Journal of Neuroscience Methods 291 (2017) 190–197

Contents lists available at ScienceDirect

Journal of Neuroscience Methods

journal homepage: www.elsevier.com/locate/jneumeth

A novel stereotaxic system for implanting a curved lead to two intracranial targets with high accuracy

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HIGHLIGHTS

- A new stereotaxic system for implanting a curved lead is fabricated.
- Following the "curved lead pathway" method, a single curved lead can be implanted to any two selected intracranial targets.
- Curved lead implantation is highly accurate.

ARTICLE INFO

Article history:
Received 20 May 2017
Received in revised form 1 August 2017
Accepted 14 August 2017
Available online 20 August 2017

Keywords:
Stereotaxic system
Deep brain stimulation
Three-dimensional printing
Parkinson's disease

ABSTRACT

Background: The multi-target deep brain stimulation (DBS) aimed at improving symptoms related to different nuclei is a promising research direction. However, to implant a single lead into multiple targets simultaneously is difficult with the current lead implantation method.
New method: We proposed a novel stereotaxic system used for implanting a curved lead to any two targets of the brain, and used the theoretical "curved lead method". First, a customized novel stereotaxic system was fabricated, and a solid cranial model with six fixed internal targets was made; second, CT scan was performed to locate the fixed internal targets; third, five curved leads were implanted to five selected pairs of targets, each following the calculated parameters of "curved lead pathway" with the novel stereotaxic system, respectively. Finally, CT scans were performed again to determine the exact locations of the curved leads.
Results: The five curved leads accurately passed through the five pairs of combined targets, respectively, and the average vector error of curved lead implantation was 0.70 ± 0.24 mm.
Comparison with Existing Method(s): In most situations, performing a multiple-target DBS procedure with the current stereotaxic systems means increased number of implanted leads, increased incidence of operative complications, and increased medical costs. However, the novel stereotaxic system could guide a single lead to reach two selected targets of the brain with high accuracy.
Conclusions: The novel stereotaxic system enables curved lead implantation with high accuracy, and can be considered as a useful complement to the current stereotaxic system.

1. Introduction

Deep brain stimulation (DBS) is a promising surgical treatment option for certain movement disorders (Delorme et al., 2016; Krause et al., 2016; Okun, 2012; Odekerken et al., 2013). It has been reported that the quadruple-targeted DBS might lead to better improvement of motor and gait scores compared to dual-targeted DBS in advanced Parkinson's disease (PD) patients (Stefani et al., 2007; Peppe et al., 2010; Khan et al., 2012), and the dual-target DBS yielded greater improvement than the single target DBS in idiopathic hemidystonia (Goulenko et al., 2017), hemidystonia (Slotty et al., 2015), holmes tremor (Romanelli et al., 2003), Huntington's disease (Gruber et al., 2014), and intractable involuntary movements (Nakano et al., 2015). Therefore, multi-target DBS aimed at improving symptoms caused by different mechanisms related to different nuclei, might be a promising research direction in the next years (Romanelli et al., 2003; Gruber et al., 2010; Castrioto and Moro, 2013; Collomb-Clerc and Welter, 2015; De Jesus et al., 2015).

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http://dx.doi.org/10.1016/j.jneumeth.2017.08.017
0165-0270/

However, a major drawback with the current stereotaxic systems is the difficulty in guiding a single lead to multiple selected intracranial targets. There are some limitations on implanting a lead into multiple targets through a "straight lead pathway" (Okun et al., 2007; Wojtecki et al., 2015; Coenen et al., 2016). In most situations, performing a multi-target DBS procedure with the current stereotaxic systems means increased number of implanted leads (Stefani et al., 2007; Peppe et al., 2010; Khan et al., 2012; Huss et al., 2015; Lizarraga et al., 2016), and increased medical costs. Moreover, Binder et al. (Binder et al., 2005) retrospectively analyzed 280 patients who underwent 481 DBS lead implantations, and found the intracerebral hemorrhage (ICH) rate was 3.3% per lead implantation during the study period. Patients who developed ICH had a slightly greater number of microelectrode trajectories than patients who did not have ICH. Conventional DBS procedure using more trajectories might lead to higher risk of operative complications.

In our previous study (Ding et al., 2017), we had proposed a theoretical "curved lead method" that enables a single lead to reach any two targets of the brain and designed the Excel algorithm needed to automatically calculate the necessary parameters for curved lead implantation. Therefore, the aim of current study was to provide a novel stereotaxic system used for implanting a curved lead to any two selected intracranial targets, and to prove the accuracy of the novel stereotaxic system in curved lead implantation.

2. Materials and methods

2.1. Materials

Three dimensional (3D) printed skull model with 6 predetermined intracranial targets was fabricated and used as the subject to prove the accuracy of the stereotaxic system.

The head CT and MRI of a volunteer were obtained and reconstructed into 3D images, then printed to solid 3D model (Medprin Regenerative Medical Technologies Co., Ltd., Shenzhen, Guangzhou, China). In this model, 6 rings, all 3D printed, (diameter = 10 mm) were fixed into pre-selected locations as the targets for the curved lead implantation. Using the sagittal middle line of the head, these targets were divided into left and right groups, and numbered accordingly, from frontal to posterior locations. These targets are: R1, R2 on the right, and L1, L2, L3, L4 on the left. The exact locations of these targets were determined based on the MRI images: R1 and R2 represented the right globus pallidus internus (GPi) and subthalamic nucleus (STN), and L3 represented the left STN. The other three targets were fixed in a way such that as many combinations of pairs of targets as possible were achieved. The study protocol was designed in accordance with guidelines outlined in the Declaration of Helsinki and approved by the local Ethics Committee of the First Affiliated Hospital of Fujian Medical University (Fujian, China). Written informed consent was obtained from this volunteer.

2.2. The novel stereotaxic system and steps of curved lead implantation

This customized stereotaxic system (Fig. 1) was fabricated (Changyonghe Machinery CO.,Ltd., Fuzhou, Fujian, China) and used based on the schematics and "curved lead pathway" method designed in our previous study (Ding et al., 2017).

The steps of curved lead implantation were described in detail in our previous study (Ding et al., 2017). Briefly, they are: 1. acquire the coordinates of the two selected targets; 2. establish the "lead pathway plane"; 3. identify the "curved lead pathway"; and 4. implant the curved lead. With the ability to define the "lead pathway plane" and to secure the "curved lead pathway", the novel stereotaxic system is able to guide a curved lead to two selected intracranial targets.

2.3. Accuracy verification of the curved lead implantation

The following steps were taken.

Step 1. The 3D printed cranial model and two positioning boards used for calculating the coordinates of any point on CT images were secured on the head frame (Anke Hi-Tech Co., LTd., Shenzhen, Guangzhou, China), and scanned with CT (Aquilion^{TM} ONE, Toshiba Co., Ltd., Tokyo, Japan) at a slice thickness of 1 mm.

Step 2. The locations of the 6 targets within the model were determined on the CT images, and the definitive coordinates of the mid-points of the 6 targets were calculated.

Step 3. Five pairs of targets were selected. Based on the previously developed algorithm (Ding et al., 2017), the curved lead pathways of the five pairs of targets were automatically calculated. The necessary parameters of implanting a curved lead with the help of this novel stereotaxic system can be calculated automatically by copying the contents of Excel Algorithm in Table 1 to the corresponding cells in an Excel sheet and filling in the needed information (Table 1).

Step 4. Five 3D printed curved leads (curve radius = 70 mm, lead body diameter = 1.3 mm, instead of the leads and guiding sheaths described in the previous schematics (Ding et al., 2017)) were implanted respectively following the calculated parameters with the help of the novel stereotaxic system. After implantation, the curved leads were glued to the skull at the points where they passed through the skull.

Step 5. CT scan was performed again to locate the curved leads. The position of each lead passing through the target was determined in stereotactic coordinates. Based on the comparisons of the coordinates of the mid-points of 6 targets measured on the pre-implantation CT images and the coordinates of the implanted curved leads measured on the post-implantation CT images, the vector errors of curved lead implantations were obtained.

In the step 3, five pairs of targets were selected. For each pair of targets, the accuracy of curved lead implantation was proved (the step 4 and step 5 were repeated) independently.

2.4. Statistical analysis

Measurement data was expressed as mean ± SD. The vector errors were calculated based on the coordinates of the mid-points of 6 targets measured on the pre-implantation and the coordinates of the implanted curved leads measured on the post-implantation CT images. Vector error= $\sqrt{(X_2 - X_1)^2 + (Y_2 - Y_1)^2 + (Z_2 - Z_1)^2}$.

3. Results

3.1. The intracranial targets

The targets within the 3D printed cranial model are shown in Figs. 1 and 2. The coordinates of the mid-points of the 6 targets (L1-L4, R1 and R2) were calculated using the pre-implantation CT images (Fig. 2, Table 2).

3.2. Implanting curved leads to combined targets

Five pairs of targets were selected: 1. R1 and R2, 2. L1 and L2, 3. L1 and L3, 4. L4 and L2, and 5. L3 and R2. The relative position between the deeper and shallower targets of each pair was different in all pairs: 1. R1 and R2 were on the same axial plane. The curved lead was designed to travel from the anterior lateral to the posterior medial direction, passing through R1 to reach R2; 2. L1