Evaluation of an Automated Algorithm for the Design of 2-Piece Molds for Patient-Specific, Flexible Bolus

INTRODUCTION

Traditionally, creation of patient-specific bolus, using wax and plaster molds formed directly on the patient, has been time consuming and the quality of the result highly dependent on skill. The introduction of 3D printing enables standardized fabrication, and commercial solutions (Adaptiiv Medical Technologies Inc.) are bridging the technological gap between patient-specific treatment planning system (TPS)-based contours and successful 3D printed rigid or semi-rigid bolus.

A previous study [1] indicates, however, that highly flexible and soft bolus, with properties akin to standard sheet bolus, is more patient friendly and results in high quality dose coverage. Current fused deposition modeling (FDM) 3D printing technology does not support direct printing of such materials, but it can instead be used to produce highly spatially accurate, patient-specific molds. A newly available commercial software algorithm (Adaptiiv Medical Technologies) enables automated two-piece mold STL model generation directly from the TPS-based bolus contour.

This work aims to demonstrate that 3D printed two-piece molds, designed with an automated software algorithm, can easily produce flexible silicone bolus for a variety of geometries, with thickness accuracy comparable to generic flexible bolus sheets but with superior surface conformity. The homogeneity, density and geometrical accuracy of the mold-based silicone boluses are also reported.

METHODS

- An anthropomorphic and solid water phantoms were CT scanned. TPS tools were used to generate 5mm thick bolus RT structures for four anatomical sites (scalp, face, ear and breast) and one slab bolus.
- CT images, bolus and body structures were imported into 3D Bolus software (Adaptiiv Medical Technologies Inc.). For each bolus, two different mold designs were generated: a two-piece block representing a bounding box around the bolus (Figure 1, a & c), and a two-piece shell which follows the shape of the bolus (Figure 1, b & d).
- Molds were 3D printed on an Axiom 20 (Airwolf 3D) FDM printer, using polylactic acid (PLA) rigid filament (3D Fuel). Mold pieces were assembled and sealed with 100% silicone. Once the seal cured, Ecoflex™ 30 (Smooth-On) silicone rubber was poured into the assembled molds. Following 4 hours of curing time, the molds were dismantled and the silicone "patient-specific" soft boluses obtained.
- The thicknesses of the resulting silicone boluses and a set of 7 generic bolus sheets (Superflab, Eckert & Ziegler) were measured using an ultrasonic thickness gauge. The thickness variation from generic bolus sheets was used to dictate the tolerance for acceptable silicone bolus thickness variation.
- Silicone boluses were positioned on phantoms and CT scanned. This process was repeated with standard bolus sheets taped to cover the same regions. Both silicone and sheet boluses were placed on the phantom and taped by an experienced RTT (Figure 2). Surface conformity was evaluated by contouring the air gaps and measuring their volumes for both bolus types.
- Silicone bolus Hounsfield Unit (HU) homogeneity was evaluated from the CT data, and the density was assessed using physical mass measurement and bolus volume reported by the software.
- Lateral dimensions of the silicone slab bolus were measured using calipers.

RESULTS

- Mold design in the software took approximately 10 minutes per case. Average mold printing times were 7 hours for slab molds and H&N cases and 30 hours for the breast case.
- A total of 183 thickness point measurements on the generic sheet bolus showed 63% of all points fell within +/- 0.0 - 0.5 mm of the expected 5 mm and 10 mm sheet thicknesses. This was then taken as the tolerance for acceptable 3D printed mold-based bolus thickness variation. The remaining 27% of generic bolus thickness point measurements fell in the range of 0.6 – 1.5 mm.
- Silicone mold-based bolus thickness measurements fell within tolerance for all bolus geometries tested (> 63% of all thickness point measurements within the range of 0.0 - 0.5 mm of the expected 5 mm thickness, Table 1).
- Air gap volume was reduced for all silicone mold-based boluses compared to generic sheet bolus (Figure 3). The forehead, nose and ear generic sheet bolus showed air gap volumes of 2.8 cc, 13.9 cc and 24.3 cc, respectively, versus 0-2.5 cc with the silicone boluses. In the breast case 75.8 cc air gap was reduced to 4 cc by using the silicone bolus (Video 1). On average, the air gap volume was reduced by 89% when using the silicone mold-based bolus over generic sheet bolus.
- Silicone bolus mass density, averaged over all 10 cases, was 1.05 ± 0.04 g/cc.
- The average HU of silicone bolus was 150 ± 19 HU. The mean HU value per bolus ranged from 125 HU to 172 HU. For the same anatomical site, the difference in mean HU values between block and shell design was small (1 – 10 HU) compared to the observed variation in the average.
- The width and height of the silicone mold-based slab bolus were accurate to within 1 mm of the expected values.

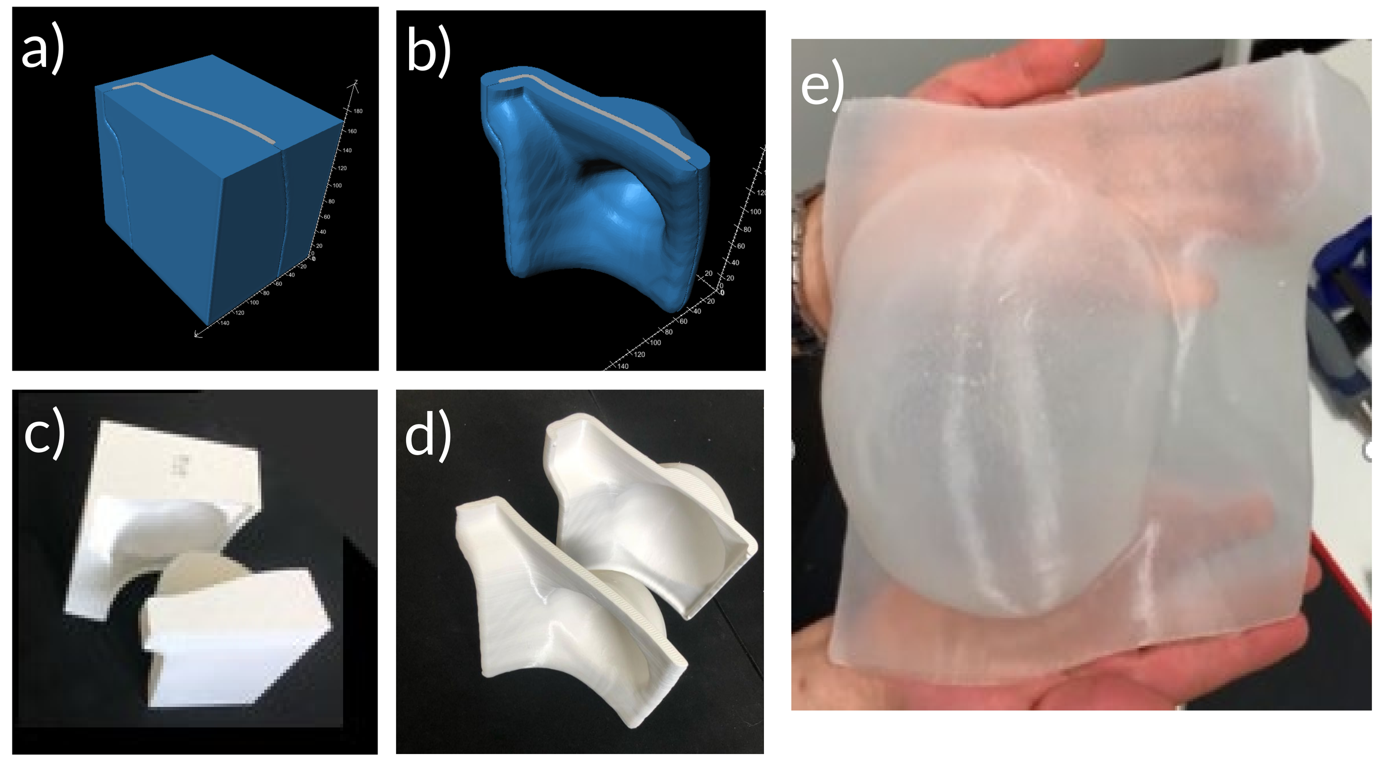

Figure 1. Mold-based silicone bolus production steps. Mold generation in 3D Bolus software: (a) block design, (b) shell design; 3D printed molds: (c) block design, (d) shell design; (e) resulting silicone bolus.

Mold Type	Bolus	% of points within 0.5 mm discrepancy	% of points above 0.5 mm discrepancy
Block	Slab	69%	31%
	Face	83%	17%
	Ear	100%	0%
	Breast	60%	40%
Shell	Slab	100%	0%
	Face	75%	25%
	Ear	90%	10%
	Breast	81%	19%
Superflab		63%	28%

Table 1. Silicone bolus and generic sheet bolus thickness measurement results.

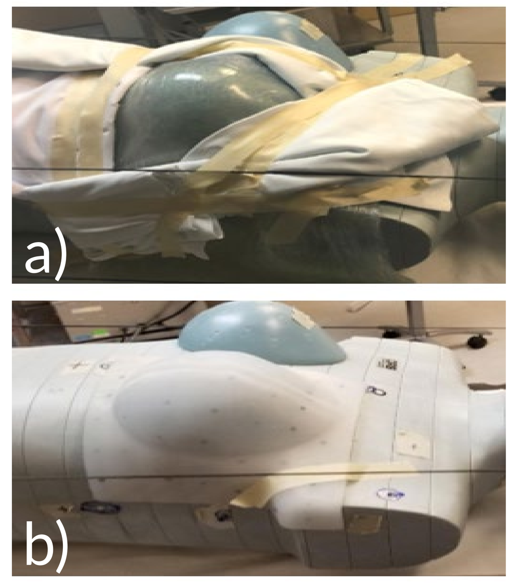

Figure 2. Sheet bolus (a) and silicone bolus (b) placed on the anthropomorphic phantom breast and taped.

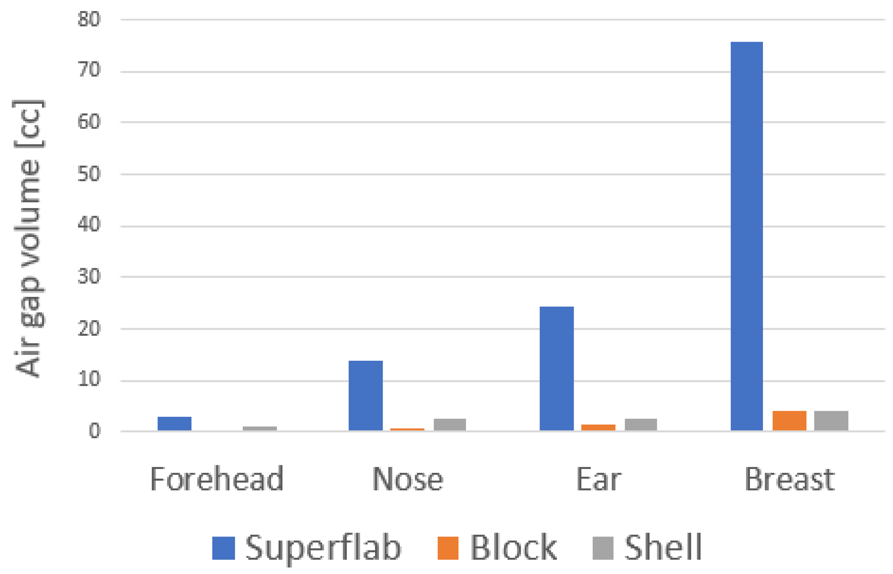

Figure 3. Air gap volume for silicone boluses, both block and shell mold designs, and generic sheet bolus.

Video 1. Conformity of silicone bolus vs generic sheet bolus for the anthropomorphic breast site.

CONCLUSIONS

- The automated algorithm for designing two-piece molds in 3D Bolus software (Adaptiiv Medical Technologies Inc.) provides a versatile method for producing spatially accurate, flexible, patient-specific bolus over a range of clinically applicable anatomical sites.
- This simple method for designing molds can be accomplished in a relatively short period of time and does not require any 3D modeling expertise.
- The accuracy in thickness of 3D printed mold-based silicone bolus is comparable or superior to that of generic sheet bolus.
- 3D printed mold-based silicone bolus provides excellent surface conformity, reducing air gap volumes by 89% compared to generic sheet bolus for the anatomical sites included in this study.
- 3D printed mold-based silicone bolus demonstrated clinically acceptable radiological properties in terms of mass density, HU uniformity and geometric accuracy.
- To date, the Moulds feature in 3D Bolus software (Adaptiiv Medical Technologies Inc.) is the only dedicated, regulatory-cleared software solution available for the purpose of designing 3D printer-based flexible bolus.

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REFERENCES

[1] Canters et al. Clinical Implementation of 3D Printing in the Construction of Patient Specific Bolus for Electron Beam Radiotherapy for Non-Melanoma Skin Cancer. Radiother Oncol 2016 121(1):148-153.

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