PERFORMANCE OF XOFT FLEXISHIELD™ FLEXIBLE X-RAY SHIELDING IN LABORATORY TESTS AND IN A GOAT MAMMARY MODEL

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ABSTRACT

Purpose: These studies measured the low energy x-ray shielding effectiveness of Xoft FlexiShield™ flexible tungsten-silicone sheets. The ability of the shielding material to lower the ambient radiation level in a treatment room was then evaluated during dose delivery to goats in the course of simulated accelerated partial breast irradiation (APBI).

Method and Materials: X-ray attenuation of 1 mm thick tungsten-silicone flexible sheeting was measured using a collimated beam from a Xoft Axxent™ X-ray Source operated at 30 to 50 kV. X-ray attenuation was calculated as the ratio of air kerma rate from the Source measured using an Exradin A600 Ionization Chamber with and without the shield in the beam path. To evaluate shielding effectiveness in a clinical setting, exposure rate was measured during simulated APBI of four Nubian milk goats with balloon applicators inserted percutaneously into simulated lumpectomy cavities in their udders. A Victoreen 451B Ion Chamber Survey Meter was used to measure exposure rates at twelve locations with nominal distances of 1 meter from the udder being treated.

Results: X-ray attenuation measured using the collimated beam was 10^4 to 10^6 at 30 to 50 kV operating voltage. A calculated lead-equivalence of 0.45 mm at 50 kVp was based on the equivalent of 0.35 mm thick tungsten in the 1.0 mm thick composite sheet. During dose delivery to goat udders draped with FlexiShield™ the average ambient exposure rates at 1 m were 1.3 and 13 mR per hour at 40 and 50 kV operating voltages, respectively. The exposure rate at 50 kV was 170x lower than without shielding.

Conclusion: Xoft FlexiShield™ flexible tungsten-silicone sheet is a conformable low energy x-ray shield that very effectively reduces the ambient exposure rate while performing APBI.

Conflict of Interest: Research was supported 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.
- The Axxent™ system has been evaluated in a Nubian milk goat animal model. Delivered doses from the Xoft Axxent™ System were well within the goal of 34 Gy ±20%, and there were no adverse tissue effects or adverse events. These results were reported at the ABS 2005 Annual Meeting.
- To reduce the ambient exposure rate while performing APBI, a conformable low energy X-ray shield, the Xoft FlexiShield™ was developed.

METHODS

Purpose

- These studies measured the low energy X-ray shielding effectiveness of Xoft FlexiShield™ flexible tungsten-silicone sheets. The ability of the shielding material to lower the ambient radiation level in a treatment room was then evaluated during dose delivery to goats in the course of simulated accelerated partial breast irradiation (APBI).

Laboratory Evaluation

- X-ray attenuation of 1 mm thick tungsten-silicone flexible sheeting was measured using a collimated beam from a Xoft Axxent™ X-ray Source operated at 30 to 50 kV. X-ray attenuation was calculated as the ratio of air kerma rate from the Source measured using an Exradin A600 Ionization Chamber with and without the shield in the beam path.

Clinical Evaluation

- To evaluate shielding effectiveness in a clinical setting, exposure rates were measured during simulated APBI of four Nubian milk goats with balloon applicators inserted percutaneously into simulated lumpectomy cavities in their udders. FlexiShields™ were placed over the goat's udders to reduce radiation levels in the treatment room during dose delivery. One or more shields were positioned on top of and along the side of the udders to attenuate radiation in directions where individuals would be observing the procedure. A Victoreen 451B Ion Chamber Survey Meter was used to measure exposure rates at twelve locations with nominal distances of 1 meter from the treated udder.
- Exposure rates were measured during the delivery of fractions 1 and 2 for all four animals. To estimate the shielding effectiveness, exposure rates were measured without shields during the delivery of fractions 3 and 7 to one animal, which was chosen because the combination of a 3-4 cm applicator and 50 kV operation resulted in the shortest dose delivery time, about 4 minutes, thus minimizing exposure of personnel remaining in the treatment room.

LABORATORY RESULTS

- X-ray attenuation values were 10^4 to 10^6 at 30 to 50 kV operating voltage. A calculated lead-equivalence of 0.45 mm at 50 kVp was based on the equivalent of 0.35 mm thick tungsten in the 1.0 mm thick composite sheet.

CLINICAL RESULTS

50 kV Operation

- Measured radiation levels for the two animals treated with sources operating at 50 kV are presented in Figures 1 and 2. The maximum exposure rate with shields in place at any in-plane location was 43 mR/hr with the exception of one measurement near the right front leg. In this case the exposure rate was 194 mR/hr because the flexible shield was not pulled down completely. Readings behind the portable shield for the veterinary nurse were 0.04 to 0.13 mR/hr. This shield was at a distance of approximately 2 m near the left front leg of the animals. All readings have been corrected to account for the survey meter's energy-dependent response using data in the instrument manual.

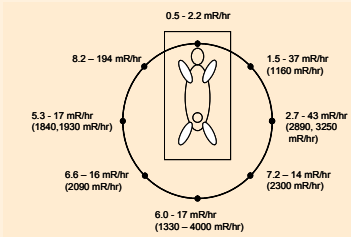

Figure 1. In-plane exposure rate readings at 50 kV. Exposure rates without shields are in parentheses.

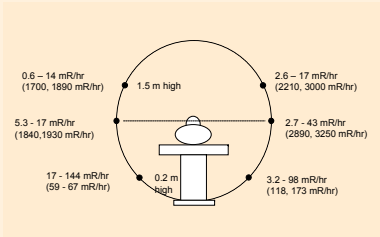

Figure 2. Out-of-plane exposure rate readings at 50 kV. Exposure rates without shields are in parentheses.

- Out-of-plane exposure rate readings above and below the animal had ranges of 0.6 to 17 mR/hr and 3.2 to 144 mR/hr, respectively. Low readings below the animal occurred when a piece of FlexiShield™ was placed under the animal during dose delivery. Also, please note that individual readings vary over a wide range depending upon which animal was being treated, source strength and which dwell position the source was in when a given reading was made.
- Exposure rates measured without shields during the delivery of fractions 3 and 7 to animal #3 are listed in parentheses in Figures 1 and 2. The average exposure rate was 2270 mR/hr for all in-plane and above-plane readings. Below-plane readings were not included in the average because partial shielding was provided by the surgical table. Exposure rates behind the veterinary nurse's portable shield were 1.02 and 1.43 mR/hr.

40 kV Operation

- The maximum exposure rate at any location for the two animals treated with sources operating at 40 kV was 3.7 mR/hr with an average over all readings of 1.3 mR/hr. All exposure readings behind the veterinary nurse's shield were 0.00 mR/hr.

FlexiShield™ Performance

- Average readings over all measurements for each animal are listed in Table 1. The average values are being used for the shielding performance estimate because individual readings depended upon animal, source strength and dwell position the source was in when a given reading was made.

Table 1. Average Ambient Exposure Rate

	Without shield	With shield	Attenuation ratio
Animal #1 - 40 kV	-	1.3	-
Animal #2 - 40 kV	-	1.2	-
Animal #3 - 50 kV	-	11	-
Animal #4 - 50 kV	2270	13	170

SUMMARY

- The average ambient exposure rates were very consistent between the pairs of animals treated with each operating voltage.
- Approximately 10x higher radiation level was observed during 50 kV operation compared to 40 kV operation.
- At 50 kV, FlexiShield™ reduced the radiation level around the animal by a factor of 170.
- FlexiShield™ in combination with a portable operator shield, resulted in an exposure rate of ≤0.1 mR/hr.
- Xoft FlexiShield™ flexible tungsten-silicone sheet is a conformable low energy X-ray shield that very effectively reduces the ambient exposure rate while using the Xoft Axxent™ X-ray Source.

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.
- Two other posters "Stability of the Xoft Axxent™ X-ray Source during Irradiation in a Goat Mammary Model for APBI" and "Monte Carlo Modeling of the Xoft Axxent™ X-ray Source" are presented at the AAPM 2005 Annual Meeting.
- An earlier study reported at the ABS 2005 Annual Meeting demonstrated that the dose delivered (prescription of 3.4 Gy per fraction, at 1 cm from the balloon surface, in a plane parallel to the source axis) was confirmed during simulated treatment in a water phantom utilizing ion chamber dosimetry and radiochromic film.
- The Xoft Axxent™ Electronic Brachytherapy System is for investigational use only. FDA clearance pending.

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