Radiography 21 (2015) 74–83

Contents lists available at ScienceDirect

Radiography

journal homepage: www.elsevier.com/locate/radi

A randomized controlled trial comparing customized versus standard headrests for head and neck radiotherapy immobilization in terms of set-up errors, patient comfort and staff satisfaction (ICORG 08-09)

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ARTICLE INFO

Article history:
Received 27 March 2014
Received in revised form
3 June 2014
Accepted 28 July 2014
Available online 22 August 2014

Keywords:
Head and neck radiotherapy
Immobilization
Headrests
Set-up errors

ABSTRACT

Purpose: To recommend a specific headrest, customized or standard, for head and neck radiotherapy patients in our institution based primarily on an evaluation of set-up accuracy, taking into account a comparison of patient comfort, staff and patient satisfaction, and resource implications.
Methods and materials: Between 2008 and 2009, 40 head and neck patients were randomized to either a standard (Arm A, $n = 21$) or customized (Arm B, $n = 19$) headrest, and immobilized with a customized thermoplastic mask. Set-up accuracy was assessed using electronic portal images (EPI). Random and systematic set-up errors for each arm were determined from 668 EPIs, which were analyzed by one Radiation Therapist. Patient comfort was assessed using a visual analogue scale (VAS) and staff satisfaction was measured using an in-house questionnaire. Resource implications were also evaluated.
Results: The difference in set-up errors between arms was not significant in any direction. However, in this study the standard headrest (SH) arm performed well, with set-up errors comparative to customized headrests (CHs) in previous studies. CHs require regular monitoring and 47% were re-vacuumed making them more resource intensive. Patient comfort and staff satisfaction were comparable in both arms.
Conclusion: The SH provided similar treatment accuracy and patient comfort compared with the CH. The large number of CHs that needed to be re-vacuumed undermines their reliability for radiotherapy schedules that extend beyond 34 days from the initial CT scan. Accordingly the CH was more resource intensive without improving the accuracy of positioning, thus the standard headrest is recommended for continued use at our institution.

Introduction

Advances in head and neck (H&N) immobilization help to provide the reproducibility required to deliver increasingly accurate radiotherapy treatments in tandem with technological advances.[1,2] This can be achieved through careful attention to immobilization and patient preparation which should help to reduce systematic and random errors,[3] and permits smaller planning target volume (PTV) margins.[4] Accordingly, it is imperative to ensure that immobilization techniques are measured and continually improved.[3] This is particularly relevant for Intensity Modulated Radiation (IMRT), where treatment precision becomes paramount due to the dosimetric impact of set-up variation in the presence of steep dose gradients.[4,5] For example as little as a 3 mm translational error in the AP direction can result in an increase of 41% in the minimum dose to the spinal cord and a decrease of 38% minimal dose to the target.[6] Customized thermoplastic masks are established as the minimum requirement for H&N radiotherapy. However, more rigorous devices need to be developed before the full benefits of dose escalation can be realized.[2]

According to the On Target guidance document, headrests that match the anatomy of the patient more closely will result in improved immobilization techniques.[3] Accordingly, some studies have demonstrated improved accuracy and reproducibility with

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http://dx.doi.org/10.1016/j.radi.2014.07.009
1078-8174/

customized headrests (CHs).[7,8] However, limitations of these studies included small sample sizes, and failure to employ reusable headrests which makes it less feasible in routine practice. In order to objectively compare the re-positioning accuracy of CH and standard headrests (SH), set-up errors must be examined for each immobilization device.[3,6,9]

Prior to this study, a customized thermoplastic mask, fitted with a SH had been employed for 13 years in our institution. Additionally, staff had become proficient in a stereotactic immobilization technique using a CH, customized mouthbite and Leibinger stereotactic frame. Accordingly, we wanted to investigate the potential benefit of using this CH in conjunction with a thermoplastic mask, for routine fractionated H&N treatment. A prospective randomized controlled clinical trial was conducted comparing the set-up errors between patients treated on a CH with those treated on a SH.

Primary objectives:

1. To evaluate and compare the treatment set-up accuracy of two immobilization techniques (standard versus customized headrests), using two-dimensional set-up error analysis.
2. To determine and compare patients' comfort with the two immobilization techniques.

Secondary objectives:

1. To evaluate Radiation Therapists' and Doctors satisfaction with the two immobilization techniques.
2. To examine any resource implications of introducing a CH

Materials and methods

Patient characteristics

All head and neck patients were screened for potential suitability for the trial by mould room staff, who were allocated this responsibility as part of the trial. Reception phoned mould room staff when patients arrived for their initial mould room appointment and eligible patients were then informed of the trial and invited to take part.

A sample of 40 patients were prospectively randomized, 19 patients on Arm A, CH and 21 patients on Arm B, SH, based on a similar immobilization trial previously conducted in our institution, but more recently published.[10] The sample size was determined based on this previous study which was sufficiently powered to find a significant difference between the two immobilization devices[10] however on post-hoc analysis it was found that the current study was underpowered to find a significant difference. A computerized randomization package was used to generate the random allocation sequence, by the clinical trials unit administrator. Block randomization was used in blocks of twenty with an even split of experimental and standard arm allocations. The Clinical Trials Resource Unit administrator then prepared numbered sealed envelopes containing numbered randomization cards for either experimental or standard arm allocations, according to the randomization sequence. These pre-prepared sealed envelopes were then given to the trial coordinator once the trial was launched. Participants were enrolled and consented by mould room staff who phoned the trial coordinator to randomize the patient. The patient was allocated the next consecutively numbered sealed envelope, and randomized according to the randomization card contained within.

The inclusion criteria were patients with histologically proven H&N cancer, treated with 6 MV three-dimensional conformal radiotherapy (3-DCRT), and aged over 18 years. Treatment arms were balanced in terms of demographic characteristics (Table 1). All patients provided written informed consent to participate and all data were collected and recorded in accordance with the declaration of Helsinki and the International Conference on Harmonization of Good Clinical Practice (ICH-GCP), and the trial received ethical approval by the local hospital research and ethics committee.

Table 1
Patient characteristics.

	Standard headrest ($n = 21$)	Customized headrest ($n = 19$)	p
Sex			
Female	10	7	0.538
Age (years)			
Mean	59.4	61.0	0.989
Surgery			
No	10	9	1.000
KPS[a]			
60–80	2	6	0.120
90–100	19	13	
Primary treatment site			
Acoustic meatus	1	0	
Pharynx	4	7	
Larynx	4	4	
Oral cavity	9	4	
Salivary glands	3	4	

Data are for number of patients unless otherwise specified.
[a] KPS = karnofsky performance status.

Materials used

Several commercially available CHs were considered for this trial including: The "*Moldcare Head Cushion*™", by Alcare and "*Instapak Quick RT*™" by Sealed Air. The Medical Intelligence "*BlueBAG*™" was chosen as it is user-friendly, re-usable and was already in use in the department for intracranial stereotactic radiosurgery. Medical Intelligence "*BlueBAG*™" vacuum cushion is an impression vacuum bag made from a strong malleable material. It required in-house modification to attach to our indexed baseplate, by adding a thin Perspex plate and nylon discs to the base of each vacbag. Three different fill volumes were used in this study, 1.5 L, 1.7 L and 2.0 L bags. The volume used was determined by patient size and the degree of neck extension required. The product was guaranteed by the manufacturer to retain its shape and the integrity of the mould for up to six weeks. The SH was produced by oncology systems limited. Size A or C was used depending on patient size and the degree of extension required.

Experimental methods

Randomization and customized headrests

Patients were randomized to SH (Arm A; Fig. 1a) or CH (Arm B; Fig. 1b), using a centrally generated list of random numbers that was transferred into sequentially numbered sealed envelopes, with one for each patient. All patients were treated using a fixed baseplate and 4-point customized thermoplastic mask (orfit) in addition to the SH or CH. All other aspects of treatment were as per departmental standard H&N 3-DCRT.

Once vacuum formed, the CHs were monitored weekly until the end of the patient's treatment to assess any change in shape/loss of vacuum. Measurements were taken in 4 planes across both the longitudinal and lateral directions (Fig. 1c) on each of the CHs using digital calipers. Any loss of vacuum was quickly identified. An action level of 3 mm was applied, whereby a change of $\geq$3 mm was equated to the mould losing its integrity. This level was considered significant in relation to an imaging displacement tolerance of 5 mm.

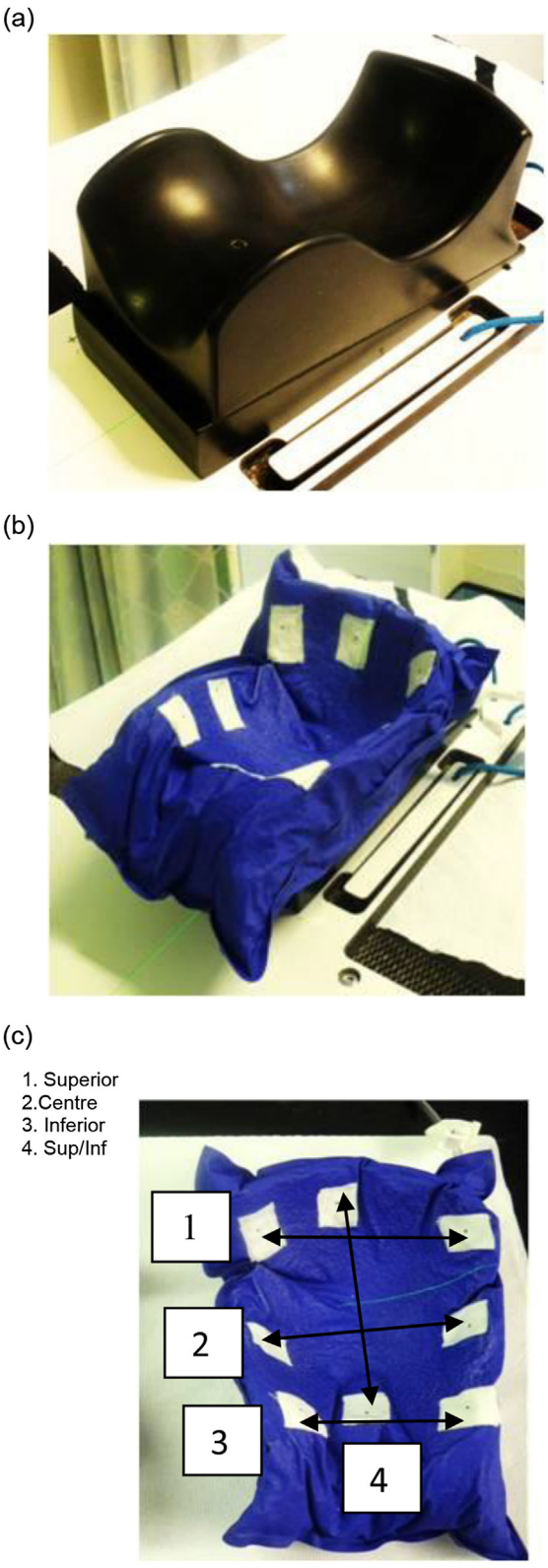


Figure 1. (a) Standard headrest; (b) customized headrest (Medical Intelligence BlueBAG™); (c) customized headrest monitoring measurement.

Imaging and set-up errors

Elekta's EPI with iViewGT software was used to assess set-up errors. EPIs were acquired according to institutional standard practice, and published recommendations[7,10]; three sets of orthogonal images (anterior and lateral) were acquired on week one and at least 1 set of images taken weekly thereafter. Set-up corrections were not applied on-set to the patients' treatment. A repeat image was requested if a discrepancy of ≥5 mm was detected on EPI. If there was a discrepancy ≥5 mm in the repeated EPI, the patient underwent a check-film (re-verification) procedure in the simulator.

Set-up errors were determined by comparing outlined field edge and bony anatomy on EPIs with reference images. This method can achieve accuracy in the order of 1 mm.[7] Each EPI was electronically matched to the corresponding reference image by one Radiation Therapist (RTT), who was blinded regarding the patient's headrest device. In line with the On Target guidance statement this RTT was fully trained to the level required locally and assessed as competent.[3] Rigid anatomical landmarks used for matching were derived from published literature (Table 2). The data from one patient was re-evaluated by an independent assessor to check the RTT's consistency and this amounted to 5% of the sample. Set-up errors were reported in the *x* and *y* directions for anterior images, and in the *y* and *z* directions for lateral images. *Y* displacements were averaged for orthogonal image sets acquired on the same fraction. Therefore, set-up errors were evaluated in three orthogonal directions *x*, *y* and *z* for both devices.

Patient comfort

Patient comfort was scored using a Visual Analogue Scale (VAS) once during the course of radiotherapy, as described by Cox[11] and was used previously in a Lung Immobilization trial at our institution.[10] This required each patient to mark an *X* on a 10 cm line which ranged from “very uncomfortable” to “completely comfortable” (Appendix 1).

Staff satisfaction

RTTs' satisfaction was measured with a questionnaire previously used in our department,[10] (Appendix 1). The questionnaire focused on: ease of patient set-up, cleaning, storage, patient stability, and recommendation for future use (Appendix 1). Doctors' satisfaction with patient position from a treatment planning perspective was also evaluated (Appendix 2). Both of these questionnaires were developed by RTTs from the institution in 2005 as no relevant validated tools existed, but the reliability and internal consistency of these questionnaires has not yet been checked.

Resource implications

Resource implications for both arms were compared. This was done by recording time required to make the customized headrest and re-form or re-vacuum the headrest over the course of radiotherapy treatment. A cost analysis was not conducted as it was beyond the scope of this study to determine the life span of the reusable customized headrest.

Table 2
Points used for image matching.

Anterior images	Lateral images
• Nasal septum • Orbital rims • Pedicles of the thoracic vertebrae • Lateral edges of the vertebral bodies • Zygomatic arches	• The body and spinous process of C2 • Lower base of skull • Posterior aspect of the vertebral bodies • Individual vertebral bodies • Palatine process of the maxilla

Statistical methods

The one-dimensional standard deviations (SD) of the systematic and random set-up errors were calculated for all 3 orthogonal directions (x, y and z), in line with the On Target guidance document using methodology previously described.[3,10,12–15] PTV margins for set-up error uncertainty were calculated using the Van Herk Margin Recipe formula[12]; Margin $= 2.5\ \Sigma + 0.7\ \sigma$; where Σ is the SD of the Systematic Error, and σ is the SD of the Random Error. Those undertaking statistical analysis were not blinded as to which treatment arm each patient was on.

Results

Patients were considered evaluable when they completed a radical course of fractionated external beam radiotherapy on a linac with EPI capability. The study design allowed for withdrawn patients to be replaced until 40 evaluable patients completed treatment. Fifty-seven eligible patients were recruited between January 2008 and May 2009. Seventeen patients were withdrawn because they were subsequently treated on a Linac without EPI capability and were therefore not evaluable. Of the 40 evaluable patients, 21 were randomized to SH Arm and 19 to the CH Arm.

Set-up errors and PTV margins for set-up uncertainty

A total of 668 EPIs were analyzed (SH arm = 360; CH arm = 308) by one RTT. The mean set-up errors in all directions were normally distributed in both arms. The mean displacement, SD of the random and systematic errors, and required PTV margin for set-up uncertainty by type of headrest are shown in Table 3. The differences in the SD of the systematic and random set-up errors between the two types of headrests were small in every direction. The differences in systematic errors between arms were −0.23, 0.21, and 0.01 in the x, y, and z directions respectively (Table 3). The margins required for set-up uncertainty was lower in the CH group than in the SH group in the x and z directions but was greater in the y direction (Table 3). The difference in the margin required between the CH and the SH arms was <1 mm in all directions.

Patient comfort

Both types of headrest were rated as comfortable by patients. The median score for both arms was 9 out of a maximum score of 10 (completely comfortable), on the VAS.

Table 3
Set-up errors by headrest type.

	Customized (mm)	Standard (mm)
x Mean displacement[a]	0.38	0.09
x SD of Systematic error[b]	1.80	2.03
x SD of Random error[c]	1.48	1.60
x Set-up margin	**5.5**	**6.2**
y Mean displacement[a]	0.19	1.22
y SD of Systematic error[b]	1.74	1.53
y SD of Random error[c]	1.16	1.07
y Set-up margin	**5.2**	**4.6**
z Mean displacement[a]	−0.48	−0.15
z SD of systematic error[b]	1.75	1.74
z SD of random error[c]	1.56	2.04
z Set-up margin	**5.5**	**5.8**

[a] Mean for the group of all the individual mean displacements.
[b] Population systematic error.
[c] Population random error.

Radiation therapist and doctor satisfaction

Feedback was positive for both types of headrests in terms of handling, cleaning, patient comfort, immobilization, and treatment position achieved. However, RTTs highlighted that it was more cumbersome to make the CHs available for monitoring, to store the CHs in the treatment room and was another piece of patient-specific equipment in addition to the mask that needed to be transported to an alternative linac/simulator if required. Dissatisfaction cited by physicians related to problems in achieving an extended chin position – attributed to individual patient factors e.g. type of surgery, or requirement for tongue depressor and not the headrest type. The number of re-verification procedures required was equal for both Arms ($n = 6$); these were related to patient/thermoplastic mask and unrelated to the headrest type.

Customized headrest monitoring and resource implications

Weekly measurements were obtained on each of the 19 CHs along 4 different planes in the lateral and longitudinal directions as shown in Fig. 1c. A total of 173 sets of measurements were taken on the CHs. In accordance with the 3 mm action level, 47% of the CHs required re-vacuuming, the range was 34–76 days from the date of formation. One headrest required a total re-vacuum due to a valve malfunction. The CH is more resource intensive, requiring 2 man-hours per patient to modify, form and subsequently monitor the headrest. Furthermore, 47% of the CHs required re-vacuuming 34–76 days from date of formation – taking approximately 15 min. Analyses were also conducted comparing set-up errors between headrests that were re-vacuumed in Arm B, versus those not requiring a re-vacuum (Fig. 2). Changes of ≥3 mm did not appear to impact on set-up errors (Table 4), however due to the small numbers involved, this analysis was not sufficiently powered to draw firm conclusions.

Discussion

The SD of the systematic and random errors observed with both immobilization techniques are in line with previously published literature and international standards.[3,4,7,8,16,17] Hurkmanns et al.[18] state-of-the-art SD of systematic and random set-up errors <2 mm was achieved without the use of stereotactic immobilization devices. More specifically the mean displacements in this study are comparable to published studies which have demonstrated a range of 0.11–0.57 on the X-axis, 0.15–0.58 on the Y-axis and, −0.48 and −0.15 on the Z axis.[4]

In contrast to some previous studies we did not find a significant difference in set-up accuracy between the CH and SH.[8,19,20] However on closer inspection it is clear that the set-up errors previously only achieved with a CH device[8] were achieved in the present study with both a CH and SH. This is most likely explained by the fact that our institution has permanently dedicated and highly experienced mould room staff and has two sizes for the SH whereas other studies only use one size.[8] Also it is important to note that although Van Lin et al.[8] report a smaller CTV-PTV expansion, this was due to the use of a conservative version of the Van Herk[21] margin recipe (Margin $= 2.5\ \Sigma + 0.7\ \sigma - 3$ mm) as opposed to smaller set-up errors.

Although the set-up errors observed in this study were slightly higher than those reported by Humphreys et al.,[19] their inclusion criteria stipulated that the tumor needed to be close to a bony structure and so their results may not be applicable to all head and neck sites. Humphreys[19] used an SH for all participants, further demonstrating that optimal set-up errors can be achieved with standard headrests. A more recent study that investigated

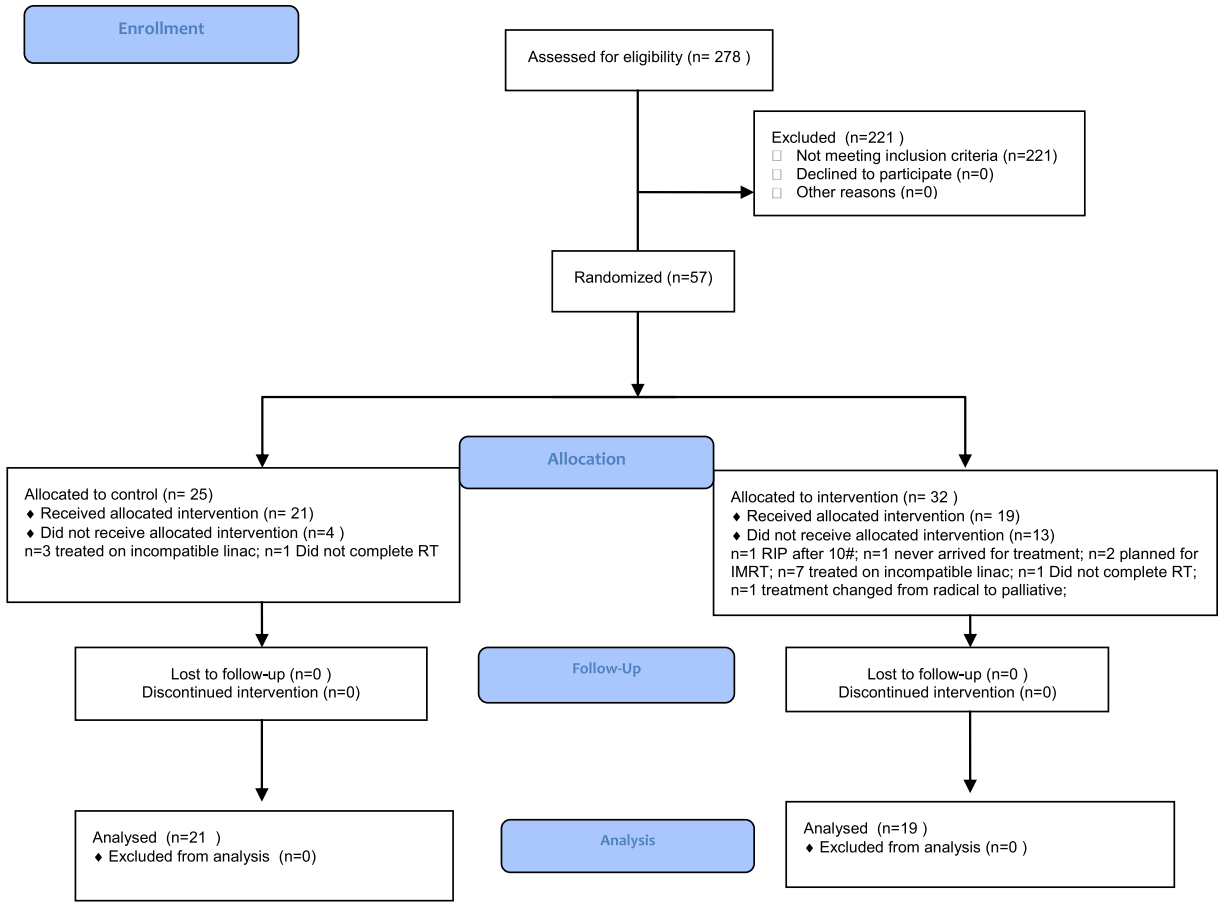


Figure 2. Enrollment flow diagram.

set-up error for nasopharyngeal patients receiving IMRT treatment reported set-up errors that were analogous to those from this trial.[17]

The CHs were considerably more resource intensive, as it took a total of two man-hours to monitor each CH. Additionally a large percentage of CHs required re-vacuuming from the date of formation, some as early as 34 days post formation despite the six week manufacturer guarantee. Conversely, some CHs did not require re-vacuuming for 74 days or at all, indicating a huge variation in the consistency of the CH over time. From a clinical perspective this makes the CHs less desirable because they are less reliable than initially forecast, particularly should the patient's treatment be protracted.

The CH and SH were comparable in terms of patient comfort and staff satisfaction, although storage and transport inconveniencies of the CHs were highlighted by staff. Another study that compared CHs did not report staff or patients' satisfaction,[20] making this one of the first reports on CHs that includes an assessment of patient comfort. However it must be stated that both of these questionnaires have yet to be validated emphasizing the need for further development in order to routinely include patient and staff satisfaction in radiotherapy immobilization research. This also highlights how this aspect of immobilization had thus far been ignored by the literature despite the fact that it could have real implications in clinical practice, considering that compliance of the patient is already recognized as a contributing factor to effective immobilization.[3]

An inherent shortcoming of the two-dimensional (2-D) imaging technique used in this trial is its limited sensitivity in detecting out-of-plane rotations. Research suggests that CHs may reduce potential flexibility in the H&N, and therefore reduce rotations,[22] which could be readily quantified using Cone Beam CT.[20,22] Future research is required to confirm this. Nonetheless EPIs are still used in many departments, even for IMRT,[17] thus this research is valid for routine radiotherapy practice, and relevant for both 2-D kV and MV imaging.

A strength of this trial is that set-up errors were reported as SDs of the random and systematic set-up errors for three orthogonal directions, allowing results to be easily compared with published data and the direct calculation of set-up margins.[12] Although the sample size seems relatively small in this trial ($n = 40$) it is actually one of the largest sample sizes in studies comparing headrests for radiotherapy, with most studies only including 11–22 participants.[9,20] However with a lack of sufficiently powered trials in this area and many conflicting results it is difficult to make firm conclusions regarding the most appropriate form of immobilization for head and neck radiotherapy techniques.

Table 4
Set-up Errors by need to re-vacuum for CH ($n = 19$).

	SD of systematic (random) errors	
	No re-vac required $n = 10$	Re-vac required $n = 9$
X (mm)	1.9 (1.4)	1.8 (1.6)
Y (mm)	1.9 (1.1)	1.7 (1.3)
Z (mm)	2.1 (1.8)	1.1 (1.2)

Conclusions

The SH provided similar treatment accuracy and patient comfort compared with the CH. The large number of CHs that needed to be re-vacuumed undermines their reliability for radiotherapy schedules that extend beyond 34 days from the initial CT scan. Accordingly the CH was more resource intensive without improving the accuracy of positioning, thus the standard headrest is recommended for continued use at our institution.

Role of the funding source

Funding was received from the Health Research Board (Ireland).

Conflicts of interest statement

No actual or potential conflict of interest exists. The manufacturers and distributors of the products investigated had no influence in the design, conduct, analysis or reporting of the results of this research.

Acknowledgments

All-Ireland Cooperative Oncology Research Group (ICORG) were the study sponsor (ICORG 08-09).

Appendix 1. Patient comfort visual analogue scale.

Patient Sticker

Pt. Study No: ____

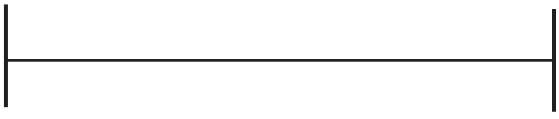
Date: _____ Fraction No:_____

Eg., If during the course of your treatment you felt "Fairly Comfortable" i.e., *"my head and neck felt fairly comfortable and fairly well supported during treatment*", you could indicate it on the line below as such:

Extremely Uncomfortable — Very Comfortable

How comfortable did you find your treatment postion during radiation treatment?

Please answer the question by marking the line with an X at a point you feel is appropriate and represents how you feel at this moment.



Very Uncomfortable** — Completely comfortable*

**Marking "Completely comfortable" indicates that you felt your head and neck were well supported and you felt comfortable for the duration of your treatment.*

***Marking "Very uncomfortable" indicates that you felt your head and neck were not supported at all and you felt major discomfort for the duration of your treatment.*

Patient Signature: _____ Date: ___ / ___ / ___

Appendix 2. RTT satisfaction questionnaire.

RT Headrest Assessment Form for Patients participating in ICORG 08-09

Form to be completed by a Radiation Therapist on treatment unit at the end of treatment:

Patient Sticker

TREATMENT SITE: _____

TOTAL DOSE: _____Gy/_____#

NO. OF FIELDS: **Phase I:** ____ **Phase II:** ____ **Phase III:** ____

IMMOBILISATION DEVICE:

Standard Headrest: **A** ☐ **C** ☐ **Customised Headrest:** ☐

Please indicate below your opinion on the following topics in relation to the specific immobilisation of the above patient:

	Very Easy	Easy	Difficult	Very Difficult
1. Ease of handling of the device:	☐	☐	☐	☐
2. Ease of storage of device:	☐	☐	☐	☐
3. Ease of cleaning of device:	☐	☐	☐	☐
4. Achieving patient comfort:	☐	☐	☐	☐
5. Ease of set-up:	☐	☐	☐	☐

6. Overall immobilisation rating: Very Stable ☐ Stable ☐ Unstable ☐ Very Unstable ☐

Did the patient need to go for a check film during treatment? Yes* ☐ No ☐
*No. of check films required: _____

*If YES, please state reason: _____

_____

Comments and/or problems encountered with this immobilisation device:

Please be critical, highlighting both positive and negative opinions.

(a) Positive aspects of patient's immobilisation:

(b) Negative aspects of patient's immobilisation:

Do you recommend that we continue with this type of headrest for other patients? Yes☐ No☐

Please give reasons for your answer:

Date:_____

Thank you for taking the time to complete this questionnaire; your input is greatly appreciated. Completed questionnaires should be returned to the box file provided.

Signature of RT on H&N Immobilsation Group: _____

Date Form Received:_____

Pt. Study No: ____

Appendix 3. Doctor satisfaction questionnaire.

Doctor Satisfaction Questionnaire for Patients participating in ICORG 08-09

PATIENT STICKER

Pt. Study No: ____

Doctor Satisfaction Questionnaire

Q1. Please indicate which chin position was required for this patient's treatment?

Chin extended ☐ Neutral ☐ Chin flexed ☐

Q2. Was this chin position successfully achieved using the randomised headrest allocated to this patient?

Yes ☐ No ☐

Q3. In relation to the optimal treatment position required for this patient, please indicate your satisfaction with the following aspects of immobilisation: -

	Very Satisfied	Satisfied	Unsatisfied	Very Unsatisfied
1. Chin position:	☐	☐	☐	☐
2. Tongue depressor (if used):	☐	☐	☐	☐
3. Customised stent (if used):	☐	☐	☐	☐
4. Overall position achieved:	☐	☐	☐	☐

Comments:

……

……

……

……

……

Dr's Signature:_____ **Date:**_____

Thank you for completing this questionnaire.

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