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A systematic review of open face versus mask less surface guided radiotherapy for patients undergoing radiotherapy for head, neck and brain tumours

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Literature Review

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Abstract

Introduction: Accurate delivery of radiotherapy to head, neck and brain cancer relies on the use of sophisticated immobilisation devices, usually using a restrictive thermoplastic mask. These masks can cause anxiety and can make treatment difficult for many patients. Open-face or maskless techniques are alternatives which can improve the patient experience. This systematic review aimed to compare the effectiveness of open-face (OF) masks and maskless surface guided radiotherapy (SGRT) with conventional masks.
Method: Primary research papers from the last 10 years were gathered from Scopus, PUBMED, Web of Science and OVID databases. Quantitative data reporting interfractional set-up errors and intrafractional patient motion were extracted from included studies and subjected to descriptive statistical analysis. Additional qualitative data relating to patient tolerance were also extracted to inform discussion.
Results: Ten studies were identified for inclusion. The data identified that OF masks can reproduce patient set-up with an accuracy of <2 mm and <1° and can restrict movement to <1 mm and 0·4°, while maskless SGRT can achieve accuracy to within 0·05 mm and 0·1°.
Conclusion: This review indicates comparable reduction of intrafractional motion between conventional masks, Open-Face masks and maskless SGRT techniques. More research is needed into the impact of maskless SGRT techniques on translational and rotational motions compared to traditional masks.

Introduction

The proximity of target volumes to critical structures is often a dose limiting factor for head, neck and brain cancer (HNBC) radiotherapy[1–7] with several severe toxicities including brainstem necrosis or loss of vision, reported.[6,8–12] The need to increase dose conformity to limit dose to surrounding non-target tissues for these patient groups is well recognised.[1–6,9] A key factor underpinning conformal radiotherapy is the need for reproducibility of internal structure positions.[13–17] Successful treatment delivery therefore relies on the use of sophisticated immobilisation devices with patient-specific thermoplastic masks covering the head, face and shoulders being the current standard of care (SoC) in most radiotherapy departments.[18]

While these devices do reproduce set-up position and reduce intrafractional motion, many patients suffer with anxiety and distress related to their use, particularly those with past trauma, mental health struggles, or claustrophobia.[19,20] Nixon et al. report that approximately one quarter of patients experience moderate to severe anxiety attributed to the use of thermoplastic masks.[19] Fu evidence suggests that while mask anxiety significantly reduces throughout the course of radiotherapy for the majority of patients, it remains consistent, or worsens, for 22% and 6% of patients, respectively, and is a significant cause of disruption to HN and brain radiotherapy treatments.[21,22] Patients report the fear of having the face covered and movement restricted as major factors contributing to anxiety.[23]

Recent developments in HNBC immobilisation have explored open-face (OF) masks and maskless surface guided radiotherapy (SGRT) techniques as ways to immobilise patients while reducing anxiety and feelings of claustrophobia.[24] A search of the literature has failed to identify any large scale randomised controlled trials (RCT)s that compared the effectiveness of these novel immobilisation techniques to that of the current SoC. The aim of this study, therefore, was to review the existing evidence within this field to compare the reported effectiveness of the immobilisation tools at reducing translational and rotational errors.

Method

A systematic review was undertaken to compare the effectiveness of OF masks and maskless SGRT in reducing interfractional set-up errors and intrafractional patient motion with that of the SoC.

Information sources and search strategy

The initial search strategy examined abstract, title and keyword fields in Scopus, PUBMED, Web of Science and OVID online databases between December 2023 and February 2024 using the terms outlined in Table 1 and following the inclusion and exclusion criteria shown in Table 2. Search terms were selected to encompass all elements of the required papers, were derived during an iterative pilot search and agreed between the researchers. The databases stated here were used in order to ensure all relevant articles were identified. Boolean operators were used to combine keywords where relevant. Record selection and data extraction were performed by a single researcher and followed the recommended PRISMA and Cochrane guidelines.[25–27] (Supplementary materials 1); data collected are shown in Supplementary materials 2–3. References of retrieved papers were searched manually to identify any additional relevant sources that had not been retrieved in the search.

Quality assessment

Quality assessment (QA) was performed by a single researcher. The Cochrane Risk of Bias (RoB-2) and the Cochrane Risk of Bias in Non-Randomised studies of Interventions (ROBINS-I) tools were used for QA of included studies.[28,29] These tools are commonly used to reduce the risk of biased conclusions being drawn in review articles and involve the use of various signalling questions alongside professional judgement to assess risk of bias across several domains for each report.[28,30] Following this, an overall risk of bias was assigned to each study.

Data analysis

Quantitative data for each study were grouped according to the outcomes measured and are displayed in Supplementary Materials 3: Data Summary Tables. Themes were identified and collated directly from the extracted data without use of a prior framework to inform discussion of the findings.

Results

Included studies

Overall, 10 studies were passed forward for data extraction and analysis as seen in the PRISMA flowchart in Figure 1.[26] Common reasons for exclusion were studies comparing the use of SGRT with IGRT for positional verification, studies comparing the use of OF masks to other immobilisation methods that were not FH masks, studies comparing the use of different headrests or mouth bites with OF masks, and studies aimed at calculating CTV-PTV margins when using OF masks. Two of the 10 included studies were randomised studies,[31,32] with the remaining eight being non-randomised.[33–40] Two studies investigated the use of OF masks,[35,38] seven studies compared the use of OF masks with FH masks,[31–34,37,39,40] and one study investigated the use of maskless SGRT.[36] All included studies used patient participants with one study also using healthy volunteers.[33] The characteristics of all included studies are shown in Supplementary Materials 2: Study Summary Table.

Table 1. Search terms used for identification of records

Keyword	Search terms used
Radiotherapy	Radiotherapy OR “Radiation Therapy” OR “Radiation Treatment”
Head and Neck	“Head and neck” OR Oral OR Throat OR brain OR Neuro* OR Intracranial
Immobilisation	Immobili?ation OR Mask OR Shell OR “Open Face” OR Faceless OR “Surface Guided” OR SGRT

Table 2. Inclusion criteria used to identify studies for inclusion

Inclusion criteria	Rationale
Studies reporting translational and/or rotational errors or motions using open-face or maskless SGRT masks for HNBC radiotherapy	To ensure reports relevant to the review question were included
Records published in last 10 years	To ensure all relevant evidence is included within the timeline for mask technology development
Articles published in English	Lack of funding for translation
Comparative studies, observational studies and randomised controlled trials.	To ensure all data is derived from primary sources

Risk of bias analysis

Risk of bias assessment results are shown in Supplementary Materials 2. Eight non-randomised studies were assessed using the ROBINS-I tool and two randomised studies were assessed using the RoB-2 tool.[28,29] None of the included studies were considered to be at a low risk of bias. Based on the ROBINS-I tool, four studies were deemed to be at moderate risk of bias,[34,36–38] and four studies were deemed at serious risk of bias.[33,35,39,40] One study showed some concerns of bias,[31] and one study was considered to be at high risk of bias according to the RoB-2 tool.[32] No studies were excluded, but risk of bas was used to inform discussion related to the relative impact of the reported data.

Key findings

Quantitative data for each study are displayed in Supplementary Materials 3: Data Summary Tables. These results indicate that FH masks, OF masks and maskless SGRT all allow for clinically acceptable and reproducible patient set-up with submillimetre intrafractional immobilisation.[31–40] Five themes were identified from the extracted data: translational set-up errors, rotational set-up errors, translational intrafractional motion, rotational intra-fractional motion and patient experience. These frame the following results and discussion.

Translational and rotational set-up errors

Four studies reported translational set-up errors for FH masks,[31,32,34,37] and six for OF masks.[31,32,34,35,37,38] Three studies reported rotational set-up errors for FH masks,[32,34,37] and five for OF masks.[32,34,35,37,38] None of the included studies reported translational or rotational set-up errors using maskless SGRT.

Data regarding translational and rotational set-up errors are displayed in Figures 2 and 3. The range of means were similar

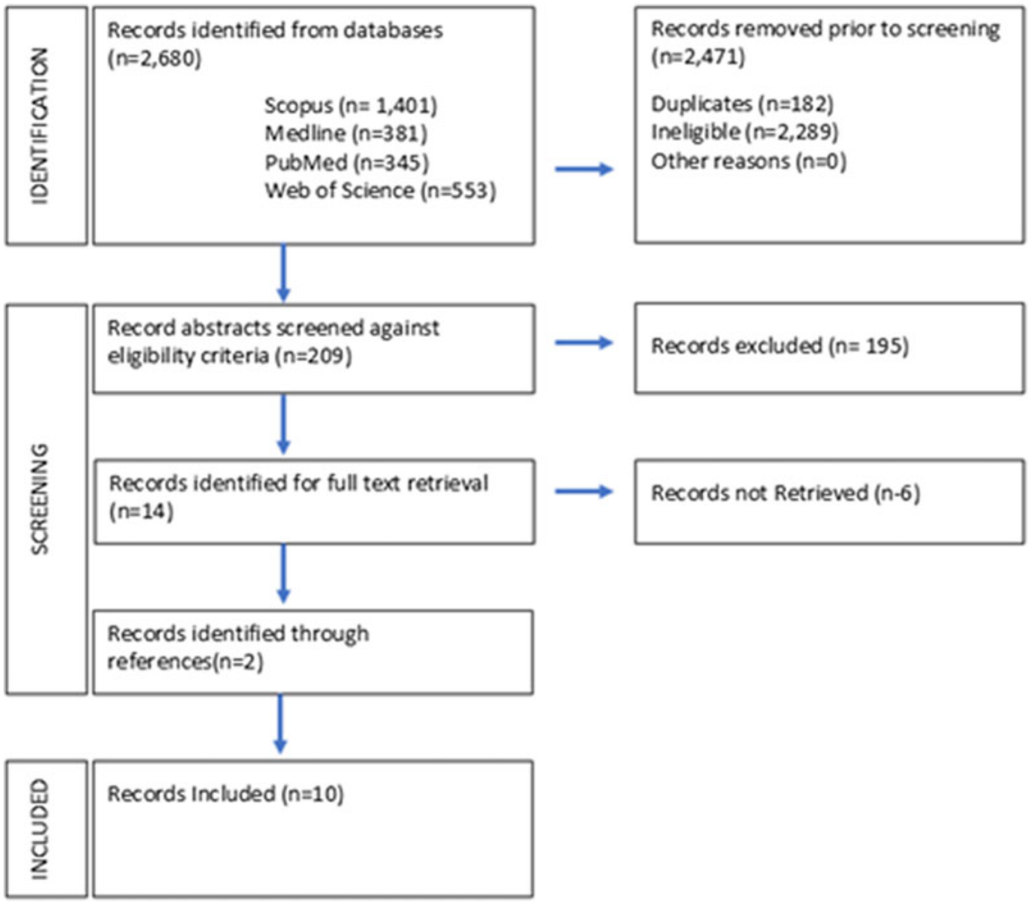

Figure 1. PRISMA flow diagram for identification of studies for inclusion.

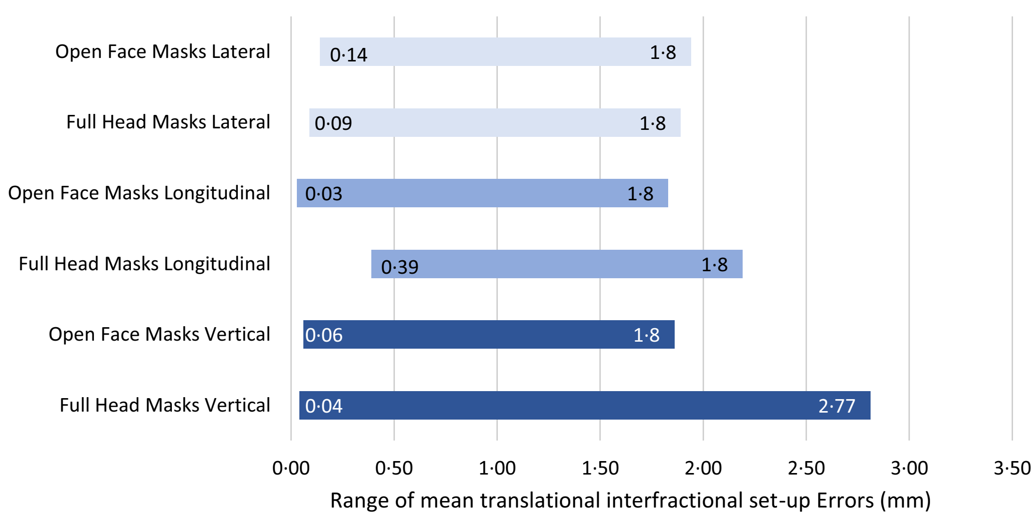

Figure 2. Bar chart showing the range of mean translational set-up errors (mm) for full head masks and open face masks.

between FH and OF masks for both translational and rotational set-up errors. The data presented here suggest that FH masks can provide set-up accuracy to <3 mm and <1°, while OF masks can provide set-up accuracy to <2 mm and <1°.

Both the largest and smallest translational set-up errors were reported by Wei et al., with the greatest error being reported in the FH mask group (2·77 mm), and the smallest in the OF mask group (0·03 mm).[37] However, OF mask groups were reported to show both the highest and lowest rotational set-up errors, 0·68° and 0·00°, respectively.[34,37]

Translational and rotational intrafractional motion

One study reported translational intrafractional motion for FH masks,[39] five for OF masks,[31,33,35,38,39] and one study reported this for maskless SGRT.[36] One study reported rotational intrafractional motion for FH masks,[39] 5 for OF masks,[31,33,35,38,39] and one for maskless SGRT.[36] Data regarding translational and rotational intrafractional motions are displayed in Figures 4 and 5. The data presented indicate that FH masks, OF masks, and maskless SGRT can all provide submillimetre intrafractional immobilisation. All

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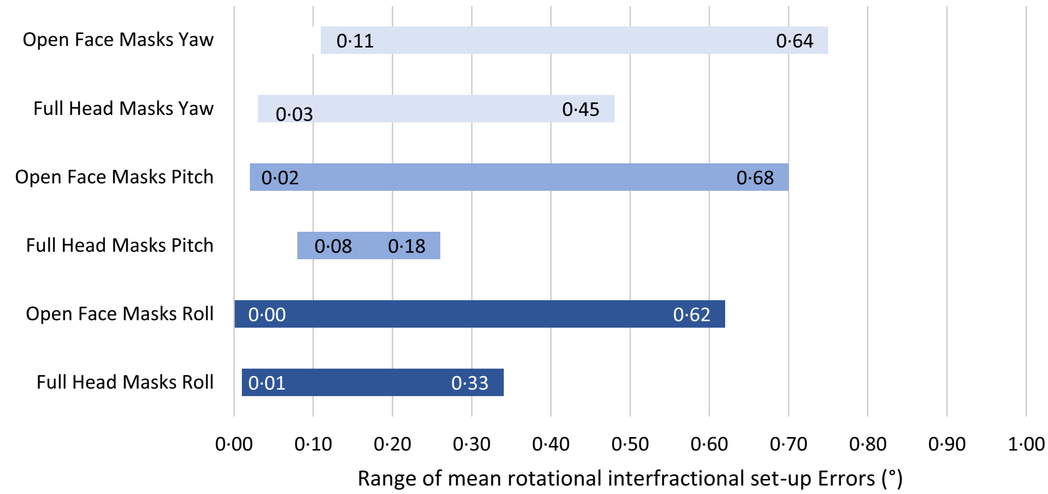

Figure 3. Bar chart showing the range of mean rotational set-up errors (°) for full head masks and open face masks.

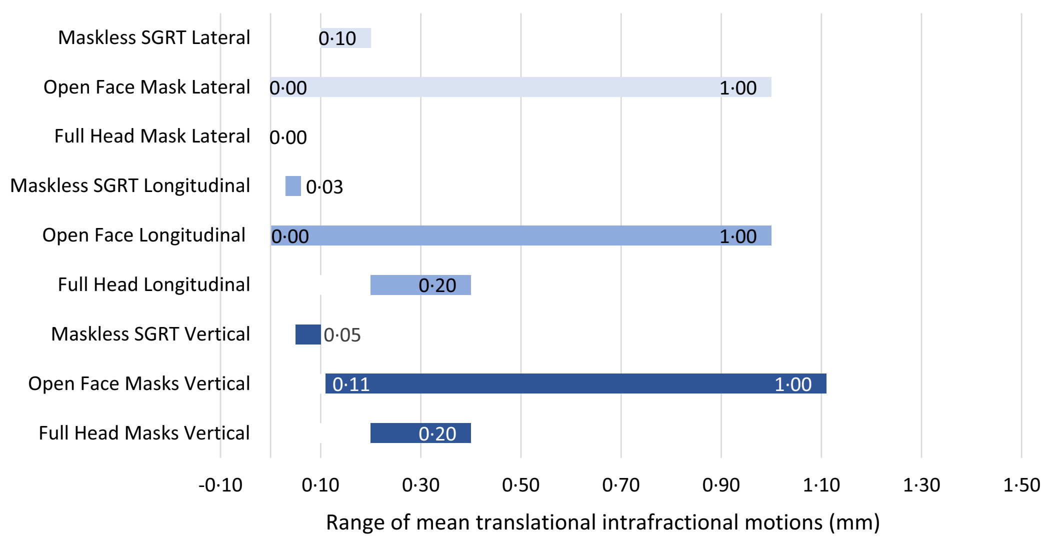

Figure 4. Bar chart showing the range of mean translational intrafractional motions (mm) for full-head masks, open-face masks and maskless SGRT. Note only a single mean value was reported for full head mask and maskless SGRT translational intrafractional motions, and therefore it is not possible to present a range of means and only a single value is presented in the above figure.

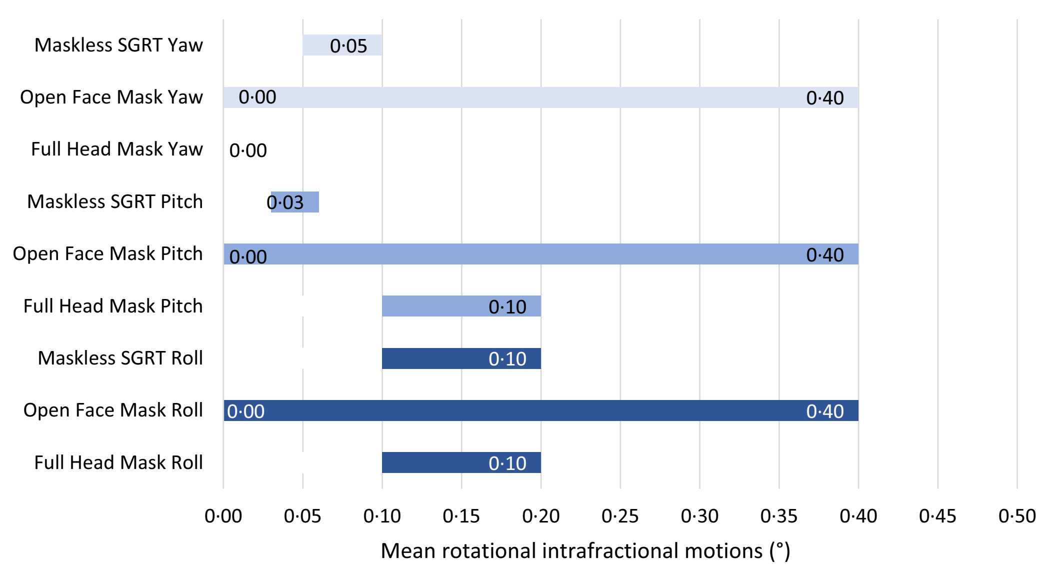

Figure 5. Bar chart showing the range of mean rotational intrafractional motions (°) for full head masks, open face masks, and maskless SGRT. Note only a single mean value was reported for full head mask and maskless SGRT translational intrafractional motions, and therefore it is not possible to present a range of means and only a single value is presented in the above figure.

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reported intrafractional motions were ≤1 mm or <1° in all studies for all three immobilisation methods. Motions of 0·00 mm and 0·00° were reported for both FH and OF masks,[31,39] while the lowest reported intrafractional motions for maskless SGRT were 0·01 mm and 0·03°.[36] The largest intrafractional translation was reported by Li et al. and was for OF masks (1·00 mm), while the largest rotational intrafractional motion was reported for FH masks (0·4°).[33]

Discussion

While the current SoC FH masks adequately prevent interfractional set-up errors and intrafractional motion, they can be a significant cause of patient anxiety and treatment disruption.[22,41,42] Novel immobilisation devices may allow for comparable immobilisation while improving patient comfort. This review aimed to assess the possibility of using OF masks or maskless SGRT as the future SoC immobilisation for HN and brain radiotherapy by assessing their ability to limit set-up errors and intrafractional motion. These findings suggest that the current SoC FH masks, OF masks, and maskless SGRT can allow for comparable set-up accuracy and intrafractional motion restriction. Radiotherapy centres may therefore consider transitioning towards the use of novel immobilisation methods to improve patient comfort.

Translational and rotational set-up errors

This review proposes that translational and rotational set-up errors are comparable between FH and OF thermoplastic masks.[31,34,35,37,38] There are currently no universally agreed limits of accuracy for an immobilisation device to be considered appropriate, and published guidance suggests that tolerance levels should be defined by individual treatment centres, though tolerances of ≤5 mm and 5° are commonly accepted.[34,43–45] The findings reported here suggest that both FH and OF masks meet these tolerances in all translational and rotational directions[31,34,35,37,38] although it would be interesting to see the impact of Adaptive or IGRT on this. This review cannot compare the set-up accuracy of maskless SGRT because no study meeting the inclusion criteria has published relevant data. All studies included in this review have reported similar set-up errors despite the use of different study designs, a range of different mask manufacturers, patient subgroups, and methods of analysing set-up accuracy, suggesting these findings are reliable and hold external validity.[31,34,35,37,38]

The accuracy of FH masks has been extensively researched and an accuracy of 2–5 mm and 1° is widely reported in scientific literature.[46–53] While the effectiveness of OF masks is not as clearly defined, evidence suggests they can allow for submillimetre translational set-up precision.[54] This review agrees with previous reports and acknowledges that the set-up accuracy of OF masks is comparable to that of the current SoC, with all included studies reporting translational and rotational set-up errors to be <3 mm and <1°, respectively for FH masks, and <2 mm and <1° for OF masks.[31,34,35,37,38]

Although this review shows a trend towards reduced translational set-up errors with the use of OF masks, this is not the case for rotational set-up errors; OF mask groups showed a trend towards greater pitch and roll rotations.[32,37] Although most studies reported that these differences were not statistically significant, Mulla et al. did report significantly ($p = 0{\cdot}016$) increased rotational set-up errors for OF masks compared to FH masks.[32] It is likely that Mulla's study has a reduced risk of bias compared to other studies in this review due to the randomised study design.[32] Age, gender, tumour type, tumour site, and history of claustrophobia were similar between groups in this study, so it is unlikely that these variables have influenced the findings.[32] Despite the potential increase in rotational set-up errors seen with OF masks, all rotations reported were minimal and within accepted tolerances.[32,34,35,37,38]

Translational and rotational intrafractional motion

This review suggests that the ability to prevent intrafractional motion is comparable between FH masks, OF masks and maskless SGRT. However, translational and rotational motions for FH masks and maskless SGRT were each only reported by a single study in this review, reducing the reliability of this finding, especially when considering the small patient sample included in each of these reports.[36,39] Further research using multi-centre, prospective RTCs comparing these immobilisation methods would be useful to increase the reliability of these data.

While Ohira et al. were the only authors in this review to publish data regarding the translational and rotational intrafractional motion restriction of FH masks, previous studies have well defined the ability of the current SoC to immobilise patients during treatment.[39,48,52,55] Data from Ohira et al. are similar to those previously published which suggest that FH masks can limit motion to <1 mm and <1° during treatment according to differences in pre- and post-treatment CBCT data.[39,48,52,55]

Various studies in this review have reported consistent translational and rotational intrafractional motions for OF masks, suggesting a good level of accuracy in these data.[31,33,35,38,39] Studies imply that the motion restriction of OF masks is comparable to that of the current SoC, with the ability to restrict patient movement to ≤1 mm and <1°.[31,33,35,38,39] Li et al. reported the greatest intrafractional translations and rotations for OF mask groups in this review; 1·0 mm and 0·4°, respectively.[33] The higher intrafractional motion reported here is possibly subjected to sampling bias, attributed to the inclusion of just 5 patients from a single institution, all of which suffered with claustrophobia and were unable to tolerate FH masks.[33] These patients likely suffered high levels of anxiety making it difficult to remain still.[33] In contrast, Wiant et al. reported the smallest intrafractional motions for OF masks, with all mean motions at 0·00 mm and 0·00°, except for AP motions which averaged at 0·4 mm.[31] The randomised study design used by Wiant suggests that their results are more accurate and reliable than those reported by Li et al., though results from both studies do suggest that OF masks can immobilise patients to within accepted tolerances.[31,33] The findings of this review agree with data from other studies; for example, Han et al. compared the use of OF masks to frame-based bite-block fixation and reported submillimetre motion restriction for OF masks.[54]

Dekker et al. report average translational and rotational intrafractional motion errors of <0·05 mm and 0·1°, respectively, for maskless SGRT, suggesting this may be more effective than FH masks.[36] While Dekker concluded that this was a feasible method of immobilisation for 98% of patients, their study included only those receiving a palliative course of radiotherapy to the brain and any patients who suffer from trembling or who were not deemed able to lie still by a clinician were excluded from.[36] This data is therefore not applicable to all patients undergoing HN or brain radiotherapy, though it is able to suggest that masks may be omitted for certain patient groups.[36] A 3 mm and 3° beam hold tolerance was used in this study, this is deemed appropriate

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considering the 5 mm PTV margin frequently used for such treatments, however, it is noted that 16/28 patients exceeded this limit and needed repositioning at least once during treatment.[36] While the authors have not commented on the average total treatment time, it would be important to consider the increased time required to account for repositioning if this were to become standard practice in the future. Considering quantitative intra-fractional motion data for the clinical use of maskless SGRT is not yet widely available in current literature, it is not possible to compare the data presented here to that of other studies, though the promising results of Dekker's study suggest it is likely that the possibility of maskless SGRT for HNBC radiotherapy will be investigated further in the near future.[36] It would be useful to include a wider range of patients in these studies and report average treatment times to help inform treatment centres of the clinical feasibility of introducing maskless SGRT techniques.

Patient experience

The key driver for moving towards open masks is to improve the patient experience[56–60] and the additional data extracted from the reviewed papers provides some insight into the success of this strategy. Five studies in this review reported participant experiences, all of which found that experiences were more positive with the use of OF compared to FH masks.[31–33,35,38] Li et al. note that OF masks can allow patients who suffer from claustrophobia and would not tolerate treatment with a FH mask to receive radiotherapy.[33] Furthermore, Mulla et al. found that patients receiving treatment with OF masks reported greater levels of comfort and less distress than FH mask groups.[32] The number of patients with previous claustrophobia were similar between groups in this study, suggesting such factors are unlikely to have influenced this finding, increasing the reliability of the results.[32] A trend towards greater tolerability for the OF mask in comparison to the FH mask is clear and considering their comparable effectiveness it is sensible to suggest that radiotherapy centres should consider the implementation of such immobilisation devices.

There is little evidence available regarding patient experiences with maskless SGRT, and no study in this review has considered this. Clover et al. suggest that fear of having the face covered is a main contributor to anxiety for FH mask users, meaning the complete lack of face covering with maskless SGRT could make this better tolerated than both FH and OF masks.[23] However, there is a possibility that the pressure to remain completely still without aid could cause anxiety in some patients; future studies investigating the effectiveness of maskless SGRT should include open-ended patient interviews and questionnaires to gain insight into their experiences and investigate this hypothesis.

Study limitations

Although the extent of this literature search was increased through the inclusion of multiple databases, only a single researcher conducted the database search and assessed studies against the inclusion and exclusion criteria. It is recommended that a healthcare librarian is employed to assist in literature searching and that prior to starting a literature search the search strategy is peer reviewed to identify potential risk of bias; this was not done in this review due to such resources being limited.[25–27,61]

Furthermore, two studies have been identified to meet the inclusion criteria but were published after February 2024 when the literature search for this review had concluded (one published in March 2024 and another in July 2024), so these were not included in this review.[62,63] This highlights the importance of continuously reviewing the literature and updating current reviews to ensure researchers remain up to date with emerging information.

There was a range of reported outcome measures and poor homogeneity of the data, making statistical analysis challenging. Furthermore, no RCTs were identified for inclusion in this review, and the physical appearance of the devices frustrates attempts at blinding, limiting the ability to control variables.[61] No study in this review was deemed to be at low risk of bias according to the ROB-2 and ROBINS-I assessment tools. This indicates the data presented in these studies may lack validity and reliability due to the risk of bias influencing the results.[64,65]

Finally, five studies were identified to meet the inclusion criteria, but were not included in this review due to a lack of free access to full text articles for the researcher. The lack of open access to scientific publications can be a major source of bias and may impact the reproducibility and recommendations made in this review.[66]

Conclusion

These findings suggest that the current SoC FH masks, OF masks, and maskless SGRT can allow for comparable set-up accuracy and intrafractional motion restriction. Radiotherapy centres may therefore consider transitioning towards the use of novel immobilisation methods to improve patient comfort. OF masks used alongside SGRT are as effective at providing immobilisation as the current SoC and could improve patient experiences without compromising clinical outcomes. Despite the current evidence base being limited to small scale non-randomised studies, this could influence radiotherapy centres to consider their own in-house investigations into the potential transition towards these new devices.

Evidence is currently limited regarding maskless SGRT, but early reports show positive results and suggest it may be a safe and effective method of immobilisation. It is likely that in the future this may be deemed a suitable method of immobilisation for a subset of HN and brain cancer patients, particularly those who are able to lie still without restriction, though it Is unlikely this method will be suitable for all patients, for example, those with comorbidities such as Parkinson's disease, or those unable to follow instructions.

It is recommended that radiotherapy departments consider the use of novel immobilisation techniques such as OF masks alongside SGRT for HN and brain treatments to improve patient comfort without compromising clinical outcomes. In centres that do not have capacity to use SGRT for all HN and/or brain patients, it is sensible to consider offering this to patients for whom it will give the most benefit.

Future research should aim to further the evidence base regarding the effectiveness of OF masks and maskless SGRT through multicentre RCTs. These should assess the set-up accuracy and intrafractional motion restriction of these immobilisation devices, making use of SGRT systems. Further research into which subgroups will benefit most from OF masks or maskless SGRT should consider patient characteristics, for example, anxiety, claustrophobia, and other co-morbidities using qualitative questionnaires. Large scale, multicentre RCTs would provide the most valid and reliable data regarding the use of novel immobilisation devices, though none have been conducted on this topic so far.

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