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Additive Manufacturing of Compensator Devices for Radiation Therapy

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Abstract

Radiation therapy is a powerful and effective treatment which targets malignant tumors. Thus, improvements in radiation therapy devices such as compensators can have an immediate impact on the treatment of cancer patients. This paper investigates the design and manufacturing of customized radiation modulation devices. This research proposes a thin-walled device design that can use recyclable fillable media such as water. This approach has several advantages including localized radiation exposure, eco-friendly design, and lower fabrication costs. The Fused Deposition Modeling (FDM) technique was used to develop a hollow bottle-like electron bolus with higher precision (μm resolution). The radiation modulation properties of acrylonitrile butadiene styrene (ABS) and polycarbonate (PC) materials were investigated. The compensator devices were subjected to high radiation doses and mechanical loads to check for dimensional deformations which can impact subsequent radiation profiles. Our findings showed that both ABS and PC materials had superior radiation tolerance as evaluated by the dimensional deviation analysis. Further, the devices had adequate mechanical properties as confirmed by deformation tests and finite element analysis. This paper provides a framework for the design and manufacture of custom compensators for radiation therapy.

Keywords

3D printing, Additive Manufacturing, Compensator, Medical Device, Radiation Therapy.

1. Introduction

The national cancer institution estimated more than 1.7 million new cancer cases in 2019 in the United States and an estimated death toll of 600,000 cases [1]. Globally, the estimated deaths from cancer related illness have reached about 9.6 million every year [2]. The growing number of cancer patients indicates the importance of new discoveries and inventions to effectively treat cancer [3]. Radiation therapy is a powerful and effective treatment to treat malign tumors, even though, it might damage normal tissue within the vicinity of the radiation dose. Thus, the implementation of medical devices such as electron bolus or proton compensator is important for optimizing the radiation dosage distribution [4].

The current manufacturing methods such as computer numerical controlled (CNC) machines, computerized milling machines (CMM), and the plunged technique have limitations to fabricate compensators design. Some of these techniques offer lower resolution to the compensators' profiles and require dedicated machinists [5]. Moreover, these traditional methods incur high costs and have longer lead times that affect the patient treatment [6]. CNC machines require~~s~~ significant capital resources and tool path planning to fabricate complex radiation therapy devices [7]

In recent years, additive manufacturing technology popularly called as "3D printing" has been used for medical devices and thermoforming tools due to its versatility for fabricating complex shapes [8, 9, 10]. In addition, 3D printing can be conducted in a variety of materials such as metal, wax, sands, ceramic, and polymers for different applications [11, 12, 13]. In this research, our team proposed the design and manufacture of a compensator device to focus radiation beams on the tumor site while minimizing the damage to the healthy tissue. Additive manufacturing is used for fabricating a novel compensator design that can be customized for patient specific requirements [14]. The proposed method offers higher dosing accuracy thereby limiting the radiation exposure to the healthy tissue within the tumor vicinity. Moreover, this method can be applied to all radiation treatments including proton, electron, and photon beam therapies. Further, the new design and manufacturing methodology is cost-effective, has lower lead times and eco-friendly over the current solid compensator design [15].

2. Methodology

The Fused Deposition Modeling (FDM) additive manufacturing technique was used to develop a thin-walled compensator design with higher precision (µm resolution). The methodology of this study was carried out in three steps which include device design, manufacture, and test.

2.1. Device Design

The novel design consisted of a thin-walled hollow compensator design and the use of a recyclable fillable media such as water. The thin-wall design makes the fabrication process much faster and requires 80% less material usage, compared to traditional solid system design. Further, the fillable media makes the device locally recyclable, thereby reducing the cost and material usage. Figure 1 shows a double-walled design that consists of a cylindrical outer wall and a 3D-profile inner wall that conforms to the shape of the tumor being treated. Acrylonitrile butadiene styrene (ABS) and polycarbonate (PC) polymeric materials were used to fabricate the compensator device based on their mechanical properties [16].

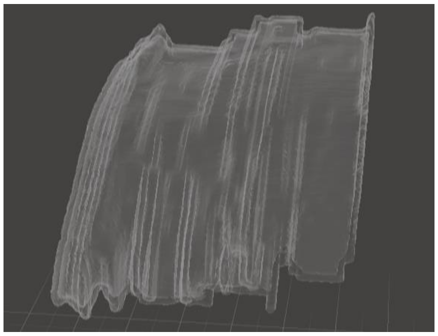

Figure 1: Design of a thin-walled compensator radiation therapy device

2.2. Device Manufacture

The device manufacturing process begins with the scanning of the cancer tumor dimension of the patient (shape, size, and location) using radiographic scanning such as CT or MRI. The scanned tumor dimensions were translated into a 3D profile for the compensator design based on the radiation dosimeter profile. Using the Insight© 3D manufacturing software, the 3D profile was transformed into a point cloud in order to be converted into a 3D solid model. The 3D model was sliced into multiple layers for building the final 3D shape of the compensator device. The (Fortus 400mc) FDM system was used to fabricate the compensator device.

2.3. Device Test

Several tests were conducted on the 3D printed compensator device to validate its performance for in-field usage during radiation therapy sessions. Details of the test are included below:

- Leak-proof test: After the desired compensator device was 3D printed it was checked for leakage. This was performed by filling the device with liquid (water) and closing the hole with a rubber plug (Figure 2).
- Radiation Exposure: The devices were subjected to heavy radiation dosages to evaluate their radiation tolerance. Material integrity and dimensional deviation analysis were conducted for each of the device design.
- Mechanical deformation test: A mechanical loading test was performed using a 3-point bend flexural and a force to failure test (ASTM D790_10 Standard for Flexural Testing of Plastics) [17] using an MTS hydraulic load frame to evaluate shape conformance device (Figure 3). The sample size was eight (n=8) devices for each material with different wall thicknesses and 3D printing build orientations. The compensator devices were

loaded to 80 N for the 3-point bend test based anthropometric force standards for the human grip [18]. In addition, the maximum force to failure was recorded to determine the load to failure and device cracking.

- Finite Element Analysis: A finite element analysis (FEA) was conducted to evaluate the mechanical strength and regions of stress concentrations within the compensator device. Different devices based on variations in their material type (ABS and PC), wall thickness (1 mm and 3 mm) and loading (80 N and failure load) were simulated. The compensator device was constrained in a similar fashion to the mechanical deformation tests. The load was applied from the top and the device was constrained at the bottom edges. The element mesh size for the finite element analysis (FEA) model was 1.5 mm with an aspect ratio of 1.

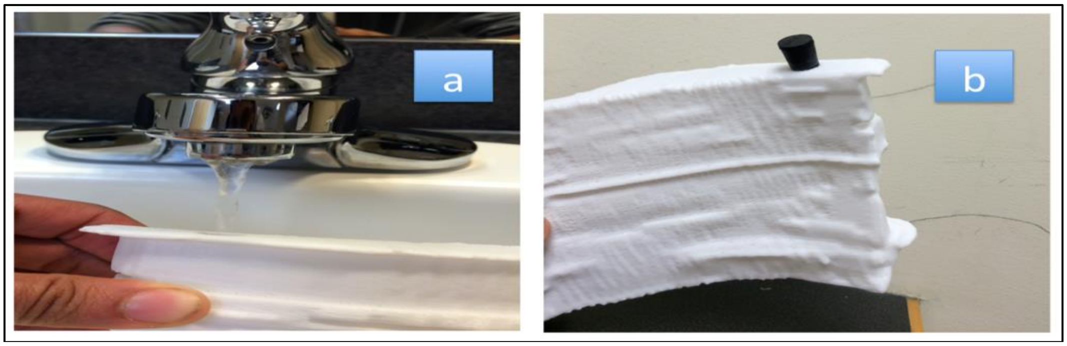

Figure 2: Testing device for leaks **(a)** Step 1: Device filled with water, and **(b)** Step 2: Hole closed with a rubber plug.

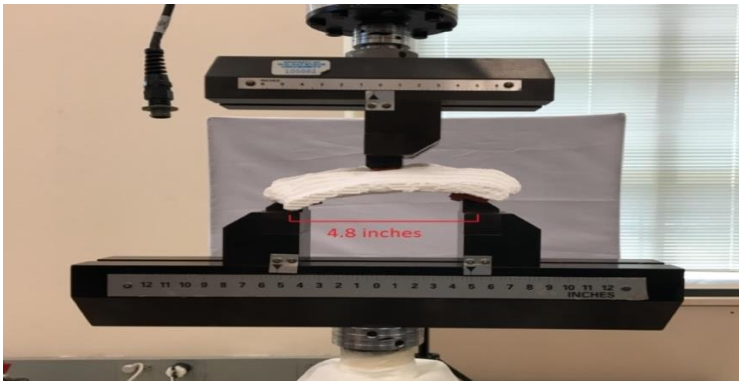

Figure 3: Mechanical deformation test setup showing 3 point bend test on the MTS hydraulic load frame.

3. Result and Discussion

3.1. Leak-proof Test:

The compensator devices were fabricated with different wall thicknesses. Devices with wall thickness less than 0.5 mm displayed leaks due to the irregular shape of the compensator and the layered approach during fabrication of the device. After the fabrication of the devices, they were coated using a waterproof spray (Clear Acrylic Sealer) to ensure a leak-proof design. However, devices manufactured with a wall thickness equal to or greater than 1 mm did not have any leakage issues. Thus, compensator devices were fabricated with a wall thickness of 1 and 3 mm for further tests.

3.2 Radiation Exposure

Different manufactured compensator devices were subjected to 50 Gy irradiation in order to test the integrity of the bolus. A range of 10 Gy - 20 Gy is the clinical dose level of radiation. The devices were under an electron beam about 18 MeV using a Siemens Artiste linear accelerator. The results of this test showed that there was no significant impact on the devices prior and post radiation exposure, which was confirmed by the dimensional deviation analysis. The boluses were scanned prior to radiation exposure (n=6) and post radiation using a laser scanner. The maximum dimensional variation was around 0.54% which is lower than the maximum permissible limit of 3%. Thus, the new compensator device design and material were deemed suitable for implementation in field tests and further mechanical deformation analysis was carried out.

3.3 Mechanical Deformation Test

The mechanical deformation tests revealed the maximum displacement of the compensator device under different loading conditions. In this test, two different force loads were applied: an 80 N force (figure 4), and the maximum force to failure (figure 5). From the material failure test and the maximum displacement values, it was clear that the ABS material had higher strength as compared to the PC material for both 1 mm and 3 mm thickness devices. Figure 5 shows that the maximum failure force for ABS device with 1 mm thickness is 200 N, whereas, the PC material cracks before the load reaches 150 N. For devices with 1 mm thickness the vertical orientation had lower displacement and higher load to failure as compared with the horizontal fabrication orientation. However, for the 3 mm devices in both ABS and PC materials, higher strength was observed for the horizontal build orientation. This can be attributed to the fact that the vertical orientation was parallel to the loading direction thereby, causing slippage of polymeric layers along the build orientation. The mechanical deformation tests showed that both ABS and PC materials with different thicknesses were capable of withstanding the maximum force of 80 N generated by an average human grip.

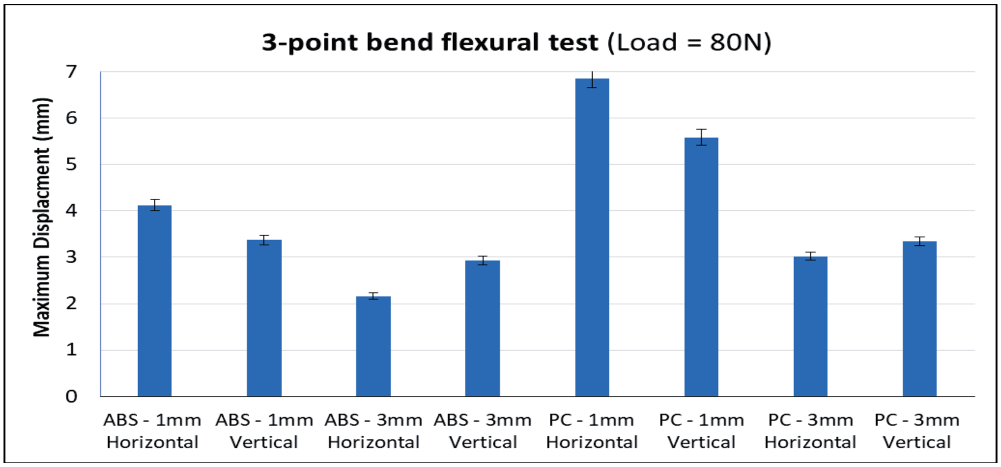

Figure 4: Maximum displacement for different compensator devices (load = 80N)

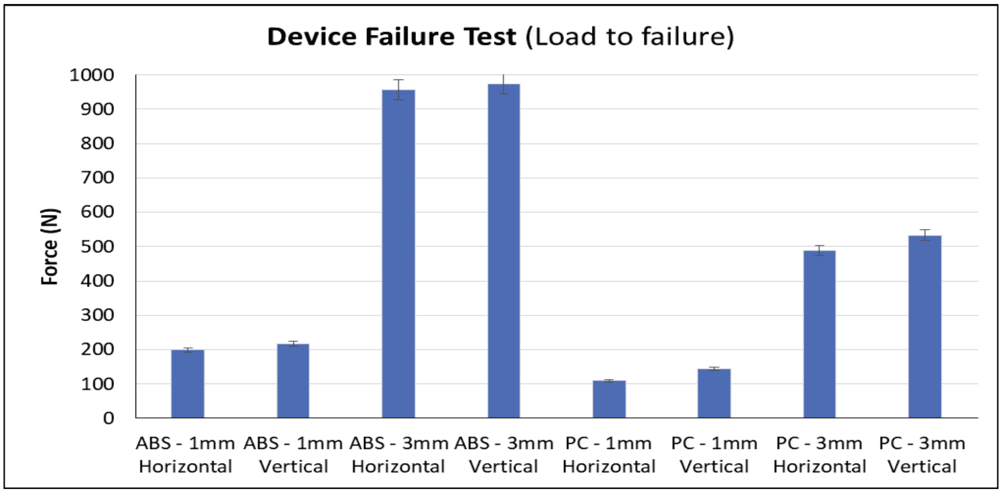

Figure 5: Load to failure for different compensator designs

3.4 Finite Element Analysis

The finite element analysis (FEA) results were consistent with the maximum displacement results from the mechanical deformation integrity test (Figure 4). The maximum displacement values for ABS were lower as compared to PC material for both the 1 mm and 3 mm thickness devices. Thus, ABS material offered higher strength which was consistent with mechanical deformation tests. The compensator device fabricated with ABS material and 1 mm wall thickness showed that the maximum displacement was 3.32 mm (Figure 6) and the maximum stress of 9.78e6 N/m^2 (Figure 7). The finite element analysis was particularly important as it revealed regions of maximum stress concentrations within the compensator devices. These regions displayed potential failure modes of the devices which were validated with mechanical deformation tests that showed cracked devices. Table 1 shows both the maximum displacement and von Mises stress values for compensator devices with different materials and wall thicknesses.

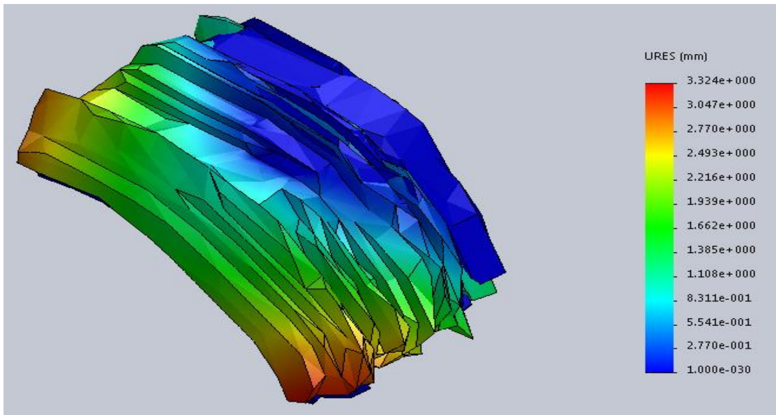

Figure 6: Finite element analysis (Maximum Displacement: mm)

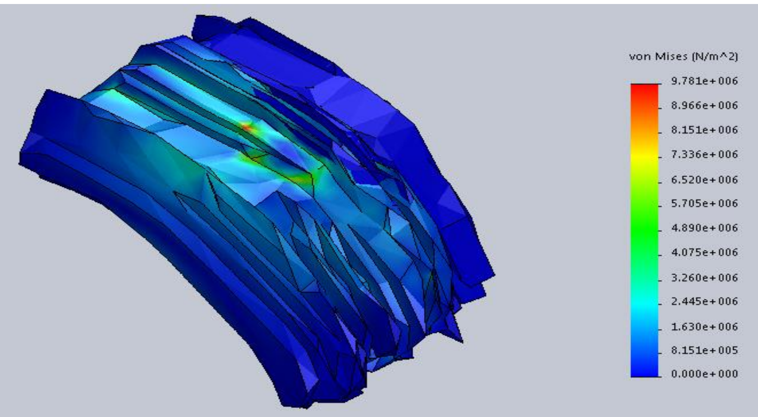

Figure 7: Finite element analysis (von Mises Stress: N/m^2)

Table 1: Maximum displacement and von Mises stress values for finite element analysis

Compensator Design *(Material – thickness)*	Maximum Displacement *(mm)*	Von Mises stress *(N/m^2)*
ABS – 1 mm	3.32	9.78e6
ABS – 3 mm	2.16	7.96e6
PC – 1 mm	6.21	11.39e6
PC – 3 mm	3.09	9.57e6

4. Conclusion

This research investigated the design and manufacture of novel radiation modulation devices such as compensators for cancer treatment. A thin-walled compensator device was proposed which can accommodate different media such as water or high z- materials. The fused deposition modeling (FDM) additive manufacturing technology was implemented to fabricate complex devices shapes based on the dosimetry algorithm. ABS and PC materials were evaluated for their effectiveness in the fabrication of these devices with 1 mm and 3 mm wall thicknesses, respectively. The compensator devices were subjected to several tests such as a leak proof test, radiation exposure - material validation, and mechanical deformation tests. An experimental design was conducted based on differences in the material type, wall thickness, and manufacturing orientation. The mechanical deformation tests showed that ABS had higher strength as compared to PC material for both 1 mm and 3 mm device designs. The failure tests for the compensators indicated the maximum force to failure and regions of crack propagation. The horizontal build orientation displayed marginally higher strength over the vertical orientation due to the higher interlaminar strength of the 3D printed layers. Finite element analysis (FEA) revealed regions of stress concentrations and potential failure modes that were consistent with the mechanical integrity tests. This research provides compensator design rules, manufacturing method, and testing protocols that can be implemented for proton, electron, and photon cancer therapies.

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