耳科手術のための安全領域リアルタイムモニタリングを用いた警報ナビゲーションシステム

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Warning navigation system using real-time safe region monitoring for otologic surgery

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Abstract

Purpose We developed a surgical navigation system that warns the surgeon with auditory and visual feedback to protect the facial nerve with real-time monitoring of the safe region during drilling.

Methods Warning navigation modules were developed and integrated into a free open source software platform. To obtain high registration accuracy, we used a high-precision laser-sintered template of the patient's bone surface to register the computed tomography (CT) images. We calculated the closest distance between the drill tip and the surface of the facial nerve during drilling. When the drill tip entered the safe regions, the navigation system provided an auditory and visual signal which differed in each safe region. To evaluate the effectiveness of the system, we performed phantom experiments for maintaining a given safe margin from the facial nerve when drilling bone models, with and without the navigation system. The error of the safe margin was measured on postoperative CT images. In real surgery, we evaluated the feasibility of the system in comparison with conventional facial nerve monitoring.

Results The navigation accuracy was submillimeter for the target registration error. In the phantom study, the task with navigation (0.7 ± 0.25 mm) was more successful with smaller error, than the task without navigation (1.37 ± 0.39 mm, $P < 0.05$). The clinical feasibility of the system was confirmed in three real surgeries.

Conclusions This system could assist surgeons in preserving the facial nerve and potentially contribute to enhanced patient safety in the surgery.

Keywords Otologic surgery • Surgical navigation • Warning system • Auditory feedback• Visual feedback

Introduction

Otologic surgery requires drilling of the temporal bone to approach small anatomical targets without damage or injury [1–3]. Despite the introduction of advanced surgical tools, such as an operating microscope, a surgical drill, and intraoperative facial nerve monitoring (IFNM), the risks associated with drilling the temporal bone remain high. In particular, for revision surgeries or patients with congenital malformations of the ear, even the most experienced and capable surgeons may have difficulty identifying anatomical structures [4–6]. To reduce the iatrogenic risk and difficulty in these cases, conventional surgical navigation systems are becoming popular and have proven practical in otologic surgery because they enable surgeons to perform surgery under the guidance of radiographic images safely and with less risk [7–10]. However, when using a navigation system, the surgeon's visual focus must move between the operating field and the navigation monitor to identify the position of the drill, causing a temporary interruption in the temporal bone dissection. Although IFNM can provide auditory feedback without movement of the surgeon's attention from the actual surgery [11–13], it requires physical contact between the electrode and the bone, thus limiting its application. In addition, IFNM cannot be used to monitor other important organs which are not responsive to electrical stimulation.

To overcome the limitations of conventional surgical navigation and IFNM, there have been several studies using auditory feedback as a novel user interface. This has a number of advantages, such as freedom from cumbersome graphic display hardware and the feasibility of continuous surgery [12–14]. To investigate its feasibility in clinical applications, we designed our proposed system to continuously monitor the safe distance between the drill tip and important organs without affecting the surgeon's attention during drilling. This system also offers auditory feedback based on predetermined safe distances. When the drill approaches organs inside a safe distance between the drill tip and the organ, the navigation system informs the surgeon of the degree of risk by varying audio signals as well as visual information on the display, allowing the surgeon to drill continuously while maintaining a safe distance.

To evaluate the effectiveness of the proposed system in otologic surgery, we selected the facial nerve as the target organ for monitoring. In the phantom study, we performed experiments in which a young and inexperienced surgeon drilled temporal bone models while preserving the facial nerve, with and without the proposed system. In clinical applications, we assessed the reliability of the proposed system by comparing IFNM with conventional surgery without the system. The aim of this study was to develop a novel navigation system for otologic surgery and to assess the effectiveness, reliability and feasibility of the proposed system in phantom studies and actual surgery. The proposed system can also be applied to other surgeries that require information regarding the distance between a surgical tool and an anatomical target to reduce iatrogenic risk.

Materials and methods

We used a free open source software (3D Slicer, Version 3.4, Brigham Women's Hospital, Boston, MA, USA) installed on a Linux workstation, as a software platform. The warning system consists of 3D slicer, registration tool and optical tracking system (Fig. 1). The user interface of the proposed navigation system was developed as a plug-in module and incorporated into the 3D Slicer. The registration was completed outside of the Slicer with a separate program we developed. The output transformation matrix was then used in the 3D Slicer. An optical position sensor (Polaris, NDI, Waterloo, Canada) was used to detect and track the position of the surgical drill [15]. Infrared markers were attached to the end of the drill, and calibration files were prepared for drill burrs of various radii and lengths.

Temporal bone computed tomography (CT) images in digital image and communication in medicine (DICOM) format were used. No specific scanning parameters were required for the surgical navigation. The pixel width and height was 0.1–0.3 mm and the slice thickness was 0.5mm.

For registration, we fabricated CT-based temporal bone models with the precise anatomy of a patient and a high precision laser-sintered template of the patient's bone surface (Ohno & Company Ltd., Tokyo, Japan). Infrared markers were attached to the template for registration (Fig. 2a).

In order to compensate for patient head movement due to drilling pressure or repositioning of the surgical bed during surgery, a reference marker was fixed on a tooth attachment [16]. This resin extension was custom made for each patient by a dentist using acrylic fitted over the patient's teeth (Fig. 2b). For patients who did not have teeth, we fitted the reference markers to the gingiva instead.

Registration

To obtain high reliability and accuracy, we used the preregistered surface template-assisted marker positioning (STAMP) method which uses a template fitting to the temporal bone surface with the attachment of infrared markers (Fig. 3) [17, 18]. The virtual markers defined on CT images were realized as holes in the template for registration. In preparation for the template, we included anatomical landmarks inside the temporal bone to prevent registration error from increasing with the depth from the surface [19]. The target registration error (TRE) was computed from the distance between the drill tip and the target point in image space when the surgeon pointed to the target in physical space. To examine TRE values with increasing depth from the surface in the phantom study, we used anatomical landmarks located approximately 30 and 60 mm from the surface of the temporal bone model (Fig. 4). In surgery, after completing the registration, we calculated TRE for the points on the temporal bone surface first. Whenever the surgeon found the anatomical landmarks during mastoidectomy, TRE was calculated and displayed on the monitor in real time. When measuring TRE, the surgeon's manipulation was assumed to be accurate. In fact, pointing to target landmarks in CT images and then pointing to the corresponding landmarks on the patient with one-pixel accuracy is almost impossible.

Calculation of the closest distance

Figure 5 shows the preoperative preparation for monitoring of the target organ. To obtain the surface voxel data of the facial nerve, surface rendering was performed for the segmented facial nerve from CT images. The surface-rendered facial nerve data were saved in standard triangulation language (STL) file format and the surface voxels of the facial nerve were extracted from this STL file. The surgeon then determined the safe distances (distance a, b and c) between the drill tip and the surface of the facial nerve. The risk increases with the distance to the facial nerve and the proposed system continuously calculates the closest Euclidean distance (d) between the drill tip and the nearest surface of the facial nerve (Fig. 6a). When the drill tip approached the surface of the facial nerve and entered safe zone *'A'*, *'B'* or *'C'*, the proposed system provided auditory feedback that gradually increased frequency, simultaneously with the visual text appearing on the monitor.

To accelerate the calculation of the closest distance, we performed collision detection using bounding spheres (Fig. 6b) [20, 21]. We separated the surface voxel data for the facial nerve into two or three parts and wrapped the data in the bounding sphere with a radius of 0.5 mm. When the drill tip approached the facial nerve, its sphere collided with a sphere of the voxel set. The closest distance was then calculated between the position of the drill tip and the surface voxel data. Each time the position of the drill tip was updated, collision detection was repeated and the distance was recalculated.

Assessment of the phantom study

The effectiveness of the proposed system was evaluated using the required surgical tasks with a temporal bone model. A young and inexperienced surgeon drilled 10 bone models following the procedure for a basic mastoidectomy in which the task was to maintain a 2-mm safe margin from the surface of the facial nerve (Fig. 7). Five models were resected with the proposed navigation system and the others were resected without the navigation system. The task was performed with two temporal bone models per day, for five days. The surgeon performed the first procedure with the proposed system and the second without the system to prevent a learning effect from influencing the results.

Preoperatively, the surgeon segmented the facial nerve from CT data and determined 3 safe distances from the surface of the facial nerve during drilling of the temporal bone (1, 3 and 5 mm). After completing registration, TRE were incorporated into the preoperative safe distances so that the final safe distances were 2, 4 and 6 mm. In order to compensate for patient movement, a reference marker was fixed on the temporal bone model. The audible warning to alert the surgeon was set at 900, 600 and 300 Hz for 20 ms as the drill tip approached the surface of the facial nerve. During drilling of the temporal bone model, the closest distance was computed in real time. The value of the closest distance was displayed and the warning sound was generated if the drill tip entered the safe region. After drilling, the bone models were subjected to CT scan and analyzed. Drilling accuracies with a margin of safety of 2 mm to the surface of the facial nerve were compared with and without the navigation system in thirteen CT slices near the facial nerve for each temporal bone model.

Clinical application

The proposed system was used in two cochlear implantation surgeries and an acoustic tumor resection performed by an experienced surgeon. Preregistered STAMP was applied and TRE was measured on the surface of the temporal bone model. Measured TRE was then incorporated into the predetermined safe distances (1, 3 and 5 mm) for final safe distances of 2, 4 and 6 mm. To confirm reliability and accuracy, the system was compared with a nerve integrity monitoring system (NIM, Medtronic Xomed, Jacksonville, FL) to identify the facial nerve (Fig. 8). Two types of NIM tools were used to monitor the facial nerve: a monopolar stimulator probe and a continuous facial nerve stimulating burr (Stim Bur Guard) that combines an electric drill with stimulation [22]. During mastoidectomy, the surgeon stopped drilling when he learned that the resected area in the bone was approximately 3 mm from the facial nerve. Based on the surgeon's experience, the NIM current was set at 0.8–1.0 mA for electrical stimulation approximately 3 mm from the facial nerve. The responses of the proposed system and NIM were then observed. For the case using the monopolar stimulator probe, the surgeon selected a point based on experience. When the monopolar stimulator probe and the tracked pointer device were alternately directed at that point, we examined the responses of NIM and the proposed system. To track the position of the drill tip and stimulate the facial nerve simultaneously when using the Stim Bur Guard, the surgeon used both the surgical drill with infrared markers attached to the end and the Stim Bur Guard. We investigated whether both systems generated auditory feedback at the same time.

Results

Accuracy of registration

The accuracy of registration was measured to evaluate the reliability of the navigation system and determine the safe distances (Table 1). Ten temporal bone models were used in the phantom study and the preregistered STAMP method was performed three times per temporal bone model. For thirty registrations, FRE was 0.40 ± 0.05 mm, and the TRE values for the surface of the bone model, the foramen lacerum (FL) and posterior cranial fossa (PCF) were 0.78 ± 0.04 mm and 0.66 ± 0.03 and 0.68 ± 0.04 mm, respectively. The time to complete the registration was 23.07 ± 1.93 s. In the 3 real surgeries, FRE was 0.35 ± 0.04 mm and the landmarks for the surface of the bone, the round window (RW) and porus acusticus (PA) were 0.71 ± 0.07, 0.77 ± 0.05 and 0.87 ± 0.06 mm, respectively. The time for registration was 26.67 ± 3 s. In determining a safe region, TRE values were incorporated into the predetermined safe distances.

Evaluation of the task in the phantom study

In the phantom studies, we investigated postoperative CT images to check the safe margin from the facial nerve after drilling of the temporal bone models, with and without the navigation system.

After performing the registration, TRE was measured and added to the predetermined safe distances (1, 3 and 5 mm) for final safe distances of 2, 4 and 6 mm. During drilling, the proposed navigation system alerted the surgeon using different audio sounds according to the safe distances (2, 4 and 6 mm) simultaneously with 3D real-time views of the drill tip location and visual text on a monitor (Fig. 9). After drilling the temporal bone, the safety margin to the surface of the facial nerve was checked using thirteen postoperative CT axial plane images from the resected area (a to a') (Fig. 10a). To assess the CT images, parameter d was defined as the Euclidean distance in the lateral direction from the surface of the facial nerve to the resected area (Fig. 10b). For the case of facial nerve injury, the value of d was set to 0. Figure 10c shows the distance d as a to a' after drilling of the bone models. The uniformity of the safe margin in the resected area appeared greater when using the navigation system. Four of the five bone models sustained iatrogenic facial nerve injury when drilling without the navigation system. In contrast, only one was damaged when drilling with the navigation system. Overall mean values of distance d were much less than 2 mm due to registration error and the surgeon's mental stress in maintaining the 2-mm margin of safety. We used the Student's t test for a statistical analysis of the error of a given safe margin. Comparing the two tasks statistically, the one with the warning navigation system (0.7 ± 0.25 mm) could be performed with a significantly higher accuracy than the conventional approach (1.37 ± 0.39 mm), with $P < 0.05$ (Fig. 10d). Based on the results of the phantom study, the proposed system is expected to be very effective for young and inexperienced surgeons.

Clinical application

After completing the registration, TRE (approximately 1 mm) was incorporated into the preoperative safe distances, thus the new safe distances were set at 2, 4 and 6 mm. During drilling, the surgeon confirmed the location of the drill, which was approximately 3 mm from the facial nerve. When the tracked pointer device and the monopolar stimulator probe were directed at the same point, both systems generated an audible alert (Fig. 11a). The proposed system provided auditory feedback as well as the distance and location of the drill tip on the monitor. NIM and the navigation system simultaneously generated auditory feedback when the drill tip neared the 3-mm area from the facial nerve and contacted the bone. Compared with conventional navigation systems, the proposed system made it possible for the surgeon to drill continuously while receiving auditory feedback without removing visual focus from the actual surgery (Fig. 11b). Additionally, the proposed system provided continuous and different warning sounds for each degree of risk according to the safe distances.

Discussion

Improvement of reliability

The two factors to affect the reliability of the system for patient safety were the registration and segmentation. In otologic surgery, a registration error with submillimeter accuracy is one of the most important requirements for patient safety. Although template-based markers have disadvantages such as dislocation and bad fit [23, 24], the proposed preregistered STAMP method was suitable for otologic surgery because it is highly accurate, simple and noninvasive [17, 18] (Table 1). The preregistered STAMP method uses not only virtual surface points determined from CT data, but also anatomical landmarks inside the temporal bone model, to obtain high accuracy. Increasing and spreading points for registration over a wider area by obtaining deeply seated anatomical points inside the temporal bone model resulted in reduction of TRE [24, 25]. The accuracy of the segmentation was also considered to affect the reliability of the proposed system, because inaccurate segmentation of the facial nerve leads to errors computing the closest distance. Manual segmentation for the facial nerve was more accurate than other methods such as auto segmentation [13]. Thus, although it was time consuming and labor intensive, the surgeon manually segmented all structures except the temporal bone using the module of “Editor” in 3D Slicer.

Time delay of the system

There was a time delay between generating the alarm and repositioning the surgical devices. Even using acceleration algorithms to reduce data calculation, the delay was approximately 500 ms. The delay was caused by transferring data from the tracker system to the 3D Slicer software and the updating frequency of the tracker system. Fortunately, it did not significantly affect the performance of the warning system in the clinical applications because the surgeon moved the drill very slowly in the vicinity of critical anatomy. To minimize the risk caused by the delay, we used multiple step warning sounds depending on the degree of risk, as this allowed the surgeon to know the current risk and possible margin before approaching the region of highest risk.

Possible applications

The facial nerve is one of the most important organs to preserve in otologic surgery. Fortunately, an approximate location can be determined and monitored by electrical stimulation, which helps to reduce the risk of iatrogenic injury. However, other important organs are not responsive to electrical stimulation, which helps to reduce the risk of iatrogenic injury. However, other important organs are not responsive to electrical stimulation and cannot be monitored during surgery. In addition, the distance from the drill tip to other anatomical structures is important information, even when approaching the facial nerve. To address this, the proposed system monitors and provides auditory feedback to maintain safe distance without physical contact, for organs such as the cochlea, semicircular canals and internal acoustic canal, when the surgeon wants to know the distance to these organs (Fig. 12). This system can also be applied to other anatomical fields that require image-guided surgery.

Comparison with NIM system

In actual surgery, when using the Stim Bur Guard, we have yet to determine the most appropriate warning sound to attract the surgeon's attention without causing confusion or distraction, because the proposed system and NIM generated similar feedback sounds at the same time. Although the simultaneous warning demonstrates that the navigation system is working at least as accurately as NIM, the simultaneous warning may confuse or distract the surgeon. Thus, future clinical tests of the system should carefully consider the sound frequency, amplitude, and switching on/off so they are easily distinguishable without the confusing or distraction. We may need to turn on the sound only when the warning is required for critical moments.

The proposed system and NIM complement each other during surgery and, for patient safety and the reliability of the system and, the two systems are best used together. To validate the proposed system using NIM, points 3 mm from the facial nerve and a NIM current of 1 mA for 3 mm were determined, based on the surgeon's experience and opinion. Without intraoperative CT scanning, it is very difficult to accurately identify a distance 3 mm from the facial nerve. However, during temporal bone dissection, the surgeon could identify the region using anatomical landmarks, changes in bone color and texture [26, 27]. Additionally, the responses of the facial nerve to electrical stimulation differed between patients, so the current of the Stim bur guard should be carefully determined. More clinical tests are required to investigate the reliability and clinical feasibility of the proposed system and determine the correlation between the system and NIM in actual otologic surgery.

Conclusions

We developed a warning navigation system for otologic surgery. The proposed system computed the closest distance between the drill tip and critical organs, and provided different warning sounds for various degrees of risk. It also displayed the exact distance from the drill tip to the facial nerve in real time. The phantom study showed that the proposed system could help to preserve the facial nerve, particularly for a young and inexperienced surgeon. The clinical feasibility of the navigation system was investigated with a facial nerve monitoring system in real surgeries. The proposed navigation system potentially helps to enhance patient safety in otologic surgery, and may be applicable to other fields to protect important organs.

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Conflict of interest We certify that there is no real or potential conflict of interest in relation to this article.

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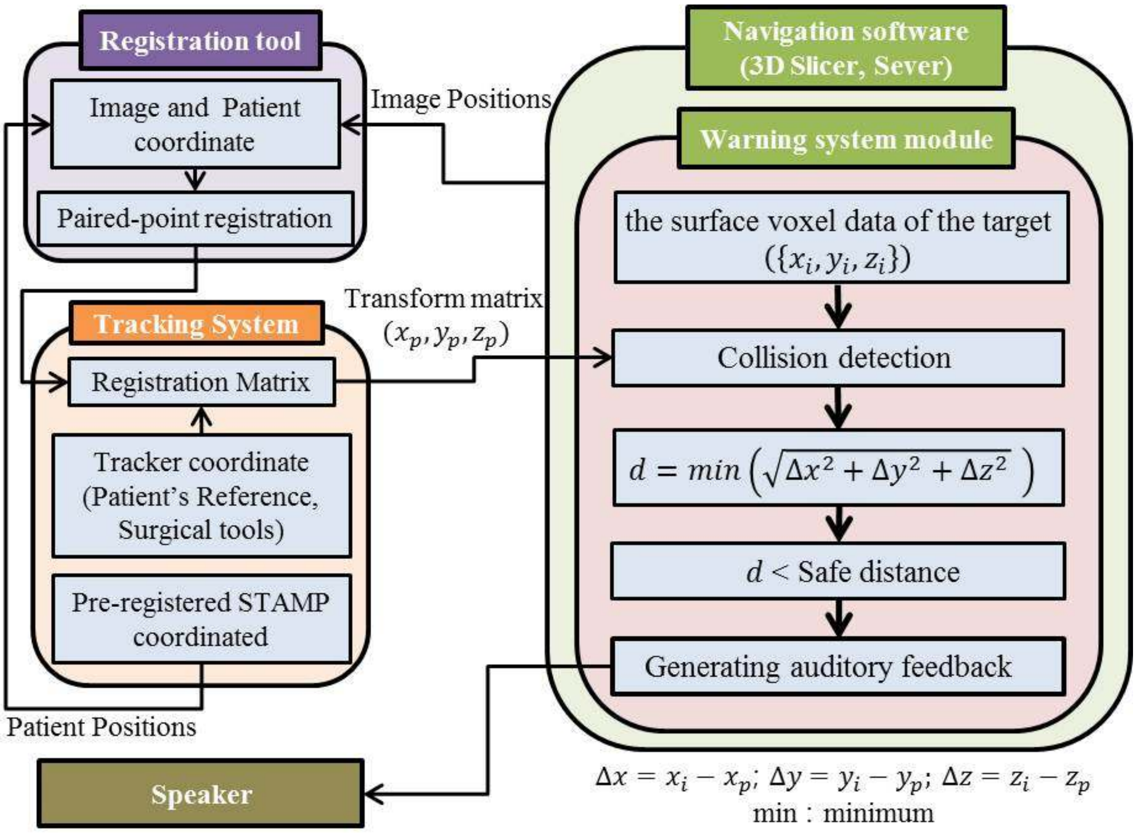
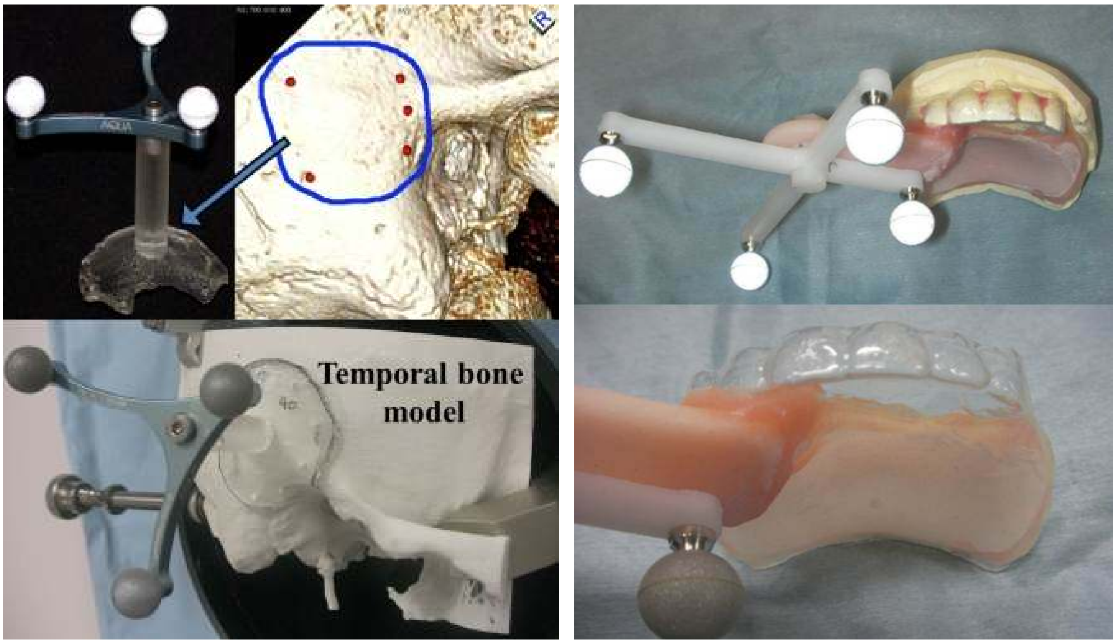


Fig. 1 Configuration of the warning navigation system



(a) (b)

Fig. 2 Preparation for registration. **a** template on the temporal bone model and **b** patient-specific tooth template as a reference marker for tracking the patient's head movement

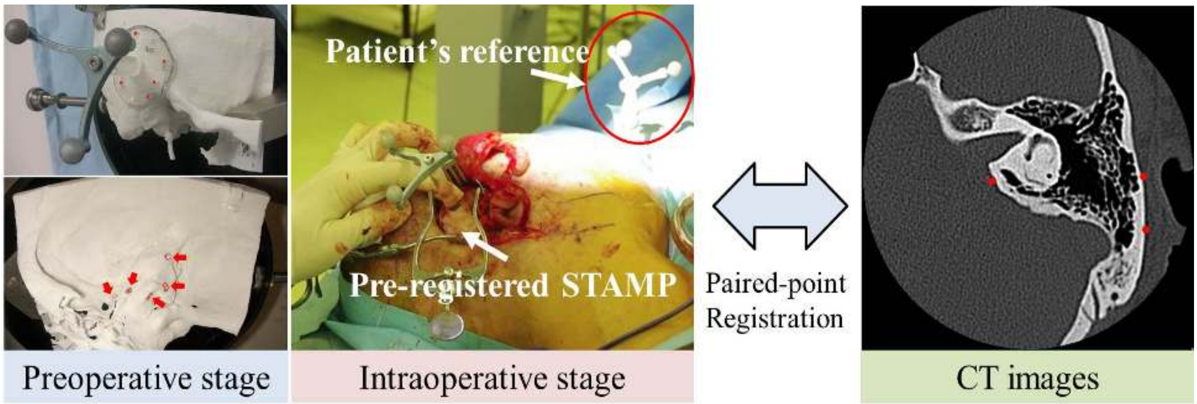


Fig. 3 Paired-point registration using a pre-registered STAMP registration method

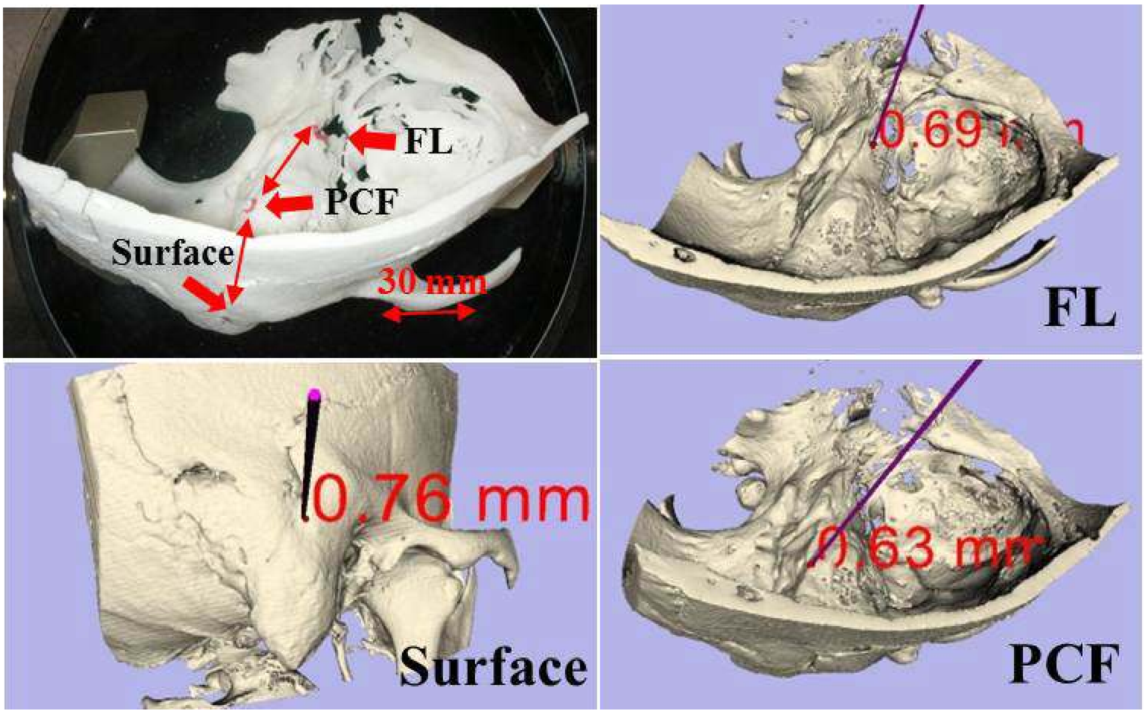


Fig. 4 TRE values for anatomical landmarks approximately 30 mm and 60 mm from the surface

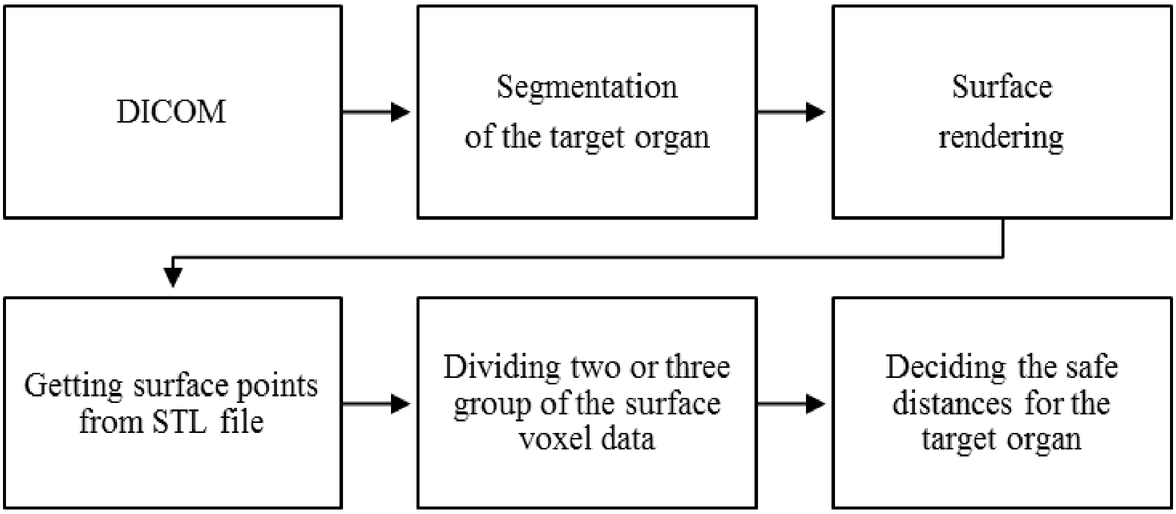
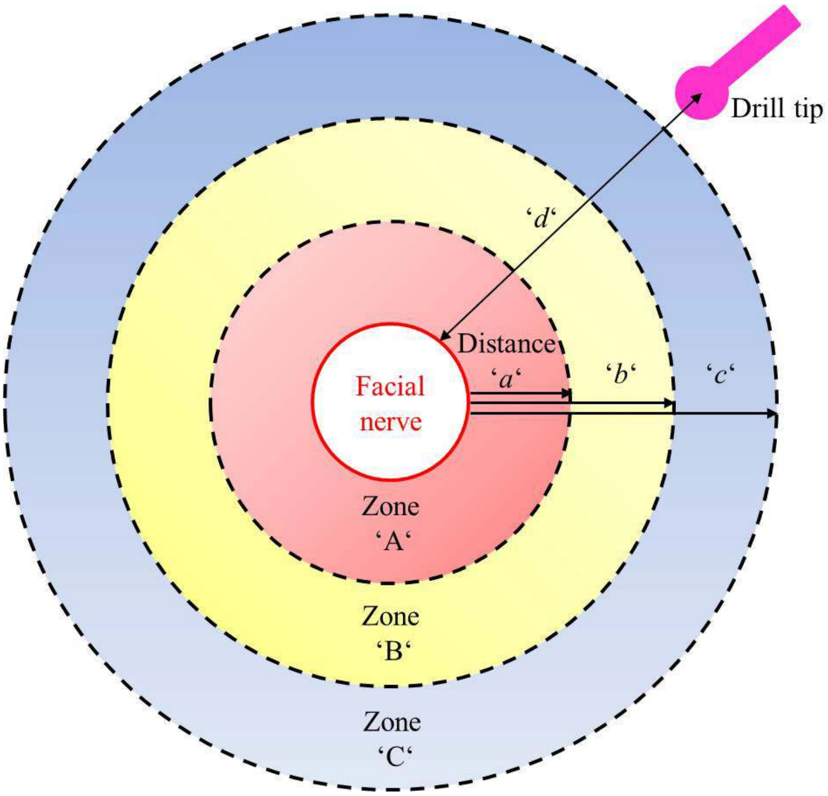
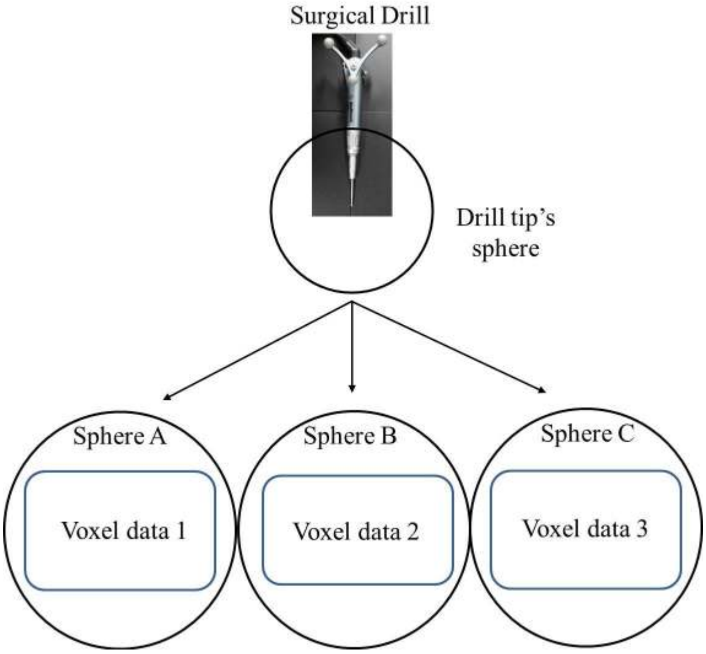


Fig. 5 Preoperative preparation for monitoring of the target



(a)



(b)

Fig. 6 Calculating the closest distance between the drill tip and the surface of the facial nerve. **a** the degree of risk when the drill tip approached the surface of the facial nerve and **b** method for reducing computing time when calculating the safe distance

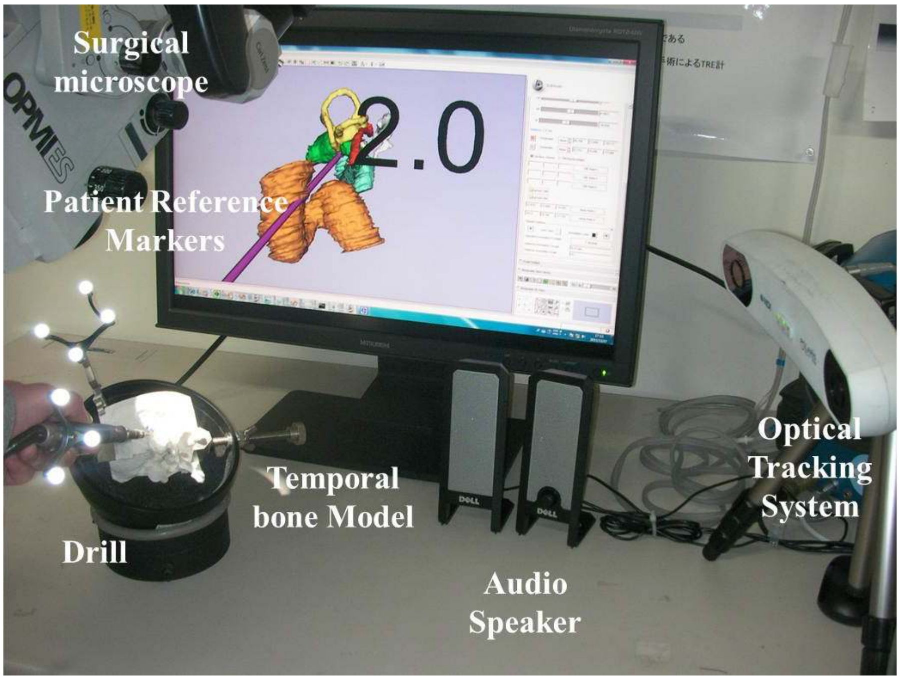


Fig. 7 Experimental set-up for the warning system in the phantom study

Fig. 8 Intraoperative set up for the navigation system

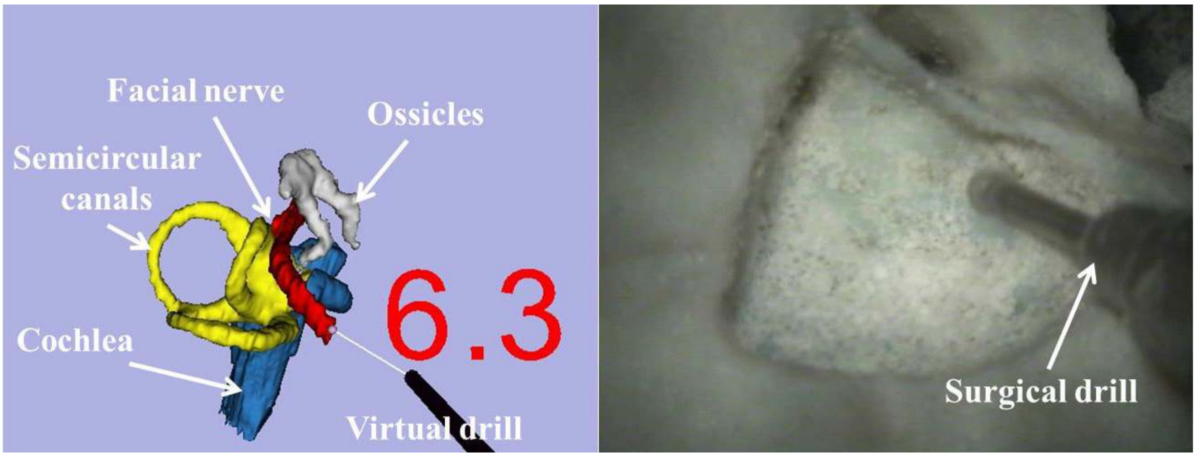
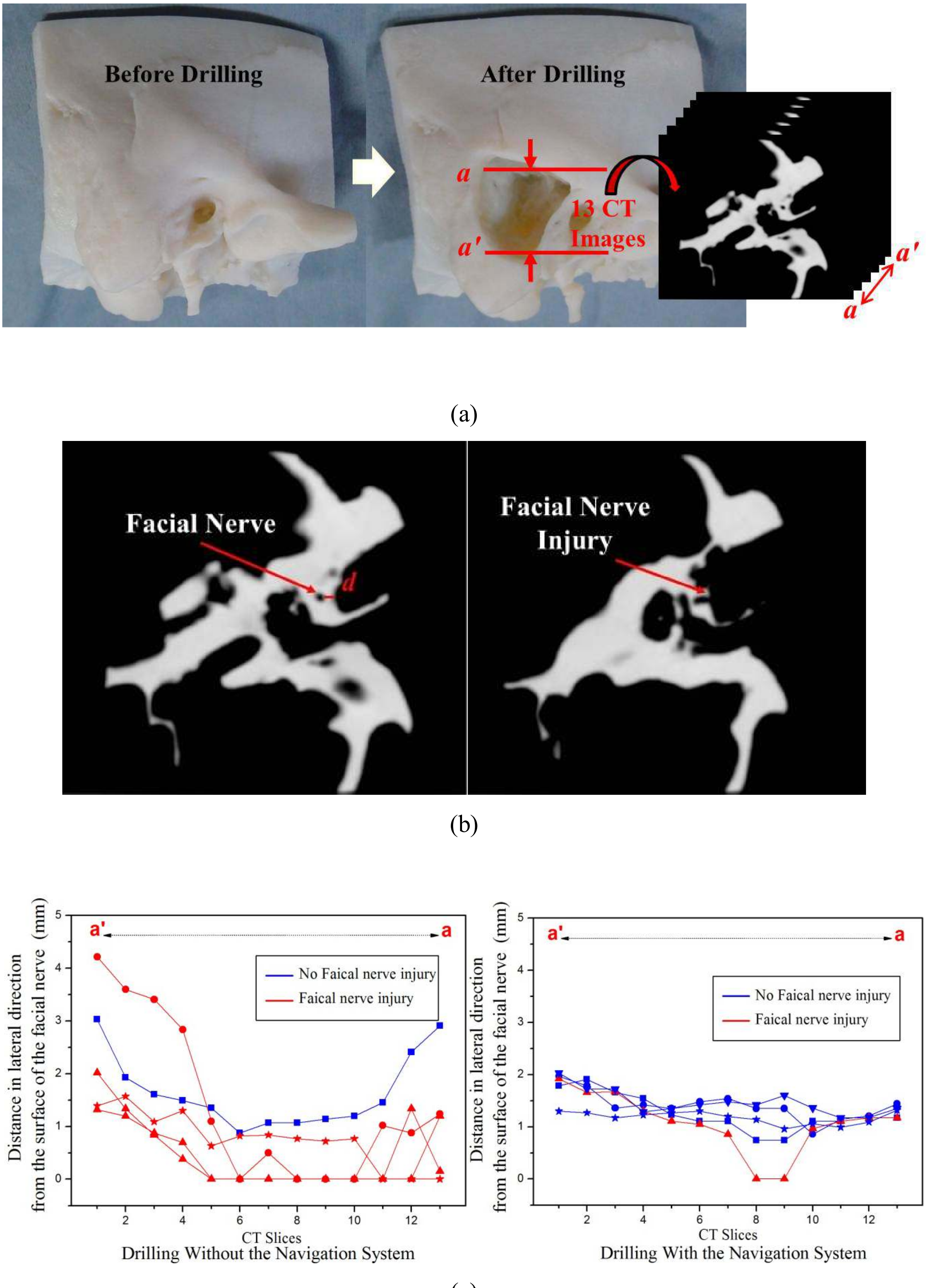


Fig. 9 The drilling task of maintaining a desired safety margin to the surface of the facial nerve in the phantom study

Before Drilling
After Drilling
a
a′
13 CT Images
a′
a
(a)
Facial Nerve
d
Facial Nerve Injury
(b)
Distance in lateral direction from the surface of the facial nerve (mm)
a'
a
No Faical nerve injury
Faical nerve injury
0
1
2
3
4
5
2
4
6
8
10
12
CT Slices
Drilling Without the Navigation System
Distance in lateral direction from the surface of the facial nerve (mm)
a'
a
No Faical nerve injury
Faical nerve injury
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8
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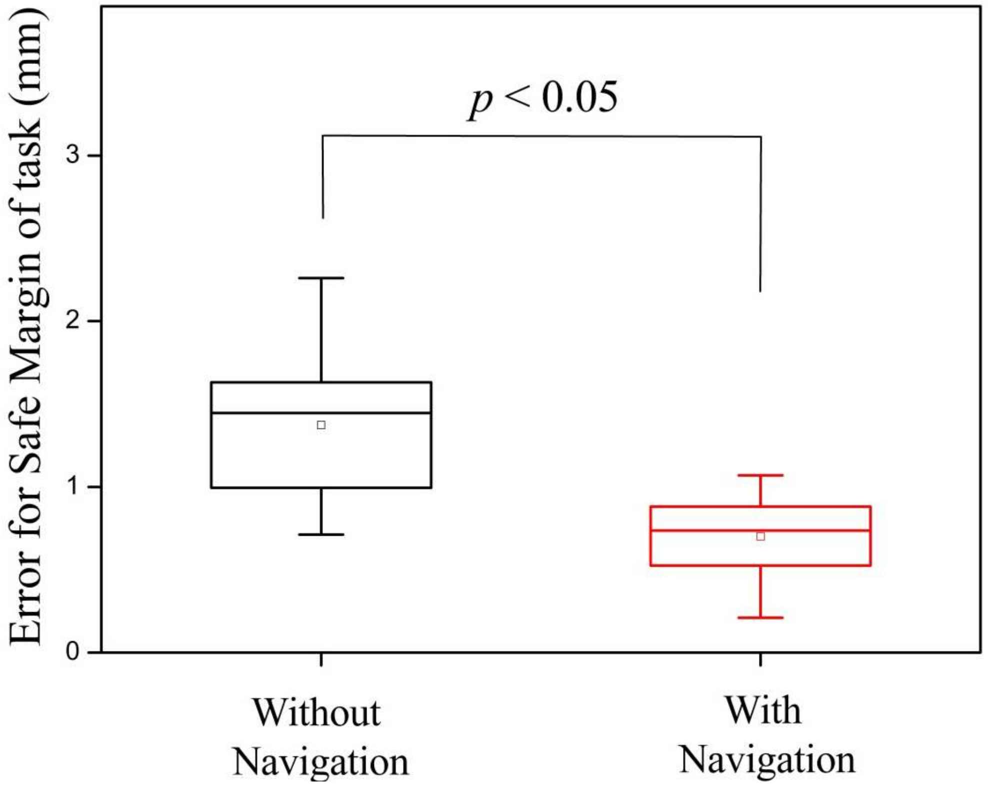
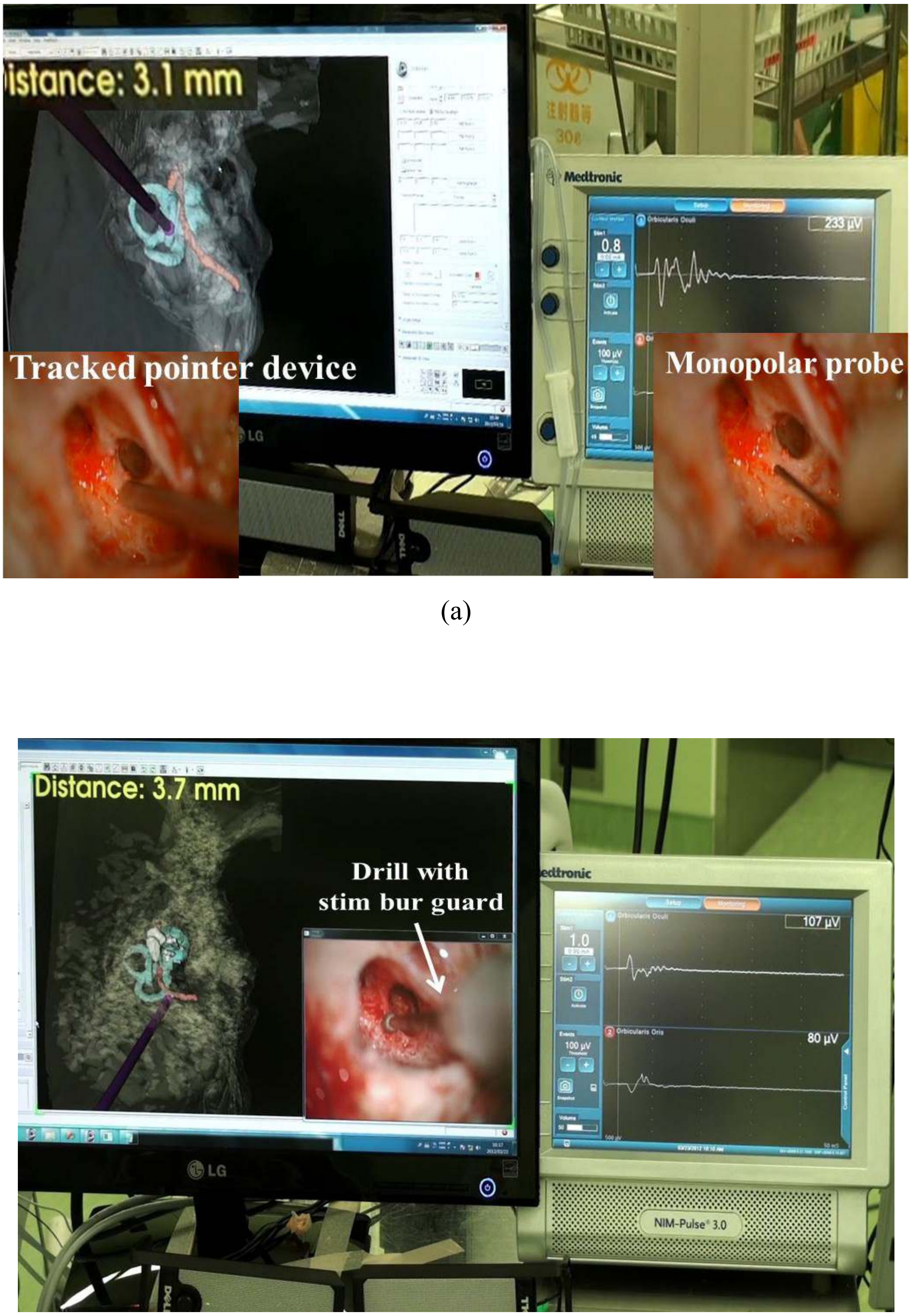
12
CT Slices
Drilling With the Navigation System
(c)



(d)

Fig. 10 Warning system evaluations. **a** the bone model before and after drilling, **b** distance *d* and facial nerve injury in CT images of a bone model after drilling, **c** distance *d* from the surface of the facial nerve after drilling the temporal bone model in the phantom study, **d** comparison of error of the safe margin with and without the warning navigation system



(a)

(b)

Fig. 11 Facial nerve monitoring using the warning system in a clinical application in real-time. **a** the tracked pointer device and the monopolar stimulator probe directed at the same point approximately 3 mm from the facial nerve and **b** continuous drilling of the bone using the surgical drill with the Stim Bur Guard

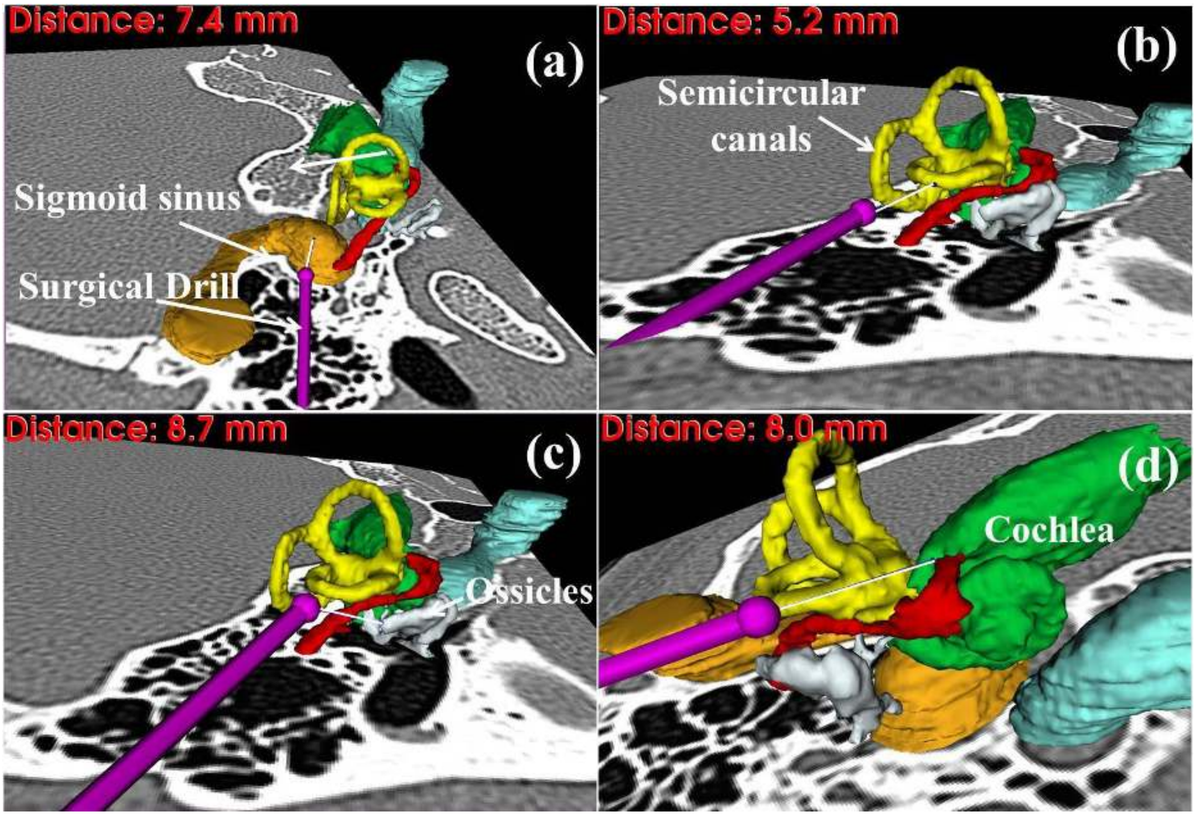


Fig. 12 The proposed system can monitor the closest distances between the drill tip and a variety of organs when the drill tip approaches the facial nerve. **a** sigmoid sinus, **b** semicircular canals, **c** ossicles, **d** cochlea

Table 1 Errors in phantom studies and clinical application (mean ± SD)

	FRE (mm)	**TRE (mm)**			**Processing Time For Registration (s)**
		Surface	PCF (RW)	FL (PA)	
Phantom study (*N*=30)	0.40±0.05	0.78±0.04	0.66±0.03	0.68±0.04	23.07±1.93
Clinical application (*N*=3)	0.35±0.04	0.71±0.07	0.77±0.05	0.87±0.06	26.67±3.1

FRE: fiducial registration error; TRE: target registration error; PCF: posterior cranial fossa; FL: lacerum; RW: round window; PA: porus acusticus