Use of a Novel Software Technology for Design and Production of Patient-Specific Silicone Bolus

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INTRODUCTION

Silicone boluses provide a conformal and flexible solution to achieving required dose build-up in radiation therapy. This approach has been shown to be feasible for head-and-neck radiation therapy [1] and when applied to treatment of non-melanoma skin cancer, has introduced both dosimetric and workflow advantages [2].

However, the method requires detailed software design to provide a mold for fabrication of silicone bolus. To date, no dedicated or regulatory-cleared software solution has been available. This case study evaluates a new module of a commercial solution facilitating this technique.

AIM

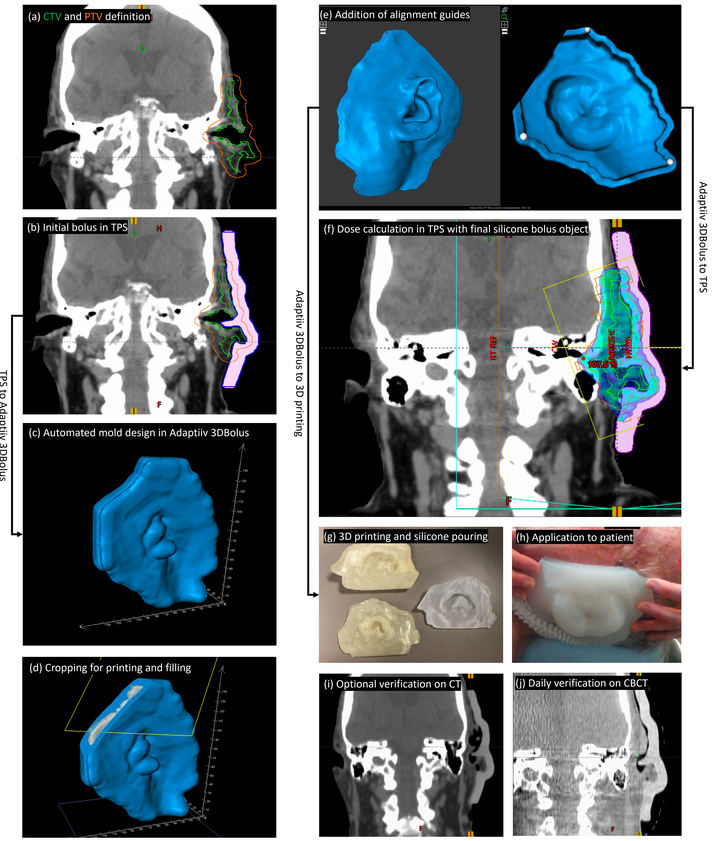
The aim of this study was to develop and evaluate a workflow using a novel, CE-mark and FDA 510(k)-cleared software technology (3Dbolus, Adaptiiv Medical Technologies, www.adaptiiv.com) facilitating design and production of a 3D printed silicone mold bolus, interfacing directly with the treatment planning system (TPS). The method is demonstrated in the treatment of an 81-year-old male patient presenting a squamous cell carcinoma of the left ear and pre-auricular area.

METHOD

- The clinical target volume (CTV) and planning target volume (PTV) were defined based on CT in TPS (Eclipse v13.6) to include the left ear and pre-auricular area (**figure a**).
- An initial 1 cm-thick bolus was defined in the TPS to cover the PTV with an approximate 2 cm margin (**figure b**).
- The TPS interfaces with the 3DBolus application (Adaptiiv Medical Technologies) to allow import of the CT and structure data. Upon import, the bolus structure is smoothed adaptively to avoid CT-slice artifacts.
- With knowledge of the bolus and skin surface, 3DBolus automatically produces a two-part shell-type mold that includes a seam (**figure c**) for subsequent separation and releasing of the bolus.
- The planner can crop the mould with up to two planes, e.g., to create an opening for filling, and to provide a flat surface to support on the 3D printer bed (**figure d**).
- To ensure precise fitting of the two halves of the mold, alignment guides are included in the 3DBolus application, adding a set hemispherical mortise/tenon interlocking features. These are configurable in number and dimension (**figure e**).

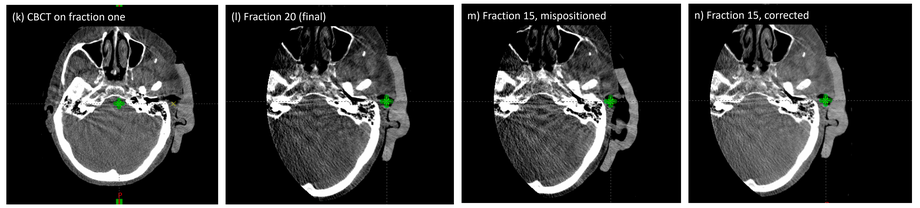
METHOD, CONTINUED

- When the mold design is complete, the model of the digital object of the bolus (inside the mold) is exported to the planning system to confirm shape, location, and to allow dose calculation. Upon import to the TPS, the object is predefined with the relative electron density of the silicone material (**figure f**), which is configurable in the application.
- The planning approach for this case was delivery of 50 Gy in 20 fractions, using three co-planar, ipsilateral 6 MV VMAT arcs.
- The mold object is 3D-printed using Fused Deposition Modeling (FDM) using polylactic acid (PLA). The mold object may be printed with low infill (e.g. 15%) for speed. For this case, the printing required approximately eight hours with 0.5 mm layer height but did not require user interaction during this time.
- When complete, the mold halves are assembled and sealed with caulking. A skin-safe silicone (EcoFlex 30) is poured in the mold and allowed to set for four hours, then released (**figure g**). No desiccation was used, e.g., for evacuation of air during the curing process.
- The final silicone bolus is fitted to the patient (**figure h**). The bolus was held in place using a gauze mesh. Patient immobilization is formed over the bolus.
- A verification CT may be performed to check the fit and uniformity of the bolus (**figure i**). Although the step in (**figure f**) can provide a final treatment plan with the assumption of accurate positioning, optionally, the plan can be recalculated on this CT dataset for comparison. On treatment, daily CBCT was used to assess positioning and fitting of the bolus (**figure j**).



RESULTS

- The new software application provided fast and largely automated design of a silicone bolus, requiring approximately 10 minutes at the software step.
- The manufacturing process required approximately 4 hours for 3D printing, although this step requires no user interaction. The pouring/removal process requires approximately 30 minutes.
- The verification CT confirmed accurate shape and positioning of the bolus (**figure i**) relative to the designed object exported to the treatment planning system (**figure f**).
- The resultant silicone bolus was seen to be highly uniform on CT with a mean HU of 160 (approximate relative electron density of 1.13). No air voids were apparent.
- Daily CBCT showed consistent and accurate positioning throughout the treatment course (**figures k and l**).
- Only one fraction of 20 required a correction of bolus positioning (**figures m and n**).



CONCLUSIONS

- The novel software technology introduces an efficient solution for design of a 3D printable mold for silicone bolus, requiring approximately 10 minutes for the software steps in the 3DBolus application.
- Dedicated software tools enabled necessary steps for mold fabrication, including cropping for 3D printing and silicone pouring, as well as addition of alignment guides for the mold.
- The workflow provides a closed-loop approach, exporting the designed object back to the TPS, allowing verification recalculation of the plan, incorporating the final bolus object.
- The manufactured bolus showed excellent uniformity and a mean relative electron density of 1.13 based on CT imaging.
- The silicone bolus was easily positioned by therapists and well tolerated by the patient.
- The bolus showed acceptable accuracy, with repositioning and re-acquisition of CBCT required only once in 20 fractions over the treatment course.

ACKNOWLEDGEMENTS

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DISCLOSURES

JR is a co-founder and board member of Adaptiiv Medical Technologies.

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