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Research Article

A prospective randomized study comparing two frameless immobilization systems for cranial stereotactic radiotherapy

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ABSTRACT

Introduction: The Dual Shell Encompass Fibreplast™ System (DS-Encompass) by CQ Medical™ is validated for frameless immobilization in stereotactic brain radiotherapy. An alternative mask model has been proposed with the rear shell replaced by a Moldcare® cushion (M−Encompass). To validate the use of this model in our cranial stereotactic workflow method including HyperArc™, we performed a prospective randomized study comparing inter-and intrafractional motion and patients comfort between both masks.

Materials & Methods: A prospective randomized study between DS-Encompass and M−Encompass was conducted involving 60 participants. Stratification between DS-Encompass and M−Encompass was carried out based on the fractionation scheme. Treatment plans were created with HyperArc™. During treatment, surface guidance was used for patient positioning and monitoring. A pre-treatment cone-beam CT (CBCT) was acquired to correct interfractional motion and a post-treatment CBCT was acquired to quantify the intrafractional motion. Patients reported comfort was analyzed with a Likert-scale at the end of the treatment. Unpaired t-tests were conducted to determine the level of significance.

Results: No significant difference in interfractional translations is present. A significant difference is revealed in roll-axis rotation, where DS-Encompass allows for smaller deviations. Since interfractional motion can be corrected through daily CBCT-scans and 6D-couch corrections, they are clinically irrelevant. Intrafractional motion does not differ significantly and remains below 0.5 mm and 0.5° for both systems. There is no statistical difference in patient-reported comfort.

Conclusion: We conclude that Encompass with Moldcare offers a safe alternative to Duall Shell Encompass for non-coplanar stereotactic brain radiotherapy. There is no significant difference in intrafractional motion nor difference in comfort levels.

Introduction

Historically, cranial stereotactic radiotherapy (SRT) involved invasive frame–based fixation systems to treat various malignant and benign conditions with infra-millimetric, and infra-degree accuracy [1–5]. The application of a stereotactic invasive headframe required a procedure under local anesthesia for fixation, posing potential risks of infection and bleeding during and after surgical procedure. Moreover, patients experienced pain and raised specific anxiety concerns [6,7].

The emergence of on-board imaging systems on the linear accelerator in combination with 6-degrees of freedom (6-DoF) couch motions, enabled the evolution towards frameless immobilization in fractionated SRT (FSRT) and stereotactic radiosurgery (SRS) with an identical level of accuracy as frame-based treatments [8–10]. In recent years, the integration of X-ray tracking and, more recently, surface guidance for additional intrafractional motion monitoring has been introduced [11–13]. The latter is combined with open-face mask systems [11,14]. The essential combination of the aforementioned elements has paved the way for frameless SRS/FSRT with HyperArc™ (Varian, a Siemens Healthineers Company, Palo Alto, CA, USA), an automated treatment planning solution utilizing standard non-coplanar beam arrangements for mono-isocentric frameless SRT [14,15].

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An open-face mask system that is validated for HyperArc™ and that can be used with surface guidance for intra-fractional monitoring, is the Dual Shell (DS) Encompass mask by CQ Medical (Avondale, PA, USA). This clamshell style Fibreplast thermoplastic mask consists of an anterior and a posterior shell, connected through pushpins [16]. Intrafractional motion smaller than 0.5 mm and 0.5° have been reported, leading to a stereotactically compliant of patient movements during therapy [17–19]. Besides the DS-Encompass, CQ Medical provides an alternative option in which the rear shell is replaced with a supportive AccuForm-Moldcare® (M) neck cushion.

On the one hand, it could be hypothesized that the Encompass with Moldcare would allow for more comfort but with more freedom of movement during non-coplanar treatments, as a rigid thermoplastic clamshell has been replaced by a support cushion. On the other hand, this should not impact intrafractional motion to ensure the safe delivery of radiation with planning target volume (PTV) margins of $\leq$ 1 mm. Until now, no comparative study has been conducted between the two mask systems. Our aim is to prospectively compare inter- and intra-fractional motion and patient reported comfort of the DS-Encompass and M−Encompass in a randomized trial in patients receiving cranial SRT planned with HyperArc™ and monitored with surface guidance.

Materials and methods

Study design

The prospective study protocol was reviewed and approved by the Ethical Committee of University Hospitals (UZ) Leuven. Fig. 1 outlines the inclusion pathway. Sixty patients to be treated for brain lesions with cranial SRT had to be prospectively identified during the pre-radiotherapy consultation. The fractionation schedule for potential participants could be SRS with a prescription of 12–24 Gy in 1 fraction, FSRT with a prescription dose up to 18-30y in 3 to 5 fractions or conventional fractionation (CF) with stereotactic margins prescribed at a total dose of 50.4–54 Gy in 28–30 fractions. After complete information and signature of the informed consent form, patients were randomized between DS or M−Encompass, with stratification based on fractionation schedule (SRS *vs* FSRT *vs* CF), utilizing the REDCap application (Research Electronic Data Capture).

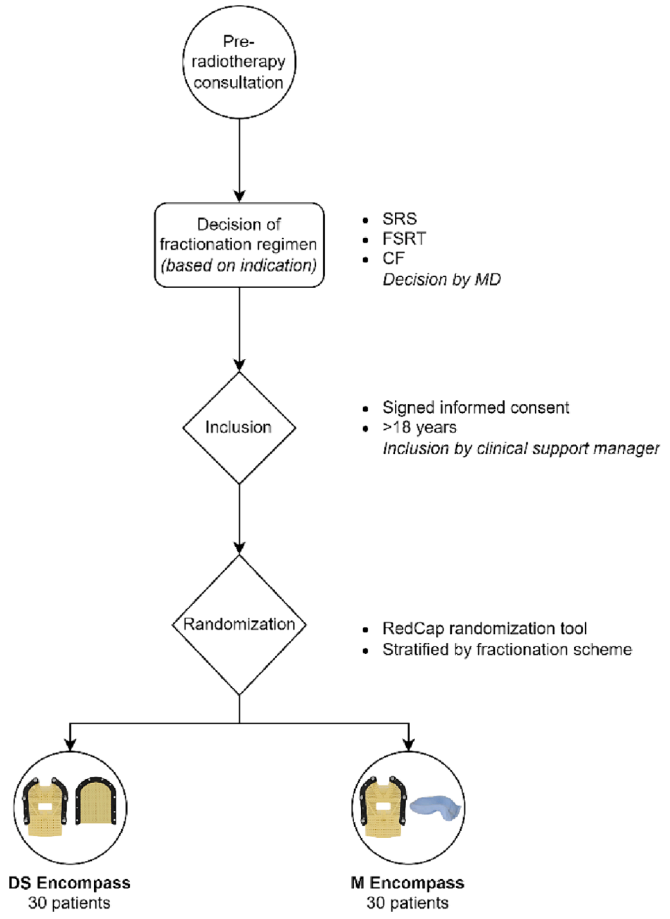

Fig. 1. From inclusion to mask creation during CT-simulation. The decision of fractionation regimen could be SRS or radiosurgery, FSRT or fractionated stereotactic radiotherapy, CF or conventional fractionation with stereotactic margins.

Treatment protocol

During the Computed Tomography (CT)-simulation, patients were immobilized by two experienced Radiation Therapists (RTT's) with either DS-Encompass or M−Encompass using the Encompass™ SRS standalone couch-top (Encompass™ SRS', CQ Medical). For the M−Encompass, the posterior part includes a Moldcare head cushion and for the DS-Encompass a thermoplastic shell. The mask was heated in the dedicated RapidHeat™ oven (CQ Medical) for 7 to 8 min at 74 °C. Once heated, the RTT's molded the posterior mask for the DS-Encompass on the dedicated SRS Headrests, based on the patient's neck curvature. In case of M−Encompass, the Moldcare was dampened with a water sprayer whereafter molded until rigid. Once the posterior side was made, the anterior shell was molded on the patient. No bite block was utilized due to past departmental challenges with patient discomfort and movement because of mouth fiddling issues, which frequently led to poorly constructed masks. The expected duration of CT-simulation for DS-Encompass remained unaltered at 45 min for M−Encompass.

Planning CT-images were taken with a slice acquisition reconstruction thickness of 1 mm using Siemens Somatom definition Edge/Drive (Siemens, Erlangen, Germany). Additionally, the patient undergoes a magnetic resonance imaging (MRI)-scan either before or after the CT simulation, within a time frame of one week, without the mask. The utilized SRS standalone solution is not compatible with MRI. Following fusion of the MRI-sequences with the CT simulation images, target structures and organs-at-risk (OAR) were delineated in Eclipse v.16 (brain metastases) or Velocity (all other conditions) *(both software packages from Varian, a Siemens Healthineers Company, Palo Alto, CA, USA)* by experienced radiation oncologists, based on the European Particle Network (EPTN)-guidelines [20]. PTV-margins of 0, 0.5 or 1 mm were used, depending on the fractionation schedule and the clinical indication.

Treatment plans were created in Eclipse™ (Varian, a Siemens Healthineers Company, Palo Alto, CA, USA) with HyperArc™-planning modality by experienced dosimetrists and medical physicists. HyperArc implements a mono-isocentric class-solution with multiple standard non-coplanar VMAT-arcs. Couch rotations include positions at 0°, 45°, 315° and 270°. Collimator rotation is optimized during treatment planning [15].

During treatment on a linear accelerator Novalis STX (Varian, a Siemens Healthineers Company, Palo Alto, CA, USA), patients were immobilized and instructed by SRT-dedicated RTT's. Before mask closure, the patient's head posture was corrected through surface guidance (VisionRT, London, UK) to minimize interfractional motion. For SRS and FSRT, a pre-treatment cone-beam CT (CBCT) was acquired and compared to the planning-CT to correct for interfractional motion with the 6-DoF table, followed by a verification CBCT to confirm the couch-adjustments. Registration was based on a traffic light protocol which starts with a bone-registration followed by an image-evaluation considering the closure of the push pins of the mask and verification of the targets. Intrafractional movement was monitored with surface guidance throughout the treatment session. In case of a deviation $>$ 1 mm or $>$ 1°, treatment delivery had to be interrupted. The table had to

return to the 6-DoF corrected couch 0° position for a new CBCT and correction of position before resuming the treatment from the interrupted point. Finally, a post-treatment CBCT at corrected couch 0° position was acquired to quantify the residual intrafractional motion. All acquired CBCTs were reconstructed with a slice thickness of 1 mm. For the long CF schedules, only a pre-treatment CBCT was obtained for evident radioprotection reasons. Therefore, within these cases, intrafractional motion was not evaluated.

Data-collection and analysis

Absolute inter-, intrafractional motion and comfort assessments were collected. Anonymized data were captured in REDCap application hosted at the UZ Leuven.

The registration at the treatment unit between the pre-treatment CBCT with the planning-CT resulted in the measurement of the interfractional translations and rotations motion. The registration of the post-treatment CBCT with the planning-CT resulted in the measurement of intrafractional translations and rotations motion. For comfort assessments, a paper version of a Likert-based survey by Pang et al. assessing general experience and the ease of remaining still during the treatment *(scale of 0–10, where 0 indicates no discomfort)* was completed by the patient at the end of the treatment [21].

The statistical analysis was executed in SPSS (IBM, v29.0.1.0, New York, USA) and Python (V 3.12.0, Delaware, USA). Since we have a data collection of 30 registrations per mask type, we assume normality [22,23]. To evaluate this assumption graphically, we examine Quantile-Quantile plots *(cf. Appendix I)*. Unpaired t-tests are conducted on absolute motion to determine the differences between DS Encompass and M Encompass with a two-sided level of significance ($p < 0.05$).

Results

Patient characteristics

Sixty patients were included in the study and randomized between DS and M−Encompass. There were more women than men treated within both groups (Table 1). Patients had a median age of 60y (DS-Encompass) and 66y (M−Encompass). Regarding fractionation regimen, more patients received a CF scheme while being immobilized with DS-Encompass compared to M−Encompass (8 versus 5). FSRT treatments occurred more frequently while patients were immobilized with M−Encompass. These variations stem from alterations in prescribed fractionation schemes by the physician during dosimetric planning, unforeseeable during randomization at the pre-radiotherapy consultation. The three most common tumor types were brain metastases, meningioma, and schwannoma. Of the 30 patients who were immobilized using DS-Encompass, 22 were treated for one lesion, four patients for two lesions and four patients for three or more lesions. While for the patients treated with the M−Encompass, 21 patients were treated for one lesion, four patients were treated for two lesions and three patients were treated for three or more lesions.

Inter-and intrafractional motion

Both inter- and intrafractional motions are categorized between DS Encompass and M Encompass (Table 2). No significant differences were observed in interfractional translational motion, neither in pitch nor yaw rotations. However, roll-axis rotations were statistically significantly smaller with DS Encompass than with M Encompass (0.6° *vs* 1.0°, $p = 0.012$). A closer examination of interfractional motion reveals a similar distribution of absolute motion between the two immobilization systems (Fig. 2). In the longitudinal direction with DS Encompass, we observe some outliers exceeding 10 mm. Rotationally, the roll-axis rotations results are affected by a few outliers in the M Encompass group, exceeding 2° (Fig. 3). 6DoF correction was applied to all patients during all fractions.

No significant differences were observed between both mask systems for intrafractional motion, either translationally or rotationally. Both immobilization systems demonstrate mean and maximum intrafractional motion below 1 mm and 1°, and even 0.5 mm and 0.5° at mean ± 1 SD (Table 2, Fig. 4, Fig. 5), with the exception of one outlier at 1.2 mm in the longitudinal direction with M Encompass. For one of the DS-Encompass patients, treatment delivery was interrupted during one fraction because of a detected deviation of more than 1 mm through surface imaging and immediately corrected before the continuation of the following beam.

Table 1
Overview of patient and treatment characteristics.

	DS-Encompass *(n)*	**M−Encompass *(n)***
Patient characteristics		
Number of patients	30	30
Median age	60	66
Sex (F/M)	19/11	20/10
Fractionation regimen		
SRS	7	5
FSRT	15	20
CF	8	5
Indication		
Brain Metastases	16 (53 %)	18 (60 %)
Fractionation (n)		
1 x 20 Gy	*1*	*/*
1 x 21 Gy	*2*	*1*
1 x 24 Gy	*1*	*1*
3 x 8 Gy	*2*	*/*
3 x 9 Gy	*7*	*10*
5 x 5 Gy	*1*	*1*
5 x 6 Gy	*2*	*5*
Meningioma	3 (10 %)	6 (20 %)
Fractionation (n)		
5 x 5 Gy	*1*	*1*
28 x 1.8 Gy	*2*	*3*
30 x 1.8 Gy	*2*	*1*
30 x 2 Gy	*/*	*1*
Schwannoma	5 (17 %)	4 (13 %)
Fractionation (n)		
1 x 12 Gy	*5*	*2*
3 x 6 Gy	*/*	*2*
Diffuse astrocytoma reirradiation	1 (3 %)	*/*
Fractionation (n)		
30 x 1,8 Gy	*1*	
Ependymoma	1 (3 %)	*/*
Fractionation (n)		
5 x 5 Gy	*1*	
Hemangioblastoma	1 (3 %)	*/*
Fractionation (n)		
30 x 1,8 Gy	*1*	
Craniopharyngioma	1 (3 %)	*/*
Fractionation (n)		
30 x 1,8 Gy	*1*	
Glioblastoma reirradiation	*/*	1 (3 %)
Fractionation (n)		
10 x 3,5 Gy		*1*
Arteriovenous malformation	*/*	1 (3 %)
Fractionation (n)		
1 x 18 Gy		*1*
Number of lesions per patient		
1 lesion	22 (73 %)	21 (70 %)
2 lesions	4 (13 %)	4 (13 %)
3 lesions	*/*	2 (7)
>3 lesions	4 (13 %)	3 (10 %)

Table 2
A comparative table between Dual Shell (DS) Encompass and Moldcare (M) Encompass based on interfractional, intrafractional motion, and patient-reported comfort. Unpaired t-tests were performed, with $p < 0.05$ accepted as a statistically significant difference.

	DS-Encompass	M−Encompass	*t-value / Two-sided p-value*
Interfractional motion *(n = 60)*			
Translations *(mm)*			
Vertical [mean (max) ± SD]	**1,7** (3,4) ± 0,8	**1,6** (3,5) ± 0,7	*0,684 / 0,497*
Long. [mean (max) ± SD]	**2,3** (13,3) ± 2,9	**2,3** (7,4) ± 1,6	*−0,027 / 0,978*
Lateral [mean (max) ± SD]	**0,7** (3,4) ± 0,6	**0,8** (2,8) ± 0,7	*−0,617 / 0,540*
Rotations *(°)*			
Pitch [mean (max) ± SD]	**0,8** (2,2) ± 0,5	**1,0** (2,5) ± 0,7	*−1,637 / 0,107*
Roll [mean (max) ± SD]	**0,6** (1,4) ± 0,4	**1,0** (3,0) ± 0,6	*−2,589 / 0,012*
Yaw [mean (max) ± SD]	**0,8** (3,0) ± 0,6	**1,0** (3,5) ± 0,8	*−0,957 / 0,343*
Intrafractional motion *(n = 48)*			
Translations *(mm)*			
Vertical [mean (max) ± SD]	**0,2** (0,5) ± 0,1	**0,3** (0,7) ± 0,2	*−0,160 / 0,873*
Long. [mean (max) ± SD]	**0,4** (0,8) ± 0,2	**0,4** (1,2) ± 0,2	*−0,724 / 0,473*
Lateral [mean (max) ± SD]	**0,2** (0,7) ± 0,2	**0,3** (0,7) ± 0,2	*−0,914 / 0,366*
Rotations *(°)*			
Pitch [mean (max) ± SD]	**0,3** (0,9) ± 0,2	**0,2** (0,6) ± 0,1	*1,928 / 0,060*
Roll [mean (max) ± SD]	**0,3** (0,8) ± 0,2	**0,2** (0,5) ± 0,2	*1,473 / 0,148*
Yaw [mean (max) ± SD]	**0,2** (0,8) ± 0,2	**0,2** (0,6) ± 0,2	*−0,146 / 0,885*
Comfort *(n = 51)*			
General Experience *(0 (no discomfort) − 10 (completely uncomfortable))*	3	2	*1,045 / 0,301*
Feeling Stability *(0 (no discomfort) − 10 (completely uncomfortable))*	3	2	*0,594 / 0,555*

Patient experience

No significant difference was observed regarding perceived comfort of the position or the ease of remaining still (Table 2). Among the 9 patients who did not fill it out, this was attributed to reasons such as patient's demise *(n = 1)*, failure to provide the questionnaire *(n = 6)*, or the patient's choice not to complete it *(n = 2)*.

Discussion

Frameless cranial SRT requires the highest accuracy in positioning and immobilization of the patient. The CQ Medical Encompass™ stereotactic mask system is delivered with either a Dual Shell or a Moldcare posterior part. The anterior part is open to allow for tracking of the patient by the surface guidance cameras. Both mask types were prospectively compared for inter- and intrafractional motion and comfort in this randomized study. The majority of maximal interfractional motion were found to be below 3 mm and 3°, which fits with the requirements of the 6-DoF maximal rotational corrections. The statistically higher difference of M−Encompass for roll-axis rotation compared to the DS-Encompass was not clinically meaningful considering the systematic 6-DoF correction. Both mask systems allow little freedom of movement during treatment, revealing average and maximal motion below 1 mm and 1°, without significant differences, leading us to conclude that both systems are equally safe and compliant with the stereotactic requirements to use during HyperArc non-coplanar cranial SRT. No significant difference of patient reported comfort levels was observed.

Both inter- and intrafractional motion align with previous DS Encompass studies. Komiyama et al revealed intrafractional motions of 0.2–0.4 mm for translational directions and 0.2–0.3° in yaw [17]. Shah et al reported similar errors of 0.2–0.3 mm translational and 0.2–0.3° rotational; with no significant differences between the open clam-shell DS Encompass and closed-faced BrainLab SRS mask (Brainlab AG, München, Germany) [19]. In both studies, the absolute maximal errors were smaller than 2 mm. In these studies, HyperArc™ was applied in combination with intrafraction registered megavoltage portal images (MV). In our clinical workflow, surface guidance is used as an alternative to MV images registrations. SGRT during HyperArc™ reduces treatment time and therefore reduces the chance of patient movement. A large cohort-study confirmed the utilization of SGRT as a reliable and more efficient alternative for MV-registrations; especially because MV-registrations are restricted to APPA-imaging [11]. Although using surface guidance in clinic, our data revealed in one patient an absolute maximal intrafraction motion of more than 1 mm, undetected by the end of treatment (Table 2, Fig. 4). This patient was positioned with M Encompass. The reason why we observe this intrafraction motion above 1 mm possibly indicates a failure in the manual detection and intervention of large intrafraction motion through the non-triggered SGRT-application, or more presumably a movement at the very end of the treatment process. This isolated case underscores the necessity of scrutinizing the SGRT evaluation of movement and triggering the beam in case of non-compliant values. All mean + 1SD intrafraction translational and rotational motion measures fell within 0.5 mm and 0.5°. This applied to both DS and M−Encompass, validating the use of 0.5 to 1 mm PTV-margins [24].

Both mask systems were made by the same experienced team of

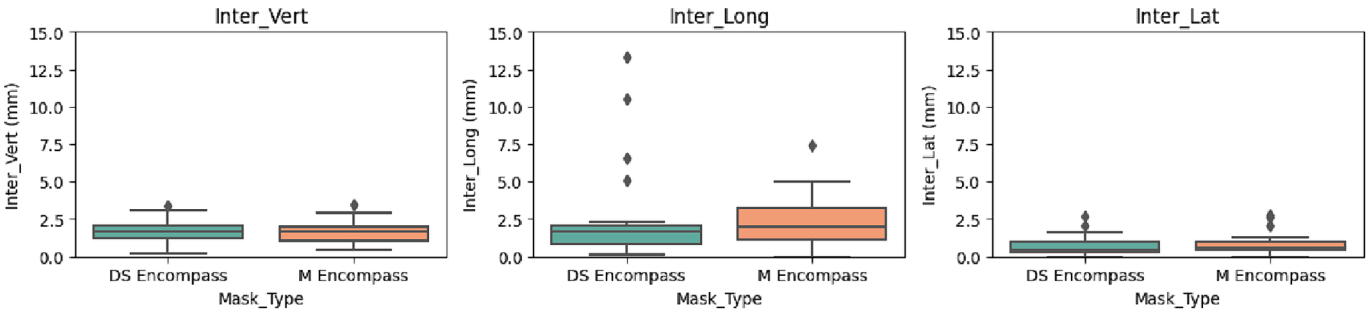

Fig. 2. Boxplot distribution of interfractional translations vertical (Vert), longitudinal (Long) and lateral (Lat) translations (mm) for both DS and M−Encompass masks.

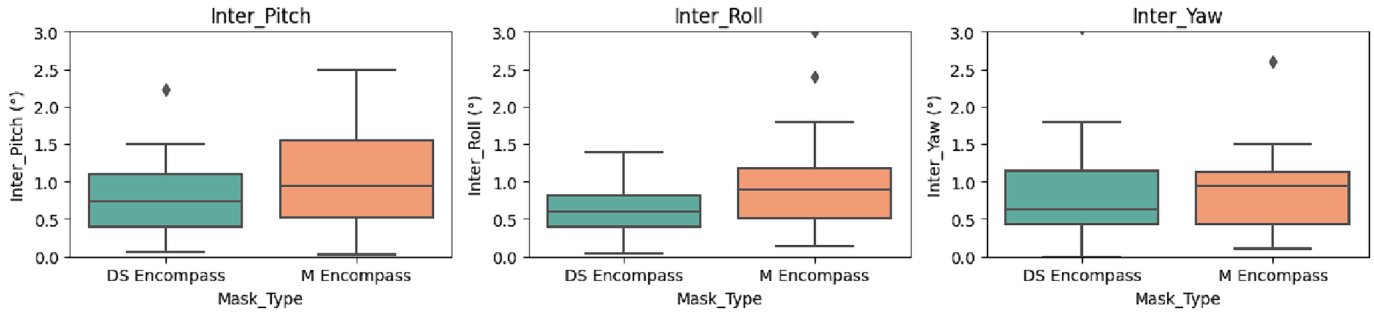

Fig. 3. Boxplot distribution of interfractional rotations pitch, roll and yaw rotations (°) for both DS and M−Encompass masks.

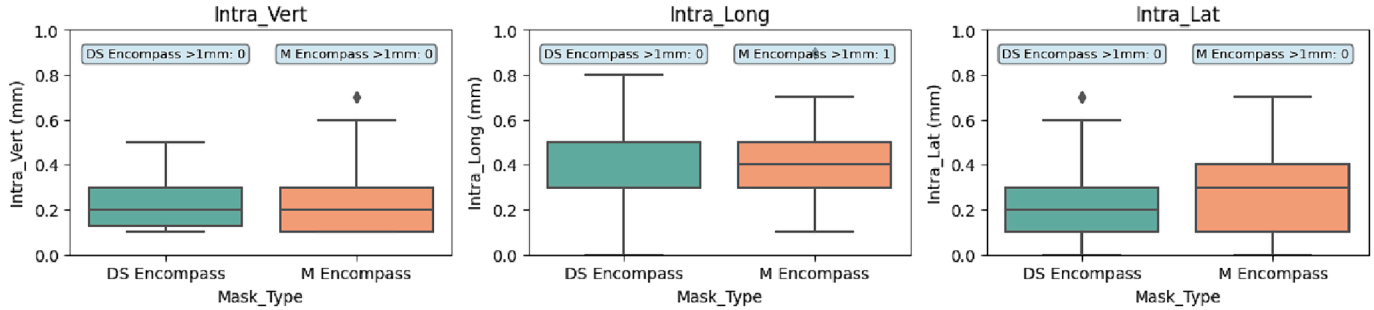

Fig. 4. Boxplot distribution of intrafractional vertical (Vert), longitudinal (Long) and lateral (Lat) translations (mm) for both DS and M−Encompass masks.

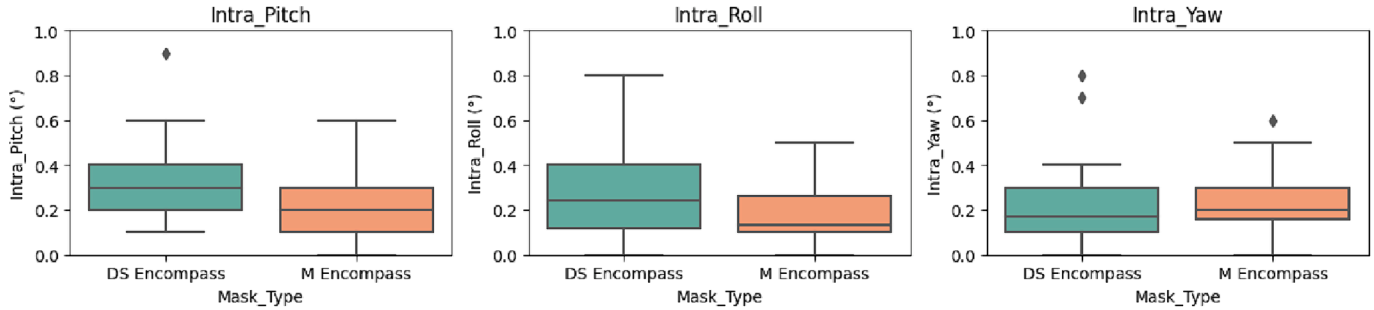

Fig. 5. Boxplot distribution of intrafractional pitch, roll and yaw rotations (°) for both DS and M−Encompass masks.

RTTs, who received extensive training in making both the DS and M−Encompass masks prior to this study, including training provided by CQ Medical's product specialists. There may be a learning curve in creating a Moldcare mask, given the limited familiarity of the group with this system. Nevertheless, our data demonstrate that despite the recent implementation of a Moldcare Encompass system in CT simulation, this does not result in significantly higher inter- and intrafractional motion.

The study has some limitations. As already mentioned, SGRT is being used for monitoring intrafractional motion, however no stringent take-action protocol or triggered-beam is coupled with dose-administration. Unfortunately, it remains impossible to correct patient's movement during the treatment at non-coplanar positions of the couch which could be a barrier for treatment staff to correct intrafractional errors. Furthermore, intrafraction motion is a dynamic process. The post-CBCT is merely a snap-shot of the movement of the patient during treatment. For the feeling of comfort and stability, patients could not experience both mask systems, which limits the evaluation of comfort. In addition, the type of comfort-survey with only two questions might not fully capture the nuanced differences in patient comfort between the two immobilization systems. Lastly, there was no quantitative check of the mask shrinkage prior to treatment.

From our study, the question arises whether we can pay more attention to the comfort of patients instead of investing in even more rigid fixation systems. As both mask systems are equally safe for use during stereotactic brain treatments, the choice between them ultimately rests on the preferences and the experience of the local team.

Conclusion

Moldcare Encompass offers a safe alternative to Dual Shell Encompass for non-coplanar frameless SRT with surface guidance monitoring. Both systems allow infra-millimetric, infra-degree intrafractional accuracy without significant difference in comfort level experienced by patients.

CRediT authorship contribution statement

Dylan Callens: Conceptualization, Methodology, Formal analysis, Writing – original draft. **Chahrazad Benazzouz:** Conceptualization, Methodology, Formal analysis, Writing – original draft. **Lise Stessens:** Conceptualization, Methodology, Formal analysis, Writing – review & editing. **Wout Piot:** Conceptualization, Methodology, Writing – review & editing. **An Nulens:** Conceptualization, Methodology, Writing – review & editing. **Maarten Lambrecht:** Conceptualization, Methodology, Writing – review & editing. **Patrick Berkovic:** Conceptualization, Methodology, Writing – review & editing. **Jean-François Daisne:**

Conceptualization, Methodology, Writing – review & editing, Supervision.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [This study was partially supported by a limited grant from CQ Medical. However, CQ Medical was not involved in any aspect of this study. The support had no impact on the results or the outcome of the study].

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