VALIDATION MEASUREMENTS OF DOSE DELIVERED FROM A NOVEL ELECTRONIC BRACHYTHERAPY X-RAY SOURCE

Steve Axelrod, Ph.D., Earl E. Dozier and Thomas W. Rusch, Ph.D., Research & Development, Xoft, Inc., Fremont, CA

ABSTRACT

- Purpose: To measure the dose delivered by an electronic brachytherapy source during simulated treatment in a water phantom utilizing ion chamber dosimetry and radiochromic film.
- Materials and Methods: The Xoft Axxent™ Electronic Brachytherapy System uses a novel miniature x-ray source operating at 40, 45 or 50 kV_p to deliver High Dose Rate levels of radiation for electronic brachytherapy treatment of breast cancer. The source is inserted into a balloon applicator which is surgically placed within the breast. During treatment, the source is retracted under computer control through a series of steps to optimize conformity of the dose to the oncologists prescription, typically 3.4 Gray per fraction at 1cm from the balloon surface.
- Results: In this study, the clinical application was simulated using a water phantom. A PTW Model 34013 Soft X-ray Chamber provided readings of the dose delivered to the prescription point. Radiochromic film-based measurements using GAFCHROMIC EBT film were made in a plane parallel to the source axis to determine depth-dose and angular characteristics of the radiation dose delivered. The measurements included calibrating the film response in a liquid water phantom for the energies and doses of interest. Image analysis tools were developed allowing quantitative comparisons of the dose delivered to the dose predicted from a BrachyVision treatment planning system.
- Conclusion: The measurements presented evaluate the fidelity of the delivered dose to the prescription of 3.4 Gy per fraction, at 1 cm from the balloon surface, in a plane parallel to the source axis.

- This work was funded by Xoft, Inc. Financial Disclosure: All authors are employees of Xoft, Inc. Off-Label Disclosure: The Xoft Axxent™ system is currently under 510(k) review by the FDA.

INTRODUCTION

- Accelerated partial breast irradiation (APBI) using brachytherapy can significantly shorten the treatment time required by radiotherapy 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 high dose rate (HDR) brachytherapy.
- Xoft has developed an electronic (non-isotopic) HDR brachytherapy device that 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.
- *See poster by JW Rieke, ABS 2005 Annual Meeting, for Treatment Results with the Axxent™ system in a Goat Mammary Model.*
- *See oral presentation by MJ Rivard, ABS 2005 Annual Meeting, for TG-43 dosimetry parameters with the Axxent™ System.*

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 source in a multi-lumen catheter that allows cooling fluid to circulate over the tube. The X-ray tube is ~2.25mm in diameter x 15mm long and is attached to a high voltage cable and encapsulated within an electrical ground.
- The Disposable Balloon Applicator Kit contains one of five balloon sizes/shapes: three spherical and two ellipsoidal. The balloon applicator, a sterile, disposable, single use device, is designed for the water-cooled x-ray source and functions as its guide.
- The Axxent™ System Controller provides power to the X-ray Source as well as allows the X-ray Source, positioned within the Applicator, to be translated. The translation or pullback movement of the X-ray Source within the balloon is designed to provide a predictable dose of radiation in the tissue surrounding the balloon. It also provides a user interface with a control panel. It houses all safety and interlock circuitry and manages coolant pump activity.
- Disposable accessories for placement of the applicator as well as an optional radiation shield and system controller accessories are available.

The Xoft Axxent™ System is for investigational use only. FDA clearance pending.

METHODS

- Objective: To measure the absolute dose delivered and dose distribution from the Xoft Axxent™ electronic brachytherapy source during simulated treatment in a water phantom using ion chamber and radiochromic film dosimetry to validate the treatment plans run in a Nubian milk goat animal model.
- Four treatment plans were generated by BrachyVision software (Varian, v6.5) for 3-4 cm spherical (inflated to 34 mm) and 5 x 7 cm ellipsoidal (inflated to 48 and 50 mm) balloons and operating potentials of 40 and 50 kV_p. Each treatment plan involves stepping the source within the balloon applicator to deliver an optimally conformal dose to the prescription point. In all cases the prescription dose was 34 Gy at 1 cm from the balloon surface allowing variations of up to 0.17 Gy (5%), delivered in 10 fractions. Dose magnitude and distribution in a water phantom were measured for a single fraction for each plan.
- GAFChromic Type EBT radiochromic film was used to determine the dose spatial distribution. Film was exposed simultaneously with the PTW dosimeter readings. Five inch square sections of film were prepared with holes cut out in the shape of the appropriate balloon applicator. Film samples were located 5 mm off the central axis of the source, in a plane parallel to the source and applicator shaft. See Figures 2 and 3.
- Absolute dose measurements were made with a calibrated PTW 34013 dosimeter and PTW UniDos electrometer and read into a computer. The dosimeter was located at the prescription depth in the transverse plane (at 90 degrees) of the balloon. Instantaneous dose rate readings were integrated by the computer program over the treatment time period to obtain the total dose. See Figure 4.

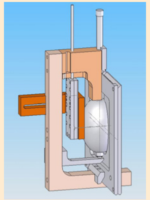

Figure 2. Schematic view of the experimental setup for dosimeter and film measurements. A balloon is shown surrounded by the film-holding frame. The source enters from above through the applicator shaft. The PTW dosimeter holder is at left with its cable exiting upward. The Solid Water™ fixture is immersed in a large water bath.

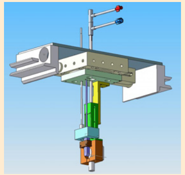

Figure 3. Schematic view of film calibration fixture. The x-ray source enters from above in the vertical cooling catheter. The upper structure holds a rotary stage and supports the fixture above a water tank. At the lower end are the film holder (orange), a water-proof dosimeter housing (purple), and a shutter for precise exposure time control (gray).

RESULTS

Dosimetry-Based Measurements

- Dosimeter measurements were performed at least once for each treatment plan. The dose delivered was averaged over runs with different sources. See Table 1. The final column, "Measured/Prescription" dose ratio, represents our best estimate of the dose delivery accuracy for each treatment plan.

Table 1. Dosimetry Data

X-ray Energy	Balloon Size / Shape	Prescription Dose	Measured Dose	Measured / Prescription
40 kVp	34 mm spherical	4.0 Gy	4.18 Gy	1.045 ± .08
40 kVp	50 x 70 mm elliptical	4.0 Gy	4.16 Gy	1.04 ± .05
50 kVp	34 mm spherical	3.4 Gy	3.04 Gy	0.89*
50 kVp	50 x 70 mm elliptical	3.4 Gy	3.45 Gy	1.015 ± .12

* The uncertainty shown is the standard deviation of two values except for only one run at 50 kVp

- Agreement of measured dose with target dose in individual measurements was within 11% or less, with an RMS difference of 8%. The most significant sources of uncertainty included position of the source anode in the balloon applicator, dosimeter-balloon surface distance and calibration factors (e.g., the dose rate constant Λ) for the x-ray sources. For the smaller (34 mm) balloon at the lowest energy (40 kV_p) the sensitivity to distance is approximately 12% per mm at the prescription point; with larger balloons at 50 kV_p it is 8% per mm at the prescription point. Therefore small inaccuracies in positioning the balloon applicator and dosimeter in the fixture will manifest as non-trivial sources of inaccuracy. We estimate our placement accuracy to be approximately 1 mm.
- The treatment planning system (TPS) sets nominal dwell times based on the nominal TG-43 parameters, and the controller adjusts these times based on the source strength as measured in a well chamber just prior to use. Dose rate constants were measured at 40 and 50 kV_p with several sources. Scatter in the readings was 6% (1 sigma of 4 measurements) at 40 kV_p, and 15% (3 measurements) at 50 kV_p. Given the limited statistics, a 5 to 10% uncertainty in Λ is reasonable for both voltage settings, which directly translated into a 5 to 10% uncertainty in the dose measurements reported here.
- Taking uncertainty in physical positioning in the fixture and that in Λ into account, the agreement between planned dose and measured dose is quite acceptable.

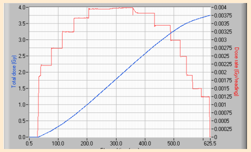

Figure 4. Display of instantaneous dose rate data (red) and integral of dose rate, hence, total dose (blue) for one treatment plan.

- The PTW dosimeter current was read into a computer during the treatment as shown in Figure 4. The red data series is the instantaneous dose rate (scale at right) in Gy per reading, which were 0.50 seconds apart. Time in seconds is plotted on the horizontal axis. As the source is stepped from distal to proximal ends of the applicator, the dose rate rises and falls at the dosimeter position as shown by the discrete steps in the data. The instantaneous rate is integrated over time to give the total dose (blue). The total dose in the figure is 3.75 Gy, where the prescription dose was 3.4 Gy, and the dose from the treatment plan for that point was 3.52 Gy.

RESULTS

Matching of Shape of Isodose Contours to Data

- Our goal is to compare the film data with the predictions of the plan, using the isodose contours from the treatment planning system. Along each contour, the values should be constant if the exposed image is in perfect agreement with the dose plan.
- A calibrated film image of 40 kV_p 34 mm balloon is shown in Figure 5, where the dose values in Gray are mapped to a false color look-up-table (LUT). Multiplying the image array data in Figure 5, by a mask from the TPS isodose contours yields a new image that has non-zero values only along the contours (Figure 6). Along each contour the values should be constant if the exposed image is in perfect agreement with the dose plan.

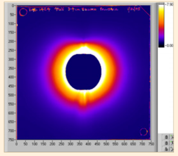

Figure 5. Calibrated film image for 40 kV_p 34 mm spherical balloon with the false color legend at upper right. The distal end of the source is toward the bottom of the image.

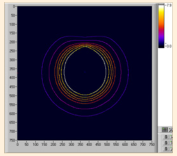

Figure 6. Product of calibrated film image with isodose contour mask, which extracts the values on the film at the positions of the contours.

- Figure 6 shows the mask-extracted film data, using the same LUT as Figure 5. If one traces around any of the contours with one's eye, the color should remain constant. Qualitatively this appears to be the case, but such a visual evaluation is unsatisfactory. However it is possible to evaluate the results more quantitatively. For each non-zero point in the image (Fig. 6), the value is recorded and the angle about the center is calculated. Contiguous points are tallied together in an array, corresponding to each of the isodose contours. The arrays are then plotted as individual data series, as a function of angle (Figure 7).
- The "unwrapped" isodose contour values are shown in Figure 7. In the ideal case the data series would be perfectly flat lines, with values corresponding to the isodose contour values from the treatment plan. The higher values correspond to the innermost contours. The results, while naturally not perfectly flat, do evidence behavior that is nicely evocative of the ideal.

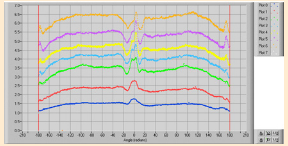

Figure 7. Values of the pixels along contour lines, "unwrapped", and plotted as a function of angle. Zero degrees is at the distal end of the balloon. The ideal case is a series of perfectly flat lines with values corresponding to the isodose contour values (40 kV_p 34 mm spherical balloon with tube 1424).

- The data for the other three treatment plans were consistent with the data from the first treatment plan. The standard deviation percentages (which quantify the flatness) for those treatment plans were all under 10% except one, which was 10.1%, indicating good conformance of the measured data to the shape of the TPS isodose contours.

RESULTS

Comparison of Measured vs Target Values

- A quantitative comparison with the BrachyVision plan dose is shown in Table 2. Columns include target Gy from BrachyVision, average measured Gy, the difference in percent, the standard deviation sigma of the data points in each series, and the sigma in percent.
- In Table 2, the absolute dose values near the prescription point are within 6% of target, with an increase further away to a maximum of 22%. Considering the uncertainties inherent in the nonlinear film calibration and the fitting process, this is very consistent behavior.

Table 2. Comparison of average measured and treatment plan target values along the "unwrapped" isodose contours. (Tube 1424, 40 kV_p, 34 mm spherical treatment plan)

Target (Gy)	Average (Gy)	Difference (%)	Sigma (Gy)	Sigma (%)
1.20	1.44	20%	0.12	8.3%
2.00	2.24	12%	0.22	9.8%
3.20	3.36	5%	0.30	8.9%
4.00	3.98	-1%	0.30	7.5%
4.80	4.53	-6%	0.28	6.2%
6.00	5.27	-12%	0.27	5.1%
8.00	6.20	-22%	0.30	4.8%

- Of greater significance than the absolute dose values is the matching of isodose contours to the data. The flatness of the individual lines in Figure 7 relates directly to this metric. The standard deviation columns of Table 2 quantify the flatness in units of Gray and percent. These data are under 10% in all cases, indicating good conformance of the measured data to the shape of the isodose contours.

SUMMARY

- Radiation treatments with the Xoft Axxent™ system were run in a water phantom following the same treatment plans used in the animal trials of January 2005. Both ion chamber and film dosimetry were used to determine the quantitative and qualitative characteristics of the dose delivered per fraction. Dosimetry indicated that the absolute dose delivered at the prescription depth in the balloon transverse plane was accurate to ± 11%.
- For validation of the spatial distribution, film measurements were made 5 mm from the plane of the source over a 5" square area. The film data was image-masked with isodose contour lines from the BrachyVision treatment plans, then dose values were extracted along the isodose contours and plotted as a function of angle. These values were then analyzed for average value and flatness.
- The flatness of the data series, as measured by the standard deviation of all points on the contour line, were all good to an average of well under 10%. This indicates very good conformance of the spatial distribution of the delivered dose to the plan dose.

Study Funded by Xoft

26th American Brachytherapy Society Annual Meeting, June 2005, San Francisco, CA