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● *Physics Contribution*

REPOSITIONING ACCURACY: COMPARISON OF A NONINVASIVE HEAD HOLDER WITH THERMOPLASTIC MASK FOR FRACTIONATED RADIOTHERAPY AND A CASE REPORT

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Purpose: To compare accuracy, clinical feasibility, and subjective patient impression between a noninvasive head holder (Vogele Bale Hohner [VBH]; Wellhoefer Dosimetry, Schwarzenbruck, Germany) developed at the University of Innsbruck and the thermoplastic mask fixation system for use in fractionated external radiotherapy. We present a case report of an actual patient fixated in the VBH head holder during radiation therapy.
Materials and Methods: The VBH head holder consists of an individualized vacuum dental cast connected to a head plate via two hydraulic arms allowing noninvasive, reproducible head fixation of even uncooperative patients. Accuracy was tested and compared with that of the thermoplastic mask using the Phillips EasyGuide navigation system on five volunteers. Specific external registration points served as landmarks and their positions were compared after each repositioning. System and operator inaccuracy were also taken into account. The times taken for production and repositioning of the respective fixation devices were compared, and subjective impressions were noted.
Results: Mean VBH head holder repositioning accuracy was 1.02 mm while that of the thermoplastic mask was 3.05 mm. 69% of mask repositionings showed a deviation > 2 mm and 41% > 3 mm (as opposed to 8% and 1% respectively for the VBH head holder) Those points located farthest away from the respective plane of fixation showed the largest deviations. Both production and repositioning times were similar between the systems; depending upon the patient, the VBH head holder was generally better tolerated than the mask system.
Conclusion: Due to its significantly better repositioning accuracy compared to that of the thermoplastic mask, the VBH head holder is especially suited for external radiation requiring precise repositioning due to critical tissues in immediate surrounding of the area to be irradiated.

Patient fixation, Head fixation, VBH head holder, Fractionated radiotherapy, Immobilization, Mask.

INTRODUCTION

Accurate delivery of a prescribed radiation dose to a target volume, while sparing surrounding normal and critical tissues, is the primary objective of radiation therapy. A significant reduction in local tumor control results from even small (7–15%) changes in dose (1–3) leading to recommendations by the International Commission of Radiation Units (ICRU) suggesting accuracy in dose delivery to be ±5% (1, 2). Such precision can only be reached by accurate field placement throughout the entire course of radiation treatment. Especially the head, quite flexible in every direction, requires accurate fixation, as critical tissues (e.g., structures of the eye) are often in close proximity to the irradiated areas. Great efforts have been undertaken to improve accuracy of head fixation and many centers have chosen mask fixation for lack of better alternatives. The advantages of thermoplastic masks are a simple and quick production process and applicability for most indications in the head and neck regions. To our knowledge, repositioning accuracy has never been statistically defined, with existing studies ranging from 0.6 mm (4) to 3.5 mm (5). It is therefore the objective of this study to introduce the noninvasive, modified Vogele Bale Hohner (VBH) head holder and to assess its repositioning accuracy in comparison with that of the thermoplastic mask. The VBH head holder (patent application May 18 1995, Deutsches Patentamt # 29508277.1), based on an individualized vacuum dental impression, was

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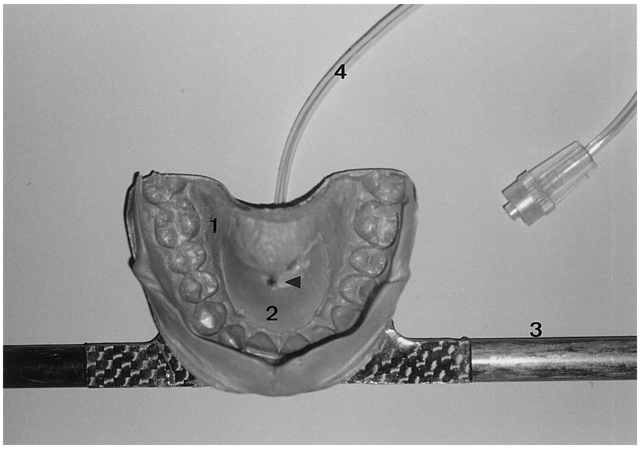

Fig. 1. Mouthpiece (MP): (1) vacuum upper dental cast in impression tray (3 sizes) with (2) vacuum chamber (sliced vacuum hose visible in center [arrow]) connected to (3) transverse rod. (4) Vacuum hose.

originally developed at the University of Innsbruck for frameless stereotactic ear, nose, and throat (ENT) operations (6) and due to its excellent results, adapted to the requirements of 3D brachytherapy (7) and fractionated external beam radiotherapy.

Repositioning accuracy between a thermoplastic mask (Orfit Raycast) and the modified VBH head holder is compared on volunteers using a 3D navigation system (EasyGuide Neuro, Phillips Medical Systems). Additionally, a case report of an actual patient during 8-week therapy is presented.

MATERIALS

The modified VBH headholder for external radiation

The core element of the VBH headholder is the (MP) (Fig. 1) which is based on an individualized vacuum dental cast. This dental cast is made by filling an appropriately

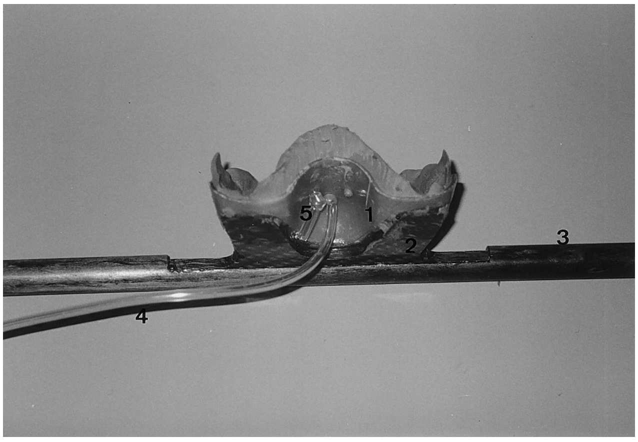

Fig. 2. MP as viewed from below: Impression tray (1) glued to transverse plate (2) glued to the transverse bar (3). Vacuum hose (4) with knot (5) on the distal end.

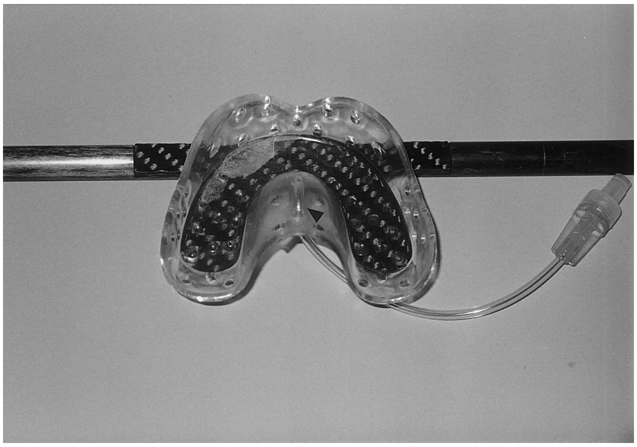

Fig. 3. ‘‘empty’’ MP, with vacuum hose visible on the inside (arrow).

sized (small, medium, large) upper dentate impression tray, to which a rubber hose has been fastened by pulling it through two holes and tying a knot on the distal end (Fig. 2). This leaves a stretch of hose on the inside of the impression tray (Fig. 3) which is then filled with a rapidly hardening, nonirritant and form-stable dental material (IMPREGNUM F; ESPE Dentalmedizin GmbH & Co. KG, Germany). Before inserting the loaded dental tray into the patient’s mouth, a 1-mm-thick self-adhesive rubber mat is pressed against the hard palate (Fig. 4).

After 3–5 minutes the hardened dental impression is gently removed from the oral cavity and the rubber mat (now on the dental impression) is peeled off, creating the vacuum chamber. At this time the rubber hose, visible just under the vacuum chamber, is cut open (Fig. 1) with a scalpel. The MP is then reinserted into the patient’s mouth and the hose connected to the vacuum pump. If an underpressure of 0.8 atm is attained and the MP rigidly clings to the upper jaw on its own, excess impression material can be removed for easier insertion into the patient’s mouth.

The transverse rod connected to the underside of the

Fig. 4. Self-adhesive rubber mat against anterior portion of the hard palate to create the vacuum area.

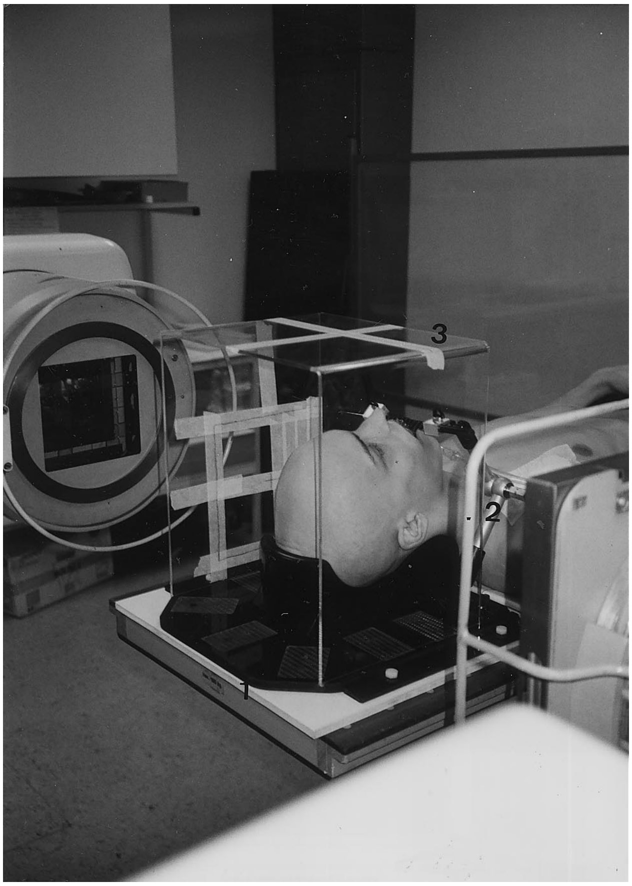

Fig. 5. Patient fixated in modified VBH head holder: (1) head plate (acting as reference plane) on base plate (white), (2) hydraulic arms, and (3) localization box.

impression tray is made of carbon fiber and protrudes from either corner of the patient's mouth. The variability of the system is given by two hydraulic arms attached bilaterally to the transverse rod, connecting the MP with the head plate (Fig. 5). This computer-numeric-control (CNC)-machined, carbon fiber head plate has multiple impressions allowing a reversible, precise, and tight fit for the base of the hydraulic arms by a turn of a thumbscrew (Fig. 6).

The head plate can be adjusted in craniocaudal direction on the base plate/modified radiotherapy couch. This allows the system to adjust to the patient's position as opposed to the conventional methods which necessitate adequate patient adjustment to fit into the respective fixation.

Localization

Depending on the field to be irradiated, the arms, having six degrees of freedom and multiple positioning impressions on the head plate, can be positioned so as to not interfere with the beam. The patient's position is adjusted under x-ray control until the desired position is attained after which the hydraulic arms are fully tightened to remain fixated for the entire treatment period.

Also during localization, patient alignment lasers, isocenter and fields are marked on a clear localization box (Fig. 5) which sits in two grooves on the head plate. After each repositioning, the box is placed in the grooves so that it abuts against the hydraulic arm base (to be in precise relation to the head) and the couch positioned so that isocenter and patient alignment lasers coincide with those on the localization box. Once correctly positioned, the box is removed before initiating therapy to minimize buildup effect and isodose distortion. After localization, the hydraulic arms are marked with the patient's ID sticker (Fig. 6), the vacuum is disconnected, and the entire rigidly fixated MP with hydraulic arms is removed and stored until therapy.

Repositioning

For repositioning, the MP with the hydraulic arms is reinserted with the vacuum on. Once the MP is sucked noticeably against the upper palate and the desired underpressure (-0.8 atm) reached, the head plate can be adjusted in craniocaudal direction until the bases of the hydraulic arms easily slip into their respective impressions on the base plate. This step is crucial for precise repositioning, because if the hydraulic arms are forced into the impression under tension, the head may not be in precise relation to the head plate. After tightening down the hydraulic arms, the position

Fig. 6. Base of a hydraulic arm (with patient sticker) (1) attached to the head plate (2) by thumb-screw (3). Also visible on the head plate are an empty impression with threaded bore (4) and a groove for the localization box (5).

Fig. 7. Setup with subject fixated in VBH head holder with navigation system (Phillips Medical Systems), operator1 (with pointer), operator2 (manning computer) not shown.

of the head plate is fixed on the base plate by a turn of a thumb screw.

Fitting of the thermoplastic mask (Orfit Raycast)

A perforated sheet of Raycast is heated in a 80°C water bath with soap added to prevent the sheet from sticking to the patient. Additionally, the patient wears a thin nylon face mask. When the mesh becomes transparent, it is removed from the bath and allowed to cool slightly. It is then centered over the patient, hooked onto the plexiglass head plate on one side, and stretched over the patient's head to be hooked contralaterally and cranially. These hooks are secured to the head plate by appropriate splints. After hardening (2–3 min), the mask and nylon cover are removed and the mask reapplied and checked for fit.

The Phillips EasyGuide navigation system (Phillips Medical Systems) (Fig. 7) consists of a mobile workstation, a position digitizer, and a freehand pointing device equipped with three light-emitting diodes (LEDs). From the position of these diodes, read by two 2D CCD cameras in the position digitizer attached by a vertical bracket to the VBH head plate/radiotherapy couch, the computer calculates the position, direction, and rotation of the tip of the instrument in space.

METHODS

Repositioning accuracy was tested on six informed, consenting volunteers with complete and stable upper dentition. Special care was taken to intimately mold the mask to the facial contours, especially of the nose. The time taken for production of both the dental and the thermoplastic mask was noted, as well as the time taken for repositioning and finally the subject's impression of rigidity of fixation and comfort.

Repositioning and accuracy testing with the EasyGuide Neuro was performed in the off hours, a week after mask/dental cast fitting. After marking the registration points (landmarks) on the skin (Fig. 8) and cutting small holes (1–2 cm in diameter) into the mask over the registration points to allow access by the probe (no other holes were cut as to not destabilize the structure of the mask), the subjects were positioned on the radiotherapy couch in supine position as they would be during therapy itself and instructed to lie motionless in their respective fixation. After initialization and baseline control, each subject was repositioned 10 times in both mask and VBH head holder in no specific order. The position of the radiotherapy couch remained in the same position throughout the experiment.

Registration itself was performed the same way for both systems, the position digitizer always in identical relation to the respective head plates.

Initialization

Initialization was performed to correlate coordinates in space to a random CT data set which had previously been loaded into the workstation. The positions of the landmarks (Fig. 8) were initialized and stored in the navigation system's reference coordinates (standard of comparison). All subsequent data of that series referred to this first positioning of the subject.

Baseline control

Immediately after initialization, to measure deviation without repositioning (sum of system error, patient movement, and operator error), we performed the following steps. Preceding every subject's first repositioning, each landmark was touched with the pointing device and, using the func-

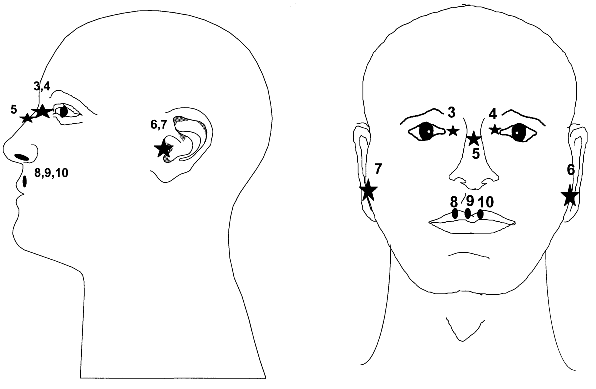

Fig. 8. Seven registration points (landmarks) were used for the VBH head holder (star): 1 and 2: fiducial markers (Phillips spots) on the head plate (not shown); 3: medial angle of the right eye; 4: medial angle of the left eye; 5: nasal bridge; 6: left tragus; 7: right tragus. Three additional points were used for the mask (circle) due to easy access to the teeth: 8: gingival border between upper right incisor and right canine (1-1 and 1-2); 9: gingival border between (1-1 and 2-1); 10: gingival border between (2-1 and 2-2). Points 3–7 were small dots on the skin made with a fine felt marker, and chosen because voluntary skin displacement in these regions is minimal (9). Points 1–2 served as system accuracy control points.

tion, ''Tip to Marker'' the distance between the tip of the pointing device and the nearest registered landmark coordinate was measured by the navigation system. After the baseline control, the vacuum and both hydraulic arms were disconnected, and the entire rigid, U-shaped MP with hydraulic arms was removed and the subjects allowed to stand up and walk a few steps before repositioning.

Repositioning

After fixation of the subjects in the above described manner, the distance from that landmark's original coordinates was again measured as above. The deviations of all landmarks were determined in this manner in the same order for each of 10 repositionings/subject, totaling 50 repositionings with 250 registration points for the VBH head holder and 400 with the mask. No repositioning was repeated with either system, regardless of results. Subjective impressions of rigidity, comfort, and claustrophobia were noted on a questionnaire.

Statistical analysis

Mask and VBH mean repositioning accuracy and standard deviations were calculated and compared. The Mann-Whitney U test (8) was used to determine if there was a significant difference between VBH and mask results before and after taking system and operator error (baseline) into account. The deviations of the individual points were also evaluated.

RESULTS

Accuracy

First, looking at the mean deviations of each series of landmarks (1 value/positioning, Table 1), it is obvious that the accuracy of the navigation system itself was well under 1 mm. Baseline registration (attributable to system error, operator error, and patient movement) was under 1 mm as well. VBH head holder accuracy (mean 1.02 mm) was significantly ($p < 0.001$) better than that of the mask (mean 3.05 mm) both before and after taking system accuracy into account.

After subtracting system or baseline deviations from the mean repositioning error, it is obvious that the VBH head holder achieves a submillimetric repositioning accuracy and thermoplastic mask system 2–3 mm accuracy (Fig. 9).

Fig. 10 depicts the deviations of the individual landmarks.

Production of the VBH mouthpiece required 20–30 min depending on expertise as some practice is necessary, while thermoplastic mask production by an experienced technician took around 15 min from the time of material insertion into the waterbath until completely set.

Subjective impressions

VBH: All subjects noticed a somewhat bitter taste of the impression material, all had the impression to be rigidly fixated, and none felt pain or uncomfortable.

Mask: While all subjects found the mask to fit very tight, three of the five subjects found the material's initial high temperature to be temporarily uncomfortable and one somewhat claustrophobic subject found the period under the mask barely tolerable.

Table 1. Mean tip-to-landmark deviations/positioning

		Mask (mm)	VBH (mm)
System control landmarks 1–2, $n = 55$	mean	0.73	0.38
	SD	0.3	0.13
	min	0.2	0.1
	max	1.7	1.0
Baseline landmarks 3–10 (7) $n = 5$	mean	0.89	0.57
	SD	0.05	0.09
	min	0.83	0.48
	max	0.94	0.70
Repositioning landmarks 3–10 (7) $n = 50$	mean	3.05	1.02
	SD	1.5	0.28
	min	0.85	0.6
	max	8.48	2.1

Case report

A 28-year-old informed, cooperative patient with adenocystic carcinoma of the sphenoidal sinus received 70 Gy (35 fractions @ 1 Gy/field) over a period of 8 weeks fixated in the VBH head holder. Repositioning accuracy was measured daily with help of three Repositioning Control Elements (RCE), precisely repositionable hydraulic arms with sharp pointers at their ends. These were set to point to specific landmarks (in this case naevi) after localization. After repositioning, the deviations of the

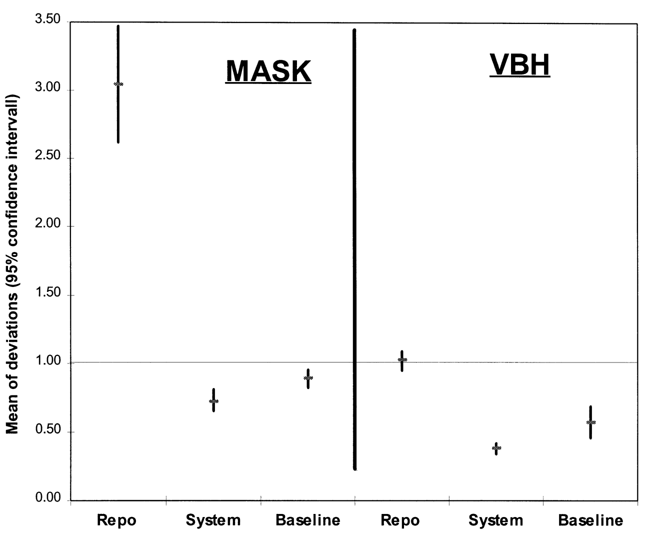

Fig. 9. Comparison of repositioning, system error, and baseline between VBH head holder and mask with vertical bars giving the 95% confidence interval for the difference in means. Repo = repositionings (including system error).

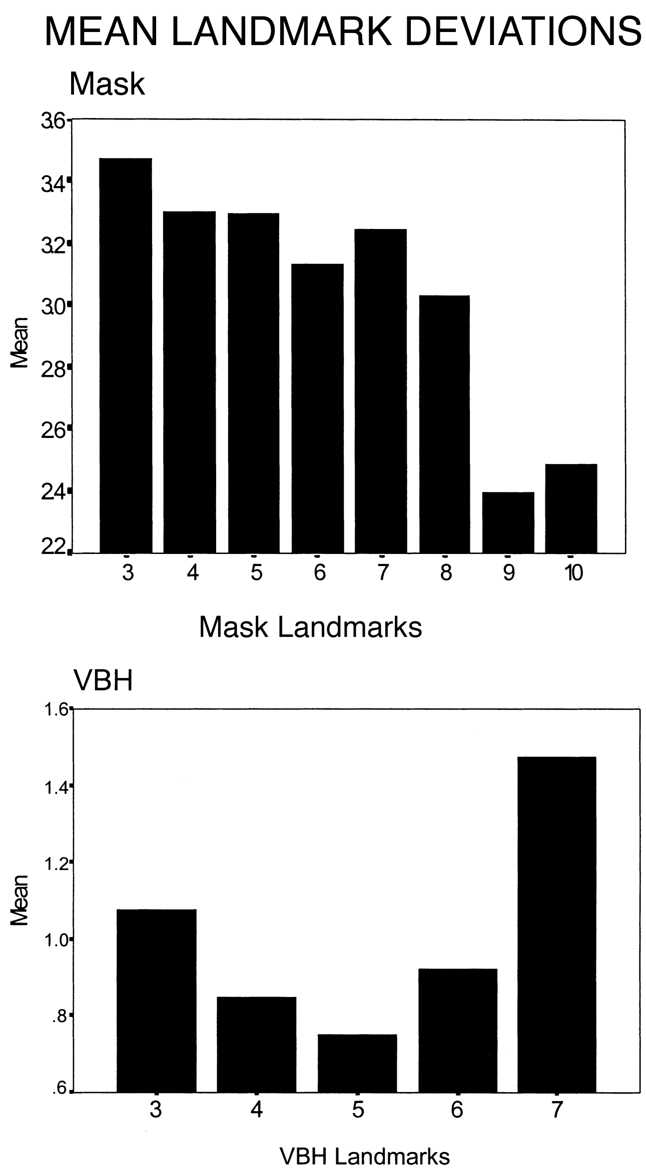

Fig. 10. Mean deviations of all repositionings/landmark.

point to landmark were measured by tape measure to the nearest millimeter. On two occasions the deviation exceeded 2 mm. In these cases, the hydraulic arms were dismounted and the head plate readjusted craniocaudally so the arms could be reattached absolutely tensionless. It was noted that a few seconds more spent on perfect alignment of the hydraulic arms to the head plate meant a higher repositioning precision.

The mean deviation of the 35 repositionings (3 RCEs, 105 measurements) was 0.74 mm (SD = 0.52) which supports the previous results and the experiences in the stereotactic ENT and brachytherapy applications. The patient tolerated the head holder very well, no lesions occurred on the oral mucosa from the underpressure, only the dental impression caused slight gingival bleeding on one occasion. The patient considered the taste of the impression material to be tolerable but bitter.

DISCUSSION

With technology for fractionated radiotherapy having reached high degrees of accuracy in tumor localization (CT, MRI) and spatial conformation of the radiation dose to the target volume (computerized treatment plans, 3D planning), these high-tech treatment aids are of little use if precise repositioning of the tumor is unreliable. While the most accurate positioning is achieved by invasive skull-pin sereotactic frames, these permit only single fraction irradiation, which is used, for example, for treatment of arteriovenous (AV) malformations. Additionally, imaging, therapy planning, and patient positioning must be performed within a given time limit as these devices are hardly relocatable.

Tumors respond better to fractionated radiotherapy due to their inferior repair characteristics compared with healthy tissue. Thus the main advantage of fractionated radiotherapy is less damage to surrounding normal tissue; this, again, is only achieved if solely the tumor volume itself is irradiated with the full dose, which requires identical fixation for each fraction. This has been widely attempted with most centers now using bite-block based or mask fixation.

From the highly significant difference between mask and VBH repositioning, even after taking system and operator inaccuracy into account, it can be clearly stated that especially where critical areas of the head lie in close proximity to the field to be irradiated, the VBH head holder would be the preferred method of fixation.

While a maximal deviation of 11.2 mm was likely an exception (Fig. 11) (VBH 3.3 mm), the fact that 69% of mask repositionings showed a deviation > 2 mm and 41% > 3 mm (as opposed to 8% and 1% respectively for the VBH head holder) is worrisome. The Phillips EasyGuide only gave absolute values of tip to landmark deviations, not the *x*, *y*, *z* coordinates per se. These would have been interesting to determine in what direction the deviations primarily occurred. Also, the system itself has an inherent inaccuracy among others surely due to the somewhat shaky stand of the position digitizer (Fig. 7). Still, the system control value of well under 1 mm is acceptable (Fig. 9).

Due to the fiducial spots (Phillips) with an impression in the center, the tip of the pointer could be placed accurately quite easily as opposed to against a dot on the skin. Another possible influence on system accuracy was the connection base plate to therapy couch, the same on both systems (two pegs on the underside of the base plate which fit into the appropriate holes in the couch). The slightly tighter fit of the VBH base plate likely caused the difference in mean system deviation between VBH head holder and mask which was almost identical to the baseline difference (Fig. 9).

Great care was taken by the pointing operator to precisely place the pointer on the landmark and a baseline mean deviation, attributable mainly to system error + operator error (including skin displacement), of only slightly more than the system error showed that the chosen method was quite accurate.

Skin dots were chosen because fiducial spots showed to

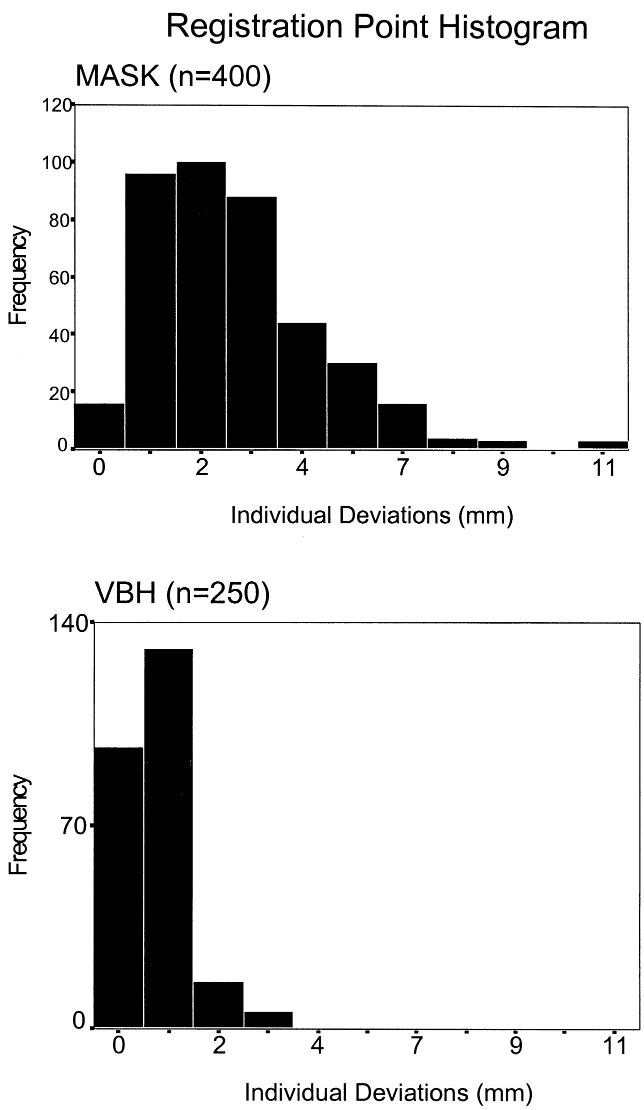

Fig. 11. Histogram of all registration point deviations of mask and VBH head holder repositionings respectively (not including landmarks #1, 2, and baseline).

be slightly more prone to displace the skin when touched with the tip of the probe during registration. These specific locations were chosen because they are least influenced by voluntary movement (9).

The landmark with the greatest deviation (Fig. 10) for the VBH head holder was the tragi landmark. This could be because these points are located furthest away from the MP (fixation plane) and/or influenced by the degree of lower jaw position, not a factor with mask fixation since it stretches over the chin. The one subject with the largest deviations under the VBH head holder was one with a pony tail, suggesting that hair is a possible source of error (also noted by Shrawder *et al.* [10]). Shrawder also suggests that use of a mask just reaching over the nose and sparing the chin, would decrease inaccuracy because movements by the mouth and jaw, when covered by the mask, would force the entire head to move. Both Shrawder *et al.* and Pilipuf *et al.* (4) used individualized head rests which detail the occiput and the base of the skull and likely increase mask system accuracy dramatically. The mask system in this study, however, covered the entire head and standard contoured head rests were used. The great variability of results (0.6–3.5 mm) in thermoplastic mask repositioning studies (4, 5, 10) could also be influenced by mask material, some materials being soft and supple allowing noticeably more distortion while others are inherently stiff.

Interestingly the mask landmarks 3–5 (gingival borders), which had no skin to displace and were thus expected to be the most precise landmarks, showed the largest deviations (Fig. 10), whereas the tragi points showed the least deviation. Again, the tragi points were the closest to the head plate (fixation plane) and it seems that the further away from the point of fixation, the greater the repositioning inaccuracy of both systems. Menke *et al.* (5), who measured repositioning accuracy of a thermoplastic mask almost identical to the one used in this study, derived an average lateral random repositioning error of 3.5 mm. Anterior–posterior and inferior–superior error was under half that value.

During localization, a certain amount of force is required to stretch the mask over the patient's head once precisely positioned possibly causing inaccurate fixation requiring repeat mask production. Tightening the arms of the VBH head holder after the patient's position is adjusted under x-ray control does not affect patient positioning, significantly simplifying the localization process. Should the facial contours change during the treatment period, be it swelling (steroid therapy, edema, etc.) or tissue loss (e.g., cachexia, superficial tumor regression), the mask becomes either unbearably tight or too loose, requiring repeat mask production and localization. This procedure would only be necessary with the VBH head holder if there is a change in the upper dentition, such as dental work or tooth loss, causing a vacuum leak. The field to be irradiated cannot be visualized on the patient's skin unless this area of the mask is cut away, possibly leading to decreased stability/accuracy. Also, a possible buildup effect of the material with ensuing dermatitis is to be considered (11). The psychologic effect of a full face mask can be an additional strain on especially labile patients, although cutting out portions of the mask over the eyes and mouth does usually solve the problem. In our study we did not take this step as to not decrease mask stability. The mask may also exert painful pressure on a patient's fresh scar from a preceding operation.

The advantage that masks have over the VBH head holder is that they can be applied independently of the patient's dental status as well as being applicable for all indications in the head and neck regions, while the VBH head holder is limited to those indications not involving pathologic processes of the hard palate (mucositis, tumor, etc.). The patient must also be able to open his or her mouth.

Repositioning of edentulous patients with the VBH head holder has been successfully performed on eight patients undergoing stereotactic ENT surgery (6) but repositioning accuracy in this subgroup has not yet been investigated.

Should the lower jaw need to be repositioned accurately as well (e.g. base of the tongue or submandibular gland tumor), a double-sided impression tray could be used.

Due to the multiple positioning capabilities of the hydraulic arms and the various head rests on the base plate, the head can be fixated in virtually every position desired for irradiation including sideways. This is especially important for computerized 3D planning. Should head position need to be changed during the period of therapy, this can be easily done without repeat MP production. In case of an emergency, the patient can be freed in as long as it takes to disconnect the vacuum and the hydraulic arms (< 3 sec) and after a brief instruction, free himself in < 10 sec without attendance.

The advantages of the VBH head holder over other bite-block based systems such as the Gill-Thomas-Cosman Relocatable Head Holder (12) and the Stanford Bite Block (13) are the absence of bulky frames and greater positioning variability, precise repositioning of non- or decreased-compliant patients due to the vacuum, no skin markings and that repositioning can be controlled by the amount of underpressure on the vacuum scale. Should the required underpressure not be attained, the patient is not precisely repositioned. The vacuum pump itself has a minimal flow rate and therefore will not create the underpressure if there is even a small leak.

A similar device, based on a vacuum bite-block attached to a stereotactic frame (U.S. Patent #5,464,411, Nov. 7, 1995) developed by Dr. Schulte *et al.* at Loma Linda University Medical Center, has been used successfully on several hundred patients where a high degree of precision was required; for example, with stereotactic radiosurgery, stereotactic radiotherapy of acoustic neuromas, or pituitary adenomas. The main difference is that production of the mouthpiece takes 1–2 days (R. Schulte M.D., written communication, Dec. 1997).

Due to a tight accelerator schedule, an important feature for the clinical applicability of the VBH head holder had to be a quick repositioning, comparable to that of the thermoplastic mask system. This led to some changes of the prototype to the modified version which greatly reduced MP production and patient repositioning- and alignment time by substituting the original plexiglass base/head plate system (14), which was more complicated, with a CNC-machined carbon fiber head plate with impressions for both hydraulic arm base and localization box.

Fixated by the modified VBH head holder, the average patient spends no more time in the accelerator room than with the thermoplastic mask. MP production still requires some practice and skill, but work is in progress to decrease production time and simplify the process significantly. While the bitter taste of the impression material was described as unpleasant but tolerable, flavored or neutral impression materials are being tested but these must meet the physical criteria of the currently used material, being nonshrinking as well as quickly and sufficiently hardening. Should a patient be fixated by the underpressure for periods >5 min or have sensitive oral mucosa, the vacuum can be decreased to -0.3 atm after positioning. If no large forces are exerted on the head, this amount of underpressure suffices to maintain positioning control.

CONCLUSION

Major technical innovations have created a need for a precise method of head fixation which allows combined planning and therapy of cranial tumors. While being quite simple and easy to operate, the VBH head holder offers rigid, accurate, and reproducible fixation with submillimetric accuracy. The same system is compatible for use in all fields requiring reproducible head fixation, including brachytherapy, ENT surgery, neurosurgery, and radiosurgery. Thermoplastic mask fixation, also featuring easy and quick repositioning, has a significantly worse accuracy of repositioning and is thus less suited for external radiation requiring precise repositioning due to critical tissues in immediate surrounding of the area to be irradiated. The results of the subject repositionings confirm our clinical experiences as well as the results of our case report. Due to its performance over the past three years, the VBH head holder has become an important tool in various departments of our university hospital.

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