Application of the iSYS1® robotic device for stereotactic neurosurgical interventions: a preclinical phantom trial

[1]G. Minchev, [2]G. Kronreif, [3]L. Holton, [1]G. Widhalm, [1]A. Mert, [1]B Kiesel,
[1]M. Martinez-Moreno, [1]A. Micko, [1]E. Knosp, [4]M. Vogele , [1]S. Wolfsberger

[1)] Department of Neurosurgery, Medical University of Vienna, Vienna, Austria
[2)] Austrian Center of Medical Innovation and Technology – ACMIT, Wiener Neustadt, Austria
[3)] Medtronic Surgical Technologies, Louisville, Colorado, USA
[4)] iSYS Medizintechnik GmbH, Kitzbühel, Austria

Kontakt: `stefan.wolfsberger@meduniwien.ac.at`
Kontakt: `georgi.minchev@meduniwien.ac.at`

Abstract:

Submillimetric precision is essential for stereotactic neurosurgical procedures. However, accuracy of standard neurosurgical procedures such as navigated biopsies and shunts is currently limited due to manual alignment of the biopsy needle or manual placement of the shunt catheter. The aim of this study is to evaluate the feasibility and accuracy of a novel robotic positioning device for stereotactic neurosurgical procedures. We conducted a preclinical phantom trial to evaluate the accuracy of the iSYS1® robotic device in a representative stereotactic neurosurgical procedure: Robotic guidance of a biopsy needle was compared to standard manual needle trajectory alignment. Biopsies were performed by 7 neurosurgeons of different levels of experience either with robotic trajectory alignment (n=81) or manual alignment using a standard mechanical biopsy arm (n=81) under navigational guidance (Medtronic StealthStation S7®). The paper describes the setup, the test methodology as well as the achieved results.

Keywords: Robotic positioning, Stereotactic procedure, Accuracy

1 Introduction

Operations involving positioning of needles and catheters are amongst the most common procedures in cranial neurosurgery. However, submillimetric precision is essential for the success of most neurosurgical procedures. Although some neurosurgical procedures are performed using a skull-mounted stereotactic frame for high precision (cf electrode placement for deep brain stimulation), this setup is costly and time-consuming. Therefore, many procedures that involve placement of a catheter for fluid drainage or a needle for obtaining tissue specimens are currently performed with limited accuracy, i.e. using a mechanical arm or even free-hand. This could potentially lead to procedural failure such as malpositioning of a catheter, inconclusive tissue sampling and even major complications, e.g. cerebral hemorrhage with consecutive neurologic morbidity.

Therefore, navigation-guidance was implemented and established over the last two decades [1-12]. Using preoperatively compiled anatomical patient data from radiological images (Computerized Tomography [CT] or Magnetic Resonance Imaging [MRI] scans) a trajectory from entry to target point can be defined and matched intraoperatively on the patient's head. Alignment of the needle or catheter with the preplanned trajectory is then performed either freehand (shunt catheter placement) or using a mechanical stereotactic arm (needle biopsy). This, however, is associated with major drawbacks due to inaccuracy of the freehand trajectory adjustment method.

Up to 40% of all shunts fail in the first year [13, 14], most commonly due to proximal obstruction with ingrowth of choroid plexus or gliosis around the catheter [15, 16] based on a misplacement of the catheter tip. Each malfunction carries the risk of additional morbidity and could lead to a shunt revision. It was reported, that approximately 4% of ventricular catheters are misplaced failing to cannulate the ventricle entirely [16] or having contact with the ventricle wall. However, Hayhurst et al compared the patient cohort undergoing electromagnetic-navigated shunt placement with the cohort undergoing standard shunt placement using anatomical landmarks [4]. 74% of the navigated shunts were classified as Grade 1 (optimal shunt position) as compared with only 37% of the shunts in the standard group [4].

In case of stereotactic needle biopsies, inaccuracy is associated with the acquisition of non-diagnostic samples in up to 24% of stereotactic biopsy series [17-20] or non-representative tumor samples in up to 64% of biopsies [21-23]. Therefore, serial biopsies could be performed to overcome this drawback. Serial biopsies on the other hand are associated with an increased risk of intracranial hemorrhages [24, 25] which have been reported in 0.3 – 59.8% of the cases [17, 26-30] and contribute considerably to the reported morbidity of 0-16.1% [18, 19, 29, 31-33] of this procedure. Therefore, a safe and reliable trajectory-positioning device that improves accuracy of navigation-guided stereotactic neurosurgical procedures seems warranted.

In the last 10 years, different surgical devices have been developed to increase procedural accuracy in the field of neurosurgery. For instance, Bumm et al. presented an automated approach with redundant navigation for minimal invasive extended transsphenoidal skull base surgery successfully performed on cadaveric heads [34]. Further, Nimsky et al. developed an assistance system for extended endoscope transsphenoidal skull base surgery allowing the simultaneous use of two instruments under endoscopic view [35]. Federspil et al. reported increased accuracy for bone milling using a force controlled robotic system on bone specimen that could be beneficial for both otoneurosurgery and otological surgery [36].

Recently, the Austrian enterprise iSYS Medizintechnik GmbH in cooperation with the competence center ACMIT (Austrian Center of Medical Innovation and Technology) developed the iSYS1® robotic device that has been established in the field of interventional radiology since July 2011 [38-40]. The iSYS1® system is a modular guidance system for surgical invasive tools which provides a precise tool positioning according to the predefined navigation data. By using a software interface – StealthLink2® – this data can be made accessible to the iSYS1® system. A StealthLink® project has recently been conducted at the Department of Neurosurgery, Medical University of Vienna [37].

The aim of the present study is to evaluate the feasibility and value of the iSYS1® guidance device for intraoperative trajectory alignment in stereotactic neurosurgical procedures as compared to the standard freehand or mechanical arm-based alignment method in a preclinical setting. iSYS1® provides a precise submillimetric trajectory alignment in accordance to navigation data and therefore may be a useful tool to overcome these described deficiencies. It has not been tested in neurosurgical interventions yet. By application of iSYS1 we expect that it may

- increase procedural accuracy of stereotactic procedures,
- decrease the number of procedure-related adverse effects, e.g. intracranial hemorrhages, in case of stereotactic needle biopsies,
- decrease the number of punctures necessary to successfully place a ventricular catheter
- decrease the number of early and long term shunt failure due to catheter tip misplacement in case of ventricular shunt placement.

Therefore we conducted a preclinical phantom trial to evaluate the accuracy of the iSYS1® robotic device in a representative stereotactic neurosurgical procedure: Robotic guidance of a biopsy needle was compared to standard manual needle trajectory alignment.

2 Methods

The iSYS1 device is a modular guidance system for surgical invasive tools (e.g. biopsy needle, catheter), which provides the possibility to precisely align the instrument direction according to a predefined plan (trajectory) derived from an (external) planning and navigation system. As soon as the positioning by iSYS1 has been completed, it holds the guidance sheath at the appropriate position and the surgeon is in control to advance the instrument through this sheath to the target point.

The core component is a four-axial robotic positioning unit (RPU), consisting of two 2DOF (degrees of freedom) modules that can be automatically relocated against one another. Combined with Needle Guide Extensions the robot modules allow a precise angulation (± 30 degrees in both angular positions) and positioning (± 20mm in both directions) of the guidance sheath. The RPU is being pre-positioned at the planned entry point and fixed by two passive 7DOF holding arms (MFA, iSYS Medizintechnik GmbH, Austria) – both MFAs are connected to the Mayfield head clamp by means of a dedicated connector bar.

The routine planning of navigation-guided stereotactic procedures is based on radiological imaging data (MRI, CCT). This data is transferred into a navigation system (Stealth Station S7® with Synergy Cranial® 2.2.6 software, Medtronic, CO, USA). On the navigation workstation, the surgeon defines the optimal target and entry point and the system displays an imaginary line (the trajectory) between these two points. iSYS1® is connected to the navigation system using the StealthLink 2® software (Medtronic, CO, USA) and a connecting software developed by ACMIT. Thereby, the data of the predefined surgical plan becomes available for automated positioning of the guidance sheath.

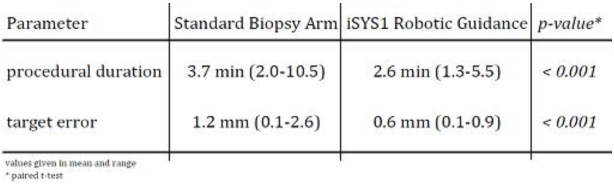
For the study presented in this paper, nine trajectories in different angles were defined on a human skull base using 9 titanium screws as targets. These targets were visualized with a standard axial CCT scan of 0.5 mm slice thickness and 512x512 matrix routinely used for neuronavigation for stereotactic procedures.

Biopsies were performed by 9 neurosurgeons of different levels of experience either with robotic trajectory alignment (n=81) or manual alignment using a standard mechanical biopsy arm (n=81) under navigational guidance (Medtronic StealthStation S7®).

During the present study we evaluated the mean procedural time (min) from trajectory selection at the navigation system to complete needle insertion at target point. Further, we determined the mean target error (mm) for each biopsy by evaluating an arithmetic mean value of three measurements of the direct target error using a submillimetric slide gauge.

3 Results

Application of the iSYS1® robotic device for needle placement was feasible in all 81 cases. Mean procedural duration from selection of the pre-planned trajectory at the navigation system to complete insertion of the biopsy needle at target position was 2.6 minutes (range 1.3-5.5) for robotic guidance versus 3.7 minutes (range 2.0-10.5) for manual positioning ($p<0.001$, paired t-test). Mean target error was 0.6 mm (range 0.1-0.9) for robotic guidance versus 1.2 mm (range 0.1-2.6) for manual positioning ($p<0.001$, paired t-test).



Parameter	Standard Biopsy Arm	iSYS1 Robotic Guidance	*p-value**
procedural duration	3.7 min (2.0-10.5)	2.6 min (1.3-5.5)	*< 0.001*
target error	1.2 mm (0.1-2.6)	0.6 mm (0.1-0.9)	*< 0.001*

values given in mean and range
* paired t-test

4 Summary

Our preclinical results indicate that the application of the iSYS1® robotic device significantly increases the accuracy and reduces operating time of stereotactic neurosurgical procedures. Its value in the routine clinical setting, however, has yet to be defined within a preliminary clinical study. During the following steps, we plan to conduct a clinical cohort study comparing robotic-assisted stereotactic procedures with the manual standard alignment of the trajectory. Future studies could comprise the evaluation of the accuracy and feasibility of the iSYS1 robotic device for stereotactic procedures in functional neurosurgery (Deep Brain Stimulation) and drill/endoscope guidance.

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