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Analysis of the intended and actual orientations of directional deep brain stimulation leads across deep brain stimulation systems

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Abstract

Deep brain stimulation (DBS) offers therapeutic benefits to patients suffering from a variety of treatment-resistant neurological and psychiatric disorders. The newest generation of DBS devices now offer directional leads, which utilize segmented electrodes to direct current asymmetrically to the neuronal tissue. Since segmented electrodes offer a larger degree of freedom for contact positioning, it is critical to assess how well the surgically intended and the actual orientation of the lead match to facilitate programming and allow appropriate interpretation of the therapeutic outcome. Postoperative image analysis algorithms, such as DiODe, are commonly used to determine DBS leads' actual orientation. In this work, we used DiODe to compare the deviation between intended and actual orientations of DBS leads across two most commonly implanted directional DBS systems, namely, Boston Scientific Cartesia™ and St. Jude Medical Infinity. This study is the first to investigate the rotation of leads from both DBS systems in a large group of 86 patients.

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I. Introduction

Deep brain stimulation (DBS) is a powerful neurosurgical tool that offers therapeutic benefits to individuals suffering from treatment-resistant movement or neurological disorders such as Parkinson's disease, epilepsy, dystonia, and obsessive-compulsive disorder [1-2]. DBS provides electrical impulses to a target brain region through implanted electrodes and an implantable pulse generator (IPG). Historically, DBS devices have utilized cylindrical, omnidirectional electrodes that provided axially symmetrical stimulation around the lead. However, the newest generation of DBS devices now offers segmented, directional electrodes that allow for current steering to asymmetrically stimulate neuronal tissue. While directional leads are demonstrated to increase side-effect thresholds [3] and/or decrease efficacy thresholds [4], they also come with substantially larger degrees of freedom for DBS programming. This makes detailed knowledge of the lead position with respect to the surrounding anatomy crucial for clinical interpretation of DBS response, as unwanted stimulation of specific brain regions can cause psychiatric and motor side effects [5].

During the implantation of DBS leads, surgeons use a stereotactic frame to establish the exact pitch, yaw, and roll angle for each lead to ensure accurate placement within the target brain region (Fig. 1). In directional DBS, however, the orientation angle of the lead adds a new degree of freedom which is hard to accurately establish using currently available surgical apparatuses. Although surgeons try to visually control for this angle by attempting to face the lead's marker toward a specific direction, the accuracy of the achieved angles are not well established.

Recently, the DiODe algorithm (standing for Directional Orientation Detection) was developed to automatically determine the orientation angle of leads from the artifact on postoperative computed tomography (CT) images [6,7]. To achieve this, DiODe calculates the exact orientation angle of the lead by analyzing unique metal artifacts that occur in CT images at levels of the marker and two-segmented electrodes (Fig. 2A). Then, the algorithm considers the center of mass of the lead artifact to identify the most probable orientation [8]. In addition to being validated through multiple phantom studies, DiODe has also produced highly correlated results with orientations determined from rotation fluoroscopy images, now making the algorithm a reliable method of lead rotation analysis in DBS research [11,12].

When localizing the postoperative leads with DiODe, large deviations of up to 90° have been reported between the intended and actual orientations in patients implanted with Cartesia™ directional DBS leads (Boston Scientific, USA) [8]. Because DiODe requires manual refinements in selecting images with the most appropriate artifact, its output is not user-independent. To our knowledge, there have been no studies assessing user agreement in the application of the DiODe algorithm. Moreover, there has yet to be a study analyzing the deviation between the intended and actual orientation of leads across the two most common DBS systems, namely, Boston Scientific Vercise (Marlborough, MA, USA) and St. Jude Medical Infinity (Chicago, IL, USA). In this paper, we examined these deviations across DBS systems while also assessing the user agreement.

Specifically, the orientation angle of 67 Boston Scientific leads and 19 St. Jude Medical Infinity DBS leads were retrospectively calculated by two independent users, K.H. and M.M, using the DiODe algorithm in the MATLAB (The MathWorks, USA) toolbox, Lead-DBS (www.lead-dbs.org). Large variations up to 90° was observed between the intended and actual orientations, however, we found no systematic bias toward clockwise or counterclockwise rotations. We additionally observed that user estimations of orientation values from DiODe were equivalent within our set range of ±30°.

II. Methods

A. Ethics

Northwestern University’s Institutional Review Board approved the use of existing imaging data for the purpose of the analysis. Due to the study's retrospective nature, no informed consent was needed from patients. All images were gathered as part of routine clinical care.

B. Patient Demographics

Forty-nine patients (98 leads) who underwent a bilateral DBS implantation surgery at Northwestern Memorial Hospital between 2017 and 2021 were retrospectively analyzed. The mean age was 65 ± 10 years, and 71% were male. Fourteen patients had the St. Jude Medical Infinity DBS system, while the other 35 patients had the Boston Scientific Vercise system. All had preoperative MRI and postoperative CT images.

C. Surgical procedure

Bilateral DBS implantations were performed by J.R. at Northwestern Memorial Hospital. Prior to the surgery, lead trajectories were planned using the patient’s preoperative MR scans in Brainlab Elements (Brainlab, Munich, Germany) planning software. Targets were selected using a combination of stereotactic atlas-based coordinates and direct target visualization on MRI. During the surgery, target and entry point coordinates for the pre-planned lead trajectory were set on a Leksell model G stereotactic frame (Elekta, Stockholm, Sweden). A burr hole was drilled at that location, and microelectrode recording and stimulation was conducted to locate the target brain structure and test a simple range of cathodic stimulations (1-3mA, pulse width of 60μs, pulse frequency of 130Hz) (Alpha Omega, Nazareth, Israel). Optimal trajectories were those with greater than 4 mm of target single unit recordings where there were appropriate neuronal responses to passive limb movements coupled with the presence of stimulation-associated benefits and a lack of significant stimulation-associated side effects. DBS electrodes were measured for implant using the standard measuring bracket and rotated to the appropriate orientation by hand prior to insertion into the brain. Lead implantation and fixation to the skull using standard burr hole devices were performed with intermittent fluoroscopy to ensure stable position.

In total, 98 leads were implanted. Two leads were removed from analysis due to having a polar angle of greater than 40°, which results in inaccurate calculations with the DiODe algorithm [6]. Ten more leads were removed since the intended orientation was not anterior. Of the 86 leads used in the analysis, 78 had been implanted into the subthalamic nucleus, 6 in the ventral intermediate nucleus of the thalamus, and 2 in the globus pallidus internus.

22.45% and 75.51% of leads were implanted first into the right and left hemisphere, respectively. Only 2.04% of patients had the right and left leads implanted on the same day. All leads analyzed were implanted facing anterior.

D. Determining actual orientation of the DBS leads

The original user-supervised DiODe algorithm, which was implemented in IDL (Exelis Visual Information Solution, USA), has been extensively validated in both geometrical and anthropomorphic phantoms [6,7]. An adaptation of DiODe implemented in MATLAB is now available and fully integrated into the open-source Lead-DBS toolbox [13].

DBS lead localization was independently completed by two users (K.H. and M.M) using the Lead-DBS manual pre-reconstruction toolbox [14]. Each user then ran DiODe within Lead-DBS, while utilizing the manual refinement option, to calculate the actual orientation angles of each DBS lead detected in the postoperative CT images [7]. All actual orientation angles were recorded for statistical testing.

E. Statistical Analysis

All statistical tests were conducted in RStudio (Boston, MA, USA) with an α of less than 0.05 considered significant.

Prior to analyzing the orientation angles, a two one-sided test (TOST), a test of equivalence, was applied to determine if the actual orientation angles estimated by each user (K.H. and M.M.) were equivalent within a predefined range of ±30°. The 30° angle was selected because it is the maximum rotation that can occur before the overlapping region of electrode contacts is less than the non-overlapping regions (Fig. 3).

To determine if the deviations between the intended and actual lead orientations were significant, a two-tailed Wilcoxon Signed-Rank test was applied.

III. Results

The agreement between the two users (K.H. and M.M.) for each DBS system is shown in Fig. 2D. The median deviation between users was 0.11° (IQR=6.97°). The TOST confirmed that user estimations of actual angles from DiODe were statistically equivalent within a range of ±30° (p-values<0.001). Because of the equivalence between users in this range, the following tests were conducted using actual orientation values collected from user K.H.

The maximum deviation from the intended angle was 86° and 74° for the Boston Scientific Cartesia™ and St. Jude Medical Directed leads, respectively. Additionally, the average deviation was 6.7 ± 38.6° for the Boston Scientific Cartesia™ leads and −5.4 ± 44.8° for the St. Jude Medical Directed leads.

The actual orientations determined by DiODe are displayed in Fig. 2B, as well as listed in Table 1. The majority of leads were rotated slightly to the left of the anterior direction. For leads in the left hemisphere, this orientation would mean deviation toward the lateral direction, while for leads in the right hemisphere, this orientation would mean leads were deviated toward the medial direction.

The distributions of the deviation from the intended orientations for each DBS system are illustrated in Fig. 2C. Deviations from −86° to 82° with respect to the intended orientation were observed for Boston Scientific Cartesia™ leads, and from −74° to 64° for the St. Jude Medical leads, respectively. Deviations of more than 30° occurred in 29 Boston Scientific leads (44%) and in 11 St. Jude Medical leads (58%). Deviations of more than 60° occurred in 10 Boston Scientific leads (15%) and in 4 St. Jude Medical leads (21%). The median deviation was 8.6° (IQR=41.6°) for Boston Scientific leads and did not differ from 0 (p-value=0.11). The median deviation was −3° (IQR=67.7 °) for St Jude Medical leads and did not differ from 0 (p-value=0.74).

IV. Conclusion

The Boston Scientific Cartesia™ and St. Jude Directed leads were the first two commercially available directional DBS leads [15]. In our sample size of 35 patients with Boston Scientific Vercise Cartesia™ leads and 14 St. Jude Medical Directed leads, we did not find a statistically significant bias for the leads to be rotated clockwise or counterclockwise around their intended orientation, albeit large deviations up to 74° were observed in both populations.

Other factors may have affected our findings, such as the dates of implantations of each lead. When bilateral leads are not implanted on the same day, it is possible to see the shifting of the first lead due to torque during implantation or the fixation to the skull of the second lead [9]. Only 2.04% of the patients analyzed in this study underwent the full bilateral implantation on the same day; therefore, the first lead may have been implanted facing the intended orientation and then later rotated during the second lead implantation. For each patient, we used the CT scan taken after the second lead implantation, so it is possible that the first implanted lead underwent an additional rotation.

Overall, these preliminary findings show that the variability of the deviation from the intended orientation that occurs during lead implantation does not vary across the two DBS systems. While leads orientations between −86 to 82° were noted, the lead rotation does not show a bias towards a single direction during the implantation for either DBS system. Because of the unbiased nature of our results, we cannot recommend any changes to the implantation procedure at this time, however, the results suggest use of additional guiding equipment might be necessary to reduce the variation. Additionally, our results were calculated with postoperative images from a single neurosurgeon. Further research is critical to validate DiODe with St. Jude Medical Directed DBS leads and to understand if similar results are seen for patients operated on by other neurosurgeons.

Acknowledgment

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Clinical Relevance—

Our results quantify the variability between the surgically intended and actual orientations of Boston Scientific Vercise and St. Jude Medical Infinity DBS systems, thus highlighting the need to develop more precise implantation procedures.

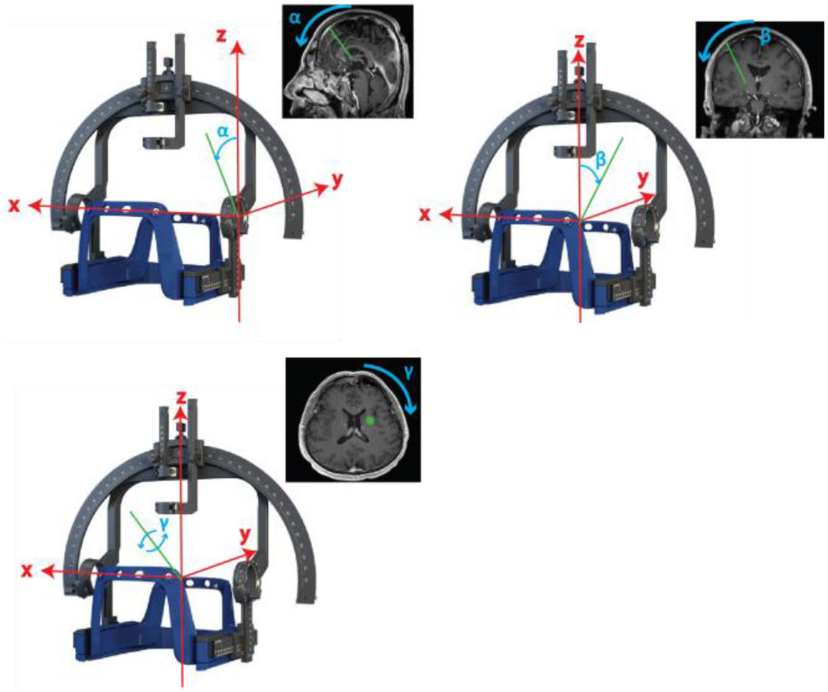

Figure 1.

A stereotactic frame showing the pitch (α), yaw (β), and orientation (γ) angles relative to a DBS lead. Pitch is the rotation around the x-axis, Yaw is the rotation around the y-axis, and the orientation angle is lead rotation around the lead’s axis.

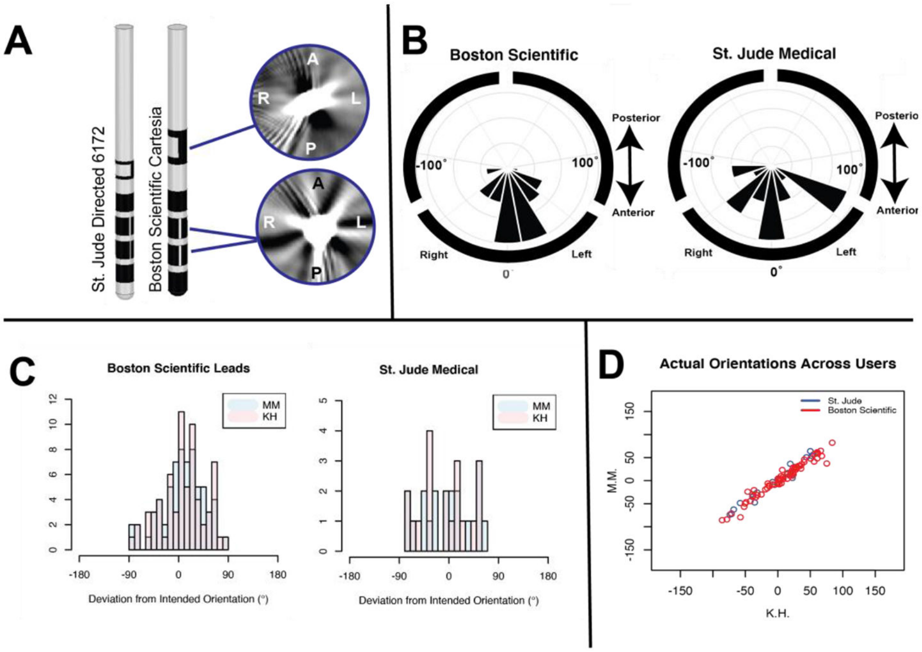

Figure 2.

(A) Boston Scientific Cartesia™ and St. Jude Medical Directed 6172 directional leads and the CT artifacts seen at the level of the marker and segmented electrodes, **(B)** Distributions of the actual orientations calculated with DiODe for leads intended to face anterior **(C)** Distributions of deviation between the actual and intended orientations for both DBS systems as calculated by each user (K.H. and M.M.), **(D)** the agreement of actual orientations calculated by each user, K.H. and M.M., for the Boston Scientific (red points) and St. Jude (blue points) leads.

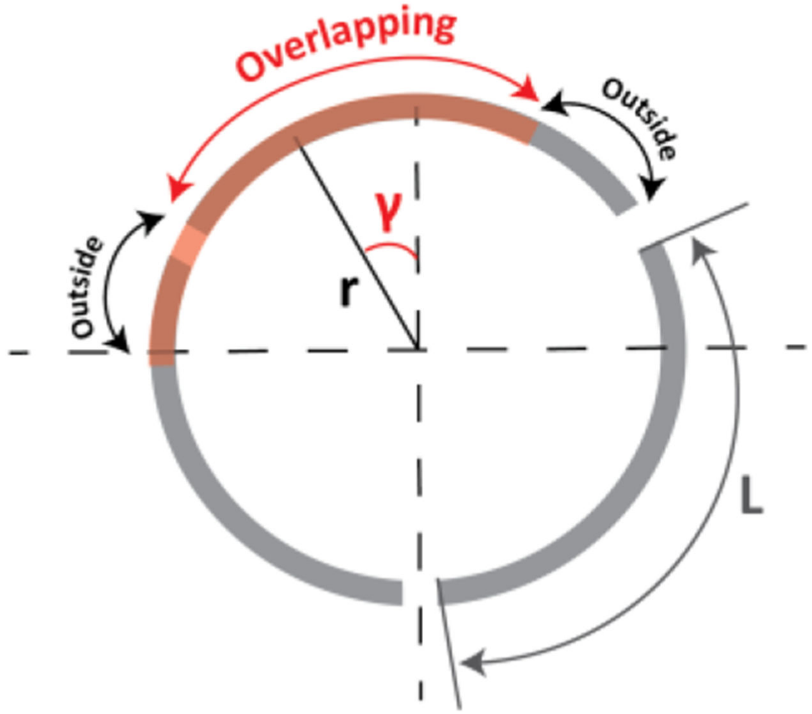

Figure 3.

Rotating a contact from its original position (gray) to a new position (red) based upon its orientation (**γ**). The overlapping region is the arc length shared by the reoriented and original contact, where the outside regions are where only the reoriented or the original contact are located. The angle that leads to the length of overlapping region to be equal to the outside region is L/3r, where L is the arc length of the contact and r is the radius of the lead. For directional leads, L=1mm and r=0.625mm, leading to a **γ**=30°.

TABLE I.

Distribution of actual and intended lead orientations across both systems, as calculated with DiODe

Angle (°)	Boston Scientific (Actual Orientation)	St. Jude (Actual Orientation)	# of Leads (Intended Orientation)
−90 to −60	4	3	0
−60 to −30	8	3	0
−30 to 0	14	4	0
0	0	0	86
0 to 30	22	4	0
30 to 60	12	5	0
60 to 90	6	1	0