delivered to the patient in one week or less. This treatment offers patients potentially improved quality of life and avoids many of the scheduling difficulties associated with EBRT.

The method of APBI with the longest reported follow-up is multi-catheter interstitial brachytherapy. This technique involves the placement of several rows of catheters around the lumpectomy cavity. This placement is accomplished with the help of image guidance, typically either ultrasound or CT scan. Radioactive sources are then inserted into the catheter needles to deliver treatment to the target volume. Several studies with over five years of follow-up show low rates of local recurrence with this APBI technique.[3,4]

Still, multi-catheter-based interstitial brachytherapy is not the ideal solution for all patients and treatment centers. The technique is complex and has a steep learning curve, and, as a result, is not offered at most medical centers. In addition, this technique is not a standard part of radiation oncology residency training. The catheter insertion can also be perceived as a painful procedure, which can lead to poor patient acceptance.

Balloon-based brachytherapy was developed to simplify the APBI procedure and make the procedure more accessible to patients. The MammoSite® catheter was the first balloon brachytherapy device to be developed for the treatment of breast cancer. The device is a double lumen catheter consisting of a port for inflating the balloon and a port for passage of the high-dose-rate (HDR) Iridium-192 radiation source. Treatment is delivered using an HDR afterloader unit in a specially shielded room to avoid exposure to the treating physician and staff. The prescription dose of 34 Gy is delivered in 10 fractions of 3.4 Gy per fraction, b.i.d. (twice a day) over 5 days.

Early reports with the MammoSite device have yielded low rates of complications and favorable cosmetic outcome.[5,6,7] More than 20,000 patients have been treated in both academic and community settings using the MammoSite catheter. In large part due to the early adoption and success of the MammoSite device, additional methods of balloon-based brachytherapy are now being explored.

Xoft Electronic Brachytherapy

A modified form of balloon-based brachytherapy, called Xoft Axxent Electronic Brachytherapy, received FDA clearance for the treatment of breast cancer in January 2006. This device uses a kilovoltage X-ray source designed to mimic the dose characteristics of the Iridium-192 brachytherapy source used in MammoSite treatments. This approach to APBI does not require a specifically shielded radiation vault or a HDR afterloader unit, both of which are needed for treatments with brachytherapy using Iridium-192. Consequently, a kilovoltage brachytherapy approach could lead to APBI being more accessible to many breast cancer patients, particularly those who do not live in close proximity to a radiation center with a HDR afterloader unit. In addition, since a shielded vault is not required for treatment, Xoft has the potential to increase the number of settings in which APBI can be performed.

The Xoft Axxent controller is a portable unit approximately the size of an ultrasound device (see Figure 1). It consists of a digital screen where the physician and physicist can input treatment data and monitor treatment progress. In addition, the unit contains an adjustable arm that provides the conduit for passage of the electronic source into the balloon catheter. The balloon catheters have three ports: a port for passage of the electronic source, a port for inflation of the balloon with saline, and a drainage port for suction of seroma fluid or air surrounding the lumpectomy cavity (see Figure 2). The wall of the balloon is covered in radiolucent material visible on a plain X-ray or CT scan. The X-ray source consists of a miniature X-ray tube that is inserted into the balloon catheter and delivers treatment to the patient (see

Figure 1

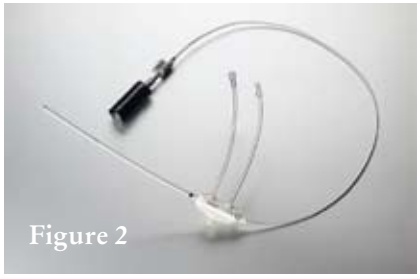
Figure 2

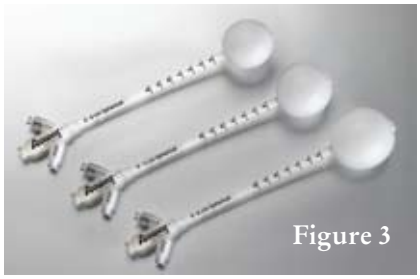
Figure 3

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Figure 3). The X-ray source generates low-energy, HDR radiation without the use of a radioactive isotope. Typical treatment is delivered in 8-12 minutes per fraction.

Dosimetric Analysis and Post-Market Study

In 2007 Dickler and colleagues performed a dosimetric analysis comparing MammoSite and Xoft balloon-based brachytherapy.[8] The authors of this study used the planning CT scans for 15 patients previously treated with the MammoSite device and developed hypothetical treatment plans using the Xoft source characteristics. Study authors found that MammoSite and Xoft offered similar target volume coverage; however, Xoft was associated with significantly increased normal tissue sparing. The mean ipsilateral lung %V30 (percent of the lung that received 30 percent of the prescription dose) was 3.7 percent vs. 1.1 percent, and the mean heart %V5 (percent of the heart that received 5 percent of the prescription dose) was 59.2 percent vs. 9.4 percent for the MammoSite and Xoft methods respectively.[8]

Enrollment was recently completed in an FDA post-market study at 10 institutions across the country to evaluate the performance and safety of the Xoft Axxent Electronic Brachytherapy device in the treatment of patients with resected, early-stage breast cancer. Five academic institutions and five community cancer centers participated in this 40-patient trial. Xoft Electronic Brachytherapy has now been launched for commercial use across the United States for the treatment of early-stage breast cancer.

Looking to the Future

Additional uses of Xoft Electronic Brachytherapy are now being explored. The company is currently awaiting FDA approval for the treatment of endometrial cancer with vaginal brachytherapy in the post-operative setting. As part of the initial research, Xoft vaginal brachytherapy was compared to standard Ir-192 based vaginal brachytherapy.[9] The study used the planning CT scans from 11 patients previously treated with Ir-192 vaginal brachytherapy and developed vaginal brachytherapy plans using the Xoft source characteristics. The dose coverage of the radiation target volume was equivalent between the two methods; however, as in the treatment of APBI, Xoft offered superior normal tissue sparing. The mean bladder %V35 (percent of the bladder that received 35 percent of the prescription dose) was 47.7 percent vs. 27.4 percent and the mean rectum %V35 (percent of the rectum that received 35 percent of the prescription dose) was 48.3 percent vs. 28.3 percent for the MammoSite and Xoft methods respectively.[9]

Plans to develop applications using Xoft Electronic Brachytherapy for the treatment of rectal cancer, prostate cancer, and other cancer sites are being developed.

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