Fixation, registration, and image-guided navigation using a thermoplastic facial mask in electromagnetic navigation–guided radiofrequency thermocoagulation

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Objective. For fixation, registration, and image-guided navigation, the aim of this study was to evaluate a thermoplastic facial mask with plastic markers in achieving frameless stereotactic radiofrequency thermocoagulation (RFT).

Study design. A thermoplastic facial mask was remolded according to each subject's face. Six markers were placed on the surface and 6 inside. Series of 1.25-mm- and 2.5-mm-slice computerized tomography (CT) scans were made to provide radiologic data. During the phantom study, each plastic sphere inside was selected in turn as the target for frameless stereotaxy. The clinical Hartel puncture of the foramen ovale (FO) was imitated using an electromagnetic navigation system. Navigation-guided RFT was tried in 3 patients.

Results. The mean location error was 1.29 mm (SD ±0.39 mm). No significant difference ($P > .05$) was proven between 1.25-mm and 2.5-mm CT slice acquisition for the image datasets used. The FO punctures in clinical trials were successful and confirmed by CT.

Conclusions. Registration and fixation via a fiducial marker–based thermoplastic facial mask is accurate and feasible for use in navigation-guided RFT. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2010;110:e43-e48)**

Trigeminal neuralgia (TN) is the most common neuralgia. Since the pioneer work on "puncture" of the foramen ovale (FO) by Taptas[1] and Hartel,[2] percutaneous radiofrequency thermocoagulation (RFT) has been used and reported in several large series.[3-6] The FO measures ~6.5 × 3 mm,[7] and conventional "puncture" is based on assessing landmarks empirically. Failure rates as high as 4%[7] and incorrect orientation rates of 5%-7%[8] are possible. Inadvertent puncture of the foramen lacerum and carotid artery, inferior orbital fissure, and jugular foramen have occurred.[3-6]

Stereotactic technique has improved the performance of many procedures in head and neck surgery. Frameless neuronavigation-guided RFT using an optical navigation system or laser system has been used.[7-11] The theoretic advantages of this approach include separation of imaging and surgery, 3-dimensional (3D) planning, real-time instrument guidance, and accurate localization of targets. To be truly stereotactic, frameless methods must provide precise guidance and convenient service performance. Therefore, reliable immobilization and repositioning are important for precision neuronavigation-guided RFT.

Invasive schemes require that the stereotactic head ring remain fixed to the patient's skull by screws. The Vogele-Bale-Hohner (VBH) headholder is a noninvasive immobilization device using bite blocks, external cranial molds, masks, or a combination of these. A headholder and a vacuum mouthpiece had been achieved for registration.[7,12,13] To this end, the patient is immobilized in an invasive headholder, with the reference frame attached to the mouthpiece.[8,14] The mouthpiece has successfully been used in computer-assisted ear, nose, throat, and brain surgery.

We found another more convenient fixation and registration device. The thermoplastic facial mask is an external cranial mold. It is available and accurate for use in stereotactic radiosurgery.[15-18] The systematic variation is ±0.6 mm and the random variation is ±0.4 mm.[17] In the present paper, we introduce the thermoplastic facial mask in combination with an electromagnetic navigation system to achieve frameless navigation-guided RFT, and we present the results of a laboratory phantom accuracy study and preliminary clinical trial.

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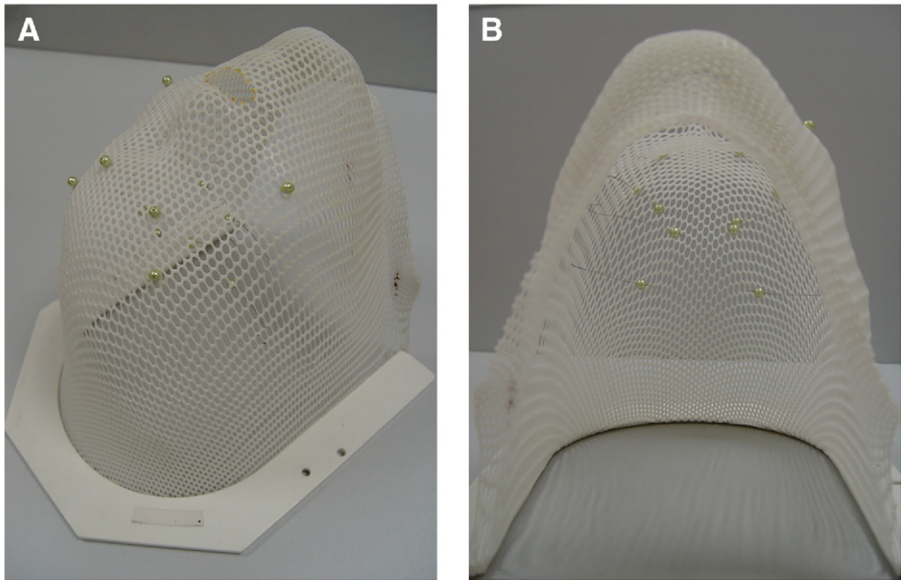

Fig. 1. Head mould for patient fixation and registration. **A,** Six plastic markers on the surface, corresponding to bilateral midforehead, midpoint of supraorbital ridge, and vertex of zygoma. **B,** Six plastic markers inside the mask to simulate intracranial arbitrary orientation.

MATERIALS AND METHODS

Description of equipment

SurgView-RFT electromagnetic navigation system (designed by Med-X Research Institute, Shanghai Jiao Tong University, Shanghai, China) was used throughout this study. The components of this device include an electromagnetic tracking system (Aurora; Northern Digital, Waterloo, Ontario, Canada), a sensor probe fitted with low-frequency electromagnetic waves, a mobile computer workstation and a 21-inch video monitor. The position of the probe is continuously displayed on the computer monitor as the intersection of standard orthogonal (axial, coronal, and sagittal) planes obtained from preoperative images. Software packages installed in the system include radiology workstation, path planning, electronic calipers, and real-time display. The guidance provides a probe's eye view, distance and angular deviation information, depth tracking information, and sound alert of dangerous error features in real time.

The patient fixation and registration system was developed from a thermoplastic facial mask (Chengdu Hongyun Medical Device Company, Chengdu, China). It can be individually molded by hot water for each patient. The mask itself extends over the chin to minimize longitudinal play and to prevent the rotation of the patient. Four plastic clips allow the system to be fixed to the CT bed and to be removed easily and quickly. Some self-adhesive fiducial plastic spheres were stuck on the surface of the forehead bilaterally, the midpoint of supraorbital ridge, and the vertex of zygoma (Fig. 1, *A*). All of the plastic spheres were designed with a dimple on the surface. These attachments were manufactured in such a manner that the probe could be positioned stably and repeatedly with minimal error, and the position of the dimple of the marker corresponded precisely with that of the imaging spheres.

The image acquired was spiral computed tomography using the LightSpeed 4 scanner (GE Lightspeed; GE Medical System Inc., Waukesha, WI, USA). The parameters for the CT scans were: 512×512 matrix, 0° gantry tilt, 1.25 mm and 2.5 mm slice thickness (in phantom study), 2.5 mm slice thickness (in clinical trial), 27.5 mm/rotation, 120 kV, and 100 mA.

Laboratory phantom accuracy study

The phantom was based on the thermoplastic facial mask. Another 6 plastic spheres were spread inside the mask and in different orientations (Fig. 1, *B*). They were fixed to the mask by rigid steel wire. The distances between the superficial markers and the inner markers was ranged from 60 mm to 120 mm. CT scans (1.25 mm and 2.5 mm) were obtained. A 3D reconstruction of the model and the registration rods was created on the navigation system (Fig. 2).

The phantom was put near the electromagnetic tracking device (Fig. 3). The clinical Hartel puncture of FO was imitated. The registration procedure was performed by using 6 superficial fiducial marker on the mask. The puncture trajectory was determined on the

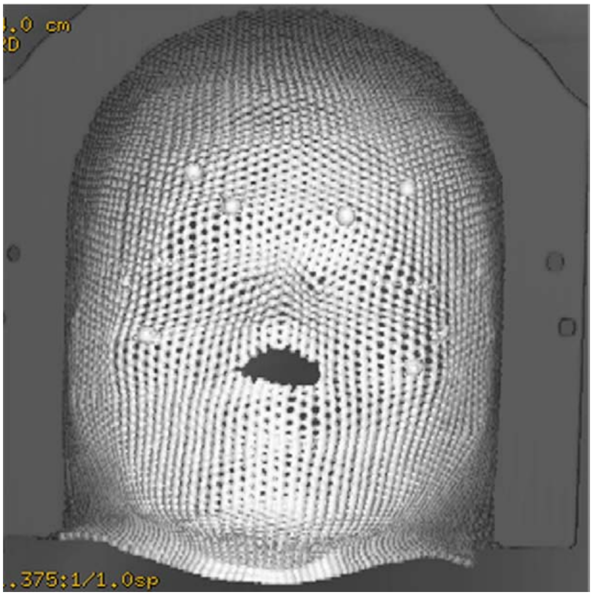

Fig. 2. Spiral computerized tomographic scan and images of the facial mask in the navigation system.

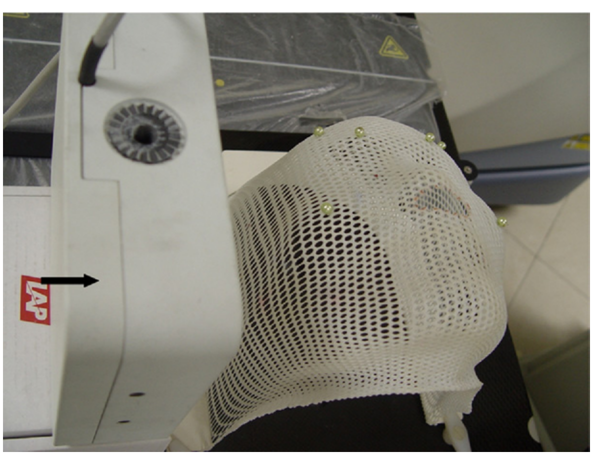

Fig. 3. The phantom in the electromagnetic navigation system (the *arrow* indicates the Aurora electromagnetic tracing service).

CT dataset on the SurgView-RFT electromagnetic navigation system. Each plastic sphere inside was selected in turn as the target for frameless stereotaxy. The entry point was selected at ~2.5 cm lateral to the corner of the mouth. The probe was inserted along the trajectory. The depth stop was set when the probe tip touched the imaging central dimple. Then the needle was fixed on the mask by a hot melt glue stick. The Euclidean distance[19] between the central dimple of plastic sphere and the tip of the needle (Fig. 4) was measured with the compasses. The target registration error (TRE) was defined as the error between corresponding target points in the image data and those in the real patient after registration was evaluated.[20]

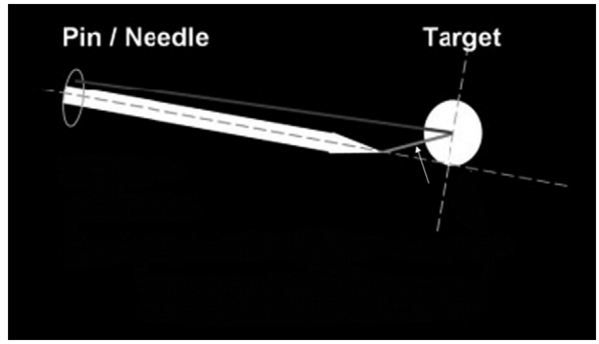

Fig. 4. The Euclidean distance between the central dimple of the plastic sphere and the tip of the needle (*arrow*).[19]

Preliminary clinical trial for TN

Three patients (2 male and 1 female; 58, 50, and 52 years old, respectively) presenting with drug-resistant TN were treated by electromagnetic navigation–guided RFT. The thermoplastic facial masks with 6 fiducial markers on the surface were remolded according to the patients' faces. The patients were scanned in the facial masks with registration spheres. In the laboratory, the target—the center of the FO, and the entry point—2.5 to 3.0 cm lateral to and just below (0.5 cm) the corner of the mouth, were determined preoperatively by trajectory planning as visualized on the 2D and 3D reconstructions of the patient's CT data (Fig. 5).

In the CT intervention room, the patients were repositioned in the facial mask with endonasal oxygen uptake. The registration procedure was performed by using 6 markers on the mask. All patients were premedicated with atropine (0.5 mg intramuscularly) and sedated with intravenous propofol. Blood pressure, heart rate, and oxygen saturation were continuously monitored during the whole procedure. Under real-time visualization, a sharp rigid needle was advanced into the FO through the hole of the mask. A control CT scan confirmed the exact placement of the needle in FO (Fig. 6). For determination of the individual trigeminal branch, square-wave testing was performed. Thereafter, controlled thermocoagulation was performed. During the coagulation procedure, patients were sedated with intravenous anesthesia.

Statistical analysis

Descriptive statistics including the mean and SD were applied. For statistical test of significance, the unpaired analysis of variance was used. Significance was established when probability was $<.05$.

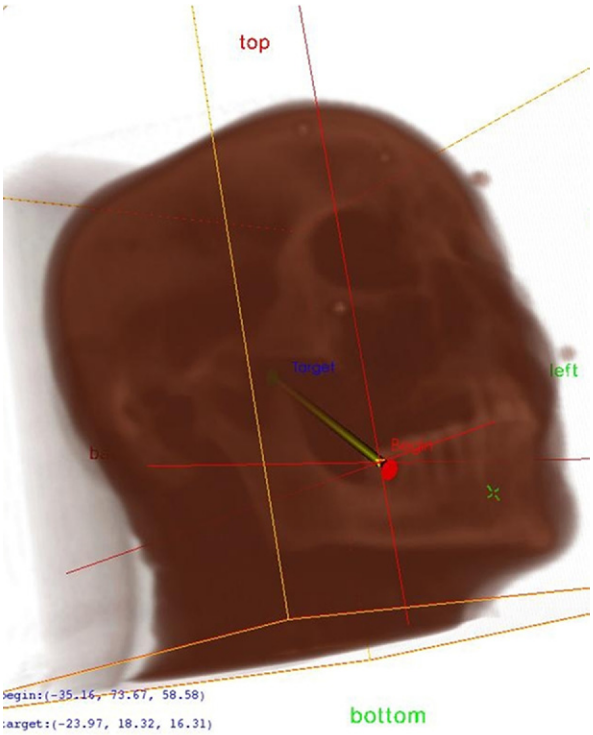

Fig. 5. Surgical path planning on 3D dataset of the navigation system.

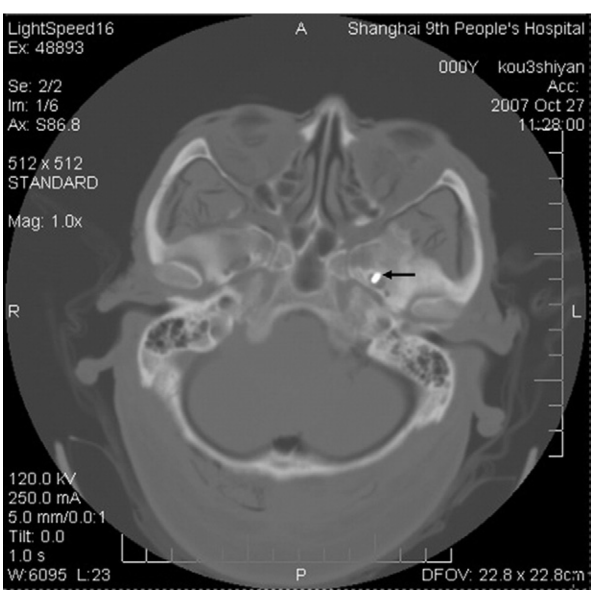

Fig. 6. Puncture of foramen ovale confirmed by computerized tomographic scan.

RESULTS

From the Aurora electromagnetic tracking device, accuracy was controlled to within 0.5 mm. DICOM image data provided an error of <0.4 mm.

Table I. Euclidean distance between the central dimple of plastic sphere and the tip of the needle (mm)

Target CT slice thickness	*I*	*II*	*III*	*IV*	*V*	*VI*	*Mean ± SD*
1.25 mm	1.2	1.5	1.3	1.6	0.8	1.0	1.23333333 ± 0.30110906
2.5 mm	1.4	0.7	0.9	1.7	1.6	1.9	1.36666667 ± 0.47187569

Phantom study

A total of 18 phantom stereotactic punctures are listed in Table I. The mean location error was 1.29 ± 0.39 mm. The 95% confidence interval (CI) was 1.10-1.49 mm. No significant difference ($P > .05$) was found when comparing 1.25-mm and 2.5-mm CT slice acquisitions.

Preliminary clinical trial

The FO was successfully cannulated at first attempt in all of the patients, as confirmed by control CT scans. No unexpected obstacles, including mucosal penetration, were encountered. No dyspnea occurred. All patients were relieved of their pain at once. The follow-up periods for the 3 clinical subjects were 18 months, 12 months, and 7 months, respectively. No trigeminal nerve–related pain recurred.

The device did not interfere with the imaging and operation procedure in any way. Facial mask preparation time was 5 minutes. Preoperative planning in the laboratory required ~15 minutes. The actual intervention, including repositioning the patient in the CT intervention room, registration, advancement of the needle to the FO, intravenous anesthesia, confirmation of correct position by CT scan and square-wave testing, and the final coagulation, took ~30 minutes per patient.

DISCUSSION

There is increasing evidence of clinical benefits in navigation-guided RFT.[7-11] A conventional stereotaxic frame is attached to the patient's skull by pins or rods under local or general anesthesia and can be considered to be too invasive to be accepted in RFT. Therefore, there is a desire to use frameless stereotaxy. Currently, some neurosurgeons use anatomic landmarks, surface matching, skin fiducial markers, or even implanted (invasive) pins for registration. However, anatomic landmarks and skin fiducial markers are sensitive to skin shift, which may lead to inaccuracy. We found that the thermoplastic facial mask used in stereotactic radiosurgery could be used as the fixation and registration system for RFT. Compared with the vacuum dental cast reported by Bale et al. in RFT,[7,13] the thermoplastic facial mask combines the headholder and registration nods in 1 device and reduces the buccal shift without blockage of surgical field.

To be truly stereotactic, frameless methods should not only provide precise guidance of delicate instruments to a preselected discrete target without deviation, but also be convenient to be used by operators. With the electromagnetic navigation system that we used in the present study, registration was performed via a fiducial marker–based thermoplastic facial mask. Compared with optical-based frameless stereotaxy, the advantage of an electromagnetic navigation system is the fact that there is no uninterrupted line of sight between the navigation tools. It allows for normal uninhibited handling within their working volume, without considering a free and undisturbed field of view.[21,22] In the present phantom study, the results were as good as those reported for guidance by an optoelectronic tracking system. The distinguishing features regarding accuracy and feasibility which differed from conventional frameless registration system included the registration method, the fixation method, and the manufacture method.

The registration method is very simple and accurate. Compared with skin fiducial markers or implanted pins, the landmarks were stuck stably and noninvasively on the surface of the mask which clung to the face. Identification of landmarks in both the patient and the imaged dataset was easy and objective. The landmarks were hollow so that the probe could be placed at nearly the same point as that shown in the CT scan. In other words, the device can increase accurate patient-image registration and then reduce the systematic error. More importantly, these markers remained in position until surgery. The accuracy of this registration system was confirmed by in vitro phantom and by in vivo clinical study.

The fixation method, which based on the same mask was valid. Soft tissue shift is one of the factors influencing navigation accuracy. In navigation-guided RFT, the buccal shift (in the absence of careful puncture technique) could change the planned surgical path and more time might be consumed to adjust puncture direction. Compared with the noninvasive headholder based on a vacuum mouthpiece,[7,8,14] ear-nasion support,[15] and orthodontic resin plate,[16,23] which were suitable in cranial, rhinopharyngeal, and maxillary surgeries, our facial mask can hold the whole head so as to reduce the buccal shift without blockage of the surgical field. Like other rigid head fixation techniques, the facial mask provided accurate immobilization of the patient's head during surgery. The registration rods can be equipped with different types of fiducial markers for accurate fusion of CT, magnetic resonance, proton-emission tomography, and single photon emission CT images. Preparation of the mask took several minutes and cost $40 per patient.

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