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# Effectiveness of personalized open-face mask combined with styrofoam fixation in radiotherapy treatment of head and neck cancers: a prospective randomized controlled trial

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## Abstract

**Objective** The primary aim of this investigation is to assess the effectiveness of implementing an innovative immobilization approach, spec ically the utilization of personalized open-face masks in combination with styrofoam fixation, for head and neck cancers receiving radiotherapy. The study seeks to evaluate the influence of this method on improving patients' precision in positioning and their overall comfort during the treatment process, in addition to exploring its potential capacity to mitigate the occurrence of anxiety and depression in this patient population.

**Methods** A prospective, randomized controlled trial was undertaken to investigate the comparative efficacy of two immobilization approaches for the radiotherapy treatment of head and neck cancers. The experimental group was randomly assigned to receive fixation using personalized open-face masks with nose and mouth apertures, while the control group was immobilized using closed-face masks. Weekly cone-beam computed tomography (CBCT) scans were conducted pre-treatment to assess and record setup errors along three axes. Comparative analysis of setup errors and the planning target volume (PTV) margin between the two groups was performed. Furthermore, the patients' comfort levels and anxiety and depression status were evaluated using the modified Likert questionnaire and the Hospital Anxiety and Depression Scale (HADS).

**Results** A total of 106 patients were enrolled in the study and randomly assigned to either the experimental group ($n = 53$) or the control group ($n = 53$). There were no statistically significant differences observed between the two groups in terms of age, sex, and disease type indicating comparability. Analysis of the setup errors along different

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directions showed no significant differences between the experimental and control groups in the X direction (0.90 ± 0.84 mm vs. 0.92 ± 0.85 mm, $p = 0.825$), Y direction (1.26 ± 0.98 mm vs. 1.37 ± 1.09 mm, $p = 0.172$), Z direction (1.18 ± 0.84 mm vs. 1.15 ± 0.98 mm, $p = 0.651$), and Rtn direction (0.65 ± 0.57 vs. 0.62 ± 0.55, $p = 0.489$). Evaluating the local setup errors in the experimental and control groups, there were no significant differences observed in the X direction (1.13 ± 1.15 mm vs. 1.01 ± 0.89 mm, $p = 0.152$) and Z direction (1.31 ± 0.88 mm vs. 1.26 ± 1.17 mm, $p = 0.549$). However, a significant difference was found in the Y direction (1.49 ± 1.19 mm vs. 1.80 ± 1.45 mm, $p = 0.003$). The Rtn direction also did not show a significant difference (0.90 ± 0.81 vs. 0.84 ± 0.73, $p = 0.328$). The PTV margin in the X, Y, and Z directions were determined as 2.20 mm, 3.12 mm, and 2.57 mm in the experimental group and 2.35 mm, 3.58 mm, and 2.86 mm in the control group, respectively. The personalized open-face mask patients reported higher levels of comfort compared to the perforated head, neck, and shoulder thermoplastic mask (31.32 ± 1.16 vs. 30.00 ± 1.49, $p < 0.001$). The prevalence rates of anxiety in the experimental and control groups were as follows: (18.8% vs. 12.5%, $p = 0.399$), (18.8% vs. 14.6%, $p = 0.584$), (23.4% vs. 25%, $p = 0.856$), and (23.4% vs. 33.3%, $p = 0.283$).

**Conclusions** In head and neck cancer radiotherapy, we propose the idea of personalized open-face mask combined with styrofoam for the first time, which can improve patient comfort without sacrificing positioning accuracy, and has a tendency to relieve patients' tension and anxiety. It is worth promoting and using in clinical positioning.

**Keywords** Head and neck cancer, Personalized open-face mask, Positioning accuracy, Comfort, Anxiety and depression

## Background

Head and neck tumors represent a prevalent malignancy, with radiation therapy as a frequently utilized treatment modality [1]. Intensity-modulated radiotherapy (IMRT) is the predominant irradiation technique employed [2–5]. Precise positioning and irradiation are critical in IMRT for head and neck tumors to avoid damaging adjacent normal tissues, potentially causing dry mouth, dysphagia, and hoarseness [6–8]. Positioning errors can significantly compromise dose coverage of the target area and increase radiation exposure to organs at risk [9, 10]. Consequently, minimal positioning errors and reproducible fixation devices are crucial.

The styrofoam fixation technique has demonstrated superior fixation outcomes in intracranial [11], head and neck [12], and breast tumors [13], offering reduced placement errors and enhanced comfort compared to conventional devices such as fixed headrests. Styrofoam effectively fills the gap between the mold and the patient's head and neck, ensuring a close fit, preventing mold displacement and discomfort, and enhancing the comfort and repeatability of treatment. Thus, it has become the preferred method for radiotherapy position fixation in head and neck tumors across many institutions.

The established clinical standard for facial immobilization in head and neck tumors has been the closed mask [2, 14, 15]. However, the prolonged course of treatment involved in IMRT for these tumors often results in significant stress and discomfort for the patients. This is particularly challenging for patients suffering from claustrophobia [16]. The associated discomfort may lead to patient movement during irradiation despite immobilization, potentially resulting in noncompliance. The discomfort and pain from immobilization may also trigger severe anxiety in some patients [14]. Anxiety and depression are commonly reported psychological issues among cancer patients undergoing treatment [8] and immobilization devices significantly contribute to anxiety, adversely affecting the emotional state of patients [17–19]. Patients with head and neck tumors exhibit higher levels of anxiety and depression compared to those with other tumors, particularly prior to undergoing radiotherapy [20]. In response to these challenges associated with closed face masks, numerous scholars have proposed an alternative immobilization method that allows partial exposure of the patient's face [2, 15, 16, 21]. However, clinical results from this approach are variable, and there is a scarcity of prospective studies with large sample sizes. Meanwhile, these studies are based on optical body surface studies, and studies based on conventional CBCT guidance are rarely reported.

Consequently, a prospective randomized controlled study was undertaken to evaluate the effectiveness of a personalized open thermoplastic mold combined with a styrofoam fixation technique in intensity-modulated radiation therapy for head and neck tumors. The study aimed to determine the impact of this method on enhancing positioning accuracy and overall comfort during treatment, as well as its potential to reduce the incidence of anxiety and depression among patients. To our knowledge, this is the inaugural randomized controlled trial employing a large sample to assess the reduction in positioning errors and improvement in comfort satisfaction using an individualized open mask combined with styrofoam fixation for patients with head and neck tumors.

## Materials and methods

### Case selection

Patients diagnosed with head and neck tumors and scheduled for radiotherapy between July 2023 and April 2024 at our centre were included in this study. Inclusion criteria: diagnosis of head and neck tumor requiring radiotherapy, age between 18 and 70 years, a Karnofsky Performance Status (KPS) score of 70 or higher, and completion of all relevant examinations to rule out contraindications to radiotherapy. All participants were required to be fully informed about the study and to sign an informed consent form. Exclusion criteria: use of fixed headrest or vacuum cushion for fixation, requirement for oral receptacles during radiotherapy, communication disorders precluding cooperation, and refusal to participate by the patients or their family members. Consecutively enrolled patients were randomly divided into two groups according to the numerical table method: one using personalized open-face head, neck, and shoulder thermoplastic moulds with styrofoam for positional fixation (open-face masks group), and the other using closed-face molds (control group). This study was a prospective randomized controlled trial (ChiCTR2300073789) and received ethical approval from the hospital's ethics committee (KY20232209-F-1).

### Patient position fixation and CT simulation

All patients were positioned using styrofoam at the back of the head and a nine-point thermoplastic mould on the face. In the open-face group (Produced by a CT localization technician with 13 years of experience, Fig. 1a), the mask was cooled on the body surface for approximately 30 min before individual openings were made in the thermoplastic film. The defined boundaries for these openings were: the anterior edge of the nasal tip as the upper boundary, 1.5 cm below the lower lip edge as the lower boundary, and 1 cm lateral to the corners of the mouth and eyes on both sides. The control group (Fig. 1b) did not receive any modifications to their masks. Localization was simulated using a Philips Big Bore Computed Tomography (Big Bore Brilliance CT) scanner to identify the approximate isocentre position, which was then marked with a red line on the thermoplastic membrane. Scanning parameters included an upper boundary at the roof of the skull, a lower boundary 3 cm below the clavicle, with a layer thickness and spacing of 3 mm. Intravenous contrast enhancement was used.

### Daily positioning and image guidance

Patients underwent volumetric rotational intensity-modulated radiation therapy using a Varian Clinac ix linear accelerator. Before the initial treatment, the treatment bed was aligned to the precise treatment position based on the planning parameters, and a black treatment line was marked on the mask. During daily sessions, patients were first immobilized using styrofoam and a head, neck, and shoulder thermoplastic wrap, followed by alignment of the treatment laser with the black treatment line. Cone beam CT (CBCT) scans were routinely performed weekly in all patients to ensure reproducible localization.

### Image analysis

Weekly CBCT images were aligned online to obtain translation vectors and rotational degrees of bed angle

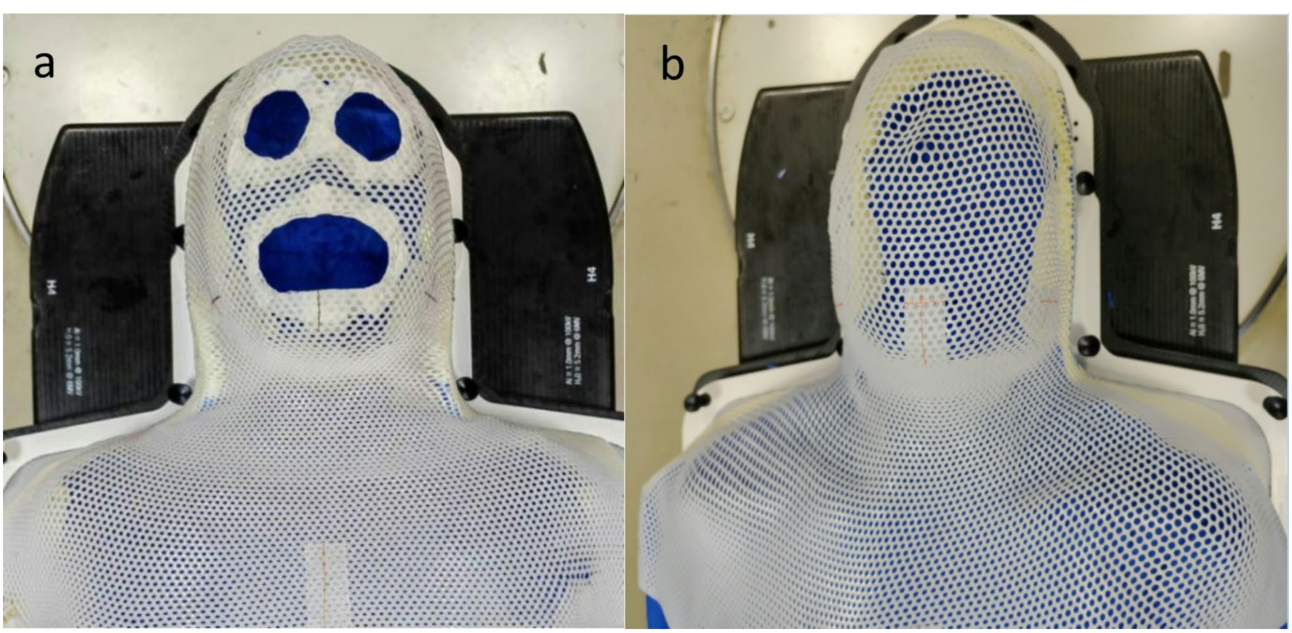


**Fig. 1** Postural fixation methods of the two patient groups. Note: **a**. Opening group fixation method; **b**. Control group fixation method

(Rtn) in the left-right (X), head-foot (Y), and ventral-dorsal (Z) directions. Positioning errors in four dimensions (X, Y, Z, and RTN) were compared between two groups for the entire alignment frame (including all scans) and the opening area. The boundaries of the opening area were defined as follows: upper boundary—the upper edge of the nasal bone; lower boundary—1.5 cm below the lower lip edge; anterior boundary—the anterior edge of the nasal tip; posterior boundary—the anterior edge of the vertebral body; and left and right boundaries—1 cm lateral to the corners of the mouth on both sides. Prior to the initial treatment, all patients underwent kV-CBCT scanning, and deviations in spatial position (overall error) were determined by comparing these images with the planned CT images. These deviations were confirmed by the treating physician and the therapist, who then recorded the details. If a deviation exceeded 3 mm in any direction, it was corrected (repositioned; if the error exceeded 3 mm on repeat measurements, isocentric correction was applied). If the error was ≤ 3 mm, it was directly transferred to another bed for treatment without isocentric correction. CBCT positioning was verified weekly; two therapists confirmed the alignment error online, while the attending physician reviewed it offline. Local area alignment error was calculated by adding the overall error from online alignment to the local area error from offline alignment.

### Observation items and time points

Weekly CBCT scans were conducted to validate positioning errors. The Hospital Anxiety and Depression Scale (HADS) was administered before treatment, at weeks 1 and 3, and at treatment completion. The Modified Likert questionnaire was assessed before treatment and in week 2, comprising eight items: (1) head, neck, and back comfort; (2) patient fit to the mold; (3) mold looseness and tightness; (4) mold temperature; (5) mold color; (6) anxiety and dyspnea induced by the mold; (7) physical discomfort; and (8) recommendation of the device to other patients. Each item was rated on a 1–5 scale, and the scores were analyzed as numerical variables.

### Statistical analysis

Data were analyzed using SPSS 25.0. Frequency data were expressed as number (n) and percentage (%), and group differences were evaluated using the χ2 test. Measurement data were presented as mean ± standard deviation, with comparisons made using the t-test. Pendulum errors were reported as absolute values. Sample size estimation by PASS 15.0 software: α is taken as 0.025 (unilateral), power = 0.8, the number of cases is the same in both groups, it can be seen by the pre-test of head and neck tumor pre-test, the main efficacy index of this study is the control group opening local Y-direction pendulum reproducibility value is about (1.87 ± 1.20) mm, and it is expected that the corresponding index of the experimental group is (1.19 ± 0.94) mm, and the consumptive The function takes the O'Brien-Fleming method, the sample size is calculated as 50*2 cases, and the estimated test shedding rate is 5%, so the total number of cases needed is 106.The Spearman correlation coefficient was used to analyze variable correlations. $p < 0.05$ was considered statistically significant. Pendulum errors for each patient were calculated according to Stroom et al. [12]. Data errors originated from two sources: systematic and random errors. The overall mean (M), representing systematic error, was calculated as the mean of all individual patient means. Systematic swing error (Σ) was determined as the standard deviation of the individual means, and random swing error (σ) was calculated as the root mean square of the standard deviations across all patients. The PTV boundaries were derived using the Van Herk formula, expressed as [$2.5\Sigma + 0.7\sigma$], ensuring that the 95% isodose line covered 90% of the CTV in patients [13].

## Results

### Patients

Between July 2023 and March 2024, a total of 106 patients were randomized, of these, 71 (66.98%) were male and 35 (33.02%) were female. Analysis included 335 CBCTs from 53 individuals in the open group and 333 CBCTs from 53 individuals in the control group. Baseline characteristic, presented in Table 1, showed no statistical difference between the groups ($p > 0.05$).

### Comparison of patient positioning errors

In the open group, positioning errors in the X, Y, and Z directions ranged from − 4 to 3 mm, -4 to 3 mm, and − 3 to 3 mm, respectively; in the control group, they ranged from − 5 to 3 mm, -5 to 6 mm, and − 3 to 4 mm. Rtn rotation errors ranged from − 2.1 to 3.4° and − 3.0 to 2.9° for the open and control groups, respectively. The incidence of pendulum errors exceeding 2° was 2.72% in the open group and 2.14% in the control group. Errors greater than 3 mm occurred at rates of 0.30%, 0.30%, and 0% in the X, Y, and Z axes, respectively, in the open group; in the control group, the rates were 0.30%, 0.90%, and 0.30%. Local errors in the open group ranged from − 4 to 6 mm, -4 to 5 mm, and − 3 to 4 mm in the X, Y, and Z directions; in the control group, they ranged from − 5 to 3 mm, -5 to 8 mm, and − 4 to 5 mm. The range of RTN rotational errors was − 4.3 to 4.6° and − 4.0 to 4.7° in the open and control groups, respectively. The percentage of errors greater than 2° was 9.36% in the open group and 7.03% in the control group. Pendulum errors greater than 3 mm were 3.02%, 6.95%, and 0.30% in the X, Y, and Z axes, respectively, in the open group; in the control group,

**Table 1** Baseline information

| | | Open-face masks | Control group | *t/x²* | *p* |
|---|---|---|---|---|---|
| Age | | 53(25–74) | 55(16–75) | *0.987* | *0.326* |
| Sex | Male | 34 | 37 | *0.384* | *0.536* |
| | Female | 19 | 16 | | |
| BMI | | 24.02 ± 3.42 | 23.76 ± 3.43 | *0.396* | *0.693* |
| Educational | attainment High school or above | 21 | 17 | *2.946* | *0.229* |
| | Secondary school | 25 | 22 | | |
| | Primary school and below | 7 | 14 | | |
| Household registration | Urban | 29 | 22 | *1.852* | *0.174* |
| | Rural | 24 | 31 | | |
| Disease type | Nasopharyngeal cancer | 28 | 24 | *1.692* | *0.792* |
| | Nasal NKT lymphoma | 2 | 1 | | |
| | Nasal sinus cancer | 6 | 5 | | |
| | Post-operative parotid adenocarcinoma | 6 | 9 | | |
| | Others | 11 | 14 | | |
| Pre-treatment anxiety incidence | | 9/47(19.1%) | 6/48(12.5%) | *0.711* | *0.399* |

Note Other includes hypopharyngeal cancer, cancer of the floor of the mouth, gum cancer, postoperative cancer of the sublingual gland, laryngeal cancer, plasma cell carcinoma of the neck, and cervical lymph node metastases

these rates were 0.31%, 11.62%, and 4.89%. For further details, see Fig. 2.

Table 2 presents the positioning errors for both groups in overall and localized areas. A comparison of pendulum errors between the open and control groups revealed no statistical difference in the overall region but a significant difference in the local region in the Y direction (1.49 ± 1.19 vs. 1.80 ± 1.45 mm, $p = 0.003$); no statistical differences were observed in the other directions.

**Table 2** Comparison of posing errors (mm) in overall and localized areas between the two groups

| | | Open-face masks group | Control group | *t* | *p* |
|---|---|---|---|---|---|
| Overall | X | 0.90 ± 0.84 | 0.92 ± 0.85 | *0.221* | *0.825* |
| | Y | 1.26 ± 0.98 | 1.37 ± 1.09 | *1.368* | *0.172* |
| | Z | 1.18 ± 0.84 | 1.15 ± 0.98 | *0.453* | *0.651* |
| | Rtn | 0.65 ± 0.57 | 0.62 ± 0.55 | *0.692* | *0.489* |
| local | X | 1.13 ± 1.15 | 1.01 ± 0.89 | *1.433* | *0.152* |
| | Y | 1.49 ± 1.19 | 1.80 ± 1.45 | *3.013* | *0.003* |
| | Z | 1.31 ± 0.88 | 1.28 ± 1.17 | *0.446* | *0.656* |
| | Rtn | 0.90 ± 0.81 | 0.84 ± 0.73 | *0.979* | *0.328* |

## Comparison of target area exotropic boundaries between the two groups

Table 3 displays the required PTV margins for both groups in overall and local areas across three directions. The closed mask in the overall area necessitated a maximum of 4 mm for exotropia in the Y direction, while 3 mm was sufficient for the other directions. The outward release was generally lesser in the open group compared to the control group. In the localized area, the open group required a maximum of 4 mm in both the X and Y directions, whereas the control group needed 5 mm in the Y direction and 4 mm in the Z direction.

## Comparison of modified likert questionnaire scale between the two groups

Before treatment, the comparison of total comfort satisfaction scores between patients in the open group and the control group was 31.28 ± 1.13 vs. 30.00 ± 1.49 ($p < 0.001$);

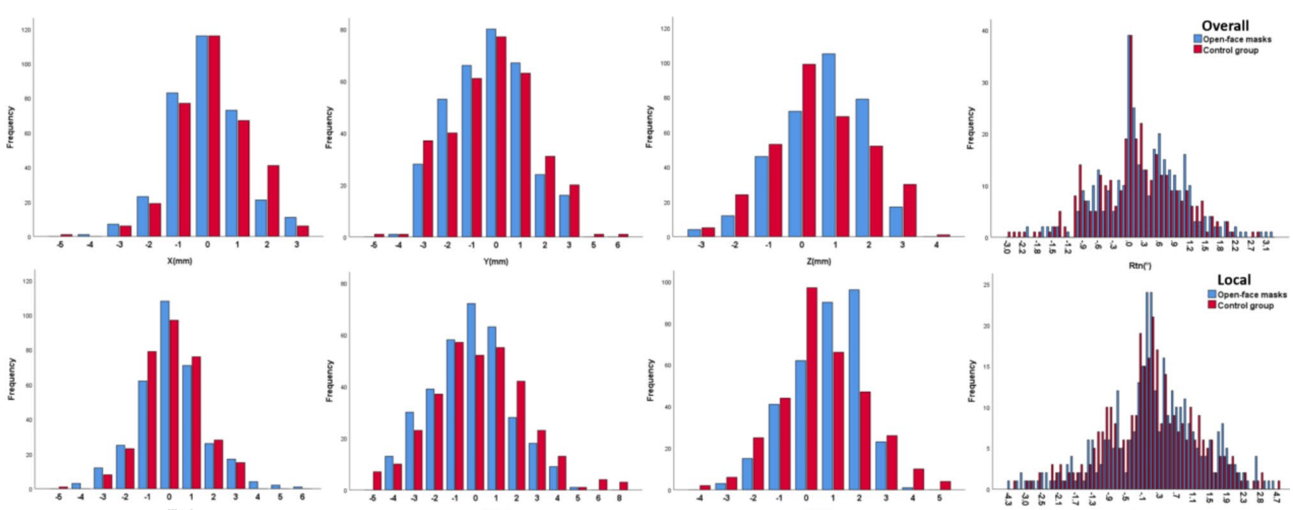


**Fig. 2** Columnar distribution of overall and localised areas for posing errors in each direction for both groups

**Table 3** Required PTV margin (in mm) in overall and localized areas between the two groups

| | | Open-face masks group | | | Control group | | |
|---|---|---|---|---|---|---|---|
| | | X | Y | Z | X | Y | Z |
| Overall | Σ | 0.78 | 1.15 | 0.95 | 0.83 | 1.29 | 1.05 |
| | δ | 0.36 | 0.36 | 0.26 | 0.39 | 0.51 | 0.36 |
| | PTV margin | 2.20 | **3.12** | 2.57 | 2.35 | **3.58** | 2.86 |
| local | Σ | 1.21 | 1.39 | 0.99 | 0.92 | 1.86 | 1.26 |
| | δ | 0.41 | 0.50 | 0.34 | 0.33 | 0.56 | 0.40 |
| | PTV margin | **3.32** | **3.82** | 2.71 | 2.53 | **5.04** | **3.43** |

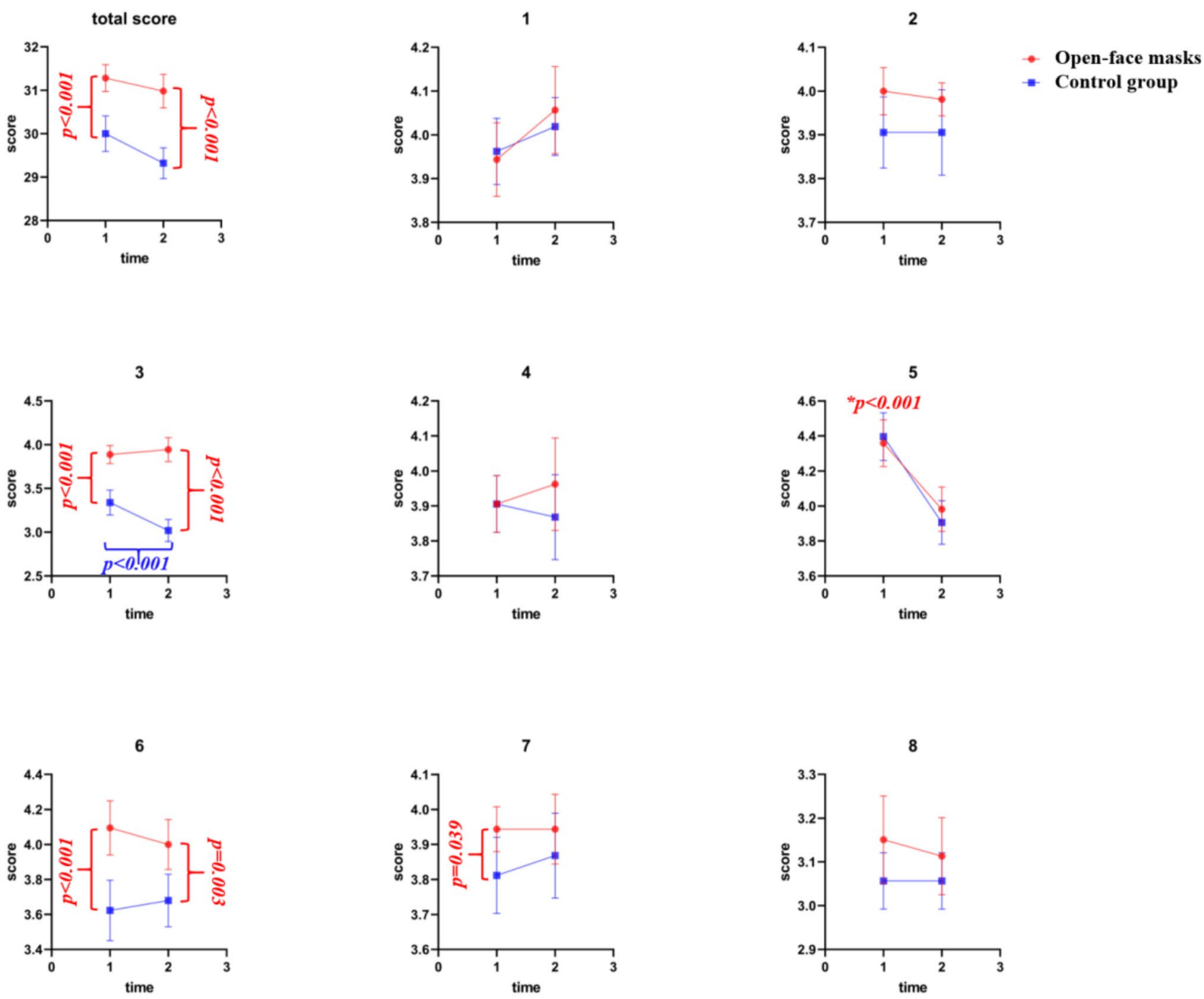


**Fig. 3** Graph comparing results of the Likert questionnaire scale survey between the two groups (1 for the horizontal coordinate represents the comfort score before the first treatment and 2 represents the comfort score during the second week of treatment; * indicates statistically significant differences in both pre- and post-assessments within the groups)

during treatment, the scores were 30.98 ± 1.41 versus 29.32 ± 1.28 ($p < 0.001$). Significant differences were noted in the third item, concerning the degree of looseness and tightness of the molds, and in the sixth item, regarding breathlessness or anxiety. Details are provided in Fig. 3.

## Comparison of HADS between the two groups

The incidence of anxiety among all patients was 15.8% before treatment and increased to 28.4% by the end of treatment. In the open group, the pre-treatment anxiety incidence was 19.1%, compared to 12.5% in the control group, showing no statistical difference. No significant differences in anxiety incidence were noted between the two groups at one week, three weeks, and the end of treatment, as outlined in Table 4. The incidence of anxiety rose by 4.3% from pre-treatment to end of treatment in the open group, and by 20.8% in the control group, $\chi 2 = 5.914$, $p = 0.015$.

### Correlation analysis

In the overall region, the open group exhibited a moderate negative correlation ($r = 0.37$) between the X direction and Rtn, and either weak or no correlation in the other directions. The control group showed a strong negative correlation ($r = 0.49$) between the X direction and Rtn, and a moderate negative correlation ($r = 0.20$) between the Y and Z directions. In the localized area, the open group displayed a strong negative correlation ($r = 0.503$) between the X direction and Rtn, and a moderate negative correlation ($r = 0.209$) between the Y direction and Rtn. Conversely, the control group revealed a strong negative correlation ($r = 0.457$) between the X direction and Rtn, and a moderate negative correlation ($r = 0.216$) between the Y and Z directions. Further details are provided in Fig. 4.

## Discussion

In this study, we aimed to enhance patient positioning accuracy and comfort satisfaction through a prospective randomized controlled trial using a personalized open face mask combined with styrofoam fixation. Our findings indicated that overall errors were comparable between the two patient groups, but the localized regional errors in the Y-direction were significantly lower in the open group compared to the control group. Additionally, the open face mask with styrofoam generally improved patient comfort and appeared to decrease patient anxiety.

The fixation effect of the mask was initially considered due to its critical role in radiotherapy [22]. Both open and closed masks exhibited similar overall regional placement errors, aligning with the studies of Van Beek et al. [23] and David Wiant et al. [2], which report comparable fixation effects for both types of masks. However, traditional commercially available open face masks used in these studies often had their openings align with the forehead and chin, and pressed against the cheeks, raising concerns about positional accuracy during routine image-guided treatments like CBCT. Zaheeda Mulla et al. [7] compared the fixation effects of open versus closed masks using CBCT, finding similar translational errors but significantly greater rotational errors in the open mask group. Notably, the open masks showed a larger swing error in the X direction (1.38 ± 1.14 mm) compared to our study (0.90 ± 0.84 mm), but similar in the Y and Z directions. Our use of styrofoam, instead of a standard headrest, likely contributed to reduced headrest-related positioning inaccuracies [11, 12], and the personalized design retained nose fixation, improving accuracy in the left-right direction and rotational errors. In the localized area, the open group exhibited a markedly smaller posing error in the Y-direction compared to the control group, with the mean error across all directions being larger than the overall area error. This observation aligns with clinical practice, Xu et al. [24] noted that overall regional positioning errors tend to underestimate localized regional errors. The reduced posing error in the Y-direction in our open mask group was likely due to the enhanced visibility of the patient's jaw and nose alignment with the fixation mold, unlike the closed mask which lacked such visualization and required more careful observation, thereby increasing posing time. This could pose a challenge for radiotherapy facilities handling large patient volumes. Furthermore, our open mask demonstrated greater stability, particularly in the Y direction (Fig. 2), suggesting that open masks provide both stable fixation and precise positional accuracy in CBCT-guided treatments compared to traditional closed masks.

We compared the margin required for the target area from CTV to PTV in both groups of patients. In the overall region, the open mask required a standard 3 mm outward release in all directions, which was sufficient, whereas the closed mask necessitated 4 mm in the Y direction to meet clinical requirements, with a greater outward release in all directions. This underscores the effectiveness of the open face mask. In the local area, both groups exhibited an increased PTV margin compared to the overall area (Table 3), with the open mask group showing a significant change in the X direction and the closed mask in the Y direction. This phenomenon is attributed to the complexity of the decortication structure in the head and neck region [25], and the necessity for patients with closed masks to excessively tilt their chins to fit the mold at the nose tip during positioning, complicating observation of this part of the mold. Another contributing factor is the choice of fixation mold. These observations align with findings from other studies [24, 26], which report deformation errors in head and neck tumor radiotherapy, showing a progressively increasing trend from top to bottom. It is recommended

**Table 4** Comparison of the percentage of patients experiencing anxiety in the two groups

| | Total patients (95) | open-face masks(47) | Control group(48) | $\chi^2$ | *p* |
|---|---|---|---|---|---|
| Before treatment | 15.8%(15) | 19.1%(9) | 12.5%(6) | *0.711* | *0.399* |
| One week of treatment | 16.8%(16) | 18.8%(9) | 14.6%(7) | *0.300* | *0.584* |
| Three weeks of treatment | 24.2%(23) | 23.4%(11) | 25.0%(12) | *0.033* | *0.856* |
| End of treatment | 28.4%(27) | 23.4%(11) | 33.3%(16) | *1.151* | *0.283* |

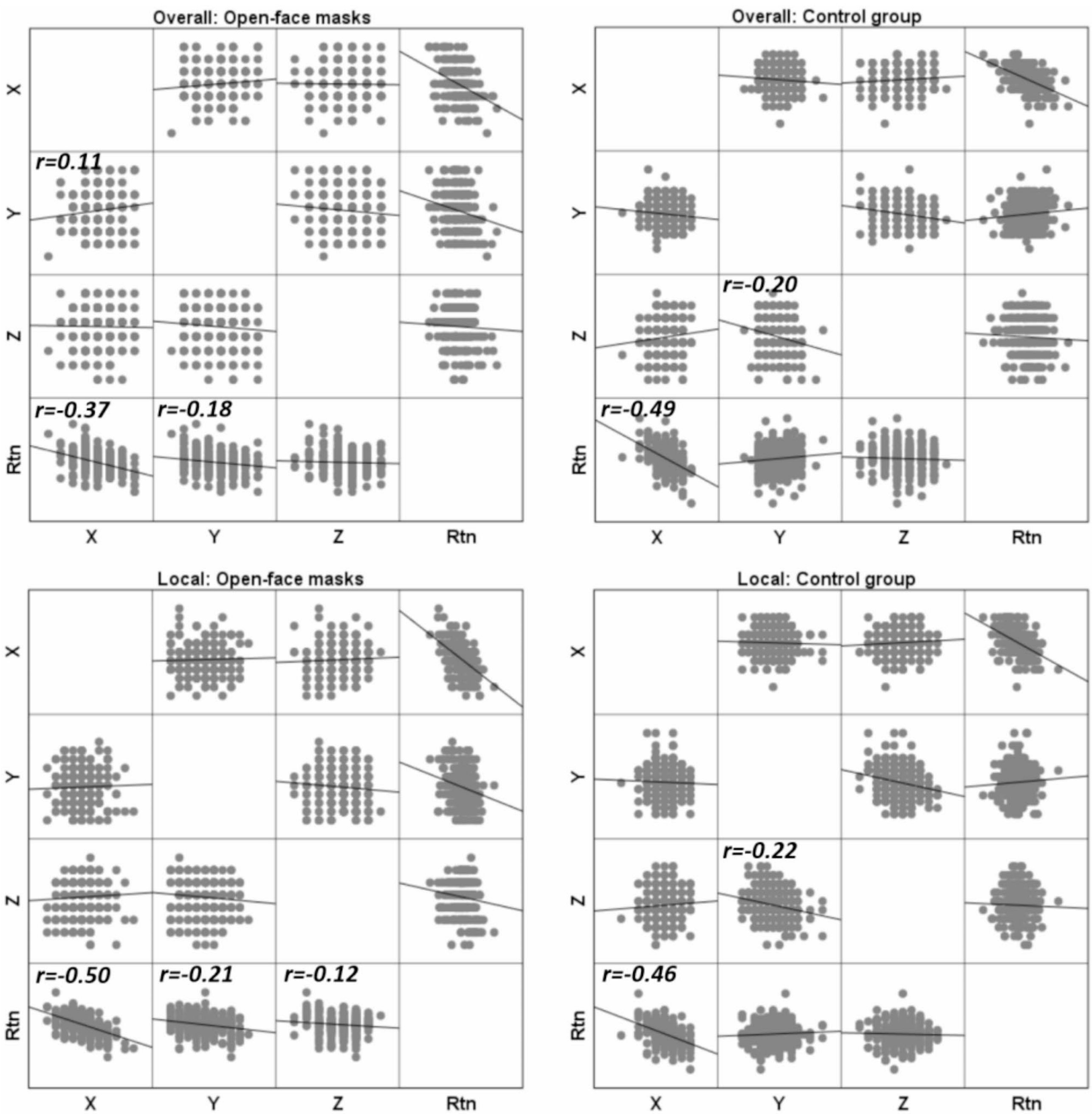


**Fig. 4** Scatter plots of overall and local positioning errors in each direction for both groups

that varying PTV margins be applied for head and neck tumors accordingly. These findings highlight ongoing issues with current fixation devices for head and neck tumors, emphasizing the urgent need for radiotherapists to either develop new or improve existing fixation devices to optimize target area accuracy.

In the era of precision radiotherapy, an increasing number of centers are prioritizing patient comfort during immobilization treatments [27, 28]. Open face masks, known for enhancing comfort and tolerance [29, 30], are becoming more prevalent. A study using [7] a 5-point Likert scale indicated that patients experienced less pain and anxiety with open face masks, reporting higher overall satisfaction during CT simulations. Li, G et al. [16] found that 80% of participants preferred open masks over closed ones. A randomized trial confirmed that open face masks reduced discomfort without compromising the accuracy of positioning and fixation [22]. These masks were standard open face types. Our research further revealed that customized open face masks offered superior comfort compared to closed masks, both pretreatment and during sessions. We observed a significant difference in terms of mask looseness and associated symptoms of dyspnea or anxiety. Customizing the mask by cutting around the eyes or mouth eliminated significant compression areas. Keane, M et al. [22] noted that closed masks caused bilateral discomfort in the infraorbital and maxillary areas, supporting our use of a personalized open mask. Our findings also indicated that physical discomfort varied significantly only in the initial survey, possibly because patients adapted to the closed mask over time. Differences in mold color preferences were noted only within groups, potentially because patients initially lacked a comprehensive understanding of the mold's color, but later expressed a preference for a specific color. Concerns about the practicality of modifying masks post-molding, such as the potential for sharp edges [16], were addressed in our clinical practice; we found the process straightforward, likely aided by the use of sharp scissors. Furthermore, we ensured that edges were smoothed or covered with adhesive tape to prevent patient discomfort. To our knowledge, while standard open face masks are slightly more expensive, patients find the financial cost acceptable given the increased comfort provided by customized openings in conventional masks.

Patients undergoing radiotherapy for head and neck tumors commonly experience anxiety, although clinical outcomes vary. Studies report fluctuating anxiety levels—increasing [20], decreasing [31], or remaining unchanged [32]—from the onset to the conclusion of treatment. Anxiety is often triggered by immobilization devices such as closed face masks, potentially impairing treatment efficacy [17]. Specifically, 26% of patients associate their anxiety with the use of fixed masks [33]. Complaints of anxiety and claustrophobia are frequent, leading some patients to request anti-anxiety medications or adjustments to their masks to reduce coverage [2]. Notably, patients with less extensive facial coverage report reduced claustrophobic distress [16], personalized open masks are particularly beneficial for those with mild to moderate claustrophobia [16]. Our study indicated an overall increase in anxiety, although the differences were not statistically significant across treatments. However, closed masks raised anxiety levels by 20.8%, compared to 4.3% with open masks, a difference that was statistically significant ($p = 0.015$). This aligns with Kohda R et al. [34] who observed an increase in anxiety levels, contrasting with Wiant, D et al. [2], likely due to differing anxiety assessment scales. They utilized a simple 0–10 point scale reflecting subjective feelings, whereas we employed the HADS scale, commonly used in research [31, 34]. It is evident that individualized open face masks with styrofoam can reduce anxiety incidence in patients.

In this study, Spearman's correlation analysis was conducted on the posing errors in each direction. The X direction exhibited a moderate negative correlation with Rtn for both groups ($r = 0.37–0.50$), independent of the area assessed; the control group displayed a weak negative correlation between the Y and Z directions across various areas (Fig. 4). These results are consistent with clinical observations, indicating that an increase in Y-direction error typically correlates with specific anatomical changes in the neck region [11]. Increased pendulum error in the head direction is associated with forward bending of the neck, while an increase in the foot direction correlates with backward tilting. A correlation was noted in the Y and Z directions in the control group relative to the open group, suggesting that posing errors in Y and Z directions under conventional thermoplastic mold fixation are interrelated. This supports the efficacy of open-ended molds in reducing Y-direction errors. An increase in X-direction error leads to an increased bed angle rotation error, echoing the findings of Li et al. [11] concerning intracranial tumors and emphasizing the necessity of selecting devices with superior fixation and repeatability for head and neck tumor patients. There remains a crucial need for therapists to develop fixation devices that combine high capacity and comfort to address the significant correlation of posing errors across directions. This also indicates that therapists should adhere strictly to the positioning protocol to minimize potential errors during the posing process.

This study possesses several limitations. Firstly, as a single-centre randomised controlled trial, its generalisability may be restricted. However, it represents the first and largest study of individualized open thermoplastic film with styrofoam for fixation in a prospective setting, providing a realistic reflection of the clinical environment. Secondly, Since our equipment does not have a six-dimensional error alignment function, we were unable to analyze posing errors in six dimensions. Although posing error data were collected, clinical observations of patient rotations necessitating repositioning by the radiotherapy technician were not quantifiable. This aspect will be addressed in future studies using a six-dimensional bed. Thirdly, the impact of weight changes on mask comfort and stability was not assessed, However, we took ART offline and remade masks when there was a significant change in body weight that affected the dose to the target area. In the weekly error analysis, we also did not find any difference in the weekly errors, nor was there a clear pattern of error changes (Supplementary Information Fig. 1). This suggests that the stability of mask immobilization is still clinically acceptable even with the influence of weight changes (which are small)".

In the future, we will continue to conduct multicenter randomized controlled studies incorporating the Sixth Bed, Quality of Life Scale, weight, anatomical variations, treatment effects, and ongoing psychological effects to improve the level of evidence for this method.

## Conclusion

We have developed a novel individualized open face mask integrated with a styrofoam fixation device for positional stabilization of head and neck tumor patients during radiation therapy. This approach has significantly decreased positioning errors in the Y-direction locally, while maintaining accuracy, enhanced patient comfort and experience, and substantially reduced patient anxiety. It is advised that this individualized open face mask be extensively adopted and utilized in clinical settings.

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13014-025-02609-8.

Supplementary Material 1

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Not applicable.

### Author contributions

Fating Yang and Jingling Li were involved in experimental design and finished article writing, Bo Li and Lihua Zhang were involved in article design, Jie Li, Xiaowei Yao, and Qiuxia Hu were involved in data collection, Changhao Liu and Jian Zang were involved in reviewing, Lin Xu was involved in article verification, and Lina Zhao and Fei Bai were involved in data analysis and final review.Yutian Yin participates in article data analysis.

### Funding

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### Data availability

No datasets were generated or analysed during the current study.

## Declarations

### Ethics approval and consent to participate

This study was a prospective randomised controlled trial (ChiCTR2300073789), which received ethical approval from the Ethics Committee of the First Affiliated Hospital of the Air Force Military Medical University (KY20232209-F–1), with registration date 2023/07/20.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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