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Postoperative Determination of Directional DBS Lead Orientation: A Comparison of CT-Based Software and Rotational Fluoroscopy

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Keywords

Directional leads · Deep brain stimulation · Circular statistics · Lead orientation · Iron sights

Abstract

Introduction: During evaluation of the Brainlab Elements™ software for postoperative determination of directional deep brain stimulation lead orientation, we noted a lack of published in vivo comparative agreement data. At the same time, prior reports have described substantial variability in implanted lead rotation angles, underscoring the need to verify software-based estimates. We therefore compared Brainlab Elements™ with 3D rotational fluoroscopy, analyzed using the "Iron Sights" method (ISM), by two independent observers. ***Methods:*** We prospectively analyzed 70 directional leads implanted at our center (2022–2024). Orientation was measured on postoperative rotational fluoroscopy by two independent observers and compared with postoperative CT analyzed in Brainlab Elements™. The agreement was evaluated using established reliability statistics. ***Results:*** Observers using the ISM produced highly consistent measurements, differing on average by <1° and rarely more than ±7°. Compared with CT-based analysis, the ISM showed good agreement, with differences typically within ±15°. These margins correspond to <1.5 mm displacement at 6-mm radial distance from the lead. ***Conclusion:*** Interobserver agreement using the ISM was excellent (ICC [2, 1] = 0.983). Brainlab Elements™ estimations (ICC [3, 1] = 0.864; limits of agreement ≈ ±15°) correlated well with the ISM.

Plain Language Summary

The study examined agreement between two postoperative imaging approaches used for deep brain stimulation (DBS). One method used computed tomography (CT) analyzed with dedicated lead localization software. The second method used three-dimensional rotational fluoroscopy interpreted with the "Iron Sights" technique, in which lead orientation is determined from the radiographic appearance of segmented contacts. Two independent observers evaluated fluoroscopic images to assess measurement consistency. Seventy implanted directional leads were included. Measurements obtained by the two observers using rotational fluoroscopy showed very high agreement, with small angular differences between raters. When fluoroscopy-based measurements were compared with CT software-derived estimates, overall agreement between the two methods was good, with most measurements differing within a limited angular range. In 3 cases, CT-based software did not generate orientation estimates. These instances were associated with imaging acquisition factors, including excessive lead angulation relative to the scan plane normal

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and increased slice thickness. Both imaging methods produced comparable postoperative orientation measurements under the conditions studied.

Introduction

Directional deep brain stimulation (DBS) leads to feature-segmented electrodes that allow clinicians to steer the electrical field, improve therapeutic precision, expand the therapeutic window, and reduce stimulation-induced side effects [1, 2]. This steering is particularly beneficial in targeting areas such as the subthalamic nucleus (STN), where directional stimulation can avoid spreading to the internal capsule (IC) while enhancing the coverage of functionally relevant regions.

Accurate knowledge of the final orientation of the segmented contacts is crucial for individualized stimulation planning [3–6]. Although electrodes are inserted with the intended orientation (typically anterior), intraoperative lead rotation and torsion can alter the final position. Despite the directional markers in existing commercial models, accurately determining the lead's orientation remains difficult [7]. Consequently, postoperative imaging is essential to confirm lead orientation.

During our evaluation of the Brainlab Elements™ software for determining the orientation of directional leads, we were intrigued by the scarcity of robust in vivo validation data, except for a few evaluating open-source software like DiODe and Lead-DBS [8, 9]. Despite its widespread clinical use, the literature has largely relied on phantom-based or theoretical assessments, leaving its reliability in postoperative clinical settings uncertain. Lasica et al. [10] compared postoperative reconstructions generated by several commonly used software platforms – including Brainlab Elements™, SureTune™, and Lead-DBS – and reported that the Euclidean distance between estimated active contact positions varied by up to 2.99 mm across systems, raising important questions regarding the consistency and precision of these tools. If software packages diverge by several millimeters in estimating contact locations, the reliability of angle measurements derived from Brainlab in clinical decision-making becomes equally uncertain. At the same time, several studies have highlighted that DBS leads may undergo substantial rotational deviation during or after implantation, potentially influencing programming and clinical outcomes [11, 12].

Given these concerns, we sought to assess agreement between Brainlab Elements™ and "Iron Sights" method (ISM) estimates in an in vivo clinical setting. ISM, which exploits the radiographic appearance of segmented contacts to infer orientation, has demonstrated high accuracy in phantom models [7]. Reinacher et al. [7] reported a limit of agreement (LoA) of ±2.44° and an intraclass correlation coefficient (ICC) of 0.9998 using this method [7].

To further enhance the robustness of our analysis, we also examined interobserver reliability in determining the fluoroscopic orientation. By including two independent raters – a neurosurgeon and a radiologist – we aimed to quantify this potential variability and ensure that our comparative assessment between methods accounted for human measurement error.

Commercial image-guided orientation platforms are vendor- and lead-specific, with proprietary algorithms that differ across manufacturers. We therefore focused on Brainlab Elements™ in combination with Boston Scientific Vercise Cartesia™ leads, which represented our routine clinical workflow. Accordingly, our findings apply to this specific pipeline rather than all software-led combinations. Brainlab Elements™ Lead Localization has undergone phantom-based validation using Boston Scientific Vercise Cartesia™ leads embedded in rigid acrylic phantoms, with ground-truth orientation established via high-resolution microCT and transferred to clinical CT datasets acquired across multiple scanners and protocols (personal email communication with James Paul Ridgwell, Marketing Manager, Brainlab, on January 19, 2026) [13]. Similarly, the ISM has demonstrated sub-3° precision in controlled phantom experiments. However, systematic in vivo comparison between these independently validated approaches remains limited [7].

Aim and Objectives

Aim

The aim of the study was to evaluate in vivo agreement between Brainlab Elements™ software and rotational fluoroscopy for postoperative orientation assessment of directional DBS leads.

Objectives

Objectives of the study were the following:

- To assess the inter-observer agreement of the ISM observations by estimating the inter-observer agreement between a neurosurgeon and a neuroradiologist.
- To compare orientation measurements obtained via the ISM with those derived from the Brainlab Elements™ software using postoperative CT.
- To assess the association of lead trajectory angles with measurement errors by the above methods

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Methods

Reporting in the article follows the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) to ensure the full disclosure of design and statistical decisions. This prospective exploratory study was conducted at a high-volume tertiary care center between May 2022 and December 2024.

Participants

All consecutive patients who underwent DBS surgery with directional leads (Vercise Cartesia™, Boston Scientific) during the study period were screened for inclusion. The inclusion criteria were as follows:

- Implantation of directional DBS leads (Vercise Cartesia™, Boston Scientific) for movement disorders
- The participant (or legally authorized representative) must have given consent

Patients with incomplete imaging, significant motion artifacts, or postoperative complications affecting the lead visualization were excluded. This study was performed in accordance with the Declaration of Helsinki. This human study was approved by the Ethics Committee affiliated with Jaslok Hospital, Mumbai (approval: EC/1114/2022, dated April 29, 2022). All adult participants provided written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for publication of the details of their medical case and any accompanying images. Participants were recruited from among patients who underwent DBS surgery with directional leads (Vercise Cartesia™, Boston Scientific). Both CT and fluoroscopy were performed during the postoperative period after admission. All surgeries were conducted under the stereotactic and functional neurosurgery department at our center by a single neurosurgeon (P.D.) according to the standard protocol [14]. CT scans were performed in the radiology department, and rotational fluoroscopy was performed in the Cath lab (for the acquisition of parameters, see online suppl. Table S1 in "supplementary Tables.docx"; for all online suppl. material, see https://doi.org/10.1159/000551821).

Sample Size

Sample size estimation for comparing rater reliability or agreement has not been thoroughly explored. Fleiss proposed a rule of thumb that recommends 15–20 samples for reliability studies [15]. For a continuous outcome, increasing the sample size beyond 12 per group did not significantly affect the confidence interval. Reinacher et al. [7] reported a 95% confidence interval of ±2.44° in their study of phantom models. Using Zou's formula for ICC precision with 95% CI width ≤0.1, $\alpha = 0.05$, ICC = 0.85, and 80% assurance, the required sample size was 57 leads for two raters [16]. We chose an expected ICC of 0.85 and a 95% CI width of ≤0.1 because ICC ≥0.75 suggests good reliability. Our study included 70 leads that met this threshold [17]. However, we included 70 leads to account for real-world variability in human data and to ensure robustness in statistical comparisons.

Postoperative Imaging and Orientation Measurement

Rotational Fluoroscopy (ISM)

Within 72 h postoperatively, all patients were brought to the Cathlab for 3D rotational fluoroscopy. The acquisition parameters are listed in the online supplementary materials (online suppl. Table S1 of the "Supplementary Tables.docx"). Images were reconstructed using multiple projections and independently reviewed by two raters:

- A neurosurgeon (R.A.) experienced in DBS surgery and programming
- A radiologist (C.K.) trained in neuroimaging

The observers performed measurements independently on anonymized files and had no access to each other's results. Using the ISM, each observer independently estimated the rotational orientation of each lead relative to the anterior direction, expressed in degrees (−180° to +180°) (online suppl. Fig. S1–S5 of the "Lead Orientation using ISM.pdf" in the online suppl. materials).

CT-Based Orientation (Brainlab Elements™)

Postoperative CT scans were uploaded into Brainlab Elements™ (Lead Localization module). The acquisition parameters are listed in the online supplementary materials (online suppl. Table S1 of the "Supplementary Tables.docx"). The system automatically detected the lead axis and segmented the contact positions based on CT artifact patterns (as described by Hellerbach et al. [18]), which were then visually confirmed. The lead model was set to Boston Scientific Vercise Cartesia™. The output orientation was recorded as the reference value for each lead. While no physical ground-truth reference was available in vivo, Brainlab Elements™ orientation estimation has previously undergone phantom-based validation using microCT-defined ground truth. Accordingly, this analysis should be interpreted as an assessment of in vivo agreement rather than absolute accuracy.

Statistical Analysis

All statistical analyses were performed using MATLAB (MathWorks, Natick, MA, USA) and the Circular Statistics Toolbox [19]. Statistical significance was set at p value <0.05.

Interobserver Agreement

To assess interobserver agreement using the ISM, orientation angles were treated as circular variables ranging from −180° to +180°. The circular difference, or shortest angular distance, was calculated for each lead between the two raters' measurements. Circular variance was computed to quantify the dispersion of ratings, and the circular correlation coefficient [20] was used to assess the strength of association between the neurosurgeon's and neuroradiologist's estimates. Because angular dispersion was low, we used ICC (2, 1), as defined by Shrout and Fleiss [21], which is appropriate for two-way random-effects models assessing absolute agreement between two observers. This ICC formulation accounts for subject variability, rater variability, and residual errors.

A Bland-Altman analysis [22, 23] adapted for circular data ("Circular BA plot analysis.pdf" in the online suppl. materials) was conducted to further explore the agreement, including calculation of the mean angular difference (i.e., circular bias) and standard deviation of the differences. The 95% LoAs were computed as the bias ±1.96 times the standard deviation. To express the uncertainty in these estimates, 95% confidence intervals for both the bias and LoAs were calculated. Finally, the Preiss-Fisher procedure was applied to test whether the observed agreement could have occurred by chance [24].

Method Comparison (ISM vs. Brainlab™)

For method comparison between the ISM and Brainlab Elements™, the Watson-Williams test was used to compare the circular means derived from the observers' average ratings with the angles obtained from the Elements™ software [25]. The intraclass correlation coefficient (ICC [3, 1]) was calculated to quantify consistency between the two methods using a two-way mixed-effects model. Agreement between the ISM and Brainlab™-derived orientation angles was also visualized using a Bland-Altman plot. The Preiss-Fisher test was again applied to confirm whether the observed concordance between the methods exceeded chance expectations. Before the parametric circular tests, assumptions were assessed and found to met, including angular homogeneity and concentration.

Regression Analysis

We performed two univariate linear regression analyses to investigate whether anatomical trajectory angles influenced the angular measurement differences. Linear regression of the axial, coronal, sagittal, and polar angles (see online suppl. Fig. S1 of the "Trajectory calculation.pdf" in online suppl. materials) as explained by Matias et al. [26] against the angular difference between the two observers' measurements on rotational fluoroscopy (i.e., interobserver error). A separate regression of these angles was performed against the angular differences between rotational fluoroscopy and Brainlab Elements™ (i.e., method discrepancy).

For each regression model, beta coefficients and the corresponding p values were calculated to assess the strength and significance of the association between the variables. Owing to multiple comparisons, we adjusted the p values (p_{adj}) for the false discovery rate using the Benjamini-Hochberg method [27]. Statistical significance was set at $p < 0.05$.

Results

Study Sample

Thirty-five patients were included in the final analysis, yielding 70 directional DBS leads for inter-observer agreement analysis. For the method-comparison analysis, three leads were excluded because the Brainlab Elements™ software failed to compute their orientations, leaving 67 leads for analysis. An overview of the data, including circular means, ranges, and standard deviations for all measurements, is presented in Table 1.

Interobserver Agreement: ISM on Rotational Fluoroscopy

The orientations estimated by the two observers were visualized using polar histograms (Fig. 1a–d). The Rayleigh test for uniformity demonstrated significant data clustering ($p < 0.05$), indicating that the angles were not randomly distributed around the circle, but were concentrated around a common direction.

The mean resultant length of the circular distance between the two observers was 0.9985 with a circular variance of 0.0015, indicating highly consistent measurements. The circular correlation coefficient was 0.9822, confirming a strong directional agreement. A circular Bland-Altman analysis (Fig. 2a) revealed a mean bias of 0.68° (95% CI: −0.0678° to 1.4335°). The upper LoA was 6.85° (95% CI: 5.55° to 8.15°), and the lower LoA was −5.49° (95% CI: −6.79° to 4.19°). There was no

Table 1. Descriptive statistics of directional DBS lead orientations estimated by observers and brainlab Elements™

Measurements	Circular mean (angular range), degrees	Circular standard deviation, degrees
Angles measured by observer 1 (neurosurgeon) (n = 70)	5.55° (−64° to 42°)	16.89°
Angles measured by observer 2 (radiologist) (n = 70)	4.89° (−67° to 39°)	16.36°
Angles measured by Brainlab Element™ (n = 67)	8.27° (−29° to 46°)	13.51°
Trajectories coronal angle (n = 70)	24.24° (15.64° to 36.45°)	4.33°
Trajectories sagittal angle (n = 70)	25.84° (11.31° to 41.15°)	6.38°
Trajectories axial angle (n = 70)	43.38° (21.21° to 70.45°)	10.09°
Trajectories polar angle (n = 70)	33.95° (24.48° to 46.74°)	4.57°

Descriptive summary of lead orientation measurements from postoperative rotational fluoroscopy and CT in 70 directional leads implanted at our center (2022–2024). Circular means, ranges, and standard deviations are provided for observer estimates using the ISM and Brainlab Elements™ software.

evidence of proportional bias ($p > 0.05$), suggesting that the measurement errors did not change with angle. The Preiss-Fisher test showed that the standard deviation of differences between two observer measurements yielded a Z value of −15.40 (Fig. 2b), indicating that the observed agreement was significantly greater than would be expected by chance. The intraclass correlation coefficient (ICC [2, 1]) was 0.983 (95% CI: 0.973–0.989), indicating excellent inter-observer reliability (Fig. 2c and online suppl. Table S2 of the “supplementary Tables.docx” in the online suppl. materials for calculation parameters). Repeat ISM measurements demonstrated excellent intra-rater agreement (online suppl. Fig. S1 of the “Intra-rater Reliability.docx” in the online suppl. materials).

Figure 1e shows that the histogram of the circular distances between observers exhibited a symmetric distribution, approximating a Gaussian shape. Similarly, the polar histogram of angular differences was visually compared with the von Mises distribution (Fig. 1f) and showed good conformity.

Univariate linear regression analysis revealed that the coronal angle (β = 0.1803, p value = 0.0367; p_{adj} = 0.073) and polar angle (β = 0.0792, p value = 0.0320; p_{adj} = 0.073) were associated with greater interobserver differences. Note that after controlling for the false discovery rate using the Benjamini-Hochberg procedure, these associations did not remain statistically significant at the threshold of 0.05. The sagittal angle (β = −0.0588, p value = 0.3212; p_{adj} = 0.428) and polar angle (β = 0.0364, p value = 0.6618; p_{adj} = 0.662) showed no significant association with interobserver variation.

Method Comparison: ISM versus Brainlab Elements™

Of the 70 leads, 67 were eligible for method comparison as the software failed to estimate the orientation in the three leads. In 3 of 70 implanted leads, Brainlab Elements™ did not return an orientation estimate. Failure analysis revealed that in 1 case, the polar angle of the lead relative to the CT acquisition plane exceeded the recommended angular limits, likely related to head positioning during scanning. In the other two leads, CT reconstruction was performed at a slice thickness of 1.5 mm due to a technical acquisition error, exceeding the ≤1 mm thickness recommended for reliable artifact-based orientation analysis. These findings are consistent with known technical prerequisites for CT-based orientation estimation. Orientation estimates from both methods are displayed using polar histograms (Fig. 3a–d), including circular means. The Rayleigh test again showed significant nonuniformity ($p < 0.05$), indicating that the data points were directionally concentrated.

The mean resultant length of the circular distance between the ISM and the Brainlab™-derived orientation was 0.9922, with a circular variance of 0.0078. The circular correlation coefficient between the two methods was 0.8635. Bland-Altman analysis (Fig. 4a) revealed a mean bias of −0.69° (95% CI: −2.4839° to 1.0993°), with an upper LoA of 13.48° (95% CI: 10.37° to 16.58°) and a lower LoA of −14.86° (95% CI: −17.97° to −11.76°). No significant proportional bias was observed ($p > 0.05$), and the Preiss-Fisher Z value was −10.83 (Fig. 4b), again indicating that agreement between methods was not attributable to chance. The intraclass correlation

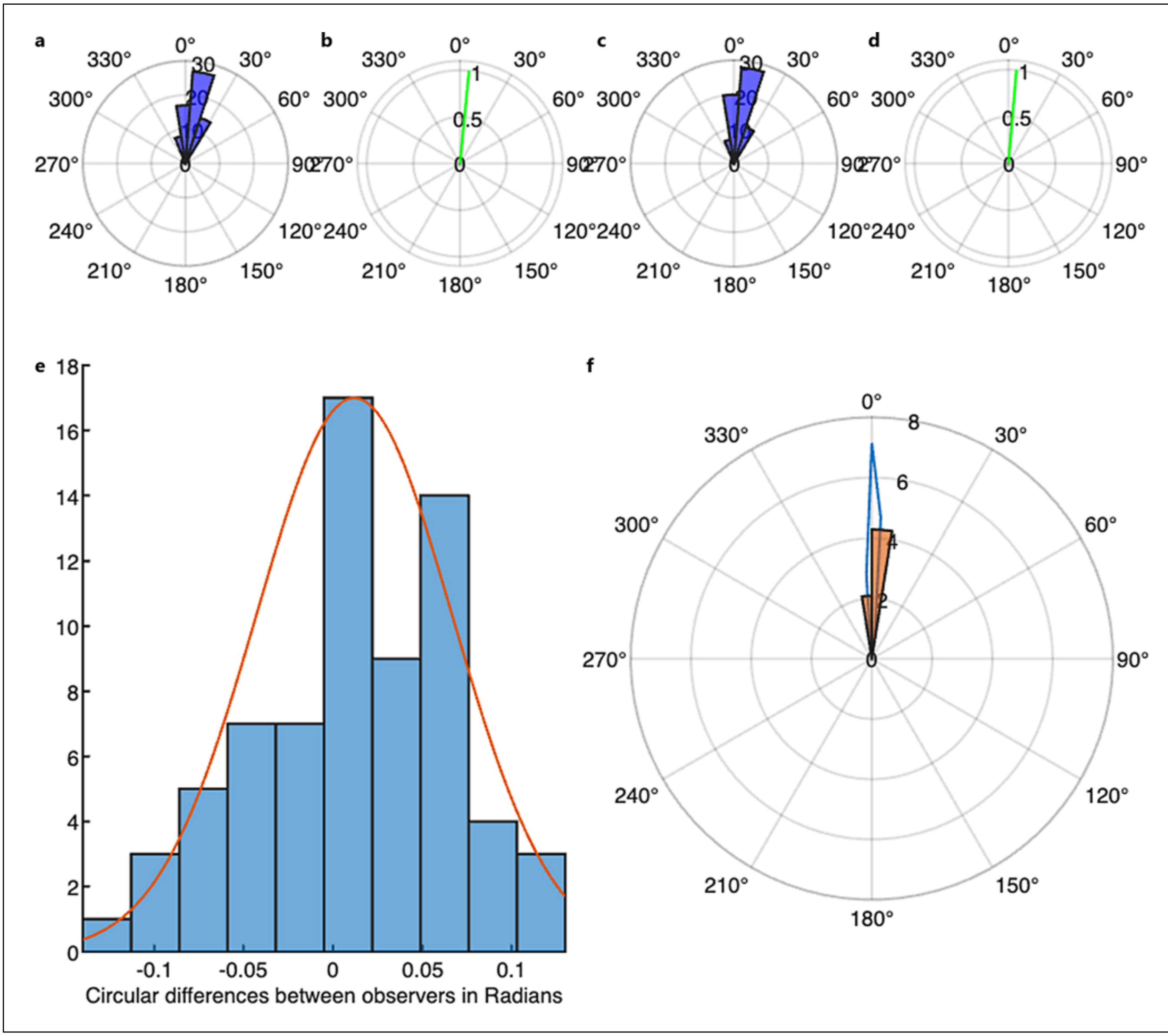

Fig. 1. Polar histograms of directional DBS lead orientations measured with the ISM from postoperative rotational fluoroscopy at Jaslok Hospital, Mumbai (2022–2024). Orientation estimates from each observer (n = 70 leads): observer 1 (RA) (**a**, **b**) and observer 2 (CK) (**c**, **d**). **e** Distribution of angular differences between observers, showing a symmetric pattern consistent with a Gaussian distribution. **f** Polar histogram of observer differences compared with the von Mises distribution. Clinically, differences between observers were minimal, with 95% of measurements within −5.49° to +6.85° (approximately ±7°).

coefficient (ICC [3, 1]) for the agreement between the ISM and Brainlab Elements™ was 0.864 (95% CI: 0.786–0.915) (Fig. 4c; online suppl. Table S3 of the "Supplementary Tables.docx" for calculation parameters), suggesting good consistency between the two approaches.

Figure 3e shows that the histogram of the circular distances between the methods approximates a Gaussian distribution. Similarly, the polar histogram of angular differences showed comparable clustering and was visually comparable to the von Mises distribution (Fig. 3f). The Watson-Williams test yielded a p value of 0.7905 (>0.05), indicating no statistically significant difference in the circular mean orientations between the two methods.

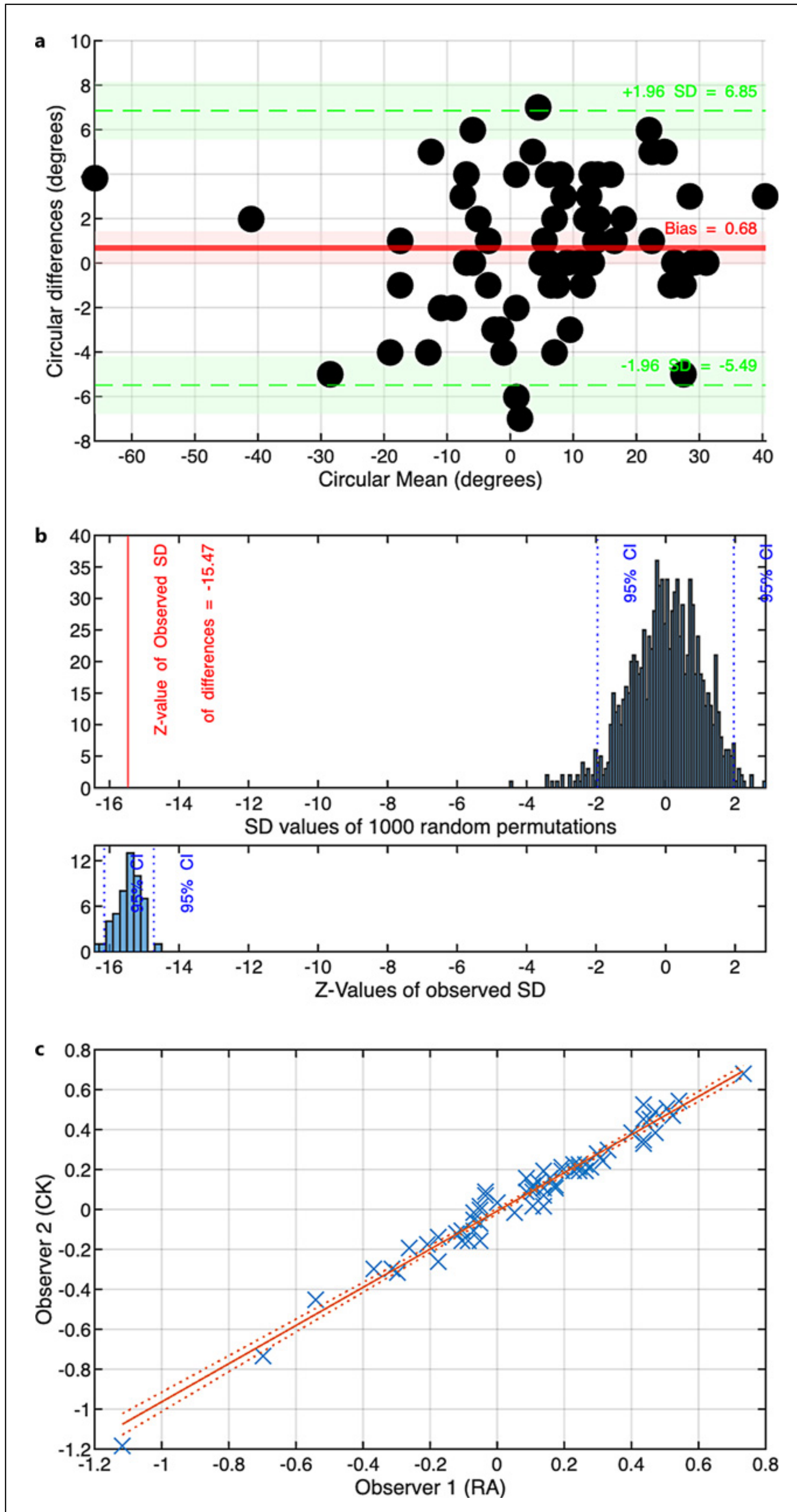

Fig. 2. Agreement analysis between neurosurgeon and radiologist estimates of DBS lead orientation using the ISM on post-operative fluoroscopy (2022–2024). **a** Bland-Altman plot showing a mean difference of 0.68° with 95% LoAs from −5.49° to +6.85°. **b** Preiss-Fisher test confirming agreement was highly unlikely due to chance. **c** Intraclass correlation coefficient (ICC [2, 1] = 0.983, 95% CI: 0.973–0.989) demonstrating excellent interobserver reliability. In practice, this means two trained observers almost always agreed within ~7° when using rotational fluoroscopy.

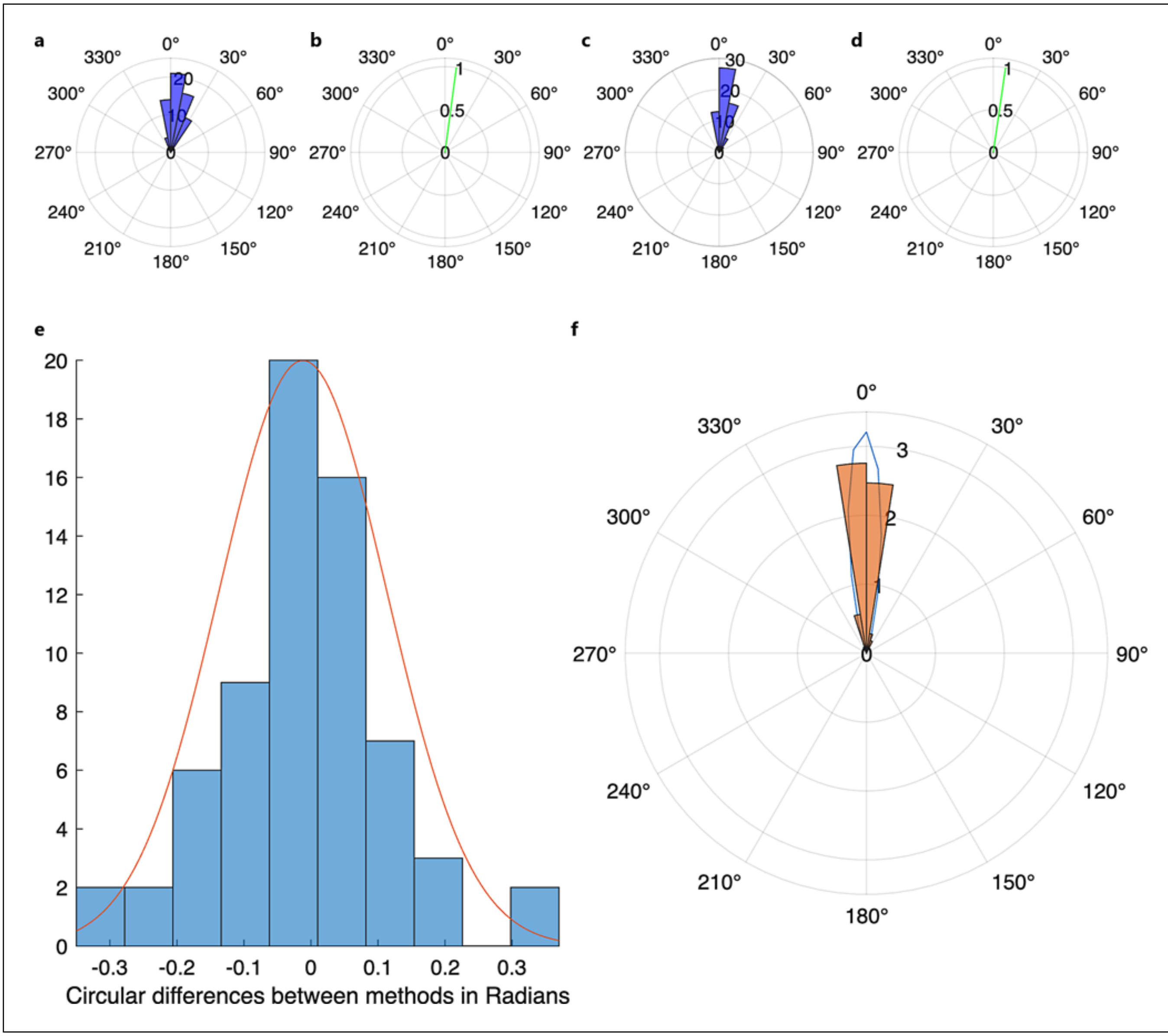

Fig. 3. Comparison of the ISM and Brainlab Elements™ CT-based software in patients (Jaslok Hospital, 2022–2024). Orientation estimates from both methods for 67 leads: ISM (**a**, **b**) and Brainlab Elements™ (**c**, **d**) **e** Distribution of angular differences approximating a Gaussian shape. **f** Polar histogram of differences compared with the von Mises distribution. On average, the two methods differed by less than 1°, with 95% of measurements within −14.86° to +13.48° (about ±15°).

None of the lead trajectory angles demonstrated a statistically significant relationship with the angular difference between the fluoroscopy-derived and Brainlab-derived orientations. The beta coefficients for the axial, coronal, sagittal, and polar angles were 0.2546 (p value = 0.2374, p_{adj} = 0.7046), 0.0315 (p value = 0.8073, p_{adj} = 0.8073), 0.0217 (p value = 0.7976, p_{adj} = 0.8073), and 0.1688 (p value = 0.3523, p_{adj} = 0.7046), respectively.

Discussion

In this study, we conducted a comprehensive evaluation of the Brainlab Elements™ software for the postoperative determination of directional DBS lead orientation by systematically comparing its performance to that of 3D rotational fluoroscopy analyzed using the ISM. To strengthen the reliability of this

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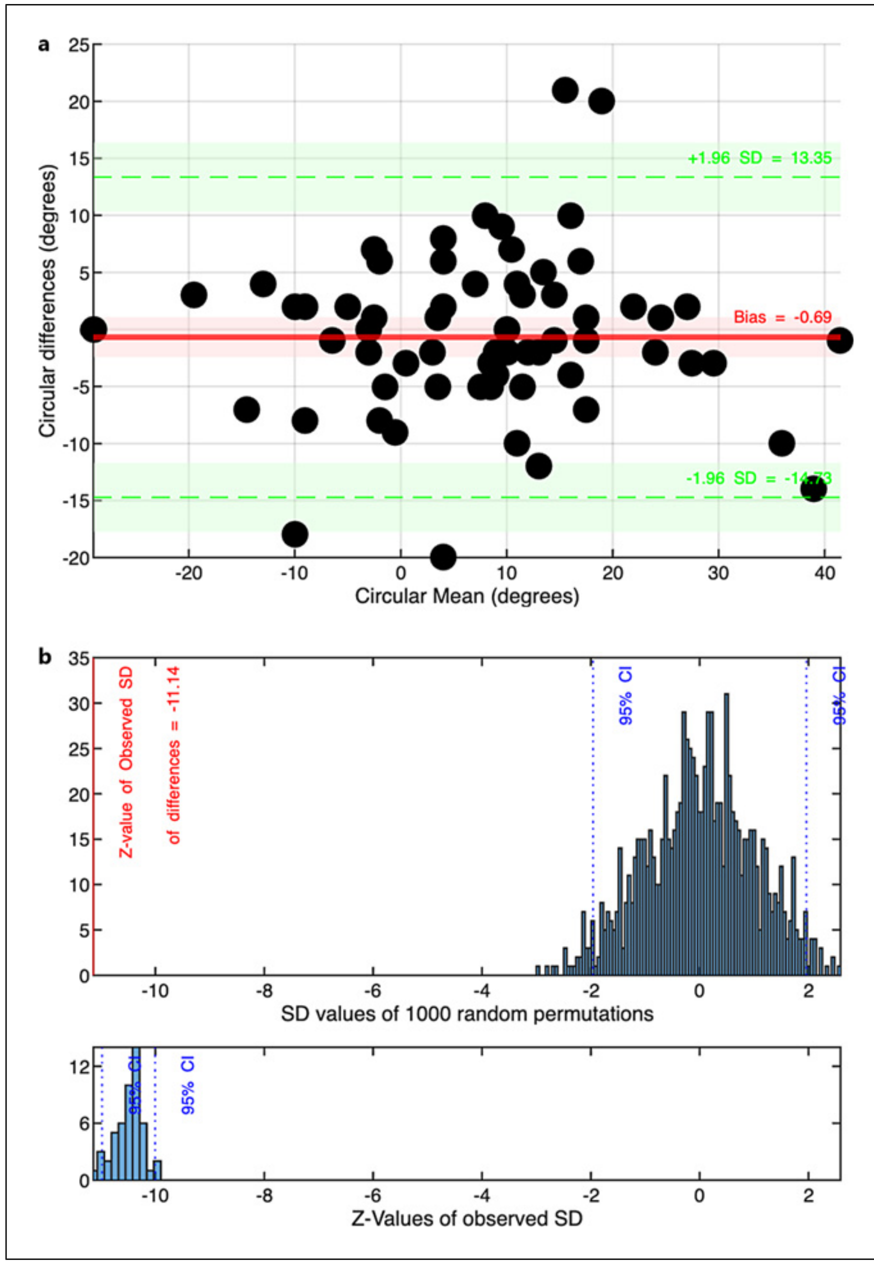

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comparison, two independent observers – a neurosurgeon and a radiologist – measured the fluoroscopic orientations to quantify interobserver variability. This dual-assessment design allowed us to evaluate both the internal consistency of the ISM and its agreement with a widely used commercial software. To our knowledge, this is one of the first in vivo clinical studies to systematically compare these two approaches using circular statistics.

Reliability of the ISM

Our findings demonstrate that the ISM yields highly consistent results when applied to postoperative 3D rotational fluoroscopy. Two independent observers – a neurosurgeon and a radiologist – achieved near-perfect agreement, with an intraclass correlation coefficient (ICC [2, 1]) of 0.983 and a mean difference of less than 1°. Ninety-five percent of measurements fell within ±7°, corresponding to a circumferential displacement of <0.7 mm at a 6-mm radial distance

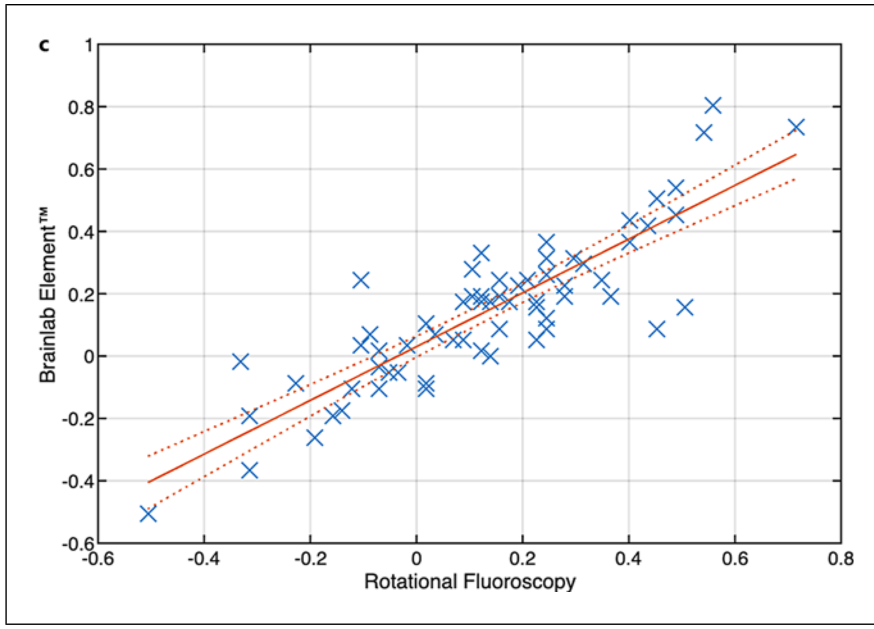

Fig. 4. Agreement between rotational fluoroscopy (ISM) and Brainlab Elements™ software in determining orientation of directional DBS leads (67 leads, Jaslok Hospital, Mumbai, 2022–2024). **a** Bland-Altman plot showing a mean bias of −0.69° and 95% LoAs from −14.86° to +13.48°. **b** Preiss-Fisher test confirming concordance was not due to chance. **c** Intraclass correlation coefficient (ICC [3, 1] = 0.864, 95% CI: 0.786–0.915) indicating good agreement between the two approaches. For clinicians, this means that both fluoroscopy and CT-based methods are broadly consistent, with most measurements agreeing within ~15° – a margin corresponding to less than 1.5 mm around the electrode circumference.

from the lead. Intra-rater analysis further confirmed the reproducibility of ISM measurements, with negligible bias and near-perfect ICC, supporting the robustness of observer-dependent interpretation. These results are consistent with the high precision reported by Reinacher et al. [7] in phantom models and demonstrate that the ISM remains highly reproducible under in vivo clinical conditions.

The extremely low angular dispersion observed in our data (circular variance = 0.0015) indicates that, when adequate image quality and observer training are ensured, the ISM provides a highly reproducible tool for confirming directional lead orientation. The associations observed between interobserver differences and the trajectory angles are not statistically significant after correction for multiple testing, which suggests that measurement precision is maintained even for moderately oblique trajectories – an encouraging finding for routine postoperative assessment.

Comparison between ISM and Brainlab Elements™

When compared with the Brainlab Elements™ software, the ISM showed good overall agreement (ICC [3, 1] = 0.864). The two methods differed on average by less than 1°, with 95% of measurements within ±15°, equivalent to ~1.5 mm at 6-mm radial distance from the lead. The Watson-Williams test indicated no significant difference in mean orientation values, and no systematic bias was detected in the Bland-Altman analysis.

Whereas the ISM provides direct visualization of segmented contacts, the Brainlab algorithm infers lead orientation based on CT artifact geometry. This method is sensitive to variations in lead tilt relative to the scanner's axial plane. Previous phantom studies have demonstrated reduced accuracy for trajectories exceeding approximately 40° [28, 29], which accounts for the slightly wider LoAs observed between the two methods in this study. In clinical practice, the voltage parameter for subthalamic stimulation rarely exceeds approximately 7 volts, which, according to computational studies, produces a volume of tissue activation with a radius of about 5 mm [30]. The observed LoAs (approximately ±15°) correspond to a circumferential displacement of 1–1.5 mm at 6 mm distance from the DBS lead. The clinical significance is that if the correct direction and the position of the contact are known, based on computational modeling, the mass of axonal activation can be shifted by 1–1.3 mm [31]. How this difference of 1.5 mm would affect clinical practice would still need to be evaluated, but it is close to the tolerable margin of displacement of the directional lead.

Orientation estimation failure occurred in three leads and was attributable to identifiable technical factors. Excessive lead angulation relative to the CT acquisition plane in 1 case excpeeded the software's angular tolerance, while suboptimal reconstruction thickness (1.5 mm) in the other two leads degraded artifact resolution. These findings highlight the importance of adherence to acquisition protocols and reinforce the role of complementary modalities, such as rotational fluoroscopy, when CT-based estimation is inconclusive, or repeat a CT scan with an optimal protocol.

Importantly, none of the lead trajectory parameters (axial, coronal, sagittal, or polar) were significantly associated with discrepancies between the two methods, which indicates that both ISM and Brainlab Elements™ maintain consistent performance across a wide range of surgical trajectories typical of functional targets such as the STN and globus pallidus internus.

Clinical and Practical Implications

Image-guided programming is widely used in clinical settings. The outcome of directional lead-based stimulation depends on the direction of the stimulated segment. In the absence of any clinical papers validating image-guided programming software, we end up depending on the industry-made claims. This study, conducted using a prospective design with independent observers and appropriate circular statistics provide in vivo agreement data between rotational fluoroscopy and a widely used CT-based software under defined imaging and hardware conditions. This information may help clinicians interpret orientation estimates and identify scenarios in which corroborative methods are warranted.

Relation to Previous Studies

Previous studies have established the feasibility and high precision of the ISM in phantom models [7] and have introduced several CT-based algorithms – such as DiODe [18] – for estimating lead orientation. However, we could not find any in vivo studies evaluating commercial software, despite its widespread use in clinical practice. Our study adds to this literature by providing one of the first clinical evaluations that directly compares a fluoroscopy-based orientation method with a commercially available CT-based software, while also quantifying observer reliability in real surgical data.

Limitations

This study had several limitations. First, these findings arise from a single center, single surgeon, single CT system, and a single directional lead platform (Boston Scientific Cartesia™). They should not be generalized to Medtronic or Abbott directional leads, or to other CT-based orientation software, without additional study. Second, this study does not establish absolute accuracy due to the absence of a ground truth reference. No phantom or intraoperative reference standard was available, so our results reflect method agreement. Third, the ISM relies on image quality and rater experience; variations in fluoroscopic acquisition or reconstruction algorithms could influence reproducibility in other settings.

Future work should focus on multicenter validation across different DBS systems and imaging platforms, as well as on correlating orientation accuracy with clinical programming parameters and patient outcomes.

In conclusion, in this in vivo comparative study, the ISM demonstrated excellent interobserver reliability and strong agreement with Brainlab Elements™ CT-based analysis for determining directional DBS lead orientation. These findings indicate that rotational fluoroscopy provides a reproducible approach for postoperative orientation assessment and may serve as a useful corroborative method when software-based estimates are unavailable or inconclusive. Together, these results help bridge the current evidence gap regarding the in vivo performance of orientation-detection software and support the integration of fluoroscopic verification into postoperative DBS workflows.

Acknowledgments

We thank Dr. Manish Baldia and Dr. Neha Rai for their assistance in setting up the initial protocol and coordinating its implementation.

Statement of Ethics

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Ethics Committee at Jaslok Hospital, Mumbai (Approval No. EC/1114/2022, dated April 29, 2022). Written informed consents were obtained from all the patients. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

Conflict of Interest Statement

Paresh K. Doshi was a member of the journal's Editorial Board at the time of submission. The other authors have no conflicts of interest to declare.

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Author Contributions

Conceptualization, data curation, project administration, methodology, investigations, resources, supervision, funding acquisition, and writing – review and editing: Doshi P. Data curation, formal analysis, methodology, investigations, resources, validation, software, visualization, writing – original draft, and writing – review and editing: Agarbattiwala R. Data curation, methodology, investigations, resources, and writing – review and editing: Karnavat C.

Data Availability Statement

All data generated or analyzed during this study are included in the online supplementary material ("Anonymized Data.xlsx"). Further inquiries can be directed to the corresponding author.

References

1 Pollo C, Kaelin-Lang A, Oertel MF, Stieglitz L, Taub E, Fuhr P, et al. Directional deep brain stimulation: an intraoperative double-blind pilot study. Brain. 2014;137(Pt 7):2015–26. https://doi.org/10.1093/brain/awu102
2 Steigerwald F, Müller L, Johannes S, Matthies C, Volkmann J. Directional deep brain stimulation of the subthalamic nucleus: a pilot study using a novel neurostimulation device. Mov Disord. 2016;31(8):1240–3. https://doi.org/10.1002/mds.26669
3 Schlaepfer TE, Bewernick BH, Kayser S, Mädler B, Coenen VA. Rapid effects of deep brain stimulation for treatment-resistant major depression. Biol Psychiatry. 2013;73(12):1204–12. https://doi.org/10.1016/j.biopsych.2013.01.034
4 Coenen VA, Rijntjes M, Prokop T, Piroth T, Amtage F, Urbach H, et al. One-pass deep brain stimulation of dentato-rubro-thalamic tract and subthalamic nucleus for tremor-dominant or equivalent type Parkinson's disease. Acta Neurochir. 2016;158(4):773–81. https://doi.org/10.1007/s00701-016-2725-4
5 Coenen VA, Allert N, Paus S, Kronenbürger M, Urbach H, Mädler B. Modulation of the cerebello-thalamo-cortical network in thalamic deep brain stimulation for tremor: a diffusion tensor imaging study. Neurosurgery. 2014;75(6):657–70. https://doi.org/10.1227/NEU.0000000000000540
6 Coenen VA, Allert N, Mädler B. A role of diffusion tensor imaging fiber tracking in deep brain stimulation surgery: DBS of the dentato-rubro-thalamic tract (Drt) for the treatment of therapy-refractory tremor. Acta Neurochir. 2011;153(8):1579–85. https://doi.org/10.1007/s00701-011-1036-z
7 Reinacher PC, Krüger MT, Coenen VA, Shah M, Roelz R, Jenkner C, et al. Determining the orientation of directional deep brain stimulation electrodes using 3D rotational fluoroscopy. Am J Neuroradiol. 2017;38(6):1111–6. https://doi.org/10.3174/ajnr.A5153
8 Henry KR, Miulli MM, Nuzov NB, Nolt MJ, Rosenow JM, Elahi B, et al. Variations in determining actual orientations of segmented deep brain stimulation leads using the DiODe algorithm: a retrospective study across different lead designs and medical institutions. Stereotact Funct Neurosurg. 2023;101(5):338–47. https://doi.org/10.1159/000531644
9 Dembek TA, Baldermann JC, Petry-Schmelzer J-N, Jergas H, Treuer H, Visser-Vandewalle V, et al. Sweetspot mapping in deep brain stimulation: strengths and limitations of current approaches. Neuromodulation. 2022;25(6):877–87. https://doi.org/10.1111/ner.13356
10 Lasica A, Filip P, Burdová K, Mana J, Růžička F, Urgošík D, et al. Precision of post-operative localization of deep brain stimulation electrodes. Sci Rep. 2025;15(1):18652. https://doi.org/10.1038/s41598-025-01449-6
11 Krüger MT, Naseri Y, Cavalloni F, Reinacher PC, Kägi G, Weber J, et al. Do directional deep brain stimulation leads rotate after implantation? Acta Neurochir. 2021;163(1):197–203. https://doi.org/10.1007/s00701-020-04568-3
12 Lange F, Steigerwald F, Engel D, Malzacher T, Neun T, Fricke P, et al. Longitudinal assessment of rotation angles after implantation of directional deep brain stimulation leads. Stereotact Funct Neurosurg. 2021;99(2):150–8. https://doi.org/10.1159/000511202
13 Kurtev-Rittstieg R, Achatz S, Nourinia A, Mittermeyer S. Orientation of directional deep brain stimulation leads on CT: resolving the ambiguity. bioRxiv. 2020. https://doi.org/10.1101/2020.09.16.298653
14 Doshi PK, Chhaya NA, Bhatt MA. Bilateral subthalamic nucleus stimulation for Parkinson's disease. Neurol India. 2003;51(1):43–8.
15 Fleiss JL. The design and analysis of clinical experiments. 1st ed. Wiley; 1999.
16 Zou GY. Sample size formulas for estimating intraclass correlation coefficients with precision and assurance. Stat Med. 2012;31(29):3972–81. https://doi.org/10.1002/sim.5466
17 Liljequist D, Elfving B, Skavberg Roaldsen K. Intraclass correlation – a discussion and demonstration of basic features. PLoS One. 2019;14(7):e0219854. https://doi.org/10.1371/journal.pone.0219854
18 Hellerbach A, Dembek TA, Hoevels M, Holz JA, Gierich A, Luyken K, et al. DiODe: directional orientation detection of segmented deep brain stimulation leads: a sequential algorithm based on CT imaging. Stereotact Funct Neurosurg. 2018;96(5):335–41. https://doi.org/10.1159/000494738
19 Berens P. CircStat: A *MATLAB* Toolbox for circular statistics. J Stat Softw. 2009;31(10). https://doi.org/10.18637/jss.v031.i10
20 Fisher NI, Lee AJ. A correlation coefficient for circular data. Biometrika. 1983;70(2):327–32. https://doi.org/10.2307/2335547
21 Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. Psychol Bull. 1979;86(2):420–8. https://doi.org/10.1037//0033-2909.86.2.420
22 Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet Lond Engl. 1986;1(8476):307–10.
23 Gerke O. Reporting standards for a bland–altman agreement analysis: a review of methodological reviews. Diagnostics. 2020;10(5):334. https://doi.org/10.3390/diagnostics10050334
24 Preiss D, Fisher J. A measure of confidence in bland–altman analysis for the interchangeability of two methods of measurement. J Clin Monit Comput. 2008;22(4):257–9. https://doi.org/10.1007/s10877-008-9127-y
25 Fisher NI. Statistical analysis of circular data. 1st ed. Cambridge University Press; 1993.
26 Matias CM, Mehanna R, Cooper SE, Amit A, Lempka SF, Silva D, et al. Correlation among anatomic landmarks, location of subthalamic deep brain stimulation electrodes, stimulation parameters, and side effects during programming monopolar review. Neurosurgery. 2015;11(Suppl 2):99–109. https://doi.org/10.1227/NEU.0000000000000645
27 Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. J R Stat Soc Ser B Stat Methodol. 1995;57(1):289–300. https://doi.org/10.1111/j.2517-6161.1995.tb02031.x
28 Sitz A, Hoevels M, Hellerbach A, Gierich A, Luyken K, Dembek TA, et al. Determining the orientation angle of directional leads for deep brain stimulation using computed tomography and digital x-ray imaging: a phantom study. Med Phys. 2017;44(9):4463–73. https://doi.org/10.1002/mp.12424
29 Fayed I, Syed M, Gingold E, Alizadeh M, Sharan A, Wu C. A novel and simple method using computed tomography streak artifact to determine the orientation of directional deep brain stimulation leads. Neurosurgery. 2023;93(5):1036–45. https://doi.org/10.1227/neu.0000000000002536
30 Mädler B, Coenen VA. Explaining clinical effects of deep brain stimulation through simplified target-specific modeling of the volume of activated tissue. Am J Neuroradiol. 2012;33(6):1072–80. https://doi.org/10.3174/ajnr.A2906
31 Ramirez-Zamora A, Giordano JJ, Gunduz A, Brown P, Sanchez JC, Foote KD, et al. Evolving applications, technological challenges and future opportunities in neuromodulation: proceedings of the fifth annual deep brain stimulation think tank. Front Neurosci. 2017;11:734. https://doi.org/10.3389/fnins.2017.00734