

# X-ray Transmission of Vaginal Cylinders for Use with the Axxent® Electronic Brachytherapy System

H Hausen, L Kelley, T Lovoi, L Mantese, TW Rusch, Xoft, Inc, Sunnyvale, CA

## INTRODUCTION

- Vaginal cylinders are commonly used for irradiation of the vaginal wall following hysterectomy in the treatment of early stage endometrial cancer.
- Typical vaginal cylinders for use with Ir-192 sources are fabricated from materials that have poor transmission characteristics for low energy x-rays such as those emitted by the Axxent® Model S700 X-ray Source.
- New vaginal cylinders were designed for use with the Axxent® System using common medical-grade polymers (Figure 1).
- A 94±5% X-ray transmission with respect to water was chosen so that the x-ray transmission characteristics of the vaginal cylinders would be equivalent to those of the Axxent balloon applicators used for irradiation of the breast.
- A test protocol was designed to characterize the x-ray transmission of these vaginal cylinders and evaluate the impact of environmental challenges on x-ray transmission stability.



Figure 1. Axxent® Vaginal Applicator

## BACKGROUND: AXSENT® SYSTEM

- The Axxent® Electronic Brachytherapy (eBx) System has been used to deliver accelerated partial breast irradiation (APBI) using an inflated balloon placed into the patient's resection cavity one to two weeks post-lumpectomy.
- A miniature x-ray source, shown in Figure 2, operating at 50 kVp is used to deliver a prescribed dose of 34 Gy to 1 cm beyond the balloon surface in 10 fractions, twice daily for five days.
- Recently FDA-clearance was granted for the Axxent® eBx System in the general treatment of "lesions, tumors and conditions in or on the body where radiation is indicated".
- Unique attributes of the Axxent® eBx System:
  - No radioactive materials handling and safety issues
  - Lower shielding requirements brings HDR treatment "out of the bunker"
  - High dose rate and unique dose sculpting capabilities
  - Self-contained unit can be wheeled from room to room

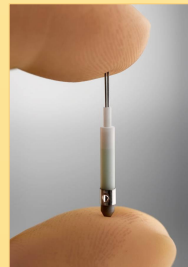


Figure 2. Axxent® Miniature X-ray Source

## METHODS

- The test protocol simulated 100 cycles of patient treatment. Each cycle consisted of:
  - X-ray transmission measurement,
  - X-ray irradiation following a treatment plan,
  - Exposure to condom contact with lubricating gel,
  - Cleaning in Cidex OPA and
  - Steam sterilization in an autoclave.
- To minimize waiting time during testing, all exposure times were increased by a factor of 10 so that 100 cycles of patient treatment could be performed in 10 extended test cycles.
- X-ray Transmission Measurement
  - The X-ray transmission of each applicator was measured after fabrication and then after each of the X-ray radiation delivery and cleaning steps to determine if any change in transmission had occurred.
    - Applicators of each size were held in a Gammex RMI 457 solid water fixture immersed in a water bath.
    - The transmission of each sample was measured using a PTW 34013 Soft X-ray Ionization Chamber set into a solid water phantom designed to contact the outer surface of the cylindrical applicator.
    - The Axxent® Model S700 X-ray Source was inserted through a rigid source channel into the inner lumen of the applicator and held in place so that the source anode was aligned with the ionization chamber window.
    - The average dose was determined from measurements taken at 500 microsecond intervals for 30 seconds using a PTW Unidos® E Dosimeter and custom LabVIEW software.
    - The X-ray source was controlled by custom LabVIEW software during each measurement for better repeatability.
    - Measurements were made with the applicator in place; then, with the fixture remaining in the water bath, the applicator was removed, and a dose in water measurement was performed for direct comparison.
- X-ray Irradiation by Treatment Plan
  - The treatment plan dwell positions and dwell times were determined for each applicator size to deliver 7 Gy to a prescription point 5 mm from the applicator surface using Varian BrachyVision™.
  - Representative times are shown in Table 1 for both a single fraction and for the extended test irradiation cycle equivalent to ten fractions.

Table 1. Treatment times using an Axxent® X-ray Source (Air Kerma Strength = 110,000 U)

Applicator Size	In Use: Treatment Time for 1 Fraction	For Testing: Exposure Time for 10 Fractions
20 mm	5.25 min	55 min
25 mm	7.19 min	75 min
30 mm	9.16 min	95 min
35 mm	11.29 min	115 min

- Environmental Challenge
  - Typical performance tests of the polymers chosen do not include the types of environmental challenges typically associated with normal vaginal cylinder use; consequently, a component of the test protocol involved an environmental exposure.
  - Each applicator was placed in a condom, coated with lubricating gel and allowed to sit for at least 2 hours. Then the condom was removed.
- Cidex OPA Cleaning
  - Each applicator was exposed to a typical two-step cleaning process. The first step was to soak the applicator in Cidex OPA.
  - The Cidex IFU recommends a 12-minute soak at a minimum of 20°C. To simulate 10 cleaning cycles, the applicators were soaked in Cidex OPA for 2.5 hours at 20°C or higher, which corresponds to a 15-minute-per-fraction soak.
- Autoclave sterilization
  - The second cleaning step was to sterilize the applicators using a steam autoclave.
  - Each applicator was subject to 10 autoclave cycles at 134°C for 20 minutes in distilled water followed by a 15-minute drying time after each cycle. (The autoclave cycle was repeated ten times because it could not be simply extended by 10x to 200 minutes and realistically simulate the environmental challenge during regular applicator usage.)

## RESULTS

- A total of 20 applicators were fabricated for the test; five 20 mm diameter, five 25 mm diameter, five 30 mm diameter, and five 35 mm diameter.
- X-ray transmission with respect to water was measured after fabrication and after completion of every 10 treatment cycles.
- The average initial transmission of the cylinders was 94.6% with 0.6% SD and after environmental exposure was 95.0% with 0.6% SD. Maximum differences from the average were +1.5% and -2.0%.
- Testing has been completed for 10 extended cycles or the equivalent of 100 patient treatments. With five applicators of each size and one x-ray transmission measurement per cycle, 55 measurements have been made on each applicator size.
- The average values and standard deviations are presented in Figure 3 as a function of extended treatment cycles. The trend line indicates that the transmission is changing by less than 1% as cycles progressed.

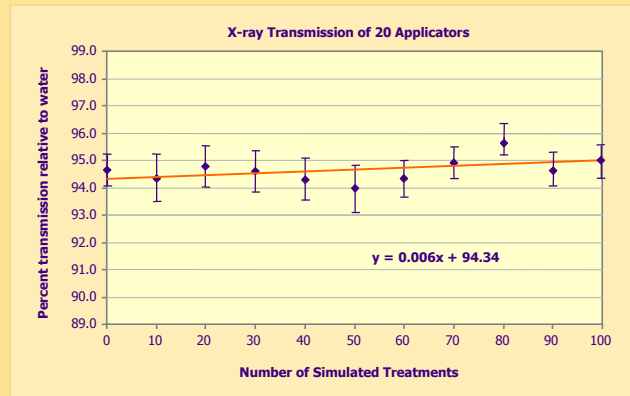


Figure 3. Average x-ray transmission of twenty applicator samples during 100 treatments with a trend line indicating less than 1% change in transmission as a function of increased environmental challenges. The error bars represent one standard deviation.

- The average x-ray transmission values and standard deviations for each applicator diameter are shown in Figure 4.
- As can be seen, the average x-ray transmission values are in the range of 94.3% to 95.0% through 10 extended cycles of environmental challenge with standard deviations less than 1%.
- These values are well within the design requirement of 94±5% and indicate the suitability of this vaginal cylinder design for use with the Axxent® Electronic Brachytherapy System.

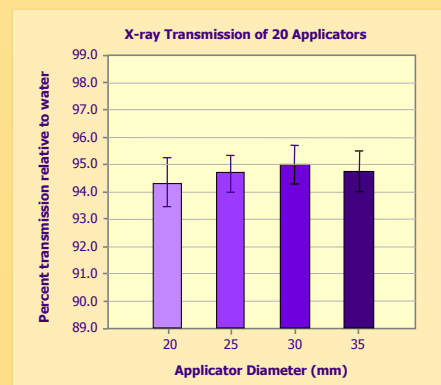


Figure 4. Average x-ray transmission of 5 samples for each of the 4 applicator sizes during 100 treatments. The error bars represent one standard deviation.

## CONCLUSION

- In this study, X-ray transmission of a set of vaginal cylinders for use with the Axxent® Electronic Brachytherapy System has been characterized during 100 cycles of simulated patient treatment and found to be constant to within ± 2%.
- In a separate study the delivered doses from the Axxent® System with 30 mm and 35 mm vaginal applicators were compared with the planned doses using radiochromic film. The dose measured in a plane parallel to the applicator axis was found to be constant along plan isodose contours with a standard deviation of about 5-6% (2 sigma). See Poster #SU-GG-T-36, "Film based treatment plan validation for a new vaginal applicator using the Xoft Axxent® 50 kVp miniature X-ray source" by S Axelrod, L Kelley, L Mantese, and T Rusch, at the AAPM 2008 Meeting.

Funding provided by **Xoft**