A novel miniature robotic device for frameless implantation of depth electrodes in refractory epilepsy

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OBJECTIVE The authors' group recently published a novel technique for a navigation-guided frameless stereotactic approach for the placement of depth electrodes in epilepsy patients. To improve the accuracy of the trajectory and enhance the procedural workflow, the authors implemented the iSys1 miniature robotic device in the present study into this routine.

METHODS As a first step, a preclinical phantom study was performed using a human skull model, and the accuracy and timing between 5 electrodes implanted with the manual technique and 5 with the aid of the robot were compared. After this phantom study showed an increased accuracy with robot-assisted electrode placement and confirmed the robot's ability to maintain stability despite the rotational forces and the leverage effect from drilling and screwing, patients were enrolled and analyzed for robot-assisted depth electrode placement at the authors' institution from January 2014 to December 2015. All procedures were performed with the S7 Surgical Navigation System with Synergy Cranial software and the iSys1 miniature robotic device.

RESULTS Ninety-three electrodes were implanted in 16 patients (median age 33 years, range 3–55 years; 9 females, 7 males). The authors saw a significant increase in accuracy compared with their manual technique, with a median deviation from the planned entry and target points of 1.3 mm (range 0.1–3.4 mm) and 1.5 mm (range 0.3–6.7 mm), respectively. For the last 5 patients (31 electrodes) of this series the authors modified their technique in placing a guide for implantation of depth electrodes (GIDE) on the bone and saw a significant further increase in the accuracy at the entry point to 1.18 ± 0.5 mm (mean $\pm$ SD) compared with 1.54 ± 0.8 mm for the first 11 patients ($p = 0.021$). The median length of the trajectories was 45.4 mm (range 19–102.6 mm). The mean duration of depth electrode placement from the start of trajectory alignment to fixation of the electrode was 15.7 minutes (range 8.5–26.6 minutes), which was significantly faster than with the manual technique. In 12 patients, depth electrode placement was combined with subdural electrode placement. The procedure was well tolerated in all patients. The authors did not encounter any case of hemorrhage or neurological deficit related to the electrode placement. In 1 patient with a psoriasis vulgaris, a superficial wound infection was encountered. Adequate physiological recordings were obtained from all electrodes. No additional electrodes had to be implanted because of misplacement.

CONCLUSIONS The iSys1 robotic device is a versatile and easy to use tool for frameless implantation of depth electrodes for the treatment of epilepsy. It increased the accuracy of the authors' manual technique by 60% at the entry point and over 30% at the target. It further enhanced and expedited the authors' procedural workflow.

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KEY WORDS robot; frameless stereotaxy; epilepsy; depth electrodes; SEEG; stereo-electroencephalography; diagnostic and operative techniques

ABBREVIATIONS EEG = electroencephalography; GIDE = guide for implantation of depth electrodes; RPU = robotic positioning unit.

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FRAMELESS stereotactic implantation of depth electrodes has been increasingly used in recent years as an alternative to frame-based stereotactic methods.^{5,11,13–15} While frame-based methods are certainly accurate and safe, they have a number of drawbacks related to the time needed for frame placement and image acquisition, the restricted access to the surgical field and consecutive limitations of possible trajectories, and the limited ability to redefine and adjust trajectories intraoperatively.^{1,3,10,17} We recently introduced a technique of frameless stereotactic depth electrode implantation that avoids these constraints and combines the high variability and flexibility of possible trajectories from the frameless technique with the convenient implantation and fixation of the electrodes used in frame-based methods.⁵ The main limitation of this and all frameless techniques in general is the reduced accuracy compared with frame-based methods.^{2,8,11,16}

To increase the accuracy and further expedite and enhance the procedural workflow of our frameless technique, we integrated a novel miniature robotic device that was recently introduced by our group for frameless intracranial biopsies and catheter placement.¹² This iSYS1 robot is a small form-factor robotic guidance device that avoids manual alignment of the trajectories when using the standard Vertek arm and was shown to significantly improve the accuracy and at the same time reduce the instrument positioning time in biopsies in the laboratory setting.¹²

We present here our initial experience with integration of the iSYS1 robot in our frameless stereotactic depth electrode placement technique.

Methods

Patient Population

The study was approved by the Ethics Committee of the Medical University of Vienna and the Austrian Agency for Health and Food Safety. Between January 2014 and December 2015, 16 patients (7 males and 9 females; median age 33 years, mean age 31.5 years, range 3–55 years) undergoing presurgical evaluation at the Vienna Epilepsy Center (Epilepsy Monitoring Units, Department of Pediatrics and Adolescence Medicine and Department of Neurology, Medical University of Vienna, 2nd Neurological Department, General Hospital Hietzing, Vienna) underwent depth electrode placement with the technique described in this report. All patients had refractory epilepsy and underwent extensive preoperative evaluation using a standardized protocol that included thorough neurological, ophthalmological, neuropsychological, and psychiatric assessment, as well as intensive video electroencephalography (EEG) monitoring. Imaging included high-resolution MRI and functional MRI, Tc-hexamethylpropyleneamine oxime SPECT, and fluorodeoxyglucose and methionine PET imaging, when indicated.

Equipment

All procedures were performed using the S7 Surgical Navigation System (Medtronic) and Synergy Cranial software (version 2.2.6, Medtronic) and the iSYS1 robot guidance device (iSYS Medizintechnik). For a detailed description of the iSYS1 robot, refer to the study by Minchev

et al.¹² The core component of iSYS1 is a 4-axial robotic positioning unit (RPU). The RPU consists of 2 flat modules that can move against one another. Combined with 2 instrument guide extensions, the RPU modules allow a precise angulation ($\pm 30^\circ$) and translational positioning (± 20 mm) of the instrument guidance sheath with submillimetric precision of < 0.1 mm. The iSYS1 robot is attached to a standard 3-pin headholder via a multifunctional arm and a specially designed “Starburst” adaptor. By this, the iSYS1 robot replaces the standard mechanical biopsy arm (Vertek), which is used for the manual frameless technique.

Stereotactic drilling, screwing of the fixation bolt, calculation of the correct depth distance, and placement of the depth electrode were accomplished by a bone-fixed guide for implantation of depth electrodes (GIDE), as described previously.⁵ This adapter tube (length 10 cm, outer diameter 7.9 mm, inner diameter 4 mm) designed by DID Medical/AD-Tech (Simbach am Inn) acts as a reducing sleeve and stabilizer of the iSYS1 robot through bony contact. Stereotactic drilling was performed using the COLIBRI battery-driven Power Tool system (Johnson & Johnson, Synthes) in all cases.

Image Acquisition

All imaging data were acquired using a 3.0-T MRI system (Siemens Magnetom Trio, Siemens Medical Systems). The standard images required for neuronavigation included T1-weighted MR images in the axial orientation with and without contrast enhancement (T1-weighted 3D gradient echo sequence, acquisition time 5.34 minutes, repetition time 1800 msec, echo time 3.79 msec, matrix size 256×256 , field of view 220 mm, flip angle 12° , slice thickness 1 mm, 192 slices) to accurately visualize the anatomy of the gyral and sulcal pattern and the targeted brain regions, as well as the vasculature. 3D surface rendering was used for planning and intraoperatively. For a detailed description of the 3D application, refer to the study by Dorfer et al.⁵

A CT scan (2-mm sequential axial images) was obtained the evening before or the morning of the day of surgery after 6 bone screws had been placed in the frontoparietal region (3 right, 3 left) under local anesthesia. These screws were placed through a stab incision and served as bone fiducials for the registration of the neuronavigation.

iSYS1 Setup and Stereotactic Drilling for Electrode Implantation

After induction of general endotracheal anesthesia, patients were fixed in the Mayfield clamp. Following patient positioning, the RPU was attached to the head clamp via the multifunctional arm and Starburst adaptor. The control unit was then connected to the RPU and to the navigation system. Patient registration was performed using the 6 bone screws as fiducials. Then, the robot was manually prepositioned to check easy reachability of all trajectories (Fig. 1). Thereafter, it was moved away from the surgical field into a parking position for sterile draping. After prepping and draping of the surgical field, the iSYS1 robot was placed near the entry point and automatically aligned to the planned trajectory. The GIDE was then introduced

FIG. 1. Overview of the operating room setup, illustrating the small size of the robot allowing for virtually any trajectory without compromising the surgeon's ability to access the patient's head. Figure is available in color online only.

through the robot's instrument guide extension and positioned on the bone through a small skin incision. As we felt that this approach might cause inaccuracy due to traction of the skin on the GIDE, we adapted our technique in the scope of this study as follows. A K-wire (diameter 4 mm) was used for tension-free skin perforation and center-punched into the bone as a first step. With the K-wire in bony contact, the GIDE was advanced to the bone through a slight enlargement of the skin perforation (Fig. 2).

Stereotactic drilling, monopolar coagulation of the dura, screwing of the fixation bolt, and calculation of the correct depth distance were performed as described previously.⁵ To further increase the accuracy of the electrode trajectory, we further adapted our technique and implanted the depth electrode with the robot's instrument guide in place. This maneuver was thought to reduce potential deviation of the electrode from the trajectory through free-hand introduction over the implantation bolt alone as described for the manual technique⁵ (Fig. 3).

After the electrode was implanted and fixed, the iSYS1 robot allowed an automated alignment of the next trajectory without manual repositioning if the next entry point was in the range of about 4 cm depending on the angulation of the different trajectories (Video 1).

VIDEO 1. Video clip showing in a step-by-step fashion the preparation and setup of the iSYS1 robot, stereotactic drilling, monopolar coagulation of the dura, screwing of the fixation bolt, calculation of the correct depth distance, and implantation and fixation of the electrode. Copyright Christian Dorfer. Published with permission. [Click here to view.](#)

Combination With Subdural Strip and Grid Electrodes

We frequently combine depth electrodes with subdu-

ral electrodes, because, in our opinion, the advantages of either method can be best exploited by their combination. To avoid inaccuracy caused by brain shift, subdural electrodes were implanted after all depth electrodes had been successfully inserted in a patient. Depending on the number and implantation sites of depth electrodes, we either combine them with subdural strip electrodes alone or use additional small subdural plates primarily for mapping of the sensorimotor or language area. For the standard bur hole or the craniotomy necessary to implant subdural electrodes, the iSYS1 robot can easily be completely moved out of the surgical field, enabling full access to the patient's head for the neurosurgeon.

Assessment of System Stability and Electrode Accuracy

We calculated the system stability by measuring the target alignment error before stereotactic drilling and after screwing of the implantation bolt.

Postoperatively, a standard CT was merged with the preoperative MR images including the planned trajectories. Measurements of the electrode position were performed in the "Probe's Eye View" setting of the user interface, as described previously.^{5,14} Using this setting, the electrode deviation from the planned trajectory was visualized (Fig. 4).

Preclinical Phantom Study

Before using the robot for depth electrode placement in patients, we created a phantom model to evaluate if the robot setup is stable enough to maintain the accuracy of the trajectory through stereotactic drilling and screwing. We obtained a CT scan from a human skull and planned 10 trajectories with a trajectory length of 50 mm on a

FIG. 2. **A:** A K-wire (4 mm in diameter) is used for a tension-free skin perforation and center-punched into the bone. **B:** With the K-wire in bony contact, the GIDE is advanced to the bone through a slight enlargement of the skin perforation.

standard neuronavigation system. In a standard operating room setting, we implanted 5 electrodes with our manual technique using the GIDE and 5 electrodes using the iSYS1 robot plus the GIDE. To maintain the stiffness of the electrodes and thereby to avoid deviation of the electrode within the empty skull through gravity, the metal stylet of the implanted electrode was left in place and cut. Measurements and calculations were performed as described for the clinical setting.

Results

Preclinical Phantom Study

In this model the iSYS1 robot maintained its stability despite the rotational forces and the leverage effect from drilling and screwing. It met our expectations regarding accuracy and the time needed to place 1 electrode. The mean deviation from the entry point was reduced from 1.4 ± 0.5 mm ($\pm$ SD) with the manual technique to 0.6 ± 0.4 mm using the iSYS1 robot. Accordingly, the mean deviation from the target point was reduced from 1.4 ± 0.7 mm using the standard Vertek arm compared with 0.8 ± 0.7 mm with the robot.

Furthermore, the mean duration to align the correct trajectory was reduced from 148 ± 76 seconds to 93 ± 18 seconds.

Clinical Study

Ninety-three electrodes in 16 patients (median 6 electrodes per patient, range 1–9 electrodes) were implanted.

Forty-four electrodes were implanted in or around a suspected lesion (frontal $n = 12$, parietal $n = 22$, central $n = 2$, temporal $n = 8$). Thirty-six electrodes were implanted in the amygdalohippocampal region: 31 via an orthogonal temporal trajectory and 5 via a longitudinal occipital trajectory. Thirteen electrodes were implanted in the insula via a frontal trajectory in 8 and a parietal trajectory in 5 patients. The median length of the trajectories was 45.4 mm (range 19.0–102.6 mm).

In 12 of 16 patients, depth electrode placement was combined with subdural electrodes. In 11 patients subdural strip electrodes were implanted via a standard bur hole; in the remaining patient a grid electrode was implanted via a craniotomy.

The procedure was well tolerated in all patients. We encountered no cases of hemorrhage or neurological deficit related to electrode placement. In 1 patient with a psoriasis vulgaris, we encountered a wound infection that needed opening and washout without any bony or intracranial involvement.

Adequate physiological recordings were obtained from all electrodes. No additional electrodes had to be implanted because of misplacement.

Accuracy and System Stability

For the entire study population, the median distance from the center of the bolt to the intended entry point was 1.3 mm (range 0.1–3.4 mm), and the median distance of the electrode tip from the intended target was 1.5 mm (range 0.3–6.7 mm).

FIG. 3. A: The robot is left in place and the electrode can be advanced through the instrument guide to reduce potential deviation of the electrode from the trajectory through free hand introduction over the implantation bolt alone. **B:** Fixation of the electrode can be performed with the robot in place.

Percutaneous Technique

When the last 5 patients (31 electrodes) who had undergone implantation with the modified technique using the K-wire for percutaneous center-punching the bone were analyzed separately, we found a statistically significant increase in the accuracy at the entry point from 1.54 ± 0.8 mm with the original skin incision technique to 1.18 ± 0.5 mm (mean $\pm$ SD) with the modified technique ($p = 0.021$). With regard to the target, an increase in the accuracy was seen from 1.82 ± 1.1 mm to 1.66 ± 1.12 mm (mean $\pm$ SD), which did not reach statistical significance ($p = 0.529$).

The mean target alignment error before and after insertion of the percutaneous bolt as measured intraoperatively by neuronavigation was 0.06 mm (range 0–0.2 mm) and 0.32 mm (range 0–1 mm), respectively, resulting in a mean setup stability of 0.25 mm (range 0–0.9 mm). Thus, the iSYS1 robot maintained the trajectories despite the rotational forces and the leverage effect from drilling and screwing.

Procedure Duration and Workflow

The mean duration of depth electrode placement from the start of trajectory alignment to fixation of the electrode was 15.7 minutes (range 8.5–26.6 minutes). All procedures were performed by 2 neurosurgeons (C.D. and S.W.).

FIG. 4. Screenshot of the neuronavigation screen showing a merged image of the preoperative MR image with the planned trajectory and the postoperative CT scan with the actual electrode position. Figure is available in color online only.

Besides the automatic alignment of a given trajectory, the iSYS1 robot allows for an alignment of multiple trajectories from 1 position without the need to manually readjust the robot, if the entry points are within a workspace of 4×4 cm and depending on the angulation of the different trajectories. This further enhanced the procedural workflow. As for the manual technique, entry points can be as near as 5 mm, if necessary.

Discussion

We established a new robot-assisted frameless stereotactic method for the implantation of depth electrodes by combining the iSYS1 miniature robotic device with our recently introduced frameless stereotactic drilling technique using the GIDE.⁵ Using this device, we were able to further increase the system's accuracy and to decrease the time needed to place an electrode when compared with our manual technique. Similarly, this robot-assisted frameless stereotactic method combines the high versatility of the frameless stereotactic drilling technique using the GIDE with the increased accuracy of automated trajectory alignment through the robot. The small size and similarity of the robot to the Vertek biopsy arm and the precision aiming device of the Medtronic navigation system allowed a seamless integration of the robot into the existing operating room workflow with a short learning curve. Neurosurgeons experienced with the manual frameless stereotactic drilling technique or with perform-

ing stereotactic biopsy using the Vertek biopsy arm can quickly adjust to this technique.

We feel that the greatest advantage in using the iSYS1 robot compared with the manual technique is avoidance of the sometimes cumbersome and time-consuming manual alignment of the trajectory with the Vertek arm that can result in significant inaccuracies. In fact, with the manual technique, a deviation from the planned entry point and trajectory was sometimes deemed acceptable in our series using the Vertek biopsy arm and GIDE alone, as long as the new trajectory met all the requirements needed for a safe electrode implantation.⁵ Compared with our data obtained from surgeries with the Medtronic Vertek biopsy arm with the GIDE alone, the mean real error at the entry point was reduced by 60%, from 3.5 ± 1.5 mm to 1.4 ± 0.75 mm. With the modification of the technique by using the K-wire for center punching the bone percutaneously as a first step, we were even able to improve the accuracy to 1.18 ± 0.55 mm ($p = 0.021$). While we did not perform a direct comparison of the manual technique and the robot in the same patient, the mean duration for the implantation of 1 electrode declined by almost 20% from 19.1 minutes (13.0–35.0 minutes) in our previously published series using the manual technique⁵ to 15.7 minutes (8.5–26.6 minutes) when using the iSYS1. Based on the fact that a substantial number of electrodes were implanted by a neurosurgeon inexperienced with the manual technique, it is very unlikely that this reduction in duration is purely attributable to an increasing familiarity of the neurosurgeons in using the GIDE for stereotactic drilling and electrode implantation but is mainly due to the application of the robotic device.

What makes the iSYS1 robot especially attractive to us is its small size. With the iSYS1 robot there is virtually no compromise of the surgeon's ability to access the patient's head, nor does it interfere with the nursing or other operating room staff. It can be used in any standard neurosurgical operating room and does not warrant special room for storage. At the same time, the iSYS1 miniature robotic device maintains the appropriate system stability needed for stereotactic depth electrode placement. The system stability assessed by the target alignment error was 0.25 ± 0.23 mm. These results prove that the rotational forces from drilling as well as the angulation forces from a leverage effect caused by the length of the drilling system did not cause deviation of the RPU and the planned trajectory.

In addition, the use of the iSYS1 miniature robotic device for stereotactic drilling and electrode implantation with the GIDE keeps the high versatility of the manual system. The small size of the RPU as well as the needle guide extension allows for virtually any trajectory, and stereotactic drilling can be performed as close as 5 mm from the next electrode entry site. The angulation of the trajectories as well as the required registration movement of the RPU has to be taken into account to avoid any compromise. A general principle we followed in our series was that if multiple entry points were within the same head region, we started with the most anterior electrode and continued backward for every consecutive electrode. Furthermore, the iSYS1 robot allowed for an alignment of multiple trajectories from 1 position without the need

to manually approximate the robot to the next entry point. This further expedited the workflow of this method.

On top of all of these advantages related to versatility, flexibility, and convenience in use, the iSYS1 miniature robotic device significantly increased the overall accuracy of the trajectories. In addition to the increase in accuracy at the entry point, the target point accuracy could be increased by 40% from 3.0 ± 1.9 mm to 1.7 ± 1.1 mm (mean $\pm$ SD).

These results are comparable with the other available robots when used in frameless mode and are slightly worse when compared with frame-based robotic applications, which are considered to reach submillimetric accuracy.^{3,4,6,9,18} However, as stated by previous authors, the requirements for accuracy in the placement of depth electrodes for epilepsy are not as stringent as those for other indications like deep brain stimulation.^{7,11} The anatomical structures to be targeted for intracranial EEG recordings are less defined and more superficial; thus, the targeting trajectories are shorter. At the same time, our technique avoids many of the drawbacks reported for other robots or frame-based methods. Whichever technique is used, the surgeon should take the anticipated error margins into account when planning trajectories, especially in more vascular or deep-seated regions.

Limitations

In contrast to our series using the manual technique, registration of the neuronavigation was accomplished with bone screws as registration points. We have to admit that the increased accuracy seen in this series was partly attributable to a decrease in the registration error. Furthermore, we did not directly compare the time needed for the placement of 1 electrode between the manual technique and the iSYS1 robot in the same patient. Due to the lack of availability, we are unable to compare the iSYS1 robot with other robots that are currently available.

Conclusions

The iSYS1 miniature robotic device is a versatile and easy-to-use tool for the frameless stereotactic navigation-guided placement of depth electrodes. According to our experience it helps to improve the accuracy of electrode placement and to reduce the duration of surgery.

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Disclosures

Stefan Wolfsberger reports that he is currently an educational consultant for Medtronic Surgical Technologies and is a consultant for and received clinical or research support for the study described from Medtronic Navigation.

Author Contributions

Conception and design: Dorfer, Wolfsberger. Acquisition of data: Dorfer, Minchev, Stefanits, Kronreif, Wolfsberger. Analysis and interpretation of data: Dorfer, Minchev, Kronreif. Drafting the article: Dorfer. Critically revising the article: Dorfer, Czech, Wolfsberger. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Dorfer. Administrative/technical/material support: Dorfer, Stefanits. Study supervision: Dorfer, Czech.

Supplemental Information

Videos

Video 1. <https://vimeo.com/170473336>.

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