SurgView-RFT Electromagnetic Navigation System in Trigeminal Ganglion RF Therapy

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***Abstract*—Percutaneous radiofrequency thermocoagulation of the trigeminal ganglion (PRTTG) is demonstrated as the first choice for most patients suffering trigeminal neuralgia (TN). The purpose of this study was to assess the safety and efficacy of SurgView-RFT electromagnetic navigation system in PRTTG therapy of intractable TN. Experiments including head model of human, live goat, cadaver guarantee the accuracy of the system. 3 cases of TN were underwent CT positioning with RFT in our department after a follow up observation of 3-24 months. All the patients got successful procedure with pain relief and without recurrence and complications such as hematoma, tinnitus and corneal palsy. SurgView-RFT electromagnetic navigation system overcomes the disadvantage of traditional positioning method and is a safe and promising method for treatment of intractable TN with better short- and long-term outcomes and lower complication rate. It is proved that the system has significant clinical clinical value.**

Keywords- riegeminal neuralgia, SurgView-RFT navigation system, trigeminal ganglion,, ovale foramen

I. INTRODUCTION

Trigeminal neuralgia (TN) is defined by the International Association for the Study of Pain as "a sudden, usually unilateral, severe, brief, stabbing, recurrent pain in the distribution of one or more branches of the fifth cranial nerve[1]. The incidence rate is about three to five cases per year per 100,000 persons and increases with age [2].

Taha and Tew [3] analyzed the results of different surgical procedures from several medical centers, and concluded that radiofrequency (RF) rhizotomy and microvascular decompression (MVD) result in the highest rates of initial pain relief and the lowest rates of pain recurrence. MVD is more dangerous and expensive than radiofrequency thermocoagulation (RFT) of the trigeminal ganglion(TGG). So it is accepted by many patients because of its safety and simplicity. Moreover, RFT is highly selective for the trigeminal ganglion damage leading to a low complication rate. Therefore, some neurosurgeons regard Percutaneous radiofrequency thermocoagulation of the trigeminal ganglion (PRTTG) as the first choice for most patients suffering trigeminal neuralgia (TN) [1, 2, 4, 5].

We knew that some limitations still exist in traditional localization method to monitor needle positioning in the oval foramen (OF) and the operator is at risk of X-ray irradiation.

First, incorrect positioning was one of the main causes of complications. Before the needle is pushed into the oval foramen, it can enter into the inferior orbital fissure and damage the optic nerve or other nearby cranial nerves if the positioning is overly prorsad. The internal carotid artery, jugular foramen, and cranial nerves can be damaged if the positioning is too far to the rear. The internal carotid artery, cavernous sinus, and nearby cranial nerves in the lateral wall can be damaged if the needle is inserted too deeply or over-medially into the oval foramen [6].

Second, complications included facial hypesthesia, corneal reflex torpidity, subconjunctival hemorrhaging, facial hypodermic effusion of cerebrospinal fluid, Subcutaneous hemorrhaging and masticatory atonia [7] were found in patients because it is typically hard for the needle to push into the corresponding area of the branch for TGG accurately and there is low possibility to accomplish branch selective RFT.

Neuronavigation has been widely applied in the treatment of trigeminal neuralgia RFT therapy [7-9] to solve the problems above. Researches on this area are popular recently at home and abroad [10-12]. But there are two pitfalls: First, the optical tracking device used in navigation systems is not so popular for its cumbersome equipments and bad accuracy if there are obstructions by patients, surgeon and surgical instruments. Second, it is hard to achieve the branch selective RFT as the operation interface targets at puncturing through OF based on CT without TGG delineation.

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In this investigation we specify a new neuronavigation system named SurgView-RFT electromagnetic navigation system with operation interface displaying CT and TGG at the same time. It uses NDI AURORA as the tracking device, which has the advantages over the traditional optical tracking device for its flexibility when scanning a patient, less radiation injury and smaller size.

II. PROPOSED MEDICAL WORKFLOW

For the described application of SurgView-RFT electromagnetic navigation surgical system, a workflow (Steps 1–7) is needed to integrate with the current treatment processes (Fig. 1). The planning CT and MRI are usually performed with the patient fixed onto a head pad with a thermoplastic mask individually molded. This minimizes the spatial deviation between the anatomy depicted in the CT and MRI scan and the surgical puncture.

1) Equipment setup. Electromagnetic tracking device was obtained form NDI AURORA. Leksell radiofrequency instruments were from Elekta Ltd.(Sweden). Coordinate reference thermalplastic mask (Fig. 2) was form Chengdu Hongyun medical device company. All CT examinations are performed with a GE (USA) LightSpeed scanner in 16-spiral way.

2) In all the cases, contrast enhanced CT and MRI were routinely performed to exclude any lesion or tumor in the cerebellopontine angle, petrous apex, cavernous sinus, and cranial base. Electrocardiograms and chest X-rays were evaluated before surgery. The entire cranium should be scanned in CT image and the range from eyebrow to muzzle skull should be scanned in MRI.

3) The data of CT and MRI were loaded into the SurgView-RFT navigation system. Preoperative preparation include complete TGG segmentation in MRI image, registration and fusion of CT and segmented MRI data and the establishment of the operation path (Fig. 3(a)) .

4) System calibration. In order to obtain the position and orientation of the image plane with respect to the tracker's world coordinate system, a calibration is necessary to derive the transformation that relates the image plane to the tracking sensor coordinates, as will be described in Section III Experiment A.

5) Percutaneous radiofrequency thermocoagulation of the trigeminal ganglion was performed under local anesthesia with dorsal positioning and Hartel's technique. Surgeon can adjust the position and depth of the needle in real time under the navigation guidance (Fig. 3(b)).

6) CT scan and square-wave test is performed to verify the accuracy of puncture.

7) Radiofrequency coagulation was carried out at 80°C for 300 seconds. Antibiotics were given to prevent infection during the surgery.

In the following sections, we describe the setup and results of experiments used for validation.

III. EXPERIMENTAL RESULTS

The main factors affecting navigation accuracy come from the following four aspects [18]: First, the navigation system errors; Second, the accuracy of the image data; Third, the selection of the reference coordinates and its registration; Fourth, tissue shift during the operation. It can be figured out that error from the navigation system is the smallest and that from the AURORA electromagnetic tracking device can be controlled within 0.2mm. Image data with DICUM (Digital Image and Communications in Medicine) standard maintain the maximal original information, which is one of the best ways to obtain the data with its error less than 0.4mm [17].

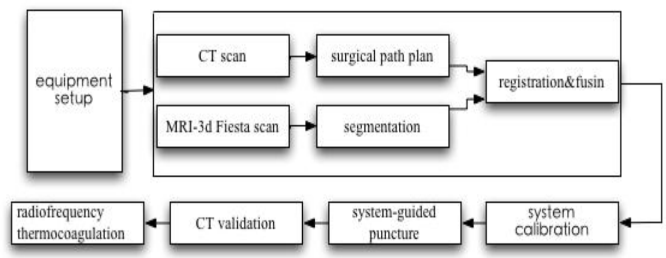


Figure 1. Workflow of the application of SurgView-RFT system

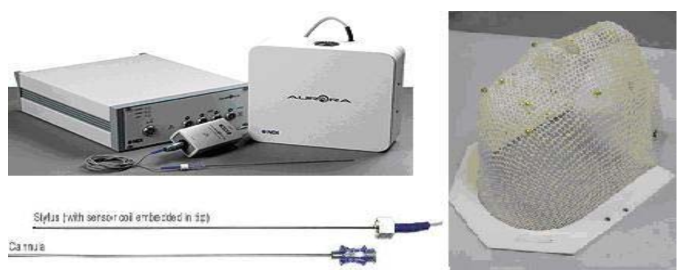
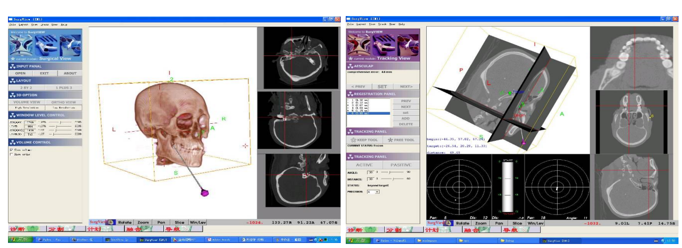


Figure 2. AURORA tracking device(left) and thermalplastic mask(right)



(a) (b)

Figure 3. SurgView-RFT system (a) preoperative preparation (b) real-time navigation

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Before the clinical application of SurgView-RFT navigation system, experiments are performed on thermoplastic masks, cadaver and goat to verify the accuracy of the system. Errors from reference coordinates will be verified in Experiment A and that from soft tissue shift will be verified in Experiment C. Experiment B shows the value of SurgView-RFT navigation system in reducing the puncture failure rate and iatrogenic injury.

A. Head Mould

The accuracy of SurgView-RFT navigation system is the key to achieve its clinical value. For the FO is less than 5mm in diameter in particular, the system accuracy is critical to avoid straying into other pores. This experiment was performed on the head module developed by our group for precision testing to determine whether the navigation system error is less than 2mm (Fig. 4(a)).

We made the head mould by putting the thermoplastic mask into the hot water to simulate the head after it is cool and adding six plastic landmarks on its surface and internal respectively. All the landmarks are hollow so that they are helpful for needles to position and can add the stability and reduce the error (Fig. 2).

First, 16-slice CT (spiral computed tomography, SCT) (LightSpeed, GE, USA) scanning is taken, in which the materials and landmarks is visible. Second, we put the head module in front of the tracking device and choose four (inside 2 and outside 2), six (inside 3 and outside the 3), eight (inside 4and outside 4) landmarks for registration. For each experiment (with the same number of landmarks), tests were performed 5 times using a different combination of landmarks.

The result is that the system error is 1.58±0.25mm, 1.28±0.21mm and 1.06 ± 0.10 mm respectively when we select four, six and eight landmarks. It demonstrated that SurgView-RFT electromagnetic navigation system fully met the specific requirements for puncturing foramen ovale and was in line with the general accuracy of navigation systems. There was no significant difference whether six landmarks or eight landmarks is taken. It demonstrates that Clinical use of the system can reduce the failure rate of puncture and iatrogenic injury.

B. Live Goat

Percutaneous radiofrequency thermocoagulation of the trigeminal ganglion was performed with Hartel's technique which makes it essential to pass the soft tissue in cheek. Soft tissue movement is the main factor affecting the navigation accuracy. The displacement of cerebral cortex is up to 10mm [13-15]. This study was intended to simulate puncture with Hartel's puncture on live animals (goats) to test the accuracy of surgView-RFT Navigation system (Fig. 4(c)) . Because of goats' skull structure is different from primates, puncture with Hartel's technique can only get to the infraorbital foramen (IOF).

Three green hands punctured OF though IOF way on six-month old goats five times with and without the guidance of SurgView-RFT electromagnetic navigation system respectively. We statistically analyzed the results with laminal basicranial CT scans as a gold standard (Software: SAS 6.12). The result (Table II) showed that none of the three experimenters puncture into IOF without navigation and the average distance between the tip of needle and the center of IOF was 14-15mm, while all of the three experimenters punctured into IOF successfully with navigation. The average deviation in the soft tissue is 4.3mm/6.2 ° and the average distance between the tip of needle and the center of IOF is 2.7-2.8mm. There were significant differences on the success rate whether the experiments are under the guidance of the system or not.

C. Cadaver

It is hard for a green hand to puncture OF accurately which will lead to unnecessary iatrogenic injury and hamper the application and promotion of RFT therapy. SurgView-RFT navigation system established a dynamic link between the virtual digital image and the actual anatomical structure based on CT scan. Our system was developed to contain preoperative planning and intraoperative navigation functions, in which puncture path can be setup before the surgery and the deviations in distance and angle of needle from the path plan can be displayed in real-time, so that the system could help the surgeon the adjust the path to reach the target.

Three green hands punctured OF on cadaver five times with and without the guidance of the electromagnetic navigation system (Fig. 4(b)). We statistically analyzed the results with laminal basicranial CT scans as a golden standard (Software: SAS 6.12). The result shows (Table I) that none of the three experimenters puncture into OF without navigation and the average distance between the tip of needle and OF is 8-9mm, while all of the three experimenters puncture into OF successfully with navigation and the error of the system is 0.5-0.6mm compared with CT. There are significant differences on the success rate whether the green hand is with the navigation.

Therefore SurgView-RFT electromagnetic navigation system can be used as training aids for green hands to get familiar with the anatomical structure and RFT therapy process.

SurgView-RFT electromagnetic navigation with the alarm system checking whether the real-time trajectory is in line with the designated trajectory can lead experimenters to reach the target by displaying the deviation on distance. Despite the diameter of IOF is much larger than OF, the deviation of the needle from the center of OF was within 3mm, less than the diameter of the planned path. So SurgView-RFT electromagnetic navigation system can overcome difficulty by the soft tissue drift in cheek and satisfy the accuracy requirement.

D. Clinical Application

It is shown in the former experiments that SurgView-RFT electromagnetic navigation system is featured with its small interference, simple operation and high-precision. Image segmentation in MRI data and fusion of MRI and CT in TGG upgrade the RFT operation interface from simply CT based to coexistent CT and MRI data. The target is TGG which is the

TABLE I. POSITIONING ERROR IN PUNCTURING OF IN CADAVER

Experimenter	**Positioning accuracy**			
	without navigation (mm)	***without navigation (mm)***	***t test (mm)***	***P test (mm)***
Ⅰ left-side	10.6±4.219	3.16±1.242	3.7826	0.0149
Ⅱ left-side	7.4±3.435	2.80±0.919	2.8926	0.0385
Ⅲleft-side	9.6±4.669	3.32±0.390	2.9971	0.0395
Ⅰ right-side	8±2.449	2.82±0.998	4.3788	0.0024
Ⅱ right-side	8.6±2.881	3.42±0.726	3.8986	0.0145
Ⅲright-side	8±3.391	3.38±0.669	2.9888	0.0373

TABLE II. POSITIONING ERROR IN PUNCTURING OF IN LIVE GOAT

Experimenter	**Positioning accuracy**			
	without navigation (mm)	***without navigation (mm)***	***T test (mm)***	***P test (mm)***
Ⅰ left-side	15.00±6.083	2.800±1.483	4.3571	0.0098
Ⅱ left-side	15.2±6.723	3.00±1.2247	3.992	0.0147
Ⅲleft-side	14.8±7.758	2.60±1.341	3.4646	0.0239
Ⅰ right-side	15.20±5.069	2.60±1.140	5.422	0.0045
Ⅱ right-side	13.8±5.630	2.80±1.303	4.256	0.0109
Ⅲright-side	13.8±4.550	2.60±1.516	5.222	0.0008

principal part of RFT therapy instead of the traditional OF (Fig. 4(d)).

In this study, our SurgView-RFT electromagnetic navigation system will applied to the patients with TN with RFT therapy and make further evaluation of its clinical value, including a total of 1 female and 2 male patients, with a mean age of 53.3±5.9 years. Among them, 2 cases were affected on the right side and 1 cases on the left side. Symptoms in all cases had been present for 6 months to 5 years. Two patients were suffering simultaneously from hypertension. Medication is considered the first choice of treatment for TN. Percutaneous radiofrequency thermocoagulation was performed when drug treatment failed because of ineffectiveness or severe side effects.

We performed the therapy just as the workflow described in Section II. The patients in the navigation group were positioned supine with the head rising slightly fixed with a head mould,. 2% Lidocaine was used for local anesthesia. The patients were lightly sedated with propofol.

In order to obtain the position and orientation of the image plane with respect to the tracker's world coordinate system, a calibration is necessary to derive the transformation that relates the image plane to the tracking sensor coordinates. After the registration, as soon as surface matching was finished, the navigation system was visualized to acquire points and report the accuracy of the registration. A registration is considered successful if the deviation is less than or equal to 2.0mm.

Along the long axial orientation of the oval foramen, the target position in the trigeminal ganglion was made and the puncture channel of Hartel's frontal approach was designed. A radiofrequency electrode with 1-mm noninsulated tip was used for the surgical procedure, which was fixed with reference arcs. After successful registration, the electrode was positioned in the TGG via the oval foramen under the navigation guidance (Fig. 4(e)). The position of electrode tip in the trigeminal ganglion was adjusted according to the sensory and displayed in the software interface. The tip of electrode was tracked in real time by the neuronavigation system (Fig. 3(b)). Once the region of stimulation response was consistent with the distribution of the trigeminal nerve, PRTTG was performed with the reversible radiofrequency coagulation. Thereafter the sensitivity of the face and cornea were tested. The treatment was performed 2 to 3 times until the pain disappeared completely and the sense of touch was blunt while adjusting the position of electrode tip in the trigeminal ganglion. Antibiotics were given to prevent infection during the surgery.

All of the three patients had a successful puncture with the average time 2'44 ". CT scan and square-wave test were performed to verify the correct location of the puncture. In all cases, pain disappeared, masticatory atonia were not found and the sense of pain in the first dominate region was remained.

It demonstrated that the application of SurgView-RFT electromagnetic navigation system on the percutaneous radiofrequency thermocoagulation in the treatment of intractable trigeminal neuralgia will improve the accuracy, shorten the time and reduce the complications.

IV. CONCLUSION

We developed methods for the integration of electromagnetic tracking device into RFT therapy and developed the SurgView-RFT navigation system in which we added the dynamic view of the surgical path and the function of segmentation and fusion to make it possible for OF and TGG to be displayed simultaneously. After system calibration by the head mould, experiments on cadaver and live goats to verify the clinical feasibility of the system, our system is applied for clinical.

First, the SurgView-RFT navigation system can improve the success rate of puncture and reduce the puncture injury, which acknowledged wide use of RFT in treatment of trigeminal neuralgia.

Second, electromagnetic tracking device has advantages over the traditional optical one for its flexibility when scanning a patient, less radiation injury and smaller size.

Third, the system error after registration was only 1.06 ±0.10mm and puncture error was 0.6mm with CT examination which met the accuracy requirements the navigation system.

Fourth, SurgView-RFT electromagnetic navigation system featured with time-saving, efficient and minimally invasive characteristics not only can be used as pre-clinical training system but also can achieve a better branch selection and

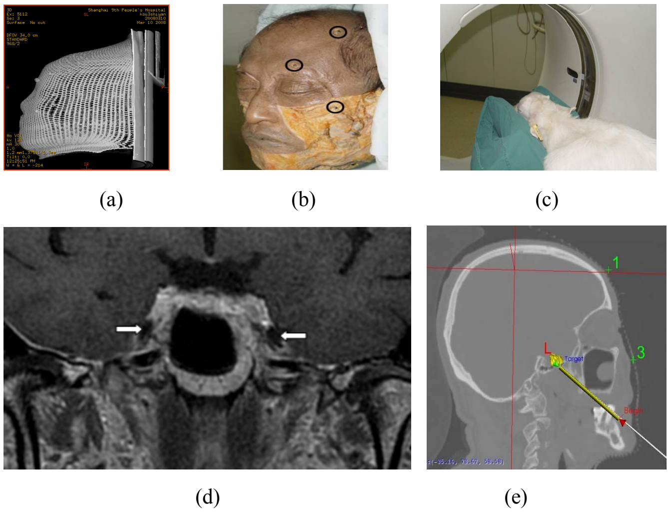

Figure 4. Different experiments used for evaluation: (a) head mould (b) cadaver (c) live goat (d) MRI of TTG (f) navigated puncturing in system

reduce the rate of corneal reflex torpidity and masticatory atoniacorneal.

However, our work is insufficient such as the number of clinical cases is too small, short follow-up period and the lack of anatomical verification of MRI data on TGG. Works will be done in the near future such as increasing the number of clinical cases so as to achieve better clinical value, expanding the application of SurgView-RFT electromagnetic navigation system like electrode measurement on visualized TGG, partitioning and preciously selecting the TGG branch.

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