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Accuracy of Deep Brain Stimulation Lead Placement Using a **Cranial Robotic Guidance Platform: A Preliminary Cadaveric Study**

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ABSTRACT

AIM: To measure the deviation rate of a custom 3D-printed Deep Brain Stimulation (DBS) lead holder assisted electrode placements from their intended targets, providing a benchmark for the system's accuracy and paving the way for its use in standard DBS workflows.

MATERIAL and METHODS: The study was conducted in an experimental lab using a cadaver obtained according to local regulations. Planned electrode trajectories, designed with Medtronic's DBS surgery planning system, were transferred to the StealthStation Autoguide. A 3D-printed DBS lead holder with integrated navigation fiducials was used to place six electrodes in the targeted brain regions. Pre-operative CT and MRI scans were used for planning, and post-operative imaging confirmed electrode placement. Deviation from planned trajectories was analyzed using Python to assess accuracy.

RESULTS: Following a 30-minute registration and draping process, the median electrode placement time was 22.5 minutes (range: 15-120). The total surgical time for all six electrodes was approximately 5 hours, including imaging, adjustments, and confirmation. The median difference was 1.73 mm (0.03-5.45) on the X-axis, 1.86 mm (0.46-2.74) on the Y-axis, and 1.95 mm (0.73-4.4) on the Z-axis. The median vectorial difference was 2.68 mm (2.3-6.71), while the median trajectory difference was 3.01 mm (1.64-6.63).

CONCLUSION: Despite 50% of leads having a vectorial difference exceeding 4 mm, most had a trajectory difference of less than 3 mm, which could be attributed to the inability to measure the length of the electrode precisely. These results suggest that with minor adjustments, the StealthStation Autoguide could be a cost-effective alternative to similar systems, though further cadaveric studies are necessary to address potential learning curves and random factors.

KEYWORDS: Deep brain stimulation, Electrode placement, Parkinson's disease, Placement accuracy, Robot-assisted

ABBREVIATIONS: 3D: Three-Dimensional, CNC: Computer Numerical Control, CT: Computed Tomography, DBS: Deep Brain Stimulation, FDM: Fused Deposition Modeling, GPi: Globus Pallidus Interna, MRI: Magnetic Resonance Imaging, PLA: Polylactic Acid, SPSS: Statistical Package for the Social Sciences, STL: Stereolithography, STN: Subthalamic Nucleus, TPU: Thermoplastic Polyurethane, Vim: Ventral Intermediate Nucleus

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This work is licensed by "Creative Commons Attribution-NonCommercial-4.0 International (CC)". Deep brain stimulation (DBS) is a widely used procedure for various movement disorders. However, its treatment efficacy is dependent on the accuracy of the electrodes. While effective, traditional stereotactic methods are less comfortable for the patient, as the patient has to be placed in a frame to obtain an MRI and then brought back to the operating room and have a longer duration (both overall and per electrode) than frameless methods (8,10,18,26).

Frameless placement of the DBS electrodes is a proven procedure used since 2019 (5,8,10,15,21,26). These systems either use highly specialized platforms that, after the navigation system specifies the insertion point, allow controlled drive into the target location (e.g., Nexframe® DB2040; Medtronic Neurological Division, Dublin, Ireland) or use a robot with a freely moving arm (e.g., now discontinued Mazor Robotics Renaissance® system (Mazor Robotics Ltd, Caesarea, Israel) and ROSA® robot (Zimmer Biomet, Warsaw, Indiana, USA). These systems may require more investment than compact systems such as StealthStation Autoguide (Medtronic, Dublin, Ireland).

Beyond DBS, robotic surgery has been increasingly adopted in various neurosurgical procedures, offering enhanced precision, reduced operative times, and improved patient outcomes. The integration of robotic systems into neurosurgery facilitates minimally invasive approaches, enhances surgical accuracy, and improves overall workflow efficiency, thereby expanding the capabilities and applications of neurosurgical interventions (1,3,4,6).

However, no studies explore the possibility of utilizing custom-made lead holders with the StealthStation Autoguide system in DBS placement. This study seeks to measure the deviation of the placed electrodes from their intended targets on a cadaveric model, providing a benchmark for the system's accuracy and reliability. It also serves as a preliminary study to justify further research.

MATERIAL and METHODS

Cadaver Preparation

This study was conducted at the Ege University Faculty of Medicine, utilizing a cadaver obtained following Turkish Law No. 2238. The local institutional review board approved the research protocol, ensuring adherence to ethical standards for using human cadaveric material in research (Decision no: 24-3.1T/40, Date: 21.03.2024).

A single cadaver with an intact calvarium was obtained from the Ege University Faculty of Medicine, Department of Anatomy. The cadaver was imaged pre-operatively to plan the trajectories for electrode placement. We used computed tomography (CT) and magnetic resonance imaging (MRI) per our local protocol for DBS placement. MRI studies were performed using a 3.0 Tesla MRI system (Magnetom[®] Verio, Siemens, Erlangen, Germany), and a 16-channel head coil, T2 SPACE sequence, and T1-MPRAGE pulse sequence were used. The CT scan was performed on a 64 detector 128 sliced CT scanner (Siemens Somatom Definition AS, Siemens, Erlangen, Germany).

Medtronic DBS model 3389 leads with 28 cm length and 2 Medtronic DBS model 3389 leads with 40 cm leads were available and were used in this study.

Surgical Planning

Using the StealthStation S8 planning station Version 1.3.2 (Medtronic, Dublin, Ireland) for DBS surgery, trajectories for the subthalamic nucleus (STN), Globus pallidus interna (GPi), and ventral intermediate nucleus (Vim) on both hemispheres of the brain were auto-calculated and then modified by an experienced neurosurgeon and neurologist. These plans were then transferred to the StealthStation Autoguide robotic system, which was used to guide the placement of six DBS electrodes (three on each side).

Electrode Placement

Currently, the StealthStation Autoguide system does not have a holder for DBS electrodes. Thus, the biopsy module and its cannula were used to design the custom 3D-printed DBS lead holder (STL files can be found at https://github.com/ AkbulutBB/DBSNav). The files were then printed using a fused deposition modeling 3D printer Ender-3 S1(Creality, Shenzen, China) with polylactic acid(PLA).

In the biopsy module, the guidance system only works within a single axis after the trajectory is locked. It requires two fiducials arranged in a single line and placed within a specific distance of each other (Figure 1A). Thus, the fiducials were placed within two cavities that were made within the holder, and a hole for the electrode to pass was placed using a drill within the fiducials.

The cadaver was positioned in the operating room (Figure 2), and the StealthStation Autoguide system was set up according to the pre-operative plans. The target distance was calculated using the provided measurement tool for biopsy cannulas (Figure 1B), and DBS electrodes were locked in the desired length using a screw-tightened system. The system's robotic arm was used to guide the DBS lead holder, ensuring precise alignment with the planned trajectories.

To guide the leads, a STar Array Lead Insertion Tube was inserted through the StealthStation Autoguide biopsy system, 5 cm proximal to the target. Then, the electrodes were inserted using the 3D printed tool to stop the leads at the correct depth (Figure 3). After placement, an X-ray image was obtained to account for any displacement when retracting the robotic system. While lead was held in place using bayonet forceps, the custom DBS holder was disengaged using the screw system, and then the robot arm was carefully retracted. After obtaining another X-ray image, ensuring the lead was not moved during this retraction process, it was locked in place by the burr hole covers provided with the leads.

After all leads were placed, the skin was approximated using silk sutures, and the cadaveric head was carefully placed in the transportation box.



Figure 1: A) Two fiducials are arranged specifically with a DBS electrode passing through. **B)** Measuring tool with screw-tightened locking mechanism.



Figure 2: Cadaver with Stealth Station Autoguide in position.

Post-operative Imaging and Analysis

Following electrode placement, CT and MRI scans were repeated with the preoperative protocols to confirm the actual locations of the electrodes. Accuracy was assessed using the method proposed by Burchiel et al. (2), where the difference between the intended and actual trajectory (trajectory difference) and the difference between the intended end-point of the electrode and the actual electrode (vectorial difference) is calculated using the post-operative scans. Coordinates were obtained from the StealthStation system, the difference between intended and actual electrode coordinates was calculated, and 3D vector fields were drawn using the Python libraries Matplotlib and Numpy (12,13). Details of the code can be found in our code repository (https://github.com/ AkbulutBB/DBSNav).

Statistical Analysis

The collected data were analyzed using IBM SPSS Statistics Version 27.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for each electrode placement. No comparative analysis was made as this is a preliminary study involving one cadaver.

RESULTS

After registration and the draping was complete (approximately 30 minutes), the actual electrode placement process took a median time of 22.5 minutes per electrode. The overall surgical time for placing all six electrodes was approximately 5 hours. This time includes the necessary imaging, adjustments, and confirmation steps. Details can be found in Table I.

Using coordinates obtained from StealthStation, the differences es in 3 axes, vectorial, and trajectory differences were calculated (Table II). The median difference was 1.73 mm on the X-axis, 1.86 mm on the Y-axis, and 1.95 mm on the Z-axis. The median vectorial difference was 2.68 mm, while the median trajectory difference was 3.01 mm. Figures 4, 5, and 6 provide visual representations of the planned trajectories and the actual placements.

DISCUSSION

The preliminary results of our study demonstrate the potential of the StealthStation Autoguide system for DBS lead placement in a cadaveric model, warranting further research to improve upon our design and possibly match the accuracy of more specialized robotic platforms.

We created and employed a specialized 3D-printed DBS lead holder due to the lack of a commercially accessible holder for DBS electrodes compatible with the StealthStation Autoguide.

No	Electrode	Time (min)	I-X	I-Y	I-Z	A-X	A-Y	A-Z
1	L STN	120	135.56	135.72	145.93	135.37	134.89	143.31
2	L Gpi	45	146.38	130.16	148.81	140.93	129.7	152.69
3	L Vim	25	137.08	138.39	149.61	136.91	139.07	147.11
4	R STN	20	111.56	135.46	145.93	113.48	133.66	142.72
5	R Gpi	15	100.86	129.67	148.82	100.89	127.49	148.09
6	R Vim	20	109.98	138.1	149.61	111.69	135.36	145.21

Table I: Placement Time and Coordinates of Electrodes

The X-axis is the medial-lateral axis, The Y-axis is the anterior-posterior axis, and the Z-axis is the superior-inferior axis in this context. "I" stands for intended, and the "A" stands for the actual coordinates. **Abbreviations: STN:** Subthalamic Nucleus, **GPi:** Globus Pallidus Interna, **Vim:** Ventralis Intermediate Nucleus

Table II: Differences in Different Axes in the Actual Electrode Position and the Planned Coordinates

No	Electrode	Delta-X (mm)	Delta-Y (mm)	Delta-Z (mm)	Vectorial Difference (mm)	Trajectory Difference (mm)
1	L STN	0.19	0.83	2.62	2.75	1.91
2	L Gpi	5.45	0.46	-3.88	6.71	6.63
3	L Vim	0.17	-0.68	2.5	2.6	1.64
4	R STN	-1.92	1.8	3.21	4.15	3.16
5	R Gpi	-0.03	2.18	0.73	2.3	2.08
6	R Vim	-1.71	2.74	4.4	5.46	2.86

Vectorial difference and trajectory difference are calculated through the process provided in the methods. **STN:** Subthalamic Nucleus, **GPi:** Globus Pallidus Interna, **Vim:** Ventralis Intermediate Nucleus.



Figure 3: The 3D-printed tool stops the lead at the correct depth.

Although our custom holder allowed the electrode placement, future versions could be enhanced to overcome the limitations of StealthStation's biopsy length calculation tool. This could enable lead advancement by 0.1 mm intervals, similar to traditional insertion systems, potentially leading to improved lead placement accuracy.

It should also be noted that fused deposition modeling, which has been used to print the DBS holder, has a reported 0.08-3.14% manufacturing accuracy (19). This means some deviations from the target may have been caused by warping and deformation during the printing process. This may be reduced by using computer numerical control (CNC) machining and industrial-grade calibration techniques.

While there is no clear literature on what constitutes a malposition, most authors report their vectorial difference is less than 3mm and consider revision when it is more than 3 mm. In comparison, 4 mm can be considered unacceptable by all accounts (2,5,7,9,16,17,22,23,27). In our experiment, while half of the leads had a high vectorial difference (more than 4 mm), the majority of the leads had a trajectory difference of less than 3 mm, possibly explained by the inability to measure the length of the electrode precisely, and extended the electrode deeper than planned. This was also partially caused by challenges in visualizing the real-time trajectory of the electrodes on the StealthStation Autoguide screen. This difficulty



Figure 4: 3D vector field (A) and the StealthStation images (B) for intended electrode vectors (blue arrows) and the electrodes placed for the STN (red arrows).



Figure 5: 3D vector field (A) and the StealthStation images (B) for intended electrode vectors (blue arrows) and the electrodes placed for the Gpi (red arrows).



Figure 6: 3D vector field (A) and the StealthStation images (B) intended electrode vectors (blue arrows) and the electrodes placed for the Vim (red arrows).

arose because the targets for DBS placement were located further from the biopsy cannula, which the system is primarily designed for. Enhancing the system's capabilities to provide real-time feedback for our specialized DBS lead holder could improve accuracy and operator confidence in further research.

An interesting observation is that the duration of the surgery significantly reduced as the primary surgeon felt more at ease with the design. Although the learning curve of the Autoguide platform may have contributed to this, the primary surgeon had ample expertise in both DBS insertion and the utilization of the robotic platform before this. Hence, this occurrence can likely be attributed to the incorporation of our recently developed 3D-printed fiducial holder into the workflow. More cadaveric specimens would be required to minimize the potential variability caused by this.

So, while platforms such as Mazor Robotics Renaissance[®] system and ROSA[®] robot offer high-accuracy placement of the DBS leads, their cost may be a barrier for some healthcare organizations, particularly in developing countries, as while their prices are not publicly listed, StealthStation Autoguide is approximately ¹/₅ of the price of the Renaissance, and ¹/₄ of the ROSA robotic platform (24). This study serves as an initial exploration of Autoguide's feasibility for DBS lead placement, and future research should investigate its cost-effectiveness compared to other robotic and frame-based systems.

An important constraint of this study is the utilization of only one cadaver. Anatomical variability between specimens can affect the generalizability of our findings. Preliminary studies are crucial for justifying additional research and funding, but bigger sample sizes are required to validate and expand upon these findings. Additionally, the biomechanical properties of a cadaver brain differ significantly from those of a living human brain. The rigidity and fragility of a cadaver brain can potentially impact the precision of electrode positioning. During this study, the increased resistance encountered when inserting the electrodes may have caused bending, resulting in deviations from the intended trajectories (11,20).

Furthermore, the absence of physiological fluids in a cadaver brain may affect its stability and lead to brain tissue displacement during transport as the fixative fluids drain out of the severed cadaveric head. While this phenomenon is not explored in the literature, there are reports of increased brain displacement in patients with CSF over drainage (14,25). This displacement may further contribute to the discrepancies between planned and actual electrode positions. Addressing these differences in future studies by simulating more realistic brain conditions (e.g., fresh frozen cadavers or whole-body cadavers) could improve the findings' relevance to clinical practice.

The precision of the StealthStation Autoguide system's biopsy length calculation tool is a notable limitation. Traditional DBS frames operate with a precision of approximately 0.1 mm, whereas the StealthStation's biopsy calculation tool has a resolution of 1 mm. This issue has not been addressed in the literature, but we believe this lower resolution may have contributed to the observed deviations in electrode placement. Modifying the 3D-printed DBS lead holder for each plan could address this limitation by bypassing the measurement tool's constraints and enhancing placement accuracy.

CONCLUSION

This preliminary study serves as the first step in the implementation of the StealthStation Autoguide cranial robotic guidance platform for DBS surgery. By demonstrating its ability to perform this surgery using a custom 3D-printed DBS holder, our research paves the way for the clinical application of this technology. The potential to shorten surgical times, reduce patient discomfort, and its affordability compared to its counterparts makes Autoguide an appealing option and warrants further research into this topic. Future studies should focus on repeating this work after addressing the technical issues we have encountered and with larger sample sizes. Such research will help refine the technique and build upon our findings, ultimately improving the safety, accuracy, and accessibility of frameless DBS surgery using the StealthStation Autoguide.

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Declarations

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Availability of data and materials: The datasets generated and/or analyzed during the current study are available from the corresponding author by reasonable request.

Disclosure: The authors declare no competing interests.

AUTHORSHIP CONTRIBUTION

Study conception and design: HB, SC, AA, TY Data collection: BBA, OD, OSA, MSB Analysis and interpretation of results: NA, KEC, CE Draft manuscript preparation: HB, BBA, MSB Critical revision of the article: HB, MSB, NA, KEC All authors (HB, BBA, OD, OSA, MSB, NA, KEC, CE, SC, AA, TY) reviewed the results and approved the final version of the manuscript.

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