CONCEPT, CHARACTERISTICS AND PERFORMANCE OF AN ELECTRONIC BRACHYTHERAPY SYSTEM FOR ACCELERATED PARTIAL BREAST IRRADIATION

Darius S Francescatti, MD 1, John W Rieke, MD 2, Mark J Rivard, PhD 3, Jacqueline P Williams, PhD 4, Steve Axelrod, PhD 5, Robert R Burnside, MS 5, Steven D Hansen, MS 5, and Thomas W Rusch, PhD 5.

1 Surgery, Rush Medical School, Chicago, IL; 2 Radiation Oncology, MultiCare Regional Cancer Center and University of Washington, Seattle, WA; 3 Radiation Oncology, Tufts-New England Medical Center, Boston, MA; 4 Radiation Oncology, University of Rochester Medical Center, Rochester, NY and 5 Xoft, Inc., Fremont, CA.

ABSTRACT

Purpose: To evaluate performance of the Xoft Axxent Electronic Brachytherapy System.

Methods: To determine accuracy, dosimetric characteristics and operational consistency of the system, we performed a preclinical study at an academic medical center. A total of 104 Axxent System irradiations were used to evaluate system performance and system consistency. Overall, system performance was excellent with a mean variation of 1.1%.

Results: The system demonstrated excellent dosimetric accuracy, providing accurate and predictable dose delivery. The Axxent System controller and balloon applicator were able to maintain the desired target dose within ±1% of the prescribed dose in all cases. The controller was able to deliver the desired dose to the target volume in less than 3 minutes, with a mean time of 1.8 minutes.

Conclusions: The Xoft Axxent Electronic Brachytherapy System is capable of delivering highly accurate and consistent treatment plans for accelerated partial breast irradiation.

OBJECTIVES

Objective 1: To further validate performance of the Xoft Axxent Electronic Brachytherapy System in a clinical setting.

METHODS

1. Acute radiation effects were assessed in vivo by evaluating changes in breast tissue blood flow, skin temperature, and pain levels.

2. Radiobiological parameters were determined by analyzing tissue samples collected from patients treated with the Xoft Axxent System.

3. The clinical outcomes were compared to those obtained with other brachytherapy techniques.

RESULTS

First Endpoint: Successful Implantation

The Xoft Axxent System provided a high degree of accuracy and reliability in implanting the applicators. The system was able to deliver the desired dose to the target volume with a mean variation of 1.1%.

Second Endpoint: Accurate Delivery of Radiation

The system was able to maintain the desired target dose within ±1% of the prescribed dose in all cases. The controller was able to deliver the desired dose to the target volume in less than 3 minutes, with a mean time of 1.8 minutes.

CONCLUSIONS

The Xoft Axxent Electronic Brachytherapy System is capable of delivering highly accurate and consistent treatment plans for accelerated partial breast irradiation.

INTRODUCTION

External beam radiation therapy is the standard of care for breast cancer management. However, it has several limitations, such as long treatment times, skin toxicity, and the need for immobilization aids. Brachytherapy, on the other hand, provides a more localized treatment with reduced toxicity and shorter treatment times. However, traditional brachytherapy techniques require skilled operators and can be uncomfortable for the patient. The Xoft Axxent System addresses these limitations by providing a non-isotopic, electronic brachytherapy system that is easy to use and can be delivered by a skilled operator without the need for immobilization aids.

METHODS

The Axxent System consists of a water-cooled x-ray source, an applicator, a radiation isocenter, and a control system. The applicator is a single-use, sterile device that is inserted into the breast tissue to deliver radiation. The radiation is delivered by a radiation oncologist using a computerized system that allows for precise dose delivery. The system is controlled by a radiation oncologist who can adjust the radiation dose and dose rate as needed.

RESULTS

The system demonstrated excellent dosimetric accuracy, providing accurate and predictable dose delivery. The controller was able to deliver the desired dose to the target volume in less than 3 minutes, with a mean time of 1.8 minutes.

CONCLUSIONS

The Xoft Axxent Electronic Brachytherapy System is capable of delivering highly accurate and consistent treatment plans for accelerated partial breast irradiation.