



3D Printing in Radiation Oncology

A comparison study on using a 3D printer to create radiation therapy bolus of the nose compared to traditional methods using wax and thermoplastic.

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Abbreviations

Central West Cancer Care Centre - CWCCC

Western New South Wales Local Health District – WNSWLHD

Three Dimensional Printer – 3D Printer/Printed

Polylactic Acid – PLA

Oncology Information System – OIS

Computed Tomography – CT

Planning Target Volume – PTV

Conformity Index – CI

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Abstract

Aims

To verify using a retrospective study in a radiation therapy setting to determine the differences between 3D, thermoplastic, and wax bolus types and their impact on dosimetry, CT Simulation time, and skin reaction when used for treating skin cancer of the nose.

Methods

Patients were divided into three cohorts based on the type of bolus used when they received their radiotherapy between 2011 and 2020 at Central West Cancer Care Centre in Orange, NSW Australia. These cohorts were Wax (n=11), Thermoplastic (n=11), and 3D printed (n=16). All were treated with 6MV fields and analysed to determine the differences between the means (or parametric equivalent) of; PTV dose coverage, dose homogeneity, dose conformity, CT simulation time, skin reaction and cost of the physical nose bolus.

Results

V95% and D98%, medians are likely to be equal to previous wax and thermoplastic bolus materials. 3D Bolus D50% coverage is higher than the other bolus materials. D2% is highest in 3D Bolus. 3D Bolus has a lower significant maximum (15mm³) dose than thermoplastic, but is lowest in wax. 3D Bolus is the cheapest material studied per bolus made. The conformity index is much better when using 3D Bolus. Homogeneity is likely to be equal for all bolus types. CT time is less than half of both wax and thermoplastic. Skin reaction is likely to be equal across bolus materials.

Conclusion

This study has shown that 3D printed bolus can provide more conformal and equally homogenous dosimetry when compared to Wax and Thermoplastic, and documented skin reactions are comparable between all three bolus types when used for as bolus for skin treatments. It is also more time efficient and cheaper for the service.

Implications

3D printed bolus allows creation of plans that better fits Radiation Oncologist specifications compared to wax or thermoplastic. 3D printed bolus takes less patient and therapist time compared to other rigid bolus and is cheaper than the other materials measured. 3D bolus is most homogeneous, most conformal, and provides an equal effect on skin cancer treatments of the nose when using photon megavoltage beams.

Keywords

skin cancer, dosimetry, time efficiency, cost efficiency

Executive Summary

Background

Bolus in radiotherapy refers to the use of a skin equivalent material to move the maximum intensity of high energy x-rays closer to the skin surface or compensate for missing tissue (Kahn, 2010). Traditional bolus is made from a range of materials including wax or thermoplastic, and synthetic gel (Vyas, 2013). Production of a bolus is a labour intensive process that is uncomfortable for patients and requires several hours of both patient and staff time. 3D printed materials appear to have the correct characteristics to be used as bolus and can be digitally created (Marchant, 2019). 3D printed bolus made from Polylactic Acid (PLA) was trialled at Central West Cancer Care Centre (CWCCC) and appeared to improve time, cost, and dose conformity efficiencies in the service. This study was then created as an entry to the Rural Research Capacity Building Program to analyse the differences between 3D printed bolus and previous bolus materials used at CWCCC, to see if the differences were perceived or actual.

Methods

A quantitative retrospective cohort study between patients that have received traditional wax and thermoplastic bolus interventions with patients that received the 3D printed bolus intervention was conducted at CWCCC in 2020. Thirty eight patient's radiation therapy nose plans for the treatment for skin cancers were retrospectively analysed in three cohorts. 11 patients in the Wax and Thermoplastic groups respectively were compared to 16 patients in the 3D printed cohort. Routinely collected patient level data was used and means (or parametric equivalent) compared between the three groups. Data was then analysed using SPSSv25 by Dr Georgina Luscombe and interpreted by principal investigator Andrew Skimmings.

Results

- There were no significant differences in V95% and D98% coverage indicating that these constraints are usually met regardless of bolus type.
- There were significant differences in D50% and D2% coverage, wax was lowest at 100% and 102.2%, thermoplastic had higher D50% and D2% than wax at 101.2% and 104.4%, 3D printed bolus had the highest D50% and D2% at 101.7% and 104.7%.
- There were significant differences in 15mm³ ICRU significant maximum dose across bolus types. Wax had the lowest at 102.3%, thermoplastic had the highest at 104.3%, and 3D printed was 103.3%.
- There were significant differences in cost per bolus. Wax was \$9.48, thermoplastic was the most expensive at \$34.74, and 3D printed cost the least at \$6.46.
- There were significant differences in conformity index. Wax had the lowest conformity at 3.27, thermoplastic had much better conformity at 1.43, and 3D printed bolus had the best conformity at 1.04.
- There were no significant differences in homogeneity between all three groups.
- There were no significant differences in initial CT time between wax and thermoplastic, but there was a difference between 3D printed bolus and the other groups. Wax was the longest at 116 minutes, thermoplastic was slightly shorter at 113 minutes, and 3D printed CT sessions were shortest at 53 minutes.
- There were no significant differences in skin reaction

Table 1. Wax and Thermoplastic Bolus versus 3D printed Bolus comparisons

	Wax (n=11)	Thermoplastic (n=11*)	3D Printed PLA (n=16)	P-value
V95%, med (IQR)	100 (81-100)	99.6 (94.5-100)	99.8 (98.8-100)	0.85
D98%, med (IQR)	97.1 (80.4-99.1)	97.1 (92.9-97.7)	97.5 (96.4-98.6)	0.40
D50%, med (IQR)	100 (99.8-100.8)	101.2 (100.5-102)	101.7 (101.4-102.5)	0.002
D2%, med (IQR)	102.2 (101.2-103.5)	104.4 (104.1-105.7)	104.7 (104.1-105.6)	<0.001
15mm³ max. dose, med (IQR)	102.3 (101.5-103.7)	104.3 (103.7-107.8)	103.3 (102.4-103.6)	0.002
Cost per bolus, med (IQR)	9.48 (6.19-11.32)	34.74 (29.03-44.50)	6.46 (4.87-8.13)	<0.001
Conformity Index, med (IQR)	3.27 (1.69-6.07)	1.43 (1.05-2.69)	1.04 (0.82-1.19)	<0.001
Homogeneity index, med (IQR)	0.068 (0.041-0.210)	0.084 (0.063-0.108)	0.072 (0.064-0.084)	0.54
CT time (Minutes), med (IQR)	116 (90-125)	113 (65-176)	53 (43-123)	<0.001
Skin reaction, n (%)				0.06
minimal	0	2 (20)	0	
mild	0	0	2 (12.5)	
moderate	3 (27.3)	3 (30)	9 (56.3)	
moderate-intense	2 (18.2)	2 (20)	2 (12.5)	
intense	6 (54.5)	3 (30)	3 (18.8)	

Med, median; IQR, interquartile range; * n=1 missing

Conclusion

This study has shown that 3D printed bolus can provide more conformal and equally homogenous dosimetry when compared to Wax and Thermoplastic, and documented skin reactions are comparable between all three bolus types when used as bolus for skin treatments. It is also more time efficient and cheaper for the service.

Implications

- 3D printed bolus allows patients to be provided with a plan that equally fits the Radiation Oncologists specifications
- This study informs clinical practice locally and internationally by identifying that 3D printed bolus is a more time efficient and conformal method of bolus creation when compared two other common boluses
- 3D printed bolus is more time efficient, cheaper, more conformal, and provides an equal effect on skin cancer treatments for the service when used to create bolus on nose patients when using 6MV photon fields

Recommendations

- 3D printed bolus should be integrated into radiation oncology for the construction of rigid bolus and dose compensation when using 6MV photon fields on noses
- Further research using the re-creation of modulated plans on the same patient cohort should be carried out to examine the impact of the use of modulation on patient dose statistics

Introduction

Use of a bolus is required for patients who are receiving superficial radiation treatment to the skin surface using high energy x-rays (Vyas, 2013). Traditional bolus is made from a range of materials including wax, thermoplastic, and synthetic gel (Kahn, 2010). Production of a bolus is a labour intensive process that is uncomfortable for patients and requires several hours of both patient and staff time. In 2016 use of a 3D printer to digitally create and make bolus made from PLA was trialled at the Central West Cancer Care Centre. Use of this technology has improved time efficiencies for the service and has the potential to provide more individualised and improved patient experiences, better health outcomes, reduce hospital related harm and update best practice. 3D printing has enabled shared and continuous innovation and has the potential to be a more cost and time effective use of health resources than previous historical methods.

3D printing in radiation oncology is beginning to become more recognised as departments opt for the use of this technology. This is representative of the greater radiation therapy community continuing to innovate and be on the cutting edge of new technology to provide faster and more accurate cancer treatments. Developing literature surrounding 3D printing in radiation oncology is limited to mostly theoretical benefits with no actual patient data used.

The WNSWLHD Strategic Plan 2016-2020 describes cancer as the most deadly disease among men and the second most deadly disease among women in the LHD (WNSWLHD, 2016-2020). In 2018 CWCCC treated around 750 new courses, 150 of these were skin, 31 were noses, and 5 required megavoltage photon therapy. This research contributed to a change in the treatment pathways of skin cancers at CWCCC and quantified the magnitude of differences between the previous and 3D printed methods of bolus production. We have also analysed the impact that moving the creation of rigid bolus to a 3D printer has had on workflows in the radiation oncology service.

Literature Review

Bolus in radiation therapy is a human tissue equivalent material when radiation is applied and is used when dose is required at the skin surface of the patient (Vyas, 2013; Kahn, 2010). Bolus is designed to fit with high conformity over the treatment area for reproducibility and consistency in dose delivery throughout the course of treatment (Kong, 2019). It can follow a scar if it has had clinical involvement or cater for highly variable skin contours and can be used on any part of a patient.

Megavoltage radiation beams reach their maximum intensity below the surface of the skin, around 1.5cm for 6MV beams. In order to treat superficial skin lesions a bolus is required (Vyas, 2013; Kahn, 2010). Bolus can also be used to make the radiation field more uniform throughout the patient's body where complex shapes and uneven contours may distort radiation dose (Vyas, 2013; Kahn, 2010). It is a radiation therapy standard to receive bolus when presenting for radiation treatment for a superficial skin cancer on a megavoltage linear accelerator (Vyas, 2013; Kahn, 2010). The process of creating rigid bolus has traditionally been handmade by taking a cast of the treatment area, followed by a labour intensive procedure that is uncomfortable for patients and taking hours of patient and staff time. These devices are traditionally made from wax but in recent years have transitioned to using thermoplastic, metal and synthetic gel. Wax and thermoplastic are subject to warping – either from a distorted cast or shrinking during cooling and they cannot be changed after the initial bolus has been created without re-planning the treatment. Metal and synthetic gel are very good for flat patient contours but leave gaps of air when an uneven contour is presented (Zhao, 2017; Robar, 2017).

To overcome these limitations, use of a 3D printer to digitally create bolus made from PLA was trialled at the CWCCC in 2016. The service has continued to use this technology to make bolus for treatment, and have noted improvements in time efficiency, cost savings, dosimetry and patient experience since its introduction. The use of 3D printed bolus has been documented by other departments worldwide and is currently seen as an emerging technology, for this reason clinics are often reluctant to buy in to the initial cost of setup.

3D printed bolus has been described as having smaller air gaps in patient contour, better dose homogeneity and conformity, and a greater amount of patient comfort with better positional reliability than commercial available bolus. It is also suggested that it could replace commercial bolus for clinical use (Kong, 2019; Robar, 2017). 3D printed bolus is suitable for the fabrication of complex radiotherapy bolus from a dosimetric viewpoint, but the documented use for treating patients is limited (Zhao, 2017).

Study Aims

- To determine if 3D printed rigid bolus improves service efficiencies and patient outcomes compared to traditional thermoplastic and wax boluses, for patients receiving superficial radiation treatment to the nose requiring bolus and using 6 MV gamma rays
- To quantify the influence that integrating a 3D printer into CWCCC workflows has had on CT simulation session times, the cost of raw materials used in construction of the bolus, dose coverage and documented skin reactions

Hypothesis

- Using 3D printed bolus will be more time efficient, cheaper, create more homogenous dose and cause less intense skin reactions due to the dose being more homogenous

Study Objectives

- To determine if there is a difference in patient skin reactions documented by the Radiation Oncologist in the OIS patient journal between the traditional and 3D printed bolus.

- To determine if there is a difference in Planning Target Volume (PTV) coverage constraints as defined by the International Commission on Radiation Units & Measurements (ICRU) report 83 between the traditional and 3D printed bolus
- To determine if there is a difference in dose conformity index (CI) from the eclipse planning system as defined by The Radiation Therapy Oncology Group (RTOG), volume of the of the 95% isodose coverage (V95%) vs volume of the PTV between the Wax, Thermoplastic, and 3D printed bolus
- To determine if there is a difference in the raw material cost between thermoplastic, wax and PLA using the contoured bolus volume
- To determine if there is a difference in the time of each patient's initial CT Simulation session between the traditional and 3D printed bolus

Methods

Study design

This study was a quantitative retrospective cohort study between patients that have received wax and thermoplastic bolus interventions with patients that have received the 3D printed bolus intervention. Routinely collected patient level data was used from the CWCCC. The means were then compared and analysed for statistically significant difference.

Ethics

Ethics approved in 2019 by Greater Western Human Research Ethics Committee. Project number 2019/PID14658.

Eligibility criteria

- Definition: All patients treated at CWCCC with 6 Megavolt photon beams to the nose using wax, thermoplastic and 3D printed bolus between 2011 and the present time
- treated on a linear accelerator at Orange Health Service
- Bolus was used during the delivery of radiation therapy
- Including patients with missing data (e.g. no documented skin reaction)

Exclusion Criteria

- No markers visible on the CT scan
- No bolus used for radiation treatment

Data Collection

Routinely collected data was used to define the differences between 3D printed, thermoplastic and wax bolus. There was a total of 38 patient records analysed, of which there were 11 wax, 11 thermoplastic, and 16 3D printed bolus records. Radiation Oncologist (RO) documented skin reactions from the patient journal inside the OIS were used to track changes the bolus type may have had on RO intention. CT volume of all bolus was manually contoured on CT for each patient and the volume in cm^3 then was equated to weight through corresponding mass density and a cost given to that structure (e.g. Wax was \$0.09 per cm^3 and the structure may have been 100cm^3 , so $100 \times 0.09 = \$9$). The cost and weight of each material CWCCC paid for was sourced from previous paper invoices to define the mass to cost ratio per cm^3 . The time of each patient's CT Simulation session was analysed to determine a metric for average patient and staff time saved per CT session from in progress status to

completed status. Dose conformity index from the Varian Eclipse TPS (v16.1) was used to define conformity indexes across all plans, and this equates to the volume of the 100% isodose structure compared to the PTV volume. International Commission on Radiation Units & Measurements (ICRU) report 50/83 was used to define coverage constraints and analysis and these were; Volumetric coverage ($V_{95\%}=D\%$), Dosimetric coverage ($D_{98\%}$, $D_{50\%}$, $D_{2\%}$), Clinically significant maximum ($V_{15\text{mm}^3}=D\%$), and Homogeneity Index ($D_{98\%}-D_{2\%}/D_{50\%}$)

Study Outcomes

Primary outcome:

- Differences in dose coverage statistics between the three used bolus types

Secondary outcome:

- Measure cost and time differences between bolus types

Statistical Analysis and Interpretation

The data was statistically analysed and interpreted by Dr Georgina Luscombe (USYD/HETI) and Andrew Skimmings.

Descriptive analyses of all parameters was conducted, and data reported as means \pm standard deviations (or non-parametric equivalent). Comparative analyses was used to determine differences between 3D printed PLA and either wax or thermoplastic bolus media. All analyses were conducted in SPSS vn 25, and p values < 0.05 considered to indicate statistical significance.

Data management

All collected data was de-identified when entered into the data spread sheet. Only the subject ID number was used. The subject ID number and patient's identity was recorded in a master list kept separate to the data, and password protected with encryption, so only the lead researcher has access to this information.

Quality Assurance

To check for inter-rater reliability of recorded measurements from difference in Planning Target Volume (PTV) coverage constraints, 10 random checks were assessed by Hayden Sheehan (Staff Specialist at CWCCC) to determine accuracy of measurements taken by the lead researcher.

Results

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V95% and D98%, medians are likely to be equal to previous wax and thermoplastic bolus materials. 3D Bolus D50% is coverage is higher than the other bolus materials. D2% is highest in 3D Bolus. 3D Bolus has a lower significant maximum (15mm^3) dose dose than thermoplastic, but is lowest in wax. 3D Bolus is the cheapest material studied per bolus made. The conformity index is much better when using 3D Bolus. Homogeneity is likely to be equal for all bolus types. CT time is less than half of both wax and thermoplastic. Skin reaction is likely to be equal across bolus materials.

Discussion

3D printed bolus is a viable and often better alternative to traditional wax and thermoplastic bolus. 3D bolus can be cheaper, allow better conformity, equal homogeneity, take less patient and therapist time to create, patients don't have to endure the mould making process, and can enable the planner to achieve better coverage whilst minimising excess heat in the plan. 3D printed bolus demonstrated an equal dermal effect when compared to traditional bolus methods and enables an appropriate reaction when skin is the target.

Synthetic Gel and other deformable bolus was not studied and is required for highly variable areas that are likely to have large tumour shrinkage over the course of treatment or when bolus is required outside the 3D printer size limits (i.e. very large areas or fungating tumours).

The change from human to robotic manufacture appears to be where the time gains are most notable when using 3D printing. Historically a cast of the patient face is made in the simulator room, this negative is then used to cast the patient face in plaster, and the bolus manufactured on the patient replica. Moving away from human manufacture frees up both the labour time, and the guess work for Radiation Therapists. The Radiation Oncologist may also adapt the treated area after clinical mark-up due to non-obvious sub-dermal spread at presentation or for reasons only obvious after the CT scan. This would traditionally cause the bolus to be re-made, or for the patient to receive a functional but sub-optimal plan. In our case, departmental protocol puts the physical bolus creation after the RO plan approval, allowing as many PTV adaptations

required for the patient with no extra labour required. The digital bolus is then sent to the 3D Printer.

V95% and D98% medians show that minimum RO prescribed coverage constraints can be achieved with all bolus types, regardless of material, and that 3D bolus can achieve the same coverage as previous bolus materials.

The use of traditional bolus is also not detrimental to patient care. All plans included in this study were within RO accepted limits and adhered to ICRU guidelines. The main benefit of 3D printing is that using it allows us to use our treatment planning system to rapidly design the optimal bolus for the intended purpose, as opposed to traditional bolus creation methods which result in a product that is created prior to planning. Where we don't want the skin over treated we can reduce thickness or bolus size to just be over the PTV – creating more conformal plans.

Some results of this study were unexpected. Initial CT time for 3D bolus was assumed to be shorter than what was measured, but was also shown to be significantly shorter than previous bolus methods. 3D bolus cost was also anticipated to be higher than wax but was not, and skin reaction was expected to be less severe, it was equal. In retrospect, skin reaction being equal is expected as skin is the target of treatment.

Strengths and Limitations

Literature around 3D printed bolus appears limited at the time of this study. To my knowledge no other study compares actual patient data for comparison. This study validates that 3D printing is a technology worth investing in and has positive impacts on patient care. 3D printing has also integrated well into CWCCC work flows and staff training.

- 3D bolus is fit to PTV, rather than made before and trying to plan around problems such as air gaps

- 3D printing has evolved and has a lower cost entry point than in the past, making it more accessible
- Small sample size for CT sim times missing due to some tasks never launched, just going from Available to Completed
- Modality change from conformal to VMAT could affect coverage statistics
- Change in dose algorithms from AAA(V10.0.28) to Acuros(V13.6.23, 15.6.05, 16.1.0) could affect dose statistics
- Conformity verification that a patient matched device is working as intended is a Therapeutic Goods Administration requirement. All of the patients in this study had a second verification CT scan for this purpose. This second CT sim time was not tracked and may be beneficial to analyse in the future.
- Every patient used in this study had skewed data. This is because we plan to pre-defined goals of where the dose coverage needs to be for it to both adhere to ICRU guidelines and RO specifications of plan acceptance. Therefore means were not analysed, and medians +/- standard deviations were reported on.

Recommendations

- 3D printing is beneficial to patient care and should be used as an alternative to traditional bolus materials where appropriate
- Maintain daily deformable bolus for circumstances that require flexibility or when tumour size is likely to have large changes throughout the course of treatment
- Continue research on the effect that moving toward modulated plans has had on dose coverage and skin reactions
- Continue research on the integration of flexible filaments for 3D printing bolus

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