The possibility of developing customized 3D-printed silicone hydrogel bolus for post-mastectomy radiotherapy

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ABSTRACT

3D printing technology is widely used for fabricating bolus in post-mastectomy radiotherapy. 3D printed boluses are usually made from hard materials like Polylactic Acid, which can’t adhere to patients’ skin perfectly in clinical practice because of the patients’ uneven surfaces of chest walls and large radiotherapy area. In this work, the feasibility of 3D printing soft self-adhesion boluses using water tissue equivalent silicone hydrogel material in post-mastectomy radiotherapy was studied, and intensity modulated radiotherapy plans were designed to study the performance of the water tissue equivalent silicone hydrogel bolus by comparing to the results of using virtual boluses with the relative electron density of 1.09 in radiotherapy. The comparison demonstrated that water tissue equivalent silicone hydrogel boluses have better adhesive property than boluses made from hard materials. The average air gap volume between the water tissue equivalent silicone hydrogel bolus and patients’ skin is 9.5 cc. The average degree of adhesion and average maximum air cavity dimension are 3.7% and 4.3 mm, respectively. The dose distribution of the virtual bolus and the water tissue equivalent silicone hydrogel bolus are roughly the same in Dose Volume Histogram.

1. Introduction

To reduce the risk of local recurrence of lymph nodes and to protect the chest walls of patients, radiotherapy is usually administrated to breast cancer patients after mastectomy [1-Rather et al., 2014]. Given the buildup effect of the radiation in the gross tumor volume close to the skin surface from the high energy x-rays applied in the post-mastectomy radiotherapy (Podgorsak, 2005), the superficial part of the tumor target area may not receive sufficient radiation dose. To increase the dose deposited in the superficial tumor target, boluses made from Polymer gel are widely used in clinical practice to help redistribute the dose (Vyas et al., 2013). In a post-mastectomy radiotherapy, a bolus will be attached to the patient’s skin surface, and the bolus position will be determined by ink lines. Considering the uneven surface of the patients’ chest wall and the scar after breast remove surgery, air gaps between the skin surface and the bolus are inevitable, which may disturb the dose distribution in the radiotherapy (Boman et al., 2018; Butson et al., 2000; Khan et al., 2013; Sroka et al., 2010).

To reduce the air gaps, the 3D printing technology has been used in fabricating boluses considering its ability of precisely customizing boluses (Aoyama et al., 2020; Dai et al., 2020). The 3D printing technology is also used for other purposes in radiotherapy, such as fabricating bite block (Huang et al., 2020; Zaid et al., 2018), fabricating masks for immobilizing patients (Loja et al., 2019), and printing phantoms for radiotherapy QA procedures (Madamesila et al., 2016; Quiñones et al., 2018). Preliminary studies of 3D printing customized boluses using hard materials like Polylactic Acid (PLA) for breast cancer radiotherapy are reported (Park et al., 2016; Robar et al., 2018). These boluses can’t attach to patients’ chest walls perfectly because of the stiffness of the materials and the variations of the patients’ chest wall features. Fabricating soft boluses for breast cancer radiotherapy is also reported (An et al., 2019). However, the 3D printed mold for shaping the bolus is made from a hard material, which makes it difficult to separate the model and the bolus. Thus, the procedure introduced in this report can only create a bolus with a volume less than 1078 mm³. In this study, a procedure of making boluses from the water tissue equivalent silicone hydrogel (WTESH) using 3D printing technology are described. The experiment results of the WTESH boluses show a good performance of dosimetric characterization.

2. Materials and methods

The WTESH is developed by Klarity Medical & Equipment (GZ) Co., Ltd. It is produced by uniformly mixing two liquids, which are labeled as liquid A and liquid B, with a mass ratio of 1:1. The mixture is then kept still for around 3 days at room temperature for...
solidification. Liquid A is produced by uniformly mixing vinyl-terminated polydimethylsiloxane (C2H3-SiC2H6-(SiC2H6)n-SiC2H6-C2H3) and polydimethylsiloxane with a mass ratio of 1:1, then adding Karstedt catalyst to the mixture with mass of 0.1% of the total mass. The viscosities of vinyl-terminated polydimethylsiloxane and polydimethylsiloxane are 500 cSt and 50 cSt, respectively. Liquid B is a mixture of hydrogen-containing silicone oil (C3H9-Si-O-(H5SiCH3-O)m-(SiC2H6-O)n-SiC2H6-C2H3) and polydimethylsiloxane with a mass ratio of 1:1. The hydrogen content and the viscosity of hydrogen-containing silicone oil are 0.5% and 50 cSt, respectively. The viscosity of polydimethylsiloxane is 50 cSt.

2.1. Dosimetric characterization of the WTESH

To understand the dosimetric characterization of boluses made from the WTESH, a cuboid WTESH bolus with a dimension of 15 cm×15 cm×0.5 cm was made for the dosimetric characterization study.

First, the WTESH cuboid bolus was scanned by a GE 570 (GE, USA) computed tomography (CT) to get the relative electron density (RED) of the silicone hydrogel material. The tube voltage and current of the CT were set to 120 kV and 400 mA, respectively. The slice thickness of the scanned images was 5 mm. The acquired imagines from the CT scanner were uploaded to Monaco TPS (version 5.11.03). The measured central RED of the bolus was 1.09, which is close to the RED of human tissue.

To study the dose distribution in the cuboid bolus, the bolus was then placed on a stack of PTW solid water (PTW, Freiburg, Germany) with a total thickness of 10 cm. The bolus was centered on top of the PTW solid water. The bolus and PTW solid water stack were placed on top of a couch with SSD = 100 cm. The field size of the x-ray was 10 cm × 10 cm with a radiation dose of 100 MU. The energy of the x-ray was 6 MV. The absolute dose at 5 cm below the upper surface of the bolus on it central axis was measured 5 times using a Farmer chamber (PTW30013, PTW, Freiburg, Germany), as shown in Figure 1. The average of the five measurements was taken as the radiation dose deposited at that point, it was named ‘Dose1.’ The experiment was also simulated by using Monaco, the dose at the same point in the simulation was recorded and named ‘Dose2.’ The dose differences between the measurements and the simulations were calculated by Equation 1, and labeled ‘Silicone hydrogel bolus,’ as shown in Table 1.

\[
\text{Dose difference} = \frac{(\text{Dose}1 - \text{Dose}2)}{\text{Dose}2} \times 100 
\]

To investigate whether a WTESH bolus can provide an equivalent dosimetric characterization as the virtual bolus in the simulation with the RED of 1.09, the measurements and the simulations with specified RED for the corresponding bolus region was also compared. In the simulation, the corresponding bolus region was delineated, and the RED of this region was set to 1.09. The simulated dose at the same point in this case was named ‘Dose3.’ The dose difference between Dose3 and Dose1 was calculated using Equation 2, the result was labeled ‘Virtual bolus,’ as shown in Table 1:

\[
\text{Dose difference} = \frac{(\text{Dose}1 - \text{Dose}3)}{\text{Dose}3} \times 100 
\]

2.2. Fabricating workflow of WTESH boluses

In the study, an Atom dosimetry phantom (Model 702 Adult ATOM Female; CIRS Inc., Norfolk, USA) with left breast removed was used to mimic a patient after the post-mastectomy radiotherapy, as shown in Figure 2 (a). A bolus was fabricate according to the surface feature of the Atom dosimetry phantom. The fabricating procedure is described below:

1. The phantom was immobilized in a radiotherapy vacuum bag. Positions on the surface of the phantom determined by the location lasers were marked for fixing the phantom's position. The phantom was CT scanned under the same CT configurations as discussed in Section 2.1 to get the CT images of the phantom. Two lead lines were placed on the surface of the phantom to provide position references for the
bolus in the radiotherapy, as shown in Figure 2(a). The CT images of the phantom were used in the TPS to design a bolus for the phantom.

2. The tumor contour and organ at risks (OARs) in the CT images was delineated by a clinical radiation oncologist. A virtual bolus with a thickness of 5 mm and a RED of 1.09 was designed in the TPS according to the tumor position and the lead line references, as shown in Figure 2(b) in yellow. The CT images and contours from the TPS were uploaded to 3D Slicer (version 4.10.1)

3. In 3D Slicer, a mold for shaping a bolus with a window at the bottom was designed, as shown in Figure 2(c) in light green. The wall thickness of the mold was set to 5 mm because of the technique limit of 3D Slicer. The designed mold was saved as a .STL file and uploaded to Materialize Magics (version 21.0) for processing before 3D printing. In Materialize Magics, the wall thickness of the mold was diminished to 1.5 mm without changing the thickness of the virtual bolus. The mold file was then uploaded to the control center of the 3D printer called Stereo Lithography Apparatus (SLA) 3D printer (UnionTech Lite 600, Shanghai, China). The printing material of the mold was C-UV9400 (Aide Polymer Material Technology Co., Ltd, Dongguan, China), which follows the standard of RoHS Directive (EU) 2015/863.

4. The residual resin of the 3D-printed mold was removed by rinsing it in water.

5. To formulate WTESH, liquid A and liquid B were mixed in a container. The container was then sealed and pumped for 10 minutes to get its inner pressure to around 0.09 MPa, which can remove the bubbles in the mixed liquid. The WTESH was then poured into the 3D printed mold from the bottom window, and kept still in the lab for roughly 3 days for solidification.

6. The mold and the solidified WTESH were heated at 80°C to remove the mold given that the solidified
silicone hydrogel can withstand 200°C while the mold becomes soft at 80°C. It is easy to separate the mold and the WTESH bolus at this temperature. The customized bolus is shown in Figure 2(d). The bolus can easily adhere to patient’s skin because of its physical property.

2.3. Design of radiotherapy plans

To design the radiotherapy plans for patients with the WTESH bolus in clinical practice, the performance of using the virtual bolus for the phantom was evaluated in the TPS. The Clinical Target Volume (CTV) and the OARs of the phantom and the patients were delineated in CT images by a clinical radiation oncologist. The CTV was expanded for 0.5 cm to create a PTV. In the phantom CT images, the virtual bolus with a thickness of 5 mm and a RED of 1.09 was created. The treatment plans (Plan 1) for the virtual bolus were designed using Monaco TPS (calculation algorithm: Monte Carlo algorithm; grid spacing = 0.3 cm; linear accelerator: Varian 23 IX) with the prescribed dose for PTV of D95% = 50 Gy (2 Gy × 25 fractions). The tuned parameters in the TPS achieving a suitable dose distribution for the phantom and patients with the virtual bolus was then applied to the phantom and the patients with the WTESH bolus.

To check the dosimetric characterization of the customized WTESH bolus in radiotherapy, the dose distributions of the phantom and the patients with the customized WTESH boluses were calculated in the TPS with the same tuned parameters, and compared with the dose distribution using virtual bolus. In the calculation, the customized WTESH bolus was attached to the surface of the phantom and the patients according to the surface ink position marks, respectively. The CT images of the phantom with the WTESH bolus and the patients with the WTESH bolus were scanned. To overcome the position errors, the CT images of the virtual bolus and the WTESH bolus were uploaded to a software called MIM (version 7.0.3) for rigid fusion. The new CT images produced after rigid fusion were then uploaded to the TPS for dose distribution calculations.

2.4. Evaluation of the conformity of the WTESH bolus

In the study, the degree of adhesion and maximum air cavity dimension between the skin surface and the WTESH bolus were used to evaluate the conformity of the bolus. All air cavities between the WTESH bolus and the patients’ skin were manually delineated in the rigid fusion CT images under SoftTissue Condition (Window: 600, Level: 40) in Monaco, as shown in Figure 3. The degree of adhesion was calculated by using the following formula:

\[
\text{Degree of adhesion} \% = \frac{\text{Volume of air gap}}{\text{Volume of the bolus}} \times 100
\]

3. Results

3.1. Comparison of the dose between the cuboid WTESH bolus and the cuboid virtual bolus

The absolute dose differences of ‘Virtual bolus’ and ‘Silicone hydrogel bolus’ are less than 0.12%, as shown in Table 1. This indicates that the dosimetric characterization of WTESH is roughly the same as the virtual bolus with the RED of 1.09.

3.2. The conformity of the WTESH bolus

The degree of adhesions of the WTESH bolus are 1.3%, 7.0%, 3.0% and 3.4% for Phantom, Patient 1, Patient 2 and Patient 3 respectively, as shown in Table 2. For phantom, the volume of air gap is only 2.9 cc, the maximum air cavity dimension is 2.6 mm, which means that the WTESH bolus has an excellent adhesion to patients’ skin.

3.3. Comparison of the dose between the virtual bolus and the WTESH bolus

The parameters in the TPS for evaluating the dosimetric characterization are shown in Table 3. For V50 (50 Gy Coverage Volume) of PCTV, the maximize absolute difference (Phantom) is 1.17% (Figure 4), the minimum absolute difference (Patient 3) is 0.02% (Figure 5). For OARs, the dosimetric difference of listed parameters were less than 2.4%, which means that the WTESH bolus has a similar dosimetric characterization as the virtual bolus.

3.4. Comparison of the conformity between the WTESH bolus and sheet bolus

To prove the outstanding conformity of the WTESH bolus, the conformity of a self-adhesion sheet bolus with a dimension of 27 cm×27 cm×0.5 cm was calculated and compared with the conformity of the WTESH bolus. For the sheet bolus, the air cavities between the sheet bolus and 5 patients were delineated under ‘Custom Condition’ in Monaco (Window: 650, Level:-200). The immobilized CTs of 5 post-mastectomy
radiotherapy patients and 15 CBCT images were randomly chosen to compare with the 4 immobilized CTs of the phantom and the 3 patients and 11 CBCT images. The comparison indicates that the WTESH bolus has a higher conformity than the sheet bolus. The results are shown in Table 4.

4. Discussion

In clinical practice, boluses play a significant role in post-mastectomy radiotherapy. Due to insufficient malleability of traditional bolus materials, and the effect of the arm on the side had surgery, the air gap between the skin and the ordinary commercial bolus is quite large in clinical practice. A lot of researches have been done to investigate the effect of air gaps to the dosimetric characterization, and the effect become more important in clinical with increasing adoption of highly conformal radiotherapy techniques such as intensity modulated radiation therapy (IMRT) (Rehman et al., 2018; Zhang et al., 2015) or

![Figure 4. DVH of phantom with virtual bolus and WTESH bolus.](image)

![Figure 5. DVH of patient 3 with virtual bolus and WTESH bolus.](image)

Table 3. Comparison of the calculated dose of virtual bolus and the WTESH bolus.

|          | Phantom | Patient 1 | Patient 2 | Patient 3 |
|----------|---------|-----------|-----------|-----------|
| PCTV     | V50 (%) | 97.51     | 99.00     | 98.00     | 97.82     |
|          | Virtual | 96.49     | 98.73     | 97.80     | 97.70     |
|          | Real bolus | 57.82 | 56.26 | 57.77 | 57.54     |
|          | Dmax   | 57.65     | 57.68     | 58.65     | 57.88     |
| Heart    | Mean dose (Gy) | 8.97 | 9.92 | 2.86 | 9.08     |
|          | Virtual | 8.84     | 10.03     | 2.91      | 9.17      |
| Lung(Tumor side) | V20 (%) | 25.18 | 25.03 | 24.71 | 23.37 |
|          | Real bolus | 24.98 | 25.11 | 24.84 | 23.22     |
| Breast(Opposite tumor side) | Mean dose (Gy) | 12.33 | 3.48 | 3.90 | 2.31     |
|          | Real bolus | 12.21 | 3.53 | 3.84 | 2.29     |
| Throat   | Dmax (Gy) | \ | 53.92 | 53.10 | 51.02     |
|          | Virtual | \ | 53.10 | 51.02     |
|          | Real bolus | \ | 54.11 | 53.33 | 52.73     |
volumetric modulated arc therapy (VMAT) (Munshi et al., 2017; Qi et al., 2020), in which the overall dose is delivered using a series of smaller multileaf collimation (MLC). To reduce the influence of air gaps to the dosimetric characterization, it is better to diminish the air gaps between the bolus and the patients’ skin.

In this work, soft WTESH boluses with self-adhesion were fabricated by using 3D printing technology. The boluses bear the features of patients’ body profile, which reduces the air cavities between the boluses and the patients’ skin. The current publications of the customized boluses for chest wall radiotherapy are using PLA as the material (Park et al., 2016; Robar et al., 2018). Given the stiffness of the PLA, it would be better to use soft materials for boluses since they are easy to accommodate the variations over the patients’ body profile, and patients’ radiotherapy experience is also better when using a soft bolus than a hard bolus.

The boluses fabricated based on the virtual contour of a specific shape and a RED have certain instructive significance. The RED of the fabricated bolus can also be adjusted by using different materials according to the requirements of clinical applications. Designing boluses based on virtual contours of different shapes and RED can provide an optimal solution for radiotherapy.

The ingredients for formulating the WTESH can be stored at room temperature. The procedure of formulating the WTESH is simple to follow for oncologists. The vacuum environment required in the formulating process can be achieved with regular pumps. So, there should be no technical difficulties to formulate the WTESH in a radiotherapy center.

The whole procedure of fabricating a WTESH bolus takes about 4–5 days. The price can be less than 800 CNY with the help of medical physicists and radiotherapists. So, the time and the price of making a WTESH bolus are affordable for patients. The dosimetric characterization of WTESH boluses has a good agreement with virtual boluses. All these advantages make WTESH boluses a good choice in clinical application.

### 5. Conclusion

We provide a workflow of designing and fabricating WTESH boluses for post-mastectomy radiotherapy. The WTESH boluses have perfect adhesiveness with patients’ skin. The characteristically soft texture improves patients’ experience during a radiotherapy.

In addition, the dosimetric characterization of a WTESH bolus is roughly equivalent to a virtual bolus. The proposed workflow can be incorporated easily into radiotherapy.

### Disclosure statement

No potential conflict of interest was reported by the author(s).

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