STABILITY OF THE XOFT AXXENT™ X-RAY SOURCE DURING IRRADIATION IN A GOAT MAMMARY MODEL FOR APBI

J. W. Rieke, MD [1], M. J. Rivard, PhD [2], S. Axelrod, PhD [3], R. R. Burnside, MS [3], E. W. Chell, PhD [3], S. D. Hansen, MS [3], T. W. Rusch, PhD [3] and D. L. Stewart [3]

[1] Puget Sound VAHCS, Seattle, WA; [2] Tufts-New England Medical Center, Boston, MA; [3] Xoft, Inc., Fremont, CA

ABSTRACT

Purpose: This study evaluated the x-ray output stability of the Xoft Axxent™ Electronic Brachytherapy System while delivering fractionated doses to a Nubian milk goat animal model.

Method and Materials: Eight balloon applicators were inserted percutaneously into simulated lumpectomy cavities created in the udders of four Nubian milk goats; active and control applicators were inserted in opposite udders. Two goats received spherical applicators and two goats received ellipsoidal applicators. These applicators were inflated to nominal diameters of 3.4 cm and 4.9 cm, respectively. Radiation treatment using 40 kV or 50 kV commenced three days after implantation. Prescription dose was 34 Gy to a point 1 cm from the applicator surface to be delivered in 10 fractions BID for 5 days as for conventional APBI. During the final three fractions for each animal, dose rate was monitored using a calibrated Victoreen 451B Ion Chamber Survey Meter positioned 40 cm from the treated udder surface.

Results: Ten fractions were successfully delivered to each goat within five days. X-ray source performance and dose delivery were stable both during treatments and between different fractions. A flexible radiation shield (which reduced radiation levels around the animals by at least 100x) was positioned to allow line-of-sight without shielding between the 451B meter and the treated udder. Radiation levels recorded at 1 second intervals during the treatments were analyzed for dose rate fluctuations and drift. The standard deviations from average dose rates varied by 1.2% for the shortest treatments (225 s) at 50 kV to 3.7% for the longest treatments (1450 s) at 40 kV with an average of 1.9% over all 12 fractions.

Conclusions: The Electronic Brachytherapy System performed as expected with respect to applicator integrity, controller hardware and software operation, x-ray source lifetime and stability, and flexible shield radiation attenuation. System stability was measured and demonstrated to be better than ± 5% for all treatment fractions.

Conflict of Interest: This study was funded by Xoft, Inc.

INTRODUCTION

- External beam radiotherapy following breast conserving therapy (BCT) lasts 6 to 7 weeks. Many women elect mastectomy or omit post-operative radiotherapy because they cannot commit the required time or resources.
- Accelerated Partial Breast Irradiation (APBI) using brachytherapy can significantly shorten treatment time but is labor intensive, requires a skilled operator, and can be uncomfortable for patients. Many radiation treatment centers cannot afford to maintain active isotopes or to build the shielded treatment room for HDR brachytherapy.
- Xoft has developed an electronic (non-isotopic) high dose rate brachytherapy device. The Xoft Axxent™ X-ray Source delivers tight, conformal doses of x-radiation to the inner surface of a body cavity such as an excised tumor bed.
- The initial application of the Xoft Axxent™ Electronic Brachytherapy System is to the conservative treatment of breast cancer utilizing balloon-based partial breast irradiation.

METHODS

- Purpose: This study evaluated the x-ray output stability of the Xoft Axxent™ Electronic Brachytherapy System while delivering fractionated doses to a Nubian milk goat animal model.
- Eight balloon applicators were inserted percutaneously into simulated lumpectomy cavities created in the udders of four Nubian milk goats; active and control applicators were inserted in opposite udders. Two goats received spherical applicators inflated to a nominal diameter of 3.4 cm (20-25 cm^3), and two goats received 5x7 cm^2 ellipsoidal applicators inflated to a nominal diameter of 4.9 cm (90-100 cm^3).
- Treatment planning was performed with BrachyVision™ software. Radiation treatment with the Xoft Axxent™ X-ray Source using 40 kV or 50 kV commenced three days after implantation. Prescription dose was set to 34 Gy to a point 1 cm from the applicator surface to be delivered in 10 fractions BID for 5 days as for conventional APBI.
- During the final three fractions for each of the four animals (12 fractions total), exposure rate was logged at 1 second intervals by a Victoreen 451B Ion Chamber Survey Meter located 40 cm from the treated udder. This data was downloaded to a MS Excel spreadsheet for analysis of dose rate fluctuations and drift.
- Prior to radiation delivery, one or more Xoft FlexiShield™ flexible radiation shields were draped over the goat's udders to attenuate radiation in directions where individuals would be observing the procedure. These shields reduced radiation levels around the animals by at least 100x. During fractions where source output monitoring occurred, the flexible radiation shield was draped so as to allow line-of-sight between the calibrated 451B meter and the applicator within the treated udder.

RESULTS

Ten fractions were successfully delivered to each goat within five days. An example of exposure rate readings for animal #4 is shown in Figure 1. The solid blue line indicates the exposure rate readings as a function of time. Treatment started at 0 seconds and stopped after 225 seconds as expected from the treatment plan for the 3.4 cm balloon size with the source operating at 50 kV. The triangles indicate the beginning and ending times for each of the seven dwell positions in this plan. As can be seen, the exposure rate dropped when the x-ray source moved 0.5 cm to the next dwell position. This was expected because the source was retracting obliquely away from the survey meter during pullback. The timing coincidence of radiation level change with dwell position change indicates that these changes are not a result of source dose rate shifts.

To evaluate source stability, an average value of exposure rate was calculated for each of the seven dwell positions; then each reading was divided by the average for that dwell position. The result of this analysis is shown in Figure 2 for the data from Figure 1. The fluctuations are less than ±0.02 during the first four dwell positions and increase to ±0.04 during the last three positions. This increase in fluctuation was a result of the signal level dropping and consequent reduction in signal-to-noise level. The standard deviation of the monitor signal was 1.2% over the total treatment time. Because the monitor signal in Figure 1 and the normalized signal in Figure 2 were constant during each dwell interval, we conclude that the source output did not drift in this clinical application.

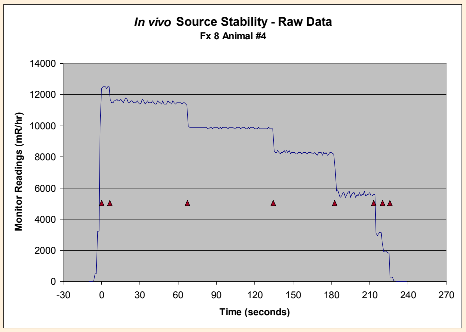

Figure 1. Exposure rate readings (blue line) during the delivery of fraction 8 to animal #4. Triangles denote the beginning and end of individual dwell times.

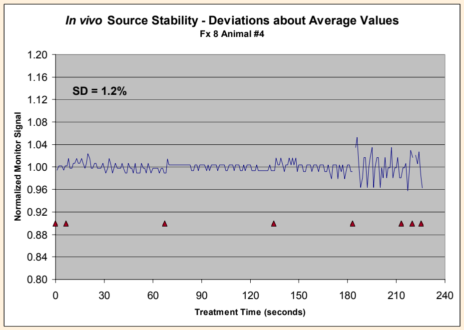

Figure 2. Exposure rate readings normalized to the average value for each dwell position.

Treatment Summary

The standard deviations for all measurements are shown in the table with applicator sizes, operating voltages and average treatment times for reference. The standard deviations from average monitor readings varied from 1.2% for the shortest treatments (225 s) at 50 kV in the 3-4 cm diameter spherical balloon to 3.7% for the longest treatments (1459 s) at 40 kV in the 5x7 cm^2 ellipsoidal balloon. Over all 12 treatment fractions, the standard deviation averaged 1.9%.

	Animal #1	Animal #2	Animal #3	Animal #4
Applicator Size	5x7 cm2	3-4 cm	5x7 cm2	3-4 cm
Operating Voltage	40 kV	40 kV	50 kV	50 kV
Treatment Time	1459 ± 10 s	622 ± 7 s	676 ± 22 s	225 ± 1 s
Standard Deviation of Monitor Signals				
Fraction 8	1.9%	2.4%	1.8%	1.2%
Fraction 9	1.3%	2.0%	1.6%	1.3%
Fraction 10	3.7%	2.4%	2.2%	1.5%

CONCLUSIONS

In summary, exposure rates were measured near four Nubian milk goats undergoing simulated APBI treatments using the Xoft Axxent™ X-ray Source. These measurements represented a direct indication of the instantaneous source dose rate stability. X-ray source performance and dose delivery were stable during treatments and between different fractions. The dose rate varied by an average standard deviation of 1.9%.

DEVICE DESCRIPTION

- The Xoft Axxent™ Electronic Brachytherapy System, consists of the X-ray Source, the Balloon Applicator and the Controller. The X-ray Source comprises an X-ray tube in a multi-lumen catheter that allows cooling fluid to circulate over the tube. The balloon applicator, a sterile, disposable, single use device, is designed for the water-cooled X-ray source and functions as its guide. The controller provides power to the X-ray Source as well as allows the X-ray Source, positioned within the Applicator, to be translated to provide a predictable dose of radiation in the tissue surrounding the balloon. It also provides a user interface with a control panel.
- The Xoft Axxent™ Electronic Brachytherapy System has been evaluated in a Nubian milk goat animal model. Results reported at the ABS 2005 Annual Meeting demonstrated that applicators could be implanted in this animal model without complications, ultrasound and fluoroscopic imaging modalities were effective, delivered doses were well within the goal of 34 Gy ±20%, and there were no adverse tissue effects or adverse events. The dose delivered (3.4 Gy per fraction, at 1 cm from the balloon surface) was confirmed during simulated treatment in a water phantom utilizing ion chamber dosimetry and radiochromic film.
- Two other posters, “Monte Carlo Modeling of the Xoft Axxent™ X-ray Source” and “Performance of Xoft FlexiShield™ Flexible X-ray Shielding in Laboratory Tests and in a Goat Mammary Model” are presented at AAPM 2005.
- The Xoft Axxent™ Electronic Brachytherapy System is for investigational use only. FDA clearance pending.

47th American Association of Physicists in Medicine's Annual Meeting, July 2005, Seattle, WA