Additive Manufacturing (AM) of Custom Applicators for Treating Skin Cancer Patients using Brachytherapy

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Introduction

Skin cancer is the most common type of cancer worldwide [1]. Currently, it is estimated that the incidence of skin cancer in the US is over 5 million cases, with many patients having more than one skin cancer diagnosis [2]. Surgery remains the standard treatment modality for skin cancer, where the primary goal of treatment is to remove cancerous lesions while minimizing cosmetic defects caused by the surgery and normal tissue function [2]. There are, however, instances where surgical techniques would be insufficient to completely eradicate all of the diseases without resulting in a poor cosmetic result or functional outcomes due to the location of the disease. Some patients may not be eligible for surgery due to associated comorbidities or refuse such treatment. In these cases, radiation therapy can play a prominent role in the treatment of skin cancer. In these specific cases, brachytherapy (BT), the treatment of a lesion using radioactive sources placed adjacent to the cancer, can be used to achieve high control rates and promising cosmetic and/or functional results [3]. BT uses radioactive sources to treat cancerous lesions <5 mm in thickness [4]. These sources are guided through catheters in a specialized applicator, which is temporarily affixed to the skin. Common radiation source types include Iridium-192 and Cobalt-60 [5]. Customized applicators are presently being explored to treat irregular surfaces [4].

BT offers many known benefits: there is rapid dose fall-off with distance from the source, therefore reducing the dose to underlying tissues and nearby organs at risk [4]. Brachytherapy also enables a reduced number of patient visits with higher radiation doses given per visit that have been shown to have comparable efficacy and cosmetic results. Limiting patient visits has been a critical concern during COVID-19 to reduce spread. Lastly, a customized applicator can conform to the variable contours of the skin, allowing better approximation to the skin surface and better disease coverage. BT has been shown to offer superior results in terms of conformity, dose coverage, and tissue sparing ability compared to external beam radiotherapy (EBRT), another option for the radiation treatment, when treating areas of the head and neck, especially in the nose and ear lobes.

The variations in contours among patients and the dramatic changes in the skin surface in regions like the head and neck where skin cancers are most common necessitate customized BT

solutions. With the rise of additive manufacturing (AM) technology, inexpensive yet robust applicators are being used to treat skin cancer. AM applicators are an attractive solution, as they enable an almost exact replica of a patient's surface and the design of tailored paths along which the radiation can be placed to treat skin cancer. These applicators can potentially lead to sophisticated dose modulation through precise placement of the radiation, achieving a more homogenous coverage of the cancerous target. This abstract presents a customized approach to treating skin cancer and also proposes a novel strategy to directly incorporate radiation shielding to limit the dose to adjacent sensitive, normal tissues.

Methods and Technical Overview

The current approach of designing and deploying a customized BT applicator has been used to treat 10 patients at Sunnybrook Odette Cancer Centre, Toronto, ON, Canada. All 10 patients had skin cancers on their noses, which is the most common area for skin cancer on the face and also one of the most challenging due to its situation close to the eye.

The general workflow to create a customized BT applicator, including shielding, was as follows and will be described in detail in the following paragraphs: **Patient anatomy modelling** - obtaining a surface or CT scan and identifying the target, **digital processing of patient data** - designing the print and sending the instructions to the printer, and **printing the physical applicator** - physically forming the object. Subsequent steps before treating a patient were **physical assessment** of the applicator and the **dosimetric assessment** of the patient plan using the applicator.

Patient Anatomy Modelling

The disease depth and appropriateness for superficial BT were determined by combining information from physical examination, high-resolution CT scans containing fiducial wires over the lesion or surgical scar, biopsy results and high-frequency ultrasound (US). The thickness of the cancer was evaluated to ensure it is less than 5 mm to be eligible for brachytherapy treatment. Once the lesion was deemed appropriate for skin BT, a CT scan was acquired to create a digital model of the patient's anatomy. A CT scan is commonly used to model patient anatomy as a starting point to design the mould. The slice thickness, an in-plane resolution, have implications for the smoothness of the applicator and, subsequently, the fit to the patient's unique anatomy. Modern computed tomography systems are capable of 0.5 mm spatial resolution in each plane. The CT scan was used to create a digital copy of the patient's face that can be further processed and manipulated to create the applicator in our clinic.

Digital Processing of Patient Data

Digital processing converts the CT images into a 3D model, smoothed and modified to remove any artifacts. The treatment area was then delineated, and an applicator solid was created that will sit on the patient's face to cover cancer completely and have sufficient thickness to allow for the design of catheter paths for the radioactive source to be introduced into the applicator object. A specialized medical software MiM Software Inc. (Cleveland, Ohio, USA) was used to process the CT images into an STL file. The STL file for the applicator and the lesion to be treated was then further processed in Autodesk Inventor 2021, Autodesk MeshMixer 2017, and Autodesk

MeshEnabler 2021 from Autodesk, Inc. (San Rafael, California, USA) to design catheter paths for the radioactive sources that maintain a constant distance of 3 mm from the skin surface, carefully tracking the topography of the patient's face yet maintaining the radius of curvature of the path to respect the limitations of treatment delivery system. A 3D spline algorithm was used to design smooth tracks to avoid potential obstruction of the radiation source during the treatment of the patient. Additionally, pockets were created around the patient's eyes that will later be filled with tungsten to limit the dose to the patient's eyes.

Printing the Physical Applicator

The BT applicators presented in this abstract were printed using SLA used to achieve a high resolution printed product, which was sufficiently smooth to be directly applied to the patients' faces. A transparent resin, Accura Clearvue, was selected such that the underlying patient's anatomy could be visualized to ensure accurate placement of the applicator during treatment. Given that their skin surface was breached in some patients and there were open wounds, a USP class VI resin was selected. The catheter paths printed into the applicator were cleared before catheters were inserted and bonded into position. The radioactive source could then safely travel within the catheters, eliminating the risk of the source getting stuck in uncured resin. The air pockets designed into the applicator were filled with powdered tungsten which acts as a highly efficient radiation shield.

Physical Assessment

Independent verification of the dimensional accuracy of the printed applicators and the lumen were conducted to ensure there was no distortion from the digital model. Ensuring that catheters can pass freely through the lumen is also essential. The geometry of the print was assessed on the verification and planning CT scan, where the applicator was placed on the patient in the treatment position and a final verification CT scan was acquired.

Dosimetric Assessment

A dosimetric assessment of the 3D printed material was conducted to ensure that the planned radiation dose was not adversely impacted by the selection of the printed material. For BT purposes, applicator materials must be dosimetrically water-equivalent, possessing the same attenuation properties. Water equivalency was validated using radiochromic film measurements and comparing the delivered dose to the calculated dose.

In general, the sharp dose fall-off that comes from BT treatment provides reduction in eye dose compared with the conventional BERT treatment. The dose reduction achieved by using the tungsten shielding in one representative patient in the eye dose was measured using the radiochromic films and found that it can reduce the eye dose up to $1/3^{rd}$ of the value without using tungsten shielding. A careful design consideration in the current workflow in the placement of catheters and the creation of air pockets for the tungsten powder is crucial in lowering the eye dose since it varies depending upon the location of lesion and catheter arrangement inside the applicator relative to eye.

Reflections and Conclusion

With the use of additive technology with a unique workflow we have configured, as described above, our cancer treatment program has been able to treat these skin cancer patients beyond the limits of conventional treatments. This technology has become an integral component in the cutting edge treatment option for skin cancer patients, primarily in nose. However, we have recently extended using this technology to treat other anatomical locations and skin diseases such as Keloids and Paget disease.

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