**ABSTRACT**

The initial application of the Xoft microTube Flexible X-ray Probe has been for the primary therapy for the majority of women with stage I and stage II breast cancer and is now being used as an alternative to interstitial or intercavitary brachytherapy for the treatment of gynecologic cancer. This development has occurred in part because of the recent development of a disposable, micro-miniature x-ray source. X-rays of 40-50 keV are produced at the tip of a cooled, flexible, disposable probe otherwise closely resembling current remote afterloading catheters. This technology is available for women without access to a facility with an HDR afterloader. This technology cannot afford to maintain active isotopes or to build the shielded treatment room for HDR brachytherapy. It is not affordable to maintain highly skilled operator, and can be uncomfortable for patients. Many radiation treatment centers cannot maintain an adequate margin of time to allow for interstitial and intercavitary radiotherapy because they cannot commit the required resources or resources.

**INTRODUCTION**

... Breast conserving surgery plus brachytherapy is an appropriate method of primary therapy for the majority of women with stage I and stage II breast cancer and is gradually becoming the standard of care for many discretionary surgical and radiation oncology practices. Our findings at 20 years still show that breastconservation therapy is an acceptable method for breast cancer therapy, especially for women in whom a longer life expectancy is anticipated.

Radiotherapy following breast conserving therapy (BCT) lasts 6 to 7 weeks. Many women experience acute and chronic postoperative irradiation because they cannot commit the required resources or resources. Remote afterloading catheters and interstitial catheters for interstitial brachytherapy can significantly shorten treatment time but a labor-intensive requirement, unlike a skilled operator, and can be uncomfortable for patients. Many radiation treatment centers cannot maintain an adequate margin of time to allow for interstitial and intercavitary radiotherapy because they cannot commit the required resources or resources.

A soft, flexible micro-miniature x-ray source has been developed (Xoft microTube Flexible X-ray Probe) by a developer (microTube, Fremont, CA) that can deliver radiation to any accessible body cavity or excised tumor. X-rays of 40-50 keV are produced at the tip of a cooled, flexible, disposable probe otherwise closely resembling current remote afterloading catheters. This technology is available for women without access to a facility with an HDR afterloader. This technology cannot afford to maintain active isotopes or to build the shielded treatment room for HDR brachytherapy. It is not affordable to maintain highly skilled operator, and can be uncomfortable for patients. Many radiation treatment centers cannot maintain an adequate margin of time to allow for interstitial and intercavitary radiotherapy because they cannot commit the required resources or resources.

**DEVICE DESCRIPTION**

The Xoft microTube Flexible X-ray Probe is a fully electronic high-dose-rate (HDR) afterloading x-ray generator system that can deliver radiation to any accessible body cavity or excised tumor. X-rays of 40-50 keV are produced at the tip of a cooled, flexible, disposable probe otherwise closely resembling current remote afterloading catheters. This technology is available for women without access to a facility with an HDR afterloader. This technology cannot afford to maintain active isotopes or to build the shielded treatment room for HDR brachytherapy. It is not affordable to maintain highly skilled operator, and can be uncomfortable for patients. Many radiation treatment centers cannot maintain an adequate margin of time to allow for interstitial and intercavitary radiotherapy because they cannot commit the required resources or resources.

**RESULTS: SAFETY**

Overall, no safety or efficacy issues were observed. An increase in proliferation (PCNA) was observed at the later time points (13-14 days post-radiation) and was confined to the ductal epithelium. The early indications appear to restrict any toxic side effects to being epithelial in nature, and therefore, probably benign. Histologic evaluation showed tissue coagulation, reactive fibroplasia and neovascularization, granulation tissue, acinar degeneration and/or squamous metaplasia, and reactive epithelial changes. The depth of consistent late parenchymal change was not more than 500 microns, even in the most severely represented sections. The late damage is felt to be thermal necrosis resulting from the coolness of the tip used in creating the simulated lumpectomy site.

**RESULTS: DEVICE PERFORMANCE**

Overall, no safety or efficacy issues were observed. An increase in proliferation (PCNA) was observed at the later time points (13-14 days post-radiation) and was confined to the ductal epithelium. The early indications appear to restrict any toxic side effects to being epithelial in nature, and therefore, probably benign. Histologic evaluation showed tissue coagulation, reactive fibroplasia and neovascularization, granulation tissue, acinar degeneration and/or squamous metaplasia, and reactive epithelial changes. The depth of consistent late parenchymal change was not more than 500 microns, even in the most severely represented sections. The late damage is felt to be thermal necrosis resulting from the coolness of the tip used in creating the simulated lumpectomy site.

**METHODS**

**Objective:** This in vivo controlled study was designed to evaluate the Xoft microTube Flexible X-ray Probe with regard to delivery of therapeutic, dose-critical, dose-dense dose in thoracic time.

**Subjects:** Five inbred Nijmegen white goats were operated on for the Xoft microTube Flexible X-ray Probe. The goats were sedated with a combination of xylazine and ketamine. Each goat was anesthetized with xylazine and ketamine and placed on a surgical bed.

**Surgical Procedures:**

- **Device Insertion:** The Xoft microTube Flexible X-ray Probe was inserted into the thoracic cavity via a small incision in the skin.
- **Device Deployment:** The Xoft microTube Flexible X-ray Probe was inserted into the thoracic cavity via a small incision in the skin.
- **Device Operation:** The Xoft microTube Flexible X-ray Probe was inserted into the thoracic cavity via a small incision in the skin.
- **Device Removal:** The Xoft microTube Flexible X-ray Probe was inserted into the thoracic cavity via a small incision in the skin.

**Dosimetry:**

- **Wound closure:** The wound closure was performed using an absorbable suture material (Vicryl 5/0).
- **Radiation Source:** The radiation source was a 140-keV x-ray generator system that can deliver radiation to any accessible body cavity or excised tumor. X-rays of 40-50 keV are produced at the tip of a cooled, flexible, disposable probe otherwise closely resembling current remote afterloading catheters. This technology is available for women without access to a facility with an HDR afterloader. This technology cannot afford to maintain active isotopes or to build the shielded treatment room for HDR brachytherapy. It is not affordable to maintain highly skilled operator, and can be uncomfortable for patients. Many radiation treatment centers cannot maintain an adequate margin of time to allow for interstitial and intercavitary radiotherapy because they cannot commit the required resources or resources.

**CONCLUSIONS**

The Xoft microTube Flexible X-ray Probe is a high-dose-rate, balloon catheter and electronic safety system. Although the architecture of the probe is intended to reduce radiation, the post-radiation appearance is significant.