

Stability of the Xoft Axxent® X-ray Source during Simulated APBI

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ABSTRACT

Purpose: To evaluate the x-ray output stability of the Xoft Axxent® Electronic Brachytherapy System while delivering fractionated doses to a phantom.

Materials and Methods: A balloon applicator was inflated in a 4.4 cm diameter spherical simulated lumpectomy cavity within an acrylic "breast" on a supine female full-body phantom. Radiation treatments for 5 "patients" were delivered in 10 fractions BID for 5 days using one x-ray source per patient. Per the usual procedure, the air kerma strength for each source was measured prior to each fraction with a calibrated well chamber; then dose delivery time was automatically adjusted to account for this source strength. During each fraction, exposure rate was monitored using a calibrated Victoreen Model 451B ion chamber survey meter positioned approximately 10 cm below the phantom. Readings were downloaded at 1 second intervals to a spreadsheet. These data were then analyzed for stability and reproducibility.

Results: Fifty fractions were delivered during the five days of simulated treatment. Average treatment time for each fraction was 11 minutes so each source had cumulative operating time of approximately 120 minutes including turn-on and calibration time. Exposure rate measurements increased with decreased source-to-meter distance and with less intervening absorbing material. Exposure rates ranged from 0.1 to 0.55 R/h. The standard deviations from average exposure rates varied from 0.5% to 2.9% with an average over 50 fractions of 0.9%.

Conclusions: The Axxent® Electronic Brachytherapy System performed well in five simulated APBI treatments. X-ray source output and system stability were demonstrated to be within 3% for all treatment fractions.

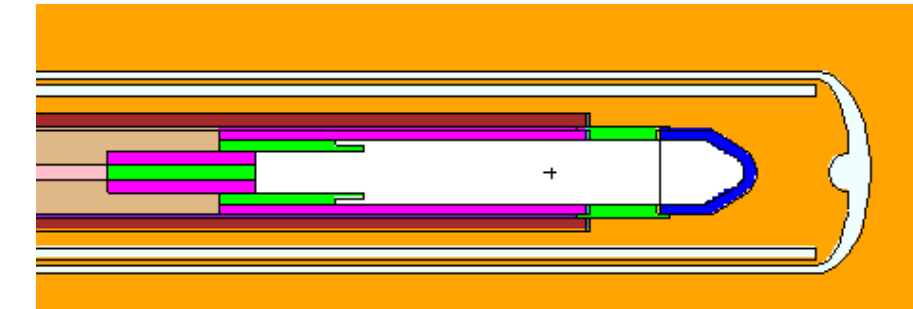
BACKGROUND

- Breast cancer is the most frequently diagnosed cancer in women, with an estimated 178,480 new cases expected in the U.S. during 2007. Breast cancer is the second leading cause of cancer deaths among women, with an estimated 40,460 deaths expected in 2007. [Ref: www.cancer.org]
- External beam radiotherapy following breast conserving therapy (BCT) lasts 6 to 7 weeks. While Accelerated Partial Breast Irradiation (APBI) using brachytherapy can significantly shorten this treatment time, it is labor intensive, requires a skilled operator, and can be uncomfortable for patients. In addition, many radiation treatment centers cannot afford to maintain active isotopes or to build the shielded treatment room for HDR brachytherapy.
- The Axxent® System, developed by Xoft, Inc., is an electronic high dose rate brachytherapy device designed to be less labor intensive, to shorten treatment time compared to external beam radiation and ultimately lessen patient discomfort. The Axxent® System does not require a heavily shielded environment, potentially bringing treatment centers closer to the patient's home. This technology also eliminates the handling and disposal of isotope sources.
- Xoft has received clearance from the U.S. Food & Drug Administration and is currently using the Axxent® Electronic Brachytherapy System for the treatment of patients with breast cancer.

METHODS

- This study was designed to evaluate the x-ray output stability of the Xoft Axxent® Electronic Brachytherapy System under simulated clinical conditions by administering accelerated partial breast irradiation (APBI) to a full-body phantom patient fabricated by The Phantom Laboratory.
- Five phantom patients were treated with two fractions per day for five days; two phantom patients were treated concurrently one week and three phantom patients were treated the following week.
- One x-ray source (Figure 1) was used per phantom patient; the phantom patient's "personal" source was attached to the controller prior to each fraction.
- A single 4.5 cm diameter spherical applicator was inflated to fill a 4.4 cm diameter spherical cavity machined into an acrylic breast phantom; the same applicator was used for all phantom patients.
- An artificially long treatment plan was prepared using Varian BrachyVision™ in order to obtain extended operating time on each source. For this balloon size, a typical treatment time would be approximately five minutes, however a nominal treatment time of ten minutes was selected in order to obtain a total source operating time of about 2 hours over the course of ten fractions. The x-ray source operating conditions were 50 kV and 300 μ A.
- Prior to radiation delivery, one or more Xoft FlexiShield™ flexible radiation shields were draped over the treated breast to attenuate radiation into the treatment room. A separate rolling shield was placed adjacent to the controller to allow the operator to remain in the room during treatment. With these shields in place, the exposure rate at the operator's position behind the rolling shield (a distance of 1.5 meters from the phantom patient) was 0.07 mR/hr.
- For an ex vivo measurement of stability of radiation during each fraction, the exposure rate was logged at 1 second intervals by a Victoreen 451B Ion Chamber Survey Meter placed 10 cm below the table supporting the phantom patient.
- This data was downloaded to an MS Excel spreadsheet for analysis of dose rate fluctuations and drift.

Figure 1. Xoft Axxent® model S700 Electronic Brachytherapy Source. The electrons originate from the hot cathode, and travel from left to right.



RESULTS

Overall Results

- All 5 treatment plans were delivered successfully with an overall standard deviation of 0.91%. The standard deviations for all fractions varied from 0.45% to 2.93% (Table 1).
- The source output for Patient E was about 3 times less stable than the others; however the mean standard deviation was only 1.77%.
- The overall standard deviation of 0.91% is consistent with an earlier evaluation, in which delivered dose reproducibility was estimated by leaving the x-ray source in a well chamber and then integrating the charge during each fraction. In that experiment, the cumulative charge collected for 90 seven-minute fractions (50 kV, 300 μ A) had a standard deviation of 0.74%.

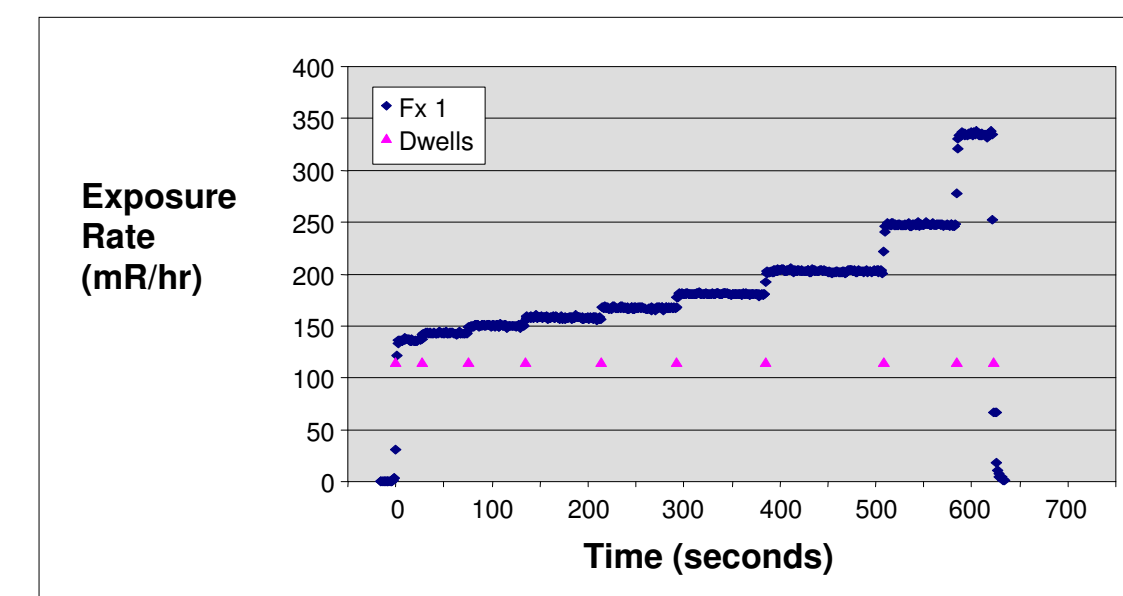
Table 1. Standard deviations for all fractions.

Fraction	Patient A	Patient B	Patient C	Patient D	Patient E
1	0.76%	0.66%	0.54%	0.58%	0.62%
2	0.84%	0.59%	1.14%	0.64%	1.34%
3	1.30%	0.55%	0.59%	0.62%	2.74%
4	1.05%	0.50%	0.53%	0.62%	1.78%
5	1.19%	0.47%	0.58%	0.58%	1.53%
6	1.05%	0.46%	0.52%	0.56%	1.91%
7	0.98%	0.45%	0.59%	0.55%	1.59%
8	1.10%	0.46%	0.49%	0.63%	2.93%
9	1.20%	0.46%	0.57%	0.60%	1.62%
10	1.31%	0.55%	0.55%	0.58%	1.63%
Average	1.08%	0.52%	0.61%	0.60%	1.77%

Exposure Rate

- Figure 2 shows an example of the exposure rate records for Patient D. The blue diamonds indicate the exposure rate readings as a function of time. Treatment started at 0 seconds and stopped after 623 seconds as expected from the treatment plan. The pink triangles indicate the beginning and ending times for each of the nine dwell positions in this plan.
- The exposure rate increased when the x-ray source moved to the next dwell position, as shown in Figure 2. This was expected due to the source moving obliquely toward the survey meter during pullback.
- The repeated coincidence of exposure rate change with dwell position change indicates that these changes were clearly a result of the planned movement rather than a result of source radiation output shifts.

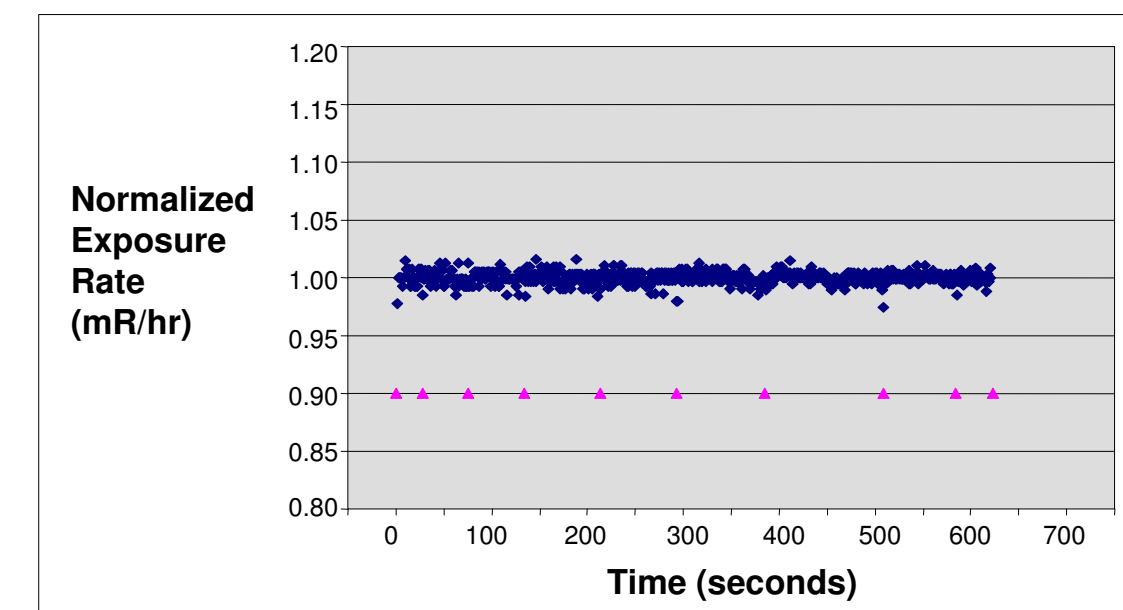
Figure 2. Exposure rate readings (blue line) during the delivery of fraction 1 to Patient D. Pink triangles denote the beginning and end of individual dwell intervals. Blue diamonds indicate the exposure rate readings as a function of time.



Source Stability

- To evaluate source stability, an average value of exposure rate was calculated for each of the nine dwell positions and then each reading was divided by the average for that dwell position.
- Figure 3 shows the results of this analysis on Patient D (data from Figure 2).
- The fluctuations were less than ± 0.02 about each average value with a standard deviation of 0.0056 over the entire 623 seconds of treatment.
- The standard deviation calculation did not include selected points at the transition between dwell positions if the reading clearly coincided with the transition time.
- Examples of these excluded points can be seen in Figure 2 at the transitions between dwell positions 6, 7, 8 and 9.

Figure 3. Exposure rate readings normalized to the average value for each dwell position of fraction 1 to Patient D. Pink triangles denote the beginning and end of individual dwell intervals. Blue diamonds indicate the exposure rate readings as a function of time.



SUMMARY

- This study demonstrated stable exposure rates from the Xoft Axxent® Electronic Brachytherapy System during 5 simulated accelerated partial breast irradiation treatment programs.
- Exposure rates measured near a full-body phantom patient represented indirect evidence of the instantaneous source dose rates, which varied by an average standard deviation of 0.91%.
- The stability of the delivered dose of the Axxent® System meets all requirements for use in the treatment of humans.

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