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Original Research Article

Setup and intra-fractional motion measurements using surface scanning in head and neck cancer radiotherapy– A feasibility study

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ABSTRACT

Background and purpose: Surface-guided radiotherapy (SGRT) is applied to improve patient set-up and to monitor intra-fraction motion. Head and neck cancer (H&N) patients are usually fixated using 5-point thermoplastic masks, that are experienced as uncomfortable or even stressful. Therefore, the feasibility of irradiating H&N patients without a mask by using SGRT was examined.

Material and methods: Nineteen H&N patients were included in a simulation study. Once a week, before the standard treatment, a maskless treatment was simulated, using SGRT for setup and intrafraction motion monitoring. Initial patient setup accuracy and intrafraction motion was determined using ConeBeam CT (CBCT) images as well as SGRT before and after the (simulated) treatment. The clinical target volume to planning target volume (CTV-PTV) margin for intrafraction motion was calculated. Using patient questionnaires, the patient-friendliness H&N irradiation with and without mask was determined.

Results: Maskless setup with SGRT and CBCT was as accurate as with a mask. SGRT showed that intrafraction motion was gradual during the treatment. The CTV-PTV margin correcting for intrafraction motion was 1.7 mm for maskless treatment without interventions, and 1.2 mm if corrected for motions > 2 mm. For 19 % of fractions, the intrafraction motion, as detected by both SGRT and CBCT, was larger than 2 mm in at least one direction. Sixteen patients preferred maskless treatment, while 3 worried they would move too much.

Conclusions: Using SGRT and a standard head rest resulted in a patient-friendly treatment with accurate patient setup and acceptably small intrafraction motion for H&N patients.

1. Introduction

In most radiotherapy departments, the standard method for setup and immobilization during radiation treatment for head and neck cancer (H&N) patients is to use a 5-point thermoplastic mask, resulting in small setup errors and intra-fractional motion. Generally, a clinical target volume (CTV) to planning target volume (PTV) margin of 3–5 mm is applied [1,2].

Despite the use of a mask, variations are still seen in patient setup. Reported residual systematic and random setup errors depend on the chosen setup protocol (on-line or offline [3,4]) and are around 1 to 2 mm [1,5,6]. Causes of setup errors of the entire treatment volume or anatomical substructures are differences in positioning on the head rest, bending of the neck, changing anatomy during the treatment [7], and differences in positioning of the shoulders [8,9]. Also, small intrafraction motion can occur, by respiration, swallowing, tongue movement, slow motion due to organ relaxation or motion in the mask [1,10].

As a result of weight loss or tumour shrinkage the patient might be able to move more freely in the mask during the course of the treatment. In contrast, due to swelling the mask might become too tight. Acquiring a new mask might be necessary as well as replanning in order to optimize the dose to the tumour and organs at risk [11,12].

Some patients experience a mask as uncomfortable or stressful, or it might even be intolerable for patients suffering from claustrophobia [13–19]. Open face masks result in reduced patient anxiety and improved patient comfort compared to full masks [14–16].

The use of surface-guided radiotherapy (SGRT) for improved patient positioning before online imaging, and for intra-fraction motion monitoring has rapidly increased. SGRT is used for treatment sites such as

Abbreviations: th_2, the intrafraction motion threshold for intervention of 2 mm translations, 3 mm vector, and 2° rotations.

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breast, thoracic, abdominal, pelvic, H&N and intracranial [14–16,20–30]] However, SGRT for H&N has only been investigated in combination with an open face mask [14–16]. Irradiation without a face mask and applying optical surface scanning for accurate patient setup and intra-fractional motion monitoring would be even more patient friendly.

The clinical feasibility of accurate patient setup and acceptable intra-fractional motion during maskless irradiation was proven in whole brain radiation therapy (WBRT) patients [26]. However, accurate setup for H&N patients is even more challenging, since non-rigid deformations can occur, and a very conformal volumetric modulated arc therapy (VMAT) plan is used. Also, the treatment takes longer, the patient population is different, and the acceptable CTV-PTV margins are smaller.

In this study, a simulated radiation treatment was performed to investigate the clinical feasibility of maskless irradiation for H&N cancer patients, using SGRT. The simulated treatment takes place prior to the actual treatment with mask. The patient setup, intrafraction motion, the resulting CTV-PTV margin, as well as the patient friendliness of irradiation with and without a mask was investigated.

2. Material and methods

2.1. Patient characteristics

Twenty H&N cancer patients, receiving a treatment with curative intention, were included in the study between August 2021 and June 2022. One patient decided to retire from the study after the first simulated treatment session and was excluded. Patient and treatment characteristics are shown in Table 1.

Informed consent was given by the participants and the study was approved by the medical ethics committee METC Brabant (CCMO register NL73858.028.20).

Table 1
Radiotherapy parameters and characteristics of the patients (n = 19).

	Number of patients (%)
Patients who completed the treatment	19 (100 %)
Fractionation scheme*	
30 x 2 Gy	1 (5 %)
30 x 2.1 / 1.7 Gy	7 (37 %)
30 x 2.1 Gy	4 (21 %)
30 x 2.2 / 1.7 Gy	1 (5 %)
33 x 2 Gy	2 (11 %)
35 x 2 Gy	2 (11 %)
35 x 2 / 1.55 Gy	2 (11 %)
Primary treatment site	
Larynx	2
Salivary glands	2
Oropharynx	4
Oral cavity	11
Number of VMAT arcs	
2	14 (74 %)
4	5 (26 %)**
Length of VMAT arcs	
180°	6 (32 %)
200–240°	8 (42 %)
360°	5 (26 %)**
Gender	
Man	13 (68 %)
Women	6 (32 %)
Age at start treatment (years)	
mean +- SD	69 ± 10 years
Median (range)	71 years (47–84 years)

*Two dose levels indicates nodes are included and are given the lower dose value. **The patients with 4 VMAT arcs all had 4 360 °arcs.

2.2. Treatment technique

Patients were treated on a Varian TrueBeam™ accelerator using 6 MV photon beams. The treatment plans were generated using the Acuros dose calculation algorithm [31,32] in ARIA 15.6 (Varian Medical Systems, Palo Alto, CA, USA). The treatment plans consisted of 2 or 4 VMAT (RapidArc) beams (see Table 1). The dose to the PTV was: $D_{98\%} > 95$ % of prescribed dose. The dose to the parotid glands, submandibular glands, oral cavity and swallow structures was minimised as much as possible. The CTV-PTV margin was 3 mm based on in-house analysis.

2.3. Optical surface scanning system

The IDENTIFY™ system (Varian Medical System, Palo Alto, CA, USA) was applied for patient set-up and intra-fraction motion monitoring during the simulation treatment, which includes the CBCT acquisitions. In the IDENTIFY™ system, stereovision based camera systems from 3 directions are used. From each direction, a camera captures the structured light pattern that is projected on the object to determine the location of every point. Real-time surface images are compared to the reference image, obtained from the CT-scan. A rigid registration algorithm calculates the translations and rotations around the isocenter to bring the two surfaces in the drawn Region of Interest (ROI) into alignment. A daily QA procedure is performed to verify the isocenter alignment. Submillimeter accuracy is achieved for the three translational and rotational degrees of freedom [33]. The raw data was stored for analysis, as well as snapshots during the simulated treatment.

2.4. Patient set-up and treatment

For actual treatment, the patients were positioned on a standard head rest in a 5-point thermoplastic Nanor® mask (Orfit Industries, Wijnegem, Belgium). The couch was moved to predicted coordinates [34, and a daily online 6D-match was applied on a six-degrees-of-freedom couch.

For the simulated treatment study, the patient was positioned on the standard head rest without the mask. An extra low-dose CT without a mask was acquired to generate a reference surface image used for SGRT set-up. In the SGRT software, a region of interest (ROI) was drawn using the entire frontal face, and a few cm at the lateral sides, excluding the eyes and mouth. Once a week, before the actual clinical treatment using the mask, a simulated maskless treatment was performed, resulting in 6 simulated treatments per patient and a total of 108 simulated sessions used for analysis, since for a few sessions, no SGRT or second CBCT data were acquired. For initial setup with SGRT, the predicted couch position was applied [34], so the position of the patient head with respect to the head rest was identical as on the planning CT. A threshold of 3 mm translations and 2 degrees rotations for initial positioning was used. After initial setup, the daily online CBCT 6D-match procedure was performed, and a new SGRT reference image was captured for patient monitoring during the simulated fraction of that day. The simulated treatment consisting of the dry run arcs (the same number and length of arcs as the actual treatment) was performed. SGRT data were not for intervention during the simulated treatment.

On the days with a simulated treatment, CBCT images were also acquired after the simulated and actual treatment, in order to determine the intrafraction motion.

2.5. Initial set-up accuracy

After initial setup, a CBCT scan was acquired to compensate for small deviations from the predicted couch position. The online 6D match parameters for maskless SGRT setup and for standard setup with a mask were taken from the Offline Review module of ARIA. A visual check of possible anatomy deformations resulting in inaccurate initial covering of the CTV by the PTV was performed. Using the Kolmogorov-Smirnov (can be used since the sample size = 108, so much larger than the minimum of 50 for an accurate test) and Shapiro-Wilk test, it was tested whether the data follows a normal distribution, for correct data representation. The mean and median online setup correction as well as its variation (standard deviation, SD and interquartile range) was compared. In addition, a Wilcoxon signed rank test was performed to check whether the pretreatment setup with and without mask was significantly different. All statistical tests in this study were performed in SPSS version 28.

2.6. Intrafraction motion and resulting CTV-PTV margin

In the ARIA Off-line Review module, the initial and post-(simulated) treatment CBCTs were matched again using exactly the same ROI for both CBCTs. Using a 6D match, the match parameters were subtracted in order to obtain intrafraction vertical, longitudinal and lateral translations, and pitch, jaw and roll rotations. Normality of the data was tested using the Kolmogorov-Smirnov and Shapiro-Wilk test. A Wilcoxon signed rank test was performed to check whether the intrafraction motion with and without mask was significantly different.

The intrafraction motion determined by SGRT was also obtained by comparing the SGRT data during the final CBCT with the SGRT reference of the day after the initial CBCT setup correction. Correlation analysis between SGRT and CBCT intrafraction motion was conducted using Pearson's correlation coefficient. In addition, Wilcoxon signed rank test was used to test significant difference between SGRT and CBCT intrafraction motion data. SGRT motion data *during* the simulated maskless treatment, was investigated to determine possible extra motion or whether the motion was sudden or gradual.

Using the intrafraction motions from a 3D match of the post- and pre (simulated)treatment CBCTs, the intrafraction motion CTV-PTV margins were calculated using the systematic (Σ = standard deviation of the means per patient) and random (σ = mean of the standard deviations per patient) intrafraction motion parameters. The PTV margin formalism developed by Van Herk et al. [35] was adjusted using Janssen et al. [36]. The latter paper states that if the intrafraction motion is a continuous drift during the treatment, the required margin is well approximated by an average position of the target at ¾ of the drift. In addition, if a motion management strategy is used by applying a threshold for intervention (repositioning the patient), the intrafraction motion distribution is truncated. With σ being the standard deviation of the distribution and c a free parameter, truncating the error distribution at $c\sigma$ results in a relative change in the margin of 0.3c [35]. In clinical practice, an intrafraction motion threshold for intervention, th_2,will be applied if the translations exceed 2 mm, the vector exceeds 3 mm, and the rotations exceed 2°.

2.7. Questionnaire on patient friendliness

The patient friendliness of the radiation treatment with and without a mask was studied using a patient questionnaire after each simulated treatment fraction (Table 2).

3. Results

3.1. Initial set-up accuracy

The initial patient setup accuracy using the predicted couch position and SGRT for the maskless simulated and actual irradiation using a mask, including relevant statistics, is shown in Table 3. For all patients, setup using surface guidance was such that deformations in anatomy (like different stretching of the neck) were small. For all treatment fractions with and without a mask, the 6D anatomy match resulted in coverage of the treatment volume by the PTV.

3.2. Intrafraction motion

In Fig. 1, the intrafraction motion determined using the CBCT matches before and after the (simulated) treatment is shown for all simulated fractions. Wilcoxon signed rank test showed that the intrafraction motion with and without mask was significantly different in all directions ($p < 0.05$). Other statistics are stated in Table 4, where the mean and median values with spread (SD) and interquartile range of the 6D intrafraction motions are given, as well as the intrafraction match based Σ and σ.

For 21 (19 %) maskless simulated treatments and 10 (9 %) treatments in a mask, the 6D intrafraction motion according to the CBCT was $> th_2$. For 17 of the 21 fractions, a motion $> th_2$ would also have been found with SGRT. For 4 fractions, the CBCT difference was 2.1 to 2.3 mm, while the corresponding SGRT measured motion between 1.6 and 1.8 mm. SGRT showed that the patient position drifted gradually during the fraction and was within th_2 for more than half of the simulated

Table 3
Initial patient setup translation and rotation deviations with and without a mask as measured with the initial CBCT. Mean and median values as well as the spread (1 SD) and interquartile range are calculated using the 108 measured simulated and corresponding treatment fractions and are given in mm.

	Without the mask	With the mask
Mean ± 1 SD		
Vertical (mm)	0.3 ± 2.4 [1,2]	1.2 ± 2.4
Longitudinal (mm)	−0.8 ± 4.0 [1]	−2.1 ± 2.8 [1,2]
Lateral (mm) [3]	−3.0 ± 3.9 [1]	−3.5 ± 3.3 [1]
Pitch (°) [3]	0.6 ± 1.3 [1,2]	0.7 ± 1.2
Roll (°) [3]	0.1 ± 1.2 [2]	0.1 ± 1.2 [2]
Rotation (°) [3]	−0.3 ± 1.4 [1,2]	−0.1 ± 1.0 [1,2]
Median (interquartile range)		
Vertical (mm)	0.1 (2.9)	1.8 (3.1)
Longitudinal (mm)	−1,1 (4.4)	−2.3 (3.8)
Lateral (mm)	−3.5 (5.0)	−3.9 (3.9)
Pitch (°)	0.6 (1.6)	0.6 (1.5)
Roll (°)	0.0 (1.6)	0.0 (1.8)
Rotation (°)	−0.3 (1.9)	−0.1 (1.4)

[1] Normally distributed according to Kolmogorov-Smirnov test.
[2] Normally distributed according to Shapiro-Wilk test.
[3] Wilcoxon signed rank test showed no significant difference between setup with and without mask.

Table 2
Questionnaire answered after weekly simulated + actual treatment fraction. Questions 1–5 were repeated for the treatment with and without a mask. Scores were: a lot (1), a little (2), hardly any (3), not at all (4).

1 Do you experience discomfort from the treatment without / with a mask?
2 Do you experience claustrophobic feelings during the treatment without / with a mask?
3 To what extent does the treatment without / with a mask cause anxiety?
4 To what extent does the treatment without / with a mask cause nervousness?
5 To what extent does the treatment without / with a mask cause feelings of isolation or loneliness?
6 To what extent does the treatment with a mask cause pain?
6 If you could chose, would you like to be treated with or without a mask?
7 Do you use anxiety medication?
8 Further remarks you would like to make?

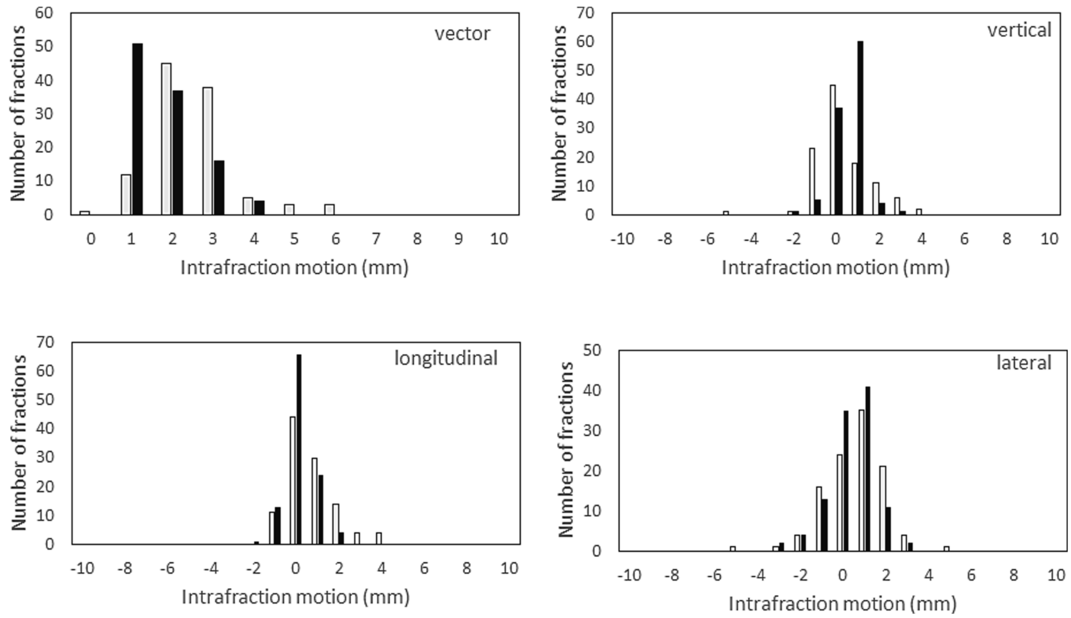

Fig. 1. Intrafraction motion vector and vertical, lateral and longitudinal motion, as measured by comparing the CBCT before and after the simulated maskless (open bars) and actual (with mask, filled bars) treatment.

fraction. For 5 fractions, the position was within th_2 during the simulated treatment and only $> th_2$ during the second CBCT.

For 3 fractions, the SGRT measured motion was slightly larger than th_2, and slightly smaller than th_2 with CBCT. The difference between the two was less than a mm. In addition, in 11 fractions (10 %), the patient moved 1–3 times very shortly (about a second) out of th_2 and then immediately back to the correct position, so the intrafraction motion measured on the CBCT was $< th_2$.

Using the subtracted post- and pre(simulated)treatment CBCT, the intrafraction motion CTV-PTV margin is 1.9, 2.1 and 2.3 mm in vertical, longitudinal and lateral direction for maskless treatment, and 0.9 mm in vertical and longitudinal, and 2.2 mm in lateral direction with a mask. Since in all simulated treatments, the patient position drifted gradually during the treatment or even only during the posttreatment CBCT, the average position of the target can be estimated at ¾ of the drift, resulting in CTV-PTV margins in vertical, longitudinal and lateral directions of 1.4, 1.5 and 1.7 mm respectively for maskless treatment, and 0.7, 0.7, and 1.6 mm for treatment with a mask. Using a motion correction threshold th_2, $c = 2.1$, 2.3 and 1.6, resulting in an intrafraction motion CTV-PTV margin of 1.2, 1.1 and 0.9 mm in vertical, longitudinal and lateral directions for maskless treatments. For treatment with a mask, the margins do not change, since we cannot apply SGRT with a threshold for repositioning.

3.3. Questionnaire on patient friendliness

The answers to the patient friendliness questionnaire are shown in Table 5. With the mask, 6 patients felt a little discomfort in most fractions and 5 a lot of discomfort. Without a mask, two patients felt a little discomfort in most fractions. No patient felt claustrophobic without a mask, whereas 3 patients felt a little claustrophobic and 4 a lot. Anxiety was felt by one patient without a mask, and by 4 patients with a mask.

4. Discussion

This study showed that the initial patient setup using SGRT is as accurate as with a mask (Table 3). The average lateral value of 3 mm could point at a difference between the head positioning device used at the CT and the one used at one the treatment machine. Using the predicted couch position [34] combined with SGRT results in a very reproducible positioning of the patient head on the standard head rest.

Intrafraction motion was slightly but statistically significant ($p < 0.05$) larger without the mask than with the mask (Table 4). Pearson's correlation coefficient analysis showed a strong correlation between CBCT and SGRT measured intrafraction motion (Table 4), Therefore, SGRT can be used to safely monitor the patient during actual H&N treatment.

In the literature, no data is available yet on maskless intrafraction motion for H&N patients. Li et al. presented data for open face mask patients [14]. The SGRT and kV intrafraction motion seemed to correlate and the spread around the mean was slightly smaller than in our study. However, no statistical analysis was provided, only 5 patients were included, and intrafraction motion was determined on kV images instead of CBCTs, which is less accurate. Zhao et al. studied the setup accuracy (with CBCT) and intrafraction motion (with SGRT only) for 20H&N patients treated with an open face mask and SGRT [15]. Besides the mean, spread around the means, and systematic and random intrafraction error, no statistical analysis was given. The systematic intrafraction errors were even slightly smaller than our mask values, but only SGRT data were available, using a large composite ROI of head and chest for SGRT motion, while in our present study we only use an ROI of the head. Wei et al. included 60H&N patients treated in an open face mask, but only the initial setup accuracy with or without the use of SGRT was tested [16]. Recent studies also showed a correlation between intrafraction motion determined with SGRT and CBCT for lung [28] and abdominal [29] stereotactic treatments. The correlation was less strong than in our study, which can be explained by the less rigid relation between external surface and tumor motion for thoracic and abdominal tumors compared to H&N tumors.

Using a threshold th_2 for treatment interruption, the intrafraction motion CTV-PTV margin is largest in vertical direction for maskless treatment (1.2 mm), which is even slightly smaller than the margin in lateral direction for treatment with mask (1.6 mm), where no intrafraction motion correction as a result of SGRT can be applied. The total CTV-PTV margin does not only correct for intrafraction motion, but also for initial setup errors, inaccuracies in the (PET-)CT, contouring, swallowing and respiratory motion [1]. Since these other errors are identical for maskless and mask treatments, the currently applied CTV-PTV margin of 3 mm can also be applied without a mask.

The questionnaires showed that especially concerning discomfort

Table 4
Intrafraction motion determined using the difference in CBCT values before and after the simulated treatment without a mask as well as the SGRT data during these two CBCTs, and difference in CBCT data for the corresponding actual treatment with a mask. For all translations and rotations the mean value of all simulated fractions, the spread around this mean (1SD), the median and the interquartile range aregiven. Pearson Correlation Coefficient (PCC) between intrafraction motion measured with CBCT and SGRT is given. Based on CBCT intrafraction motion, the patient population systematic and random error for intrafraction motion is given.

	Without mask CBCT	Without mask SGRT	With mask CBCT
Mean ± 1 SD			
Vertical (mm) [3]	−0.1 ± 1.3	0.1 ± 1.5 [1,2]	0.1 ± 0.6
Longitudinal (mm) [3]	0.2 ± 1.2	0.0 ± 1.2	−0.3 ± 0.7 [1,2]
Lateral (mm) [3]	0.2 ± 1.4 [1,2]	−0.1 ± 1.1 [1,2]	−0.1 ± 1.1 [1,2]
Pitch (°) [3]	0.0 ± 0.8	0.0 ± 0.8 [1,2]	0.0 ± 0.5
Roll (°) [3]	0.2 ± 1.2 [1,2]	−0.1 ± 1.0 [1,2]	0.0 ± 0.4 [1,2]
Rotation (°) [3]	0.0 ± 0.9 [1]	0.1 ± 0.7 [1]	−0.1 ± 0.5 [1,2]
Median (interquartile range)			
Vertical (mm)	−0.2 (1.3)	0.1 (2.1)	0.1 (0.5)
Longitudinal (mm)	0.0 (1.2)	0.0 (1.2)	−0.3 (0.7)
Lateral (mm)	0.3 (1.7)	0.0 (1.3)	0.1 (1.2)
Pitch (°)	0.0 (0.7)	−0.1 (1.1)	0.0 (0.4)
Roll (°)	0.1 (1.2)	−0.1 (1.1)	0.0 (0.3)
Rotation (°)	0.0 (1.0)	0.2 (0.7)	−0.1 (0.5)
PCC[4,5]			
vertical	0.67		
longitudinal	0.33		
lateral	0.60		
vector	0.79		
Systematic error			
Vertical (mm)	0.7		0.3
longitudinal (mm)	0.8		0.4
lateral (mm)	0.8		0.9
Random error			
vertical (mm)	0.7		0.3
longitudinal (mm)	0.8		0.4
lateral (mm)	1.2		0.5

[1] Normally distributed according to Kolmogorov-Smirnov test.
[2] Normally distributed according to Shapiro-Wilk test.
[3] Wilcoxon signed rank test showed no significant difference in intrafraction motion measured with CBCT and with SGRT.
[4] Pearson correlation coefficient (PCC): correlation is strong if between ± 0.50 and ± 1, moderate if between ± 0.30 and ± 0.49, and low if lower than ± 0.29.
[5] For all translations as well as the vector, the correlation is significant at the 0.01 level.

and claustrophobic feelings, patients preferred treatment without a mask. Sixteen out of 19 patients preferred treatment without a mask, while the 3 patients who preferred a mask only did so since they feared motion without a mask and felt they had to concentrate more in order to lie still. Recently, Macromedics (Moordrecht, The Netherlands) developed the DSPS-Prominent Occipital individual head rest mask (which can also be applied with a front face part). We expect this individual occipital head rest to give more support to the patient, and therefore to result in even less motion. Using this mask will also assure the patients that less motion is possible. We will test the accuracy in patient setup, intrafraction motion, as well as number of necessary treatment interrupts using a threshold of 2 mm (vector 3 mm) and 2° in actual head and neck treatments in a follow-up study.

In conclusion, we have shown in this study for the first time in literature, that maskless treatment of head and neck cancer patients, which is much more patient-friendly than applying a mask, is feasible, if SGRT is applied for accurate patient setup as well as monitoring (and correcting for) intrafraction motion.

Table 5
Average score to the questionnaires. Scores were: a lot (1), a little (2), hardly any (3), not at all (4).In addition, between brackets, the number of patients (#p) were the answer was 1 (#p_1) or 2 (#p_2) for all fractions, is also given (#p_1, #p_2).

	Without mask	With mask
1 discomfort	3.7 (0,2)	2.5 (5,6)
2 claustrophobic feelings	3.9 (0,0)	2.9 (4,3)
3 anxiety?	3.7 (1,0)	3.3 (2,2)
4 nervousness?	3.8 (0,1)	3.3 (2,2)
5 feelings of isolation or loneliness?	3.9 (0,0)	3.4 (2,1)
6 pain	–	3.3
6 treated with or without a mask?	16	3
7 anxiety medication?	2 patients	
8 Further remarks?	"Mask is ok, but without mask more freedom of breathing" "Without mask much more comfortable" "I can also lie still without the mask" "The mask gives me the assurance that I am correctly positioned" "I feel I have to concentrate more without a mask" "The mask is a monster"	

5. Declarations

5.1. Ethics approval and consent to participate

Informed consent was given by the participants and the study was approved by the medical ethics committee METC Brabant (CCMO register NL73858.028.20). Date of registration: 24–06-2020.

Consent for publication

Not applicable.

Availability of data and materials.

The datasets generated and analyzed during the current study are not publicly available due to the privacy of the subjects and are stored by Institute Verbeeten. The data is available from the corresponding author on reasonable request.

Authors' contributions

ME, JD, and WK designed the study. ME and LM collected the data and performed the analysis. ME and WK interpreted the data, and ME wrote the paper. All authors discussed the results, and read and approved the final manuscript.

Authors' information (optional).

Not applicable.

Trial registration

Registration number: CCMO register NL73858.028.20.

Date of registration: 24–6-2020.

CRediT authorship contribution statement

Marion Essers: Conceptualization, Data curation, Writing – original draft, Writing – review & editing, Visualization, Investigation, Validation, Formal analysis, Methodology, Supervision, Resources, Project administration, Software. **Lennart Mesch:** Formal analysis, Writing – review & editing. **Maaike Beugeling:** Writing – review & editing. **Janita Dekker:** Conceptualization, Writing – review & editing. **Willy de Kruijf:** Conceptualization, Writing – review & editing.

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