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Comparative Study of Robot-Assisted versus Conventional Frame-Based Deep Brain Stimulation Stereotactic Neurosurgery

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Keywords
Robotics · Stereotactic neurosurgery · Deep brain stimulation · Frame-based neurosurgery

Abstract
Background/Aims: Technological advancements had a serious impact on the evolution of robotic systems in stereotactic neurosurgery over the last three decades and may turn robot-assisted stereotactic neurosurgery into a sophisticated alternative to purely mechanical guiding devices. ***Objectives:*** To compare robot-assisted and conventional frame-based deep brain stimulation (DBS) surgery with regard to accuracy, precision, reliability, duration of surgery, intraoperative imaging quality, safety and maintenance using a standardized setup. ***Methods:*** Retrospective evaluation of 80 consecutive patients was performed who underwent DBS surgery using either a frame-based mechanical stereotactic guiding device (n = 40) or a stereotactic robot (ROSA Brain, MedTech, Montpellier, France) (n = 40). ***Results:*** The mean accuracy of robot-assisted and conventional lead implantation was 0.76 mm (SD: 0.37 mm, range: 0.17–1.52 mm) and 1.11 mm (SD: 0.59 mm, range: 0.10–2.90 mm), respectively. We observed a statistically significant difference in accuracy ($p < 0.001$) when comparing lateral deviations between both modalities. Furthermore, a statistical significance was observed when investigating the proportion of values exceeding 2.00 mm between both groups ($p = 0.013$). In 8.75% (n = 7) of conventionally implanted leads, lateral deviations were greater than 2.0 mm. With a maximum value of 1.52 mm, this threshold was never reached during robot-guided DBS. The mean duration of DBS surgery could be reduced significantly ($p < 0.001$) when comparing robot-guided DBS (mean: 325.1 ± 81.6 min) to conventional lead implantation (mean: 394.8 ± 66.6 min). ***Conclusions:*** Robot-assisted DBS was shown to be superior to conventional lead implantation with respect to accuracy, precision and operation time. Improved quality control, continuous intraoperative monitoring and less manual adjustment likely contribute to the robotic system's reliability allowing high accuracy during lead implantation despite limited experience. Hence, robot-assisted lead implantation can be considered an appropriate and reliable alternative to purely mechanical devices.

Introduction

The introduction of robot-assisted stereotactic neurosurgery in 1985 marked the inception of robotic surgery in the field of medicine. In search for a fast, accurate and reliable alternative to conventional stereotactic guiding

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devices, Kwoh et al. [1] employed an industrial robot during the first robot-assisted surgical procedure to place a biopsy cannula along a planned trajectory within the brain. Owing to manifold technical limitations at the time, robot-assisted surgery, however, could not be considered an appropriate alternative to purely mechanical guidance systems. In recent years, technical advancements have paved the way to more sophisticated robotic systems reaching a level where robot-assisted stereotactic neurosurgery can be considered equal if not superior to conventional approaches [2–4]. Consequently, employment of surgical robots in operating theaters has significantly increased around the world [5–12].

Deep brain stimulation (DBS) constitutes an effective treatment for a broad range of movement and neuropsychiatric disorders. During surgery, leads are advanced deep into eloquent areas of the brain in order to apply electric current to surrounding brain tissue [13]. As clinical outcome strongly correlates with proper lead placement, high precision and accuracy are imperative during electrode implantation [14, 15]. Moreover, DBS surgery is time-consuming lasting around 5–7 h. Given that the surgery is generally performed under awake conditions, an efficient workflow is required to keep operation times at a minimum and increase patient comfort while maintaining safety and accuracy. The adaption of robotic devices to these specific needs has proven a great challenge thus far. Usability and practicality of medical robots commonly proved inferior to purely mechanical systems. As a consequence, robot-assisted stereotactic neurosurgery remains largely disapproved in the majority of DBS centers around the world despite high accuracy [16–18]. The aim of this study was to investigate the efficacy of robot-assisted DBS by comparing a state-of-the-art neurosurgical robot, the ROSA Brain (MedTech, Montpellier, France) to a conventional stereotactic guiding system, the modified Riechert-Mundinger (RM) stereotactic apparatus (Inomed, Emmendingen, Germany). Introduced in the late 1940s, the RM system was among the first widely accepted guiding devices in stereotactic neurosurgery. It has proven effective during countless stereotactic interventions and is characterized by its stability and versatility [19]. Conversely, the ROSA Brain obtained the CE mark in 2008 and was approved by the Food and Drug Administration in 2009 [4]. It features a robotic arm with 6 degrees of freedom and comprises a haptic system that allows a user-friendly interaction with the robot. Moreover, the robot is able to perform autonomous movements under physician supervision. Having been installed in about 80 hospitals, the ROSA Brain is one of the most widely employed neurosurgical robots today. Several studies evaluating the accuracy of frame-based stereotactic DBS have been published to date [17, 20]. Comparison of deviations, however, proves difficult as different intraoperative imaging modalities and modes of accuracy measurement are employed for lead position verification. Finally, expertise and proficiency in performing DBS were shown to significantly influence targeting accuracy leading to great interinstitutional variances [20]. Hence, to reliably and accurately compare conventional and robot-assisted DBS, a standardized intraoperative setup and regulated means of evaluation are imperative. We achieved this by using very similar setups for both approaches; lead implantation and verification were performed by the same specialized team (F.E., S.H., M.M., C.N.) to eliminate the systemic bias.

Methods

Study Population

Retrospective evaluation of 80 patients (54 males, 26 females, mean age 57.6 years) suffering from therapy refractory Parkinson's disease ($n = 50$), essential tremor ($n = 10$) dystonia ($n = 8$), obsessive-compulsive disorder ($n = 5$) and other conditions ($n = 7$), who underwent bilateral lead implantation between November 2013 and May 2017, was performed (Table 1). From the introduction of the ROSA Brain at our department in November 2015 a total of 40 patients underwent robot-guided lead implantation in routinely employed targets (Table 1). For comparison, 40 conventionally implanted patients who consecutively received DBS prior to the introduction of the ROSA Brain were evaluated. In both groups, all patients undergoing DBS surgery were included in the study, no bilateral implantations were excluded. Two different lead models were used during DBS surgery (model 3387 or 3389, Medtronic, Minneapolis, USA). All patients gave written informed consent prior to surgery. In accordance with the German data protection law, no statement of the ethics committee was required due to the retrospective nature of this study.

Conventional Frame-Based DBS Surgery

In the preoperative course, 3-dimensional, nonstereotactic magnetic resonance imaging (MRI) scans were performed in coronal and axial sections using a 1.5-T clinical MRI system (Philips Gyroscan Intera, Philips Ltd., Best, the Netherlands). On the day of surgery, the patient's head was shaved and mounted in a modified RM frame. A stereotactic, contrast-enhanced computed tomography (CT) scan (SOMATOM Definition Flash, Siemens, Erlangen, Germany) was then obtained [21]. Imaging parameters for the CT scan were as follows: matrix size 512 × 512, field of view 300 mm, slice distance 1 mm, voltage 100 kV, current time product 350 mAs and kernel H31s. Stereotactic CT transformation, fusion of CT and MRI data sets and planning were then performed using the Praezis Plus Software (Inomed, Emmendingen, Germany). After trajectory planning, leads were implanted using the RM guiding system. Stereotactic coordinates were manually transferred to the

Table 1. Main characteristics of both study populations who underwent either conventional (RM) or robot-assisted (ROSA) deep brain stimulation

Target	Underlying disease	Patients, *n*	Electrodes, *n*
RM			
STN	PD	22	44
GPi	DY	7	14
Vim	MST/ET	5	10
NA	OCD	2	4
Other	n.a.	4	8
Subtotal		40	80
ROSA			
STN	PD	28	56
Vim	MST/ET	5	10
NA	OCD	3	6
GPi	DY	1	2
Other	n.a.	3	6
Subtotal		40	80
Total		80	160

DY, dystonia; GPi, globus pallidus internus; MST/ET, MS tremor/essential tremor; NA, nucleus accumbens; n.a., not assessed; OCD, obsessive-compulsive disorder; PD, Parkinson's disease; RM, Riechert-Mundinger stereotactic apparatus; STN, subthalamic nucleus; Vim, ventralis intermediate nucleus.

RM aiming bow and visually verified and adjusted in accordance with the phantom base. Following burr hole craniostomy, the first lead was implanted via a rigid DBS guide cannula using Ben's gun (a microdrive with five parallel channels for macro-/microneedles). Accurate lead placement was verified on flat-panel-detector-based CT (fpCT) scans employing the O arm (Medtronic Inc., Minneapolis, MN, USA). The following imaging parameters were used: matrix 512 × 512, field of view 210 mm, slice thickness 0.8 mm, voltage 95 kV and charge 20 mA. To intraoperatively control for effects and adverse events, stimulation testing was performed subsequently. If testing revealed insufficient clinical benefit or adverse events at low amplitudes, the trajectory was readjusted. However, as the decision to adjust the trajectory was based on the patient's clinical response and was thus unrelated to accuracy of the respective implantation modality, changes of the lead path based on stimulation testing were not taken into account in this study. After clinical testing the lead was anchored at the skull and the process was repeated on the contralateral side. No microelectrode recordings were performed in the RM group. The pulse generator was implanted in a subsequent procedure the same day.

Robot-Assisted DBS Surgery

ROSA-assisted DBS has been extensively described by Lefranc and Le Gars [4]. Briefly, MRI and CT data acquisitions were performed in accordance with the conventional approach. A Leksell series G stereotactic frame (Elekta, Stockholm, Sweden) was attached to the patient's head. Stereotactic transformation, image fusion with nonstereotactic MRI data sets and DBS planning were realized with the robot planning software Rosanna v2.5.8. (Medtech, Montpellier, France). After target verification the treatment plan was digitally transferred to the robot, and frame-based registration was performed using the robot's haptic capabilities [17]. Registration accuracy was considered acceptable below 0.40 mm. If values exceeded 0.40 mm during registration, the process was repeated. After marking the entry point using either the nonsterile pointer or the robot's laser probe, the scalp was locally shaved. As opposed to the conventional approach, two burr holes were successively drilled after sterile draping. For lead placement, the robotic arm was equipped with Ben's gun and placed in alignment with the predetermined trajectory at a predefined distance to the target. Lead implantation was performed manually by the neurosurgeon after paving the lead path with a rigid DBS guide cannula. Once the electrode was implanted at the predefined target, accurate placement and clinical benefit were assessed analogous to conventional DBS. Microelectrode recordings were foregone in the ROSA group. The pulse generator was implanted in a subsequent procedure the same day.

Comparison of Lead Implantation Accuracy and Precision

Accuracy of lead implantation was assessed by measuring the lateral deviation from the originally planned trajectory to the preliminary electrode position in CT image space [22]. Lateral deviation was defined as the length of a vector, that is perpendicular to the planned trajectory, starts at the center of the first contact of the planned lead and ends at the intersection of vector and the center of the realized trajectory. Thus, measurement of lateral deviation takes into account both anteroposterior and mediolateral displacements with respect to the planned trajectory. This approach was chosen for quantification as it is independent from lead implantation depth. Implantation depth during robot-assisted DBS is determined by the neurosurgeon and thus unrelated to the robot's accuracy.

To investigate and compare lateral deviations between robot-guided surgery and conventional lead implantation, the Mann-Whitney U test was used. In addition, a generalized linear mixed model was employed to investigate the effect of surgical DBS variables, namely errors resulting from bilateral lead implantation. As deviations exceeding 2.00 mm are considered clinically meaningful, a χ^2 test was used to investigate the proportion of deviations surpassing the 2.00-mm threshold versus values within clinically accepted limits (i.e., ≤2.00 mm) between both groups [14, 15]. The test was adjusted to take into account possible factors influencing the accuracy of contralateral lead implantation. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS Statistics for Macintosh, version 23.0, IBM Corp., Armonk, NY, USA).

Comparison of Surgery Duration, Workflow, Intraoperative Imaging Quality, Safety and Maintenance

Workflow, safety and maintenance were discussed empirically. Imaging quality of intra- and postoperative fpCT scans was evaluated visually. Differences in duration of surgery were assessed quantitatively using the independent samples *t* test. Duration of surgery was defined as the time between patient entry into the OR and final closure that included preoperative CT imaging, trajectory planning, intraoperative registration/calibration, lead implantation surgery and intraoperative stimulation testing.

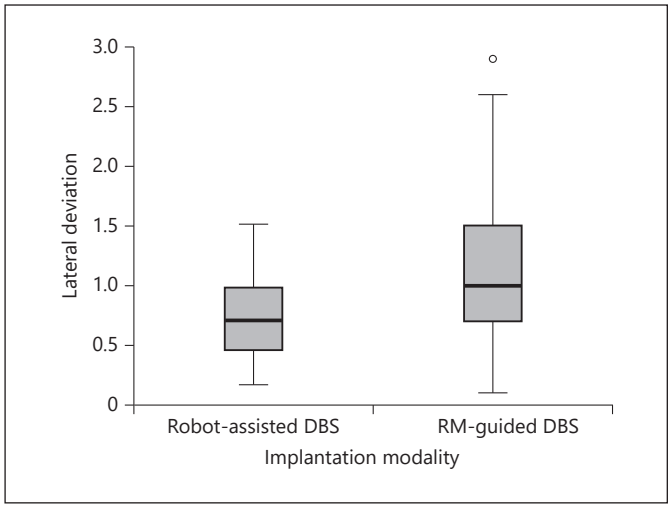

Fig. 1. A box plot displaying the lateral deviations of implanted DBS leads obtained from intraoperative fpCT scans during surgery. Implantation accuracy differed significantly between both modalities ($p = 0.00$). Box = 1st to 3rd quartiles, bold line = median value, whiskers = maximum and minimum values, circle = outlier.

Results

In all 80 patients DBS was performed successfully (n = 160 leads). Intraoperative complications associated with lead placement including intracranial bleeding and electrode dislocation during lead anchoring were not observed.

Using the RM system, the mean lateral deviation observed between planned and actual lead position was 1.11 ± 0.56 mm (range: 0.10–2.90 mm). Conversely, the mean lateral offset ascertained from fpCT scans after robot-guided DBS was 0.76 ± 0.37 mm (range: 0.17–1.52 mm) (Fig. 1). Statistical analysis revealed a highly significant difference ($p < 0.001$) when comparing lateral deviations between robot-guided and conventional DBS. Taking into account surgical DBS variables, analyses using the generalized linear mixed model continued to display highly significant differences between both groups ($p < 0.001$). In 20% ($n = 16$) of conventionally implanted leads, lateral deviations exceeded the maximum deviation measured in robot-assisted DBS (max. = 1.52 mm) (Fig. 1).

Comparison of lateral deviations ≤2.00 mm and >2.00 mm between the ROSA and RM groups revealed a significant difference ($p = 0.013$, χ^2 test). In 8.75% ($n = 7$) of conventionally implanted leads lateral deviations were greater than 2.00 mm (Fig. 2). With a maximum measured offset of 1.52 mm, clinically significant deviations were never attained during ROSA-guided DBS.

Statistical analysis of operation times using the independent-samples t test yielded a highly significant difference between robot-assisted and conventional lead implantation ($p < 0.001$). With a mean duration of 325.1 ± 81.6 min (range: 218–454 min) DBS surgery employing the ROSA Brain could be reduced by more than 1 h as compared to conventional lead implantation (mean duration of RM surgery: 394.8 ± 66.6 min, range: 243–540 min). In the course of robot-guided DBS, a gradual decrease in surgery duration was observable. Within-group comparison between the first 20 and last 20 patients undergoing DBS surgery using the ROSA Brain revealed highly significant differences in operation time ($p < 0.001$; mean duration in first 20 patients: 352.5 ± 49.8 min, range: 268–454 min; mean duration in last 20 patients: 280.5 ± 59.2 min, range: 218–423 min).

Discussion

To date, various independent studies have investigated precision and accuracy of frame-based and frame-less implantation modalities for DBS [5, 20, 23]. Evaluating the accuracy of stereotactic RM-based electrode placement Fiegele et al. [24] demonstrated a mean lateral deviation of 1.32 ± 0.75 mm (range: 0.00–4.50 mm) in 23 patients. In contrast, Lefranc et al. [23] reported a mean accuracy of 0.81 ± 0.39 mm (range: 0.00–1.61 mm) for 52 targets during frame-based ROSA-assisted surgery. The mean lateral lead deviations obtained in the present study, which to our knowledge is the largest one to date, conform with the externally reported values. Using a standardized setup, our data revealed superiority of robot-assisted lead placement over conventional DBS.

High accuracy is the key to successful patient outcome in DBS surgery. According to the literature, current stereotactic procedures are, however, associated with errors in the order of 1–2 mm [20, 25, 26]. Lead displacement with lateral deviations ≥1.40 mm during subthalamic nucleus DBS were shown to be likely associated with unfavorable spread of electrical current into adjacent eloquent areas leading to extensive stimulation-induced side effects [27]. Despite good compensatory mechanisms of directional leads, Steigerwald et al. [28] clearly point out that the employment of this novel technology "must never be an excuse for lowering the surgical standard and precision of surgical lead placement". With a mean deviation of 0.76 mm, the ROSA Brain can be considered a

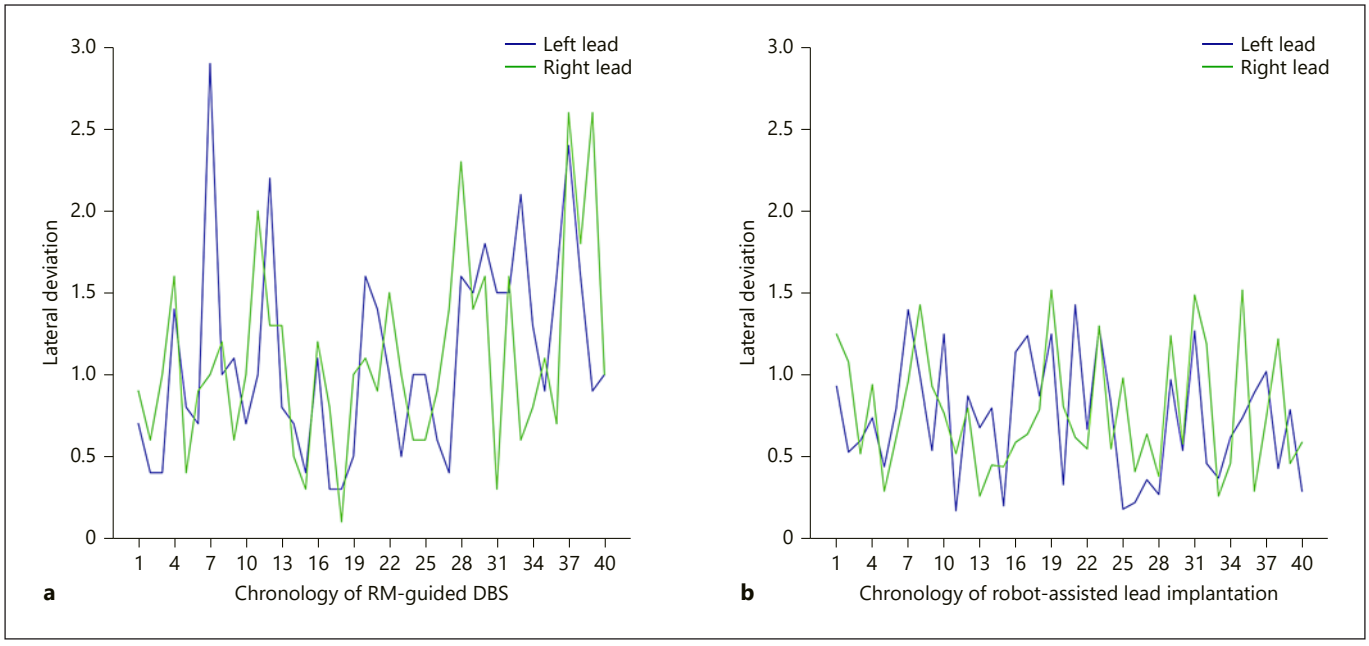

Fig. 2. Line graphs chronologically displaying lateral deviations of conventional (**a**) and robot-assisted (**b**) DBS. In both groups, a total of 40 patients underwent bilateral lead implantation. Individual cases are plotted on the *x* axis (1–40), lines indicate lateral deviations as measured from postoperative fpCT scans (blue = left lead, green = right lead). Measured lateral deviations are charted on the *y* axis. During robot-guided electrode implantation, maximum lateral deviations did not exceed 1.52 mm.

precise tool for lead implantation that not only features high accuracy, but also high reliability. The latter was ascertained by comparing the proportion of lateral deviations surpassing the 2.00-mm threshold versus values within clinically accepted limits (i.e., ≤2.00 mm) between the ROSA and RM groups. As errors exceeding 2.00 mm are associated with significant clinical effects leading to worse patient outcomes during chronic stimulation comparison of deviations was performed with respect to the 2.00 mm threshold [14, 15]. Statistical analysis revealed highly significant differences between the ROSA and the conventional groups. While lateral deviations during ROSA-guided DBS did not exceed errors beyond 1.52 mm, 21.3% of implanted leads in the RM group exceeded the maximum error measured during robot-guided DBS. 8.75% of implanted electrodes in the RM group yielded deviations >2.00 mm. This is considerable given that the ROSA Brain was newly introduced at our department and employed without prior experience. From its first employment, lateral deviations could be reduced effectively in the ROSA group. A learning curve reflecting a growing familiarity while employing the robot may be expected; however, despite the lack of experience with the robotic system, the surgeons were familiar with the implantation aspect of DBS leads and the equipment used for lead implantation (i.e., microdrive, guide cannula and DBS leads) during robot-guided DBS. Thus, the observed accuracy of the ROSA Brain reflects the inherent precision of the robot that overcomes the constraints of conventional guiding systems. Increased attention to technology and quality assurance in the early stages of robot-guided lead implantation may have positively influenced our accuracy results. The ROSA Brain, however, remained consistent throughout the observational period not exceeding deviations beyond 1.52 mm (Fig. 2). Conversely, despite extensive experience with the RM system, we were not able to achieve accuracies comparable to robot-guided DBS. Overall, this observation indicates that high accuracy and reliability may be achieved more easily and faster during robot-guided DBS requiring less experience. A learning curve may be observable in surgeons unfamiliar with the implantation aspect of DBS leads using the microdrive; nevertheless, higher accuracy may be achieved faster due to the robot's intrinsic precision.

Factors that may have led to a lower performance of RM-guided DBS include increased lack of quality control mechanisms beyond the phantom base and human errors. The modified RM stereotactic apparatus is a phan-

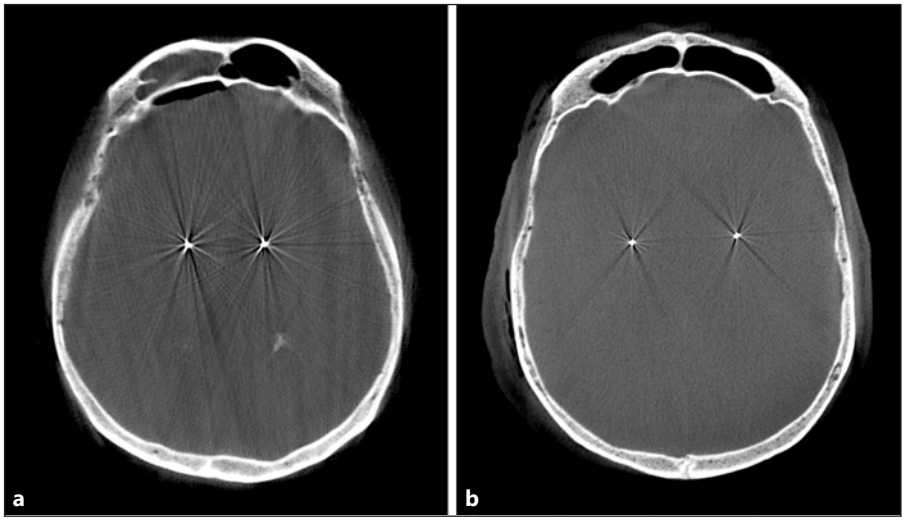

Fig. 3. Comparison of intraoperative imaging quality obtained from intraoperative fpCT scans. Corrupted image quality in conventional DBS can be ascribed to metal artifacts caused by both the frame and aiming bow of the modified RM system (**a**). During robot-guided lead implantation no guiding device is located in the beam path (**b**). Only two carbon rods that rigidly attach the patient's head to the robot are in the frontal beam projection. This, however, has insignificant effects on image quality; artifacts can be reduced to a minimum.

tom-based system that allows verification of the preliminary trajectory prior to lead implantation. Deviations due to mechanical inaccuracies of the stereotactic guiding device may thus be accounted for by manually attuning the preliminary target point to the phantom base. However, as the source of the mechanical error is generally unascertainable, deviations have to be rectified in random directions and rely heavily on the surgeon making the adjustments. In the RM group, minor adjustments of the aiming bow had to be performed in the majority of lead implantations. As these changes are subjective and primarily rely on the surgeon's decisions, reliability might have suffered as a result of adjuster-dependent inaccuracies. The employment of aiming bows that do not feature a phantom base (e.g., the Leksell stereotactic apparatus) may affect reliability likewise, as deviations owing to maladjustments may not be accounted for in the first place.

Comparison of operation times yielded statistically significant differences between both groups revealing a mean reduction of implantation time by more than 1 h during robot-guided DBS. Increases in overall implantation efficiency in the ROSA group can be attributed to the establishment of an efficient workflow and increased confidence in the robotic system. Improvements in workflow included bilateral identification of entry points prior to surgery. As the robot arm can be moved efficiently between entry points, skin incision, hemostasis and craniostomy can be performed simultaneously. This ability proves especially advantageous during procedures requiring implantation of multiple leads (e.g., during stereoelectroencephalography). Here, multiple trajectories can be targeted repeatedly and effectively without the need to manually transfer stereotactic coordinates to the aiming bow. The most relevant time-saving factors, however, are the robot's accuracy and reliability that increase the probability of targeting while reducing stimulation and surgery induced side effects. If planned correctly, trajectory adjustments, stimulation testing, and surgery-related adverse effects may be reduced to a minimum. In conjunction with an established workflow, operation times may consequently be effectively reduced or appropriated towards more relevant stages of the DBS procedure (e.g., intraoperative stimulation testing) to ensure clinical benefit from stimulation without exposing the patient to complications associated with increased surgical duration.

Beyond the phantom base, mechanical guiding devices are more prone to error as they lack viable quality control mechanisms. Individual mechanical parts of the apparatus may be attached wrongly, lock in place or wedge leading to significant and potentially life-threatening deviations that go unnoticed by the surgeon. As setting parameters are commonly being changed and/or mechanical parts being removed temporarily during surgery (e.g., during burr hole craniostomy), further errors may be evoked.

In accordance with conventional guiding systems, robots also feature inaccuracies owing to mechanical errors. Sophisticated calibration algorithms, however, reduce inconsistencies and increase reliability by removing the human-dependent component [29]. Furthermore, when employing the ROSA Brain, quality control is available at any given moment of the implant procedure. Continuous monitoring allows the localization of the current target

point at any given moment, trajectory changes are comprehensible and easily reproducible. As opposed to conventional DBS, locking and wedging of mechanical parts is less pertinent to robot-guided DBS. The robotic arm easily aligns along the predetermined trajectory and locks into position for lead implantation. If readjustment of the system is required during lead implantation (e.g., during burr hole craniostomy), the robotic arm may be removed from the surgical field and put back in place on demand with persistent accuracy of <0.1 mm. Implantation depth and laterality may be accounted for with micromovements that relocate the robotic arm in all three planes. The advantage over conventional DBS lies in the extent and degree of freedom wherein the trajectory may be adjusted intraoperatively allowing changes both on a submillimeter scale and beyond.

Maintenance of both implantation modalities is of significant importance as it directly influences the reliability of lead implantation over time. Wear of the ROSA Brain can be reduced as no extensive sterilization is necessary to reutilize the robotic system. Only a few parts including fixation screws, instrument holder and Ben's gun are required to be autoclaved. In contrast, sterilization of the modified RM system proves extensive and detrimental as not only the RM head frame, but also the phantom base and the aiming bow are being repeatedly autoclaved at temperatures exceeding 100 °C. Repeated heat exposure may cause bends, twists and dullness of mechanical components that may translate into increasing deviations during surgery over time [30]. Overall, maintenance of the ROSA Brain proves more considerate and reliable.

Intraoperative lead verification is commonly associated with artifacts during conventional DBS (Fig. 3). Owing to metal parts, namely the aiming bow, that are located within the beam path during fpCT imaging, image quality is corrupted when employing the modified RM system aggravating the delimitation of implanted leads. Furthermore, visual assessment of image fusion proves more difficult. As no guiding device is located within the beam path during fpCT, image quality is drastically improved during robot-assisted DBS (Fig. 3). Consequently, effective radiation doses applied to the patient's head may be reduced during robot-guided DBS as sufficient image quality may still be achieved with artifact-free CT data sets.

Limitations

Despite the employment of similar setups for lead localization verification, multiple factors may have biased our results. Different frames, software packages, image fusion techniques and registration procedures were employed in both groups, any of which may have influenced differences in accuracy. Moreover, increased artifacts in the RM group may have corrupted our measurements. However, in an unpublished study the accuracy of lead implantation was compared using both, the O arm and conventional X-ray. The method used for X-ray-based DBS was adapted from Hamel et al. [31]. When comparing both modalities no significant differences in accuracy were observed. Therefore, we can exclude image artifacts as a potential source for errors.

Conclusions

In this study, robot-assisted stereotactic DBS surgery was shown to be superior to conventional lead implantation in terms of accuracy and reliability. Improved quality control, continuous intraoperative monitoring and less manual adjustment likely contribute to the reliability of the robotic system. Clinically meaningful deviations were never attained during ROSA-guided DBS. Hence, robot-assisted DBS can be considered an appropriate alternative to purely mechanical guidance systems.

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Disclosure Statement

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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