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RESEARCH PAPER

Unmasking anxiety: a head-to-head comparison of open and closed masks in head and neck cancer radiotherapy

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ABSTRACT

Background: Facemasks accurately immobilise patients with head and neck cancer (HNC) receiving radiotherapy (RT). However, such masks are associated with treatment related distress, a prognostic factor for poorer survival. Open masks offer increased comfort and patient satisfaction. We investigated whether open masks could immobilise patients without affecting treatment accuracy.

Materials and methods: Over an 18-month period, all HNC RT patients with anxiety were offered open masks. Once 30 patients had completed treatment, set-up data was compared to patients in closed masks. The mean displacement and one-dimensional standard deviations (SD) of the mean, systematic and random set-up errors were calculated for translational directions: anterior-posterior (*x*), superior-inferior (*y*), medial-lateral (*z*). The mean and SD of the mean was calculated for rotational displacements. Mann-Whitney U was used to determine any significant differences between set- up data.

Results: Sixty patients were included (30 open & 30 closed masks). There was no statistically significant difference found in the x ($p = 0.701$), y ($p = 0.246$) or z ($p = 0.535$) direction for the SD of the mean displacements between both masks. No statistically significant difference was found in the SD of means for rotational displacements. The calculated planning target volume (PTV) margin requirements were minimally less for the closed masks 3.5, 2.6, and 2.7 mm (x, y, z, respectively) versus 4.2, 3.2, and 3.7 mm, respectively, for open masks.

Conclusion: Our study demonstrates that open masks maintain accuracy at levels comparable to closed masks in patients with anxiety. The minor difference in the calculated PTV margin could be rectified with daily on-line imaging or surface guided imaging.

Key words: HNC; radiotherapy; immobilisation; anxiety; open-mask

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Introduction

Radiotherapy (RT) plays a key role in the management of head and neck cancer (HNC) patients. Approximately 80% (range 73.9–84.4%) of all HNC patients will receive RT at least once during the course of their disease [1]. Advances in RT technology have led to improved locore-

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gional control, reductions in long-term side effects and improved quality of life [2–5]. Accurate immobilisation of head and neck cancer patients during radiotherapy treatment is essential to ensure the precise delivery of treatment and the avoidance of critical structures and consequential side effects. The current standard of care is to achieve this with the use of a full closed five-point head and neck thermoplastic facemask [6, 7]. Such face masks have been described as one of the most challenging aspects of RT [8]. Typically, radically treated head and neck patients undergo an intense 6-to-7-week programme of RT, which is both physically and mentally challenging. The use of closed facemasks compounds this struggle and is associated with increased anxiety, fear, distress and disruption to treatment sessions [9, 10]. A phenomenon termed "mask anxiety" has been reported to be as high as 26% in HNC patients [9] and, unfortunately, this anxiety can be poorly recognised and managed by the treatment team [11]. In patients receiving definitive radiotherapy, including head and neck cancer patients, patient reported distress before and after radiotherapy (RT) has been found to be a prognostic factor for poorer survival [12]. With this in mind, it is important that any anxiety is acknowledged and addressed. Interventions to overcome mask anxiety without affecting immobilisation and treatment outcomes are imperative. Open facemasks have been proposed as an alternative intervention for immobilisation of HNC patients suffering claustrophobia or mask distress [13]. Open facemasks in this cohort of patients are associated with better patient satisfaction and comfort [14] and show reduced anxiety and claustrophobia scores [15].

Although other studies have focused on the effects of open facemasks on patient comfort and anxiety, they have not addressed treatment accuracy and impact on PTV margins. In order to improve patients' radiotherapy treatment experience, we carried out a prospective trial piloting a "faceless" open mask in our department. The primary objective of this study was to determine if open facemasks could accurately immobilise patients and limit motion at levels comparable to closed facemasks. Therefore, we evaluated the set-up data, over the course of patient's treatment, for those immobilised with closed facemasks and open facemasks.

Materials and methods

Over an 18-month period, from July 2017 until January 2019, a consecutive cohort of head and neck cancer patients undergoing radical radiotherapy, with a history of anxiety or claustrophobia, were offered open masks. No formal screening tools for anxiety or claustrophobia were used but any patient who had concerns regarding closed mask tolerance was allowed to choose an open facemask. After 30 patients had completed radiotherapy treatment with the open mask, we analysed the set-up data by comparing this cohort of patients with open masks to a parallel cohort of patients in standard closed masks treated during the same period. The 30 patients with closed facemasks included in the study were randomly chosen from all the patients who were treated with closed facemasks in the same 18-month time period in which the first 30 patients with open masks were treated.

The open mask was a 5-point open face hybrid mask. Mask thickness was 2.8 mm (1.6 mm Efficast + 1.2 mm Nanor) supplied from "Orfit" Industries (Belgium) (Fig. 1). The closed mask was the standard 5-point 2 mm mask used in our department, also supplied by "Orfit" Industries and made of 2 mm maxi perforation efficast. All patients were treated in a supine position with a standard headrest. Our institutional policy is to use a sternal tattoo to aid with patient alignment. The standard institutional planning target volume (PTV) margin of 4 mm was used for all patients, except for those patients undergoing daily online imaging (DOI) where a 3 mm margin was used. Elekta and Varian cone beam computed tomography scans (CBCT) were used to assess set up errors, and were acquired according to institutional standard practice (day 1–3, followed by weekly).

Figure 1. Open facemask

The radiation therapist acquires a CBCT and uses the software to calculate the displacements. Any required corrections are applied online prior to treatment. No further CBCT of that corrected position are carried out for that treatment fraction. The displacement calculations were performed using the Eclipse TPS software True Beam version 2.7 for patients treated on the Varian linacs and Monaco TPS software for patients treated on Elekta linacs. Both systems employ a comprehensive methodology that involves acquiring imaging data from the treatment room, typically through cone-beam computed tomography (CBCT) or other imaging modalities, and registering these images with the planning CT scan to determine the magnitude and direction of patient displacement. Specifically, the following steps were followed for displacement calculation:

- acquisition of daily on-line imaging (DOI): patients who exhibited set-up inconsistencies underwent DOI, where imaging data were acquired using the treatment machine's onboard imaging system;
- image registration: the acquired images were registered with the planning CT scan using rigid or deformable registration techniques to align the patient's anatomy accurately;
- calculation of translational and rotational displacements: translational and rotational displacements were calculated based on the differences observed between the registered images and the planning CT scan in each direction (x, y, z for translational; pitch, roll, yaw for rotational).

Consistent methods were applied for displacement calculation across all study participants. Standardised protocols were followed for image acquisition, registration, and analysis to ensure uniformity and reliability of results. Any deviations or modifications in methodology, if applicable, were documented and accounted for in the analysis to maintain the integrity of the study findings.

Set up corrections were applied on set. The translational and rotational set-up errors in all 6 directions were recorded for each patient in an excel sheet. Evaluation of translational set-up errors was performed by defining reproducible and identifiable bony landmarks, i.e., automatic bone match. If a translation > 6 mm and/or a rotation > 3 degrees was found (i.e., a gross error), the set-up procedure was repeated from the start. As we do not have a 6 degree of freedom couch available at our institution, rotational errors were not correctable.

The mean displacement and the one-dimensional standard deviations (SD) of the mean displacements, as well as systematic and random set-up errors, were calculated for all three orthogonal directions [anterior-posterior (x), superior-inferior (y), medial-lateral (*z*)], in line with the on-target guidance using methodology previously described [16–21] PTV margins for set-up error uncertainty were calculated using the Van Herk Margin formula [18].

Differences in the standard deviation of the mean, for both groups, in translational and rotational directions were analyzed using Mann-Whitney U test and independent t-tests. IBM SPSS statistical software version 25 was used for statistical analysis. Ethical approval was not required for this study as this was introduced to our department as a quality improvement initiative.

Results

Sixty patients were included in the study. Thirty patients were treated using the standard closed facemask and 30 patients had the open facemask. The study population included 15 females and 45 males. The mean age of the closed facemask group was 61.2 years and 65.7 years in the open facemask group. A variety of head and neck subsites were included (Tab. 1). Two patients in the closed facemask group and three patients in the open facemask group required DOI due to set up inconsistencies.

Translational displacement: The mean displacement and the SD of the random and systematic errors and the SD of the mean by type of mask are shown in Table 2.

The differences in the SD of the systematic and random set-up errors between the two types of masks were small (< 0.034 cm) in every direction. The SD of the systematic error was less in all directions for the closed facemask. The random error was less for the closed mask in two directions, x and z, but was slightly more in the y direction. The differences in the translational means between the two types of masks were small in every direction. The largest difference in the mean displacement was seen in the z direction (0.009 cm). The Mann-Whitney U test found no statistically

Table 1. Patient characteristics

Characteristic	Closed masks (n = 30)	Open masks (n = 30)
Mean age	61.2	65.7
Gender		
Male	26	19
Female	4	11
Location/site		
Oropharynx	4	5
Larynx	7	5
Neck	3	6
Thyroid	0	2
Hypopharynx	2	0
Oral cavity	8	5
Scalp	0	4
Parotid	2	2
Nasopharynx	3	0
Orbit	0	1
Maxilla	1	0
Treatment intent		
Radical	29	25
Palliative	1	5
Dose fractionation		
70 Gy/35#	16	9
60 Gy/25#	0	2
55 Gy/20#	0	2
60 Gy/30#	5	6
62.4 Gy/26#	4	0
66 Gy/33#	4	4
59.4 Gy/33#	0	1
19.8 Gy/11#	0	1
30 Gy/10#	1	2
20 Gy/5#	0	2
36 Gy/12#	0	1

significant differences between the SD of the x, y and z translational means between the two mask groups.

Rotational displacement: the absolute shifts for the rotational displacement were also recorded. The mean of the SD was calculated for each rotational displacement (Tab. 3). The largest difference was seen in the pitch, where a difference of 0.13cm was seen between the closed and open facemask. Using the Mann-Whitney U test no statically significant difference was found in the SD of the pitch means, SD of the roll means or SD of the yaw means between masks. An independent t-test was also performed and this showed no significant difference in the pitch, roll and yaw between the masks.

The calculated PTV margin was greater in the open facemask group in all directions but the difference in margin required between the 2 groups was ≤ 1 mm in all directions. (Fig. 2) Margins required for set up uncertainly in the closed facemask group were all ≤ 3.5 mm and ≤ 4.2 mm in the open mask group.

Discussion

In this paper, we present our findings when comparing the set-up data for head and neck cancer patients immobilised with full closed masks and open facemasks. Results of our study show that, by analysis of set up errors, open facemasks are comparable to closed facemasks in maintaining adequate immobilisation in patients suffering from anxiety. Our findings pave the way for future research to extend open masks as an attractive alternative option

Table 2. Translational set-up errors by mask type

	Closed mask [cm]	Open mask [cm]	p-value — SD of mean (Mann-Whitney U test)
x Mean displacement	0.048	0.050	0.701
x SD Systematic error	0.079	0.106	
x SD Random error	0.219	0.225	
y Mean displacement	0.031	0.029	0.246
y SD Systematic error	0.054	0.080	
y SD Random error	0.176	0.171	
z Mean displacement	0.021	0.030	0.535
z SD Systematic error	0.068	0.101	
z SD Random error	0.144	0.174	

SD — standard deviation

Table 3. Rotational set-up errors by mask type

Rotational direction	Closed mask	Open mask	Closed mask	Open mask	p-value — Mann Whitney U test of SD
	Mean displacement		SD of Mean displacement		
Pitch	1.0	1.15	0.70	0.83	0.217
Roll	1.05	1.12	0.85	0.91	0.929
Yaw	0.79	0.93	0.74	0.70	0.918

SD — standard deviation

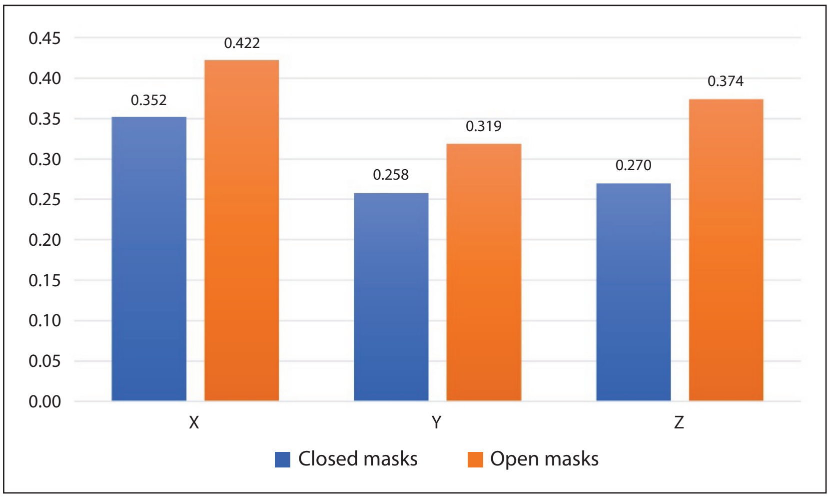

Figure 2. Calculated planning target volume (PTV) margins for open and closed face mask groups

for all radiotherapy patients who require an orfit for treatment.

In our cohort, of 60 patients, the difference in the SD of the systematic error (cm) was minimally lower for closed masks than for the open mask in all directions (x = 0.079 *vs* 0.106, z = 0.068 *vs*. 0.101, y = 0.054 *vs*. 0.080). There were similar results for the SD of the random errors apart from in the superior/inferior direction where the closed facemasks were slightly higher (0.176 *vs*. 0.171). Importantly, there were no statistically significant differences between the SD of the x, y and z translational means between the two mask groups, highlighting the non-inferiority and safety of open facemasks in this patient cohort. Our findings are consistent with Wiant et al. [15] who found that open masks could limit motion similarly to closed masks. Wiant et al. [15] conducted a study where 50 head and neck cancer patients were prospectively randomised into 2 groups, 25 closed masks and 25 open masks. Both groups underwent daily volumetric imaging which was rigidly registered to their respective planning images to evaluate spinal canal and mandible position as a check for interfraction posture change. The open mask group were monitored with surface imaging to evaluate intrafraction motion. Posture change was determined by the amount the spinal cord and mandible contours had to be expanded on the initial planning CT in order to cover the structures on each daily image. The vector length (VL) of the intrafraction linear translations, spine, and mandible positions for each open-mask patient were checked for correlation with fraction number using the Pearson r-value. No fractions had linear movements > 4 mm and only 3.7% of fractions had movements > 2 mm. All of the mean linear translations and rotations were < 1mm or 0.3 degrees. Open masks were found to provide comparable immobilization and posture preservation to closed facemasks Mulla et al. [14] prospectively randomized 40 patients to open (with customised headrest) or closed masks with standard headrest. Similar to our institutional protocol CTCB were taken on days 1–3 and weekly and registered to the planning CT to determine interfraction translational and rotational shifts. Similarly, mean SD and in the translational and rational directions were analyzed. Comfort and satisfaction were higher amongst the open facemask group. Similar to our results, there was no significant difference in the translational shifts between the groups. The SD of the systematic and random error for the pitch and jaw were statistically significantly greater in the open group but still within 3 degrees and hence not clinically significant. A limitation of Mulla et al. [15] study was the fact that it was not a direct comparison as different head rests were used in different groups. As reported in a previous trial, at our institution the use of standard head rests has become protocol as customized head rests were found to be resource intensive without improving the accuracy of positioning compared to standard headrests [22]. One of the strengths of our institution is the onsite specialized mould room staff who are experienced in managing the specific needs and concerns of this HNC patient group.

In a small study Lee et al. [23] compared 5 open masks to 8 closed ones, with pre and post KV imaging. They found the distributions of the cranium and lower jaw "open mask" absolute displacements were statistically different in favour of the "open face" mask with corresponding p-values of 0.002 for the cranium and 0.002 for the lower jaw. There was no difference for C6 vertebral body. The mean and standard deviation of the 3D shifts during treatment for the conventional mask versus "open mask" were 1.2 ± 0.7 mm *vs.* 0.7 ± 0.8 mm; 1.9 ± 1.1 mm *vs.* 1.0 ± 0.8 mm. Despite small numbers, Lee et al. concluded that open facemasks actually led to better immobilisation. Of note, in contrast to our study none of the above named studies analysed the impact of PTV margin. A strength of our study is that we calculated the impact of displacements on PTV margins. This was performed using standard deviation calculations using a similar calculation to a previously reported trial at our institution. [22] Van Herk formula was developed to calculate the PTV margin to ensure the clinical target volume (CTV) is covered by at least 95% of the prescribed dose [18]. It has been used in many head and neck research studies analysing set up data in closed facemasks. [24, 25]

To our knowledge, this is the first study to calculate PTV margin using the Van Herk formula, in head and neck radiotherapy patients using open facemasks. Efforts to reduce radiation related toxicity is of particular importance in head and neck cancer patients, and minimising PTV margins is an important way to achieve this. [26] Minimising PTV margins, in order to minimise toxicity to organs at risk, is of upmost importance in head and neck cancer radiotherapy. In an era of increasing incidence of HPV positive head and neck cancers and a subsequent younger patient population minimising side effects, maintaining quality of life and survivorship are paramount. We have shown that open facemasks can maintain immobilization at levels similar to closed and could be used as a strategy to help elevate some anxiety in patients prone to claustrophobia and anxiety.

Closed facemasks have been well characterized in terms of setup uncertainty of 2–3 mm permitting the calculation of treatment margins to account for the geometric setup uncertainty of radiotherapy [13]. In our study the closed facemasks had a mean PTV margin calculation of ≤ 3.5 mm in all translational directions. The required margins for the open facemasks were slightly higher with a set-up margin ≤ 4.2 mm in all directions. Our institutional protocol is a 4mm margin, alternatively, a 3 mm margin if using daily online imaging. All our calculated PTV margins were ≤ 4 mm apart from one direction, the x (anterior/posterior) displacement for the open facemask, which was 4.2 mm. The calculated PTV margin is in keeping with other institutes who found a 5mm safe to account for set up errors in the standard closed facemask [24, 25]. At our institution, we do however use a 4mm PTV margin. We would argue that our slightly higher margin calculation in the anterior posterior direction may not be clinically significant and if our sample size were larger, this displacement would be less and in keeping with our 4mm margin institution standard. Nonetheless, the minimal difference in the calculated PTV margin could be rectified with the addition of daily on-line imaging or surface guided imaging and this should be further investigated in subsequent studies.

Additional measures such as video-based optical surface imaging (OSI) has been reported for monitoring head motion when a patient's facial area is visible in a frameless or open mask. The use of optical surface imaging with open facemasks has been found to immobilize patients sufficiently (< 2 mm) during radiotherapy [13] and is something that could be incorporated into future studies

Whilst accurate and precise RT delivery is essential in head and neck RT, patient comfort is equally important for compliance and effective delivery of care. Mask anxiety is a significant issue that can leave some patients traumatized long after treatment has been completed [27]. Addressing ways to limit anxiety is extremely important to minimise the ongoing impact of the experience on HNC survivors [27]. Interventions to relieve mask anxiety are essential. Currently benzodiazepines are often prescribed to patients to help with mask anxiety; however, they only help a proportion of patients and the associated side effects of such medications mean it is not an ideal solution [28] and highlight the need for alternative options [28]. One strategy is the use of an open facemask. Overall, when compared to closed facemasks in volunteers and patients, volunteers preferred the open facemask to the full mask, while claustrophobic patients could only tolerate open facemasks [13]. However, if patients are not accurately immobilised, there is a potential risk of critical organ damage and/or inadequately treating tumour. Prior to implementing faceless masks, it is imperative to assess their ability to immobilise patients consistently during RT to maintain accuracy during treatment and our study has successfully achieved this. To date there have been few studies addressing the issue of accurate immobilization with the use of open facemasks. Our study adds to the current weight of studies and to our knowledge represents the largest patient study to date with 60 patients included.

There were some limitations to our study. We did not explore treatment time and whether or not open facemasks took longer or shorter to treat. One could postulate that open facemasks could increase treatment time due to the need for repositioning. However, Wiant et al. found, allowing for omitting differences in non-IMRT method of delivery, average treatment time was almost identical between the open and closed facemask groups [15]. Another area not explored was the impact on replanning and whether open facemasks could increase or decrease the need for replanning during the course of RT. Additionally, it would have added more weight to our study if patient anxiety and comfort levels were assessed over the course of treatment, a descriptive evaluation and scoring of patient anxiety was lacking in this study. However, it has already been well reported in the literature that anxiety levels are reduced with open facemasks. Whilst our study appears to be one of the largest to date, assessing immobilisation in open facemasks, it was still a relatively small sample size and a larger sample size would further validate our findings. We have not assessed the use of open facemasks in a patient population without claustrophobia or anxiety. It is possible that margin requirements may be different in patients with or without claustrophobia or anxiety.

Conclusion

Whilst there are some limitations to this study, we have demonstrated that open masks are able to maintain accuracy at levels comparable to closed masks and may be offered to patients suffering mask anxiety. The minor difference in the calculated PTV margin is not likely significant given the small sample size. However, this could be rectified with daily on-line imaging or surface guided imaging when using open facemasks. For open face masks to become standard of care in all head and neck cancer patients, a large randomized controlled trial is warranted and should incorporate the use of surface guided imagining for the monitoring of motion and guidance of treatment margins in open facemasks. This paper adds to the growing literature that open face masks are potentially practice changing and capable of changing the face of head and neck radiotherapy.

Ethical approval

Ethical approval was not necessary for the preparation of this article”

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Conflict of interest

Authors declare no conflict of interest.

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