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Skin

Improving the treatment planning and delivery process of Xoft electronic skin brachytherapy

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ABSTRACT

PURPOSE: To develop an improved Xoft electronic skin brachytherapy process and identify areas of further improvement.

METHODS AND MATERIALS: A multidisciplinary team conducted a failure modes and effects analysis (FMEA) by developing a process map and a corresponding list of failure modes. The failure modes were scored for their occurrence, severity, and detectability, and a risk priority number (RPN) was calculated for each failure mode as the product of occurrence, severity, and detectability. Corrective actions were implemented to address the higher risk failure modes, and a revised process was generated. The RPNs of the failure modes were compared between the initial process and final process to assess the perceived benefits of the corrective actions.

RESULTS: The final treatment process consists of 100 steps and 114 failure modes. The FMEA took approximately 20 person-hours (one physician, three physicists, and two therapists) to complete. The 10 most dangerous failure modes had RPNs ranging from 336 to 630. Corrective actions were effective at addressing most failure modes (10 riskiest RPNs ranging from 189 to 310), yet the RPNs were higher than those published for alternative systems. Many of these high-risk failure modes remained due to hardware design limitations.

CONCLUSIONS: FMEA helps guide process improvement efforts by emphasizing the riskiest steps. Significant risks are apparent when using a Xoft treatment unit for skin brachytherapy due to hardware limitations such as the lack of several interlocks, a short source lifespan, and variability in source output. The process presented in this article is expected to reduce but not eliminate these risks.

Keywords: Xoft; Skin; Electronic brachytherapy; FMEA; Patient safety; Process improvement

Introduction

Nonmelanoma skin cancer (NMSC), including basal cell carcinoma and squamous cell carcinoma, is one of the most common malignancies worldwide (1–3). Optimal treatment requires consideration of the efficacy of the treatment modality, the expected side effects and cosmesis, the comorbid medical conditions of the patient, the cost of the treatment, and the logistics and convenience of the treatment. Surgical treatment, including Mohs surgery, is typically the standard treatment for tumor locations where cosmesis is not a concern, which is usually in locations other than the head.

Radiotherapy is often considered as an alternative to Mohs surgery in cases where the expected cosmetic result of surgery is poor or where comorbid medical conditions make surgery a risk (such as the need to suspend anticoagulation medications) (4, 5). An older randomized study comparing surgical resection and radiotherapy showed lower recurrence risk and better cosmesis with surgery, although the radiotherapy techniques (including interstitial brachytherapy) and dose regimens used were nonstandard (Avril *et al.*, 1997). A more modern matched-pair analysis comparing Mohs surgery and electronic brachytherapy (eBx) showed equivalent disease control and cosmesis (Patel *et al.*, 2017). Mohs surgery and radiotherapy are both supported as first-line treatment for NMSC by the National Comprehensive Cancer Network.

Traditionally, radiotherapy for skin cancer has been performed with modalities including electron therapy,

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orthovoltage x-ray therapy, megavoltage x-ray therapy (for bulkier tumors), or occasionally surface-mold low-dose-rate brachytherapy (6). Improvements in high-dose-rate brachytherapy equipment have allowed for newer skin cancer treatment approaches, such as the Valencia system using a remote afterloader of a high-activity iridium source. Several eBx treatment systems have also become available in recent years (7–10). The Xoft eBx system was initially reported in 2010 for eBx of skin cancer (11–13).

The Xoft eBx system uses an electronic source to generate kV x-rays, which are delivered to the skin cancer location with a contact applicator system. The treatment field is collimated on the skin surface using cones of varying diameter, based on the tumor characteristics. The Xoft system is best-suited for smaller (up to 3 cm) NMSCs located on flat areas of the skin, although larger cancers may be treated with an available 5-cm applicator. The Xoft system has advantages over traditional forms of radiotherapy in that it has very low scatter radiation—dose exposure of the patient or surrounding room and therefore has minimal shielding requirements (12). The treatment is more conformal than electron therapy (14). Large clinical treatment series have reported very good tumor control rates and cosmetic outcome with the Xoft system (15–17). The most common dose regimen is 40 Gy given in 8 fractions of twice-weekly treatment (15, 17).

As a newer treatment modality, Xoft eBx presents its own novel safety considerations. There are unique challenges to Xoft eBx treatment in the steps of patient selection, treatment simulation, dose calculation, quality assurance, treatment delivery, and patient monitoring. For example, small NMSCs can be misidentified by staff, the Xoft eBx skin applicator is highly sensitive to daily positioning, and there are risks of delivering the wrong treatment plan on a given day.

Our department has been using the Xoft system for more than 5 years and have treated over 1000 patients. Over this timeframe, we have instituted many quality improvement measures to our eBx clinical treatment protocol. Many of these have stemmed from a failure modes and effects analysis (FMEA) project that we conducted recently. FMEA has been used to improve brachytherapy procedures for other skin cancer radiotherapy equipment such as the Esteya system (18), but it has not been described for the Xoft system when used for treating NMSCs.

The purpose of the present study is to describe our FMEA methodology and how it improved the safety of Xoft eBx treatments for NMSCs in our clinic.

Methods

A multidisciplinary team of three physicists, two dosimetrists, one physician, and two therapists gathered for three meetings to perform the FMEA. The first step of the FMEA was to agree on the process map—the steps and their order. Xoft brachytherapy for skin treatments had been performed for 2 years before generating this process map, and all the FMEA team members' accumulated clinical experience during that time.

After developing the process map, four of the team members (three physicists and one physician) listed failure modes associated with each step in the process. These failure modes were then assigned occurrence (O), severity (S), and detectability (D) scores ranging from 1 to 10. Owing to time constraints, the therapists and dosimetrists could not participate in this step. Team members were instructed to use the tables presented in American Association of Physicists in Medicine Task Group 100 (19) as guidance for determining how to evaluate the O, S, and D. The internal incident learning system provided a basis for determining O numbers. S and D were estimated using the individual experience of the team members. Four sets of O, S, and D scores were determined by four of the team members independently. The mean and standard deviation of these numbers were computed, and then the entire team of eight people met to determine the final O, S, and D values used to compute the risk priority numbers (RPNs) that are the product of O, S, and D.

The failure modes were ranked by RPNs to determine which steps carried the greatest risk. A new process map was developed to improve the safety of the skin eBx process. After several months of experience with the new process map, the same failure modes were assigned new O, S, and D scores and updated RPNs. The RPNs of the failure modes were compared between the new and old process maps to qualitatively assess the perceived change in risk.

Results

The final process map consists of 100 total steps (Table A-1). A summary of the pretreatment, daily quality assurance, and treatment delivery processes is presented in Fig. 1. It took 20 person-hours (three physicists, one physician, and two therapists) to develop the initial process map, determine failure modes, determine RPNs, and develop the final process map. The team devised 114 failure modes for this process. Tables of the top 10 RPN-ranked failure modes for the initial process and final process are presented in Tables 1 and 2, respectively. Several of the failure modes were due to the hardware design, so an additional column is present in Table 2 to distinguish which failure modes could be reduced or eliminated with a change to the design of the Xoft treatment unit.

Discussion

The purpose of this work is to develop a safer process to treat skin cancer with the Xoft eBx system. These quality improvement efforts were guided by FMEA in the same vein as the report of American Association of Physicists