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AUSTRIAN CENTER FOR MEDICAL INNOVATION AND TECHNOLOGY

Small is beautiful – a new robotic setup for neurosurgery

International Bejczy Day
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Gernot KRONREIF
ACMIT Gmbh

ACMIT Gmbh - General Introduction

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- ACMIT is an application oriented **research and development center**, providing leading edge R&D-services in selected areas of medical technology.
- ACMIT is **focused on minimally invasive procedures** and acts as a bridge between the scientific world and the medical industry.
- **ACMIT** positions itself as **quality leader**, i.e. provides its R&D services with operational excellence and compliant to all regulatory requirements.

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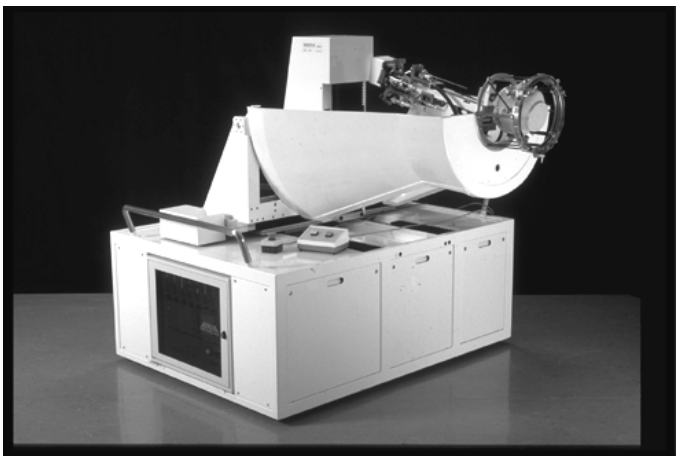
Neurosurgery

- Problem: Placement of an instrument based on pre-op imaging without harming delicate areas in the brain
  - → transfer of planned trajectory into OR setting
  - → ACCURACY!!
- "Gold Standard": Stereotactic Frame
  - Fixation of frame
  - CT-Scan
  - Planning of intervention
  - Guidance of instruments by means of passive guide mounted to the frame
- Neuro-Navigation?
- Advantages of a robot?
  - Higher precision?
  - Frameless intervention technique?

Neurosurgery

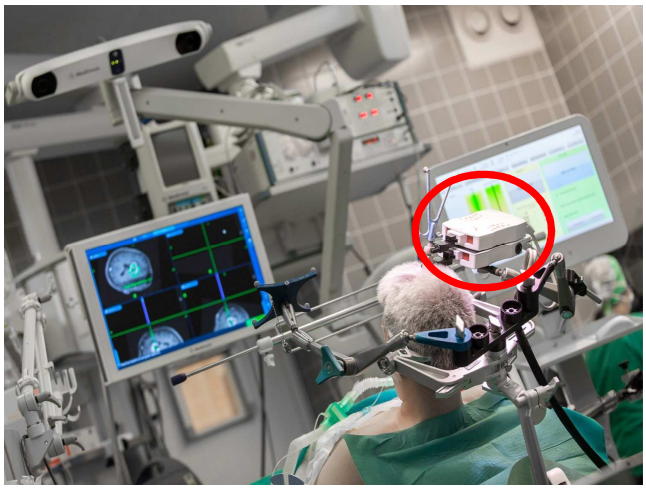
MINERVA: Ecole Polytechnique Fédérale de Lausanne (EPFL) - IMT



Neuromate: Renishaw

ROSA: Medtech SA

Can‘t it be a smaller robot?



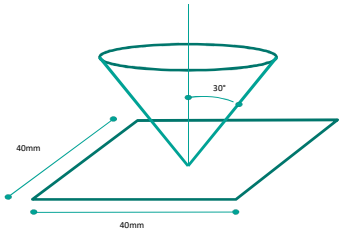
Comparison

Robotic Device	*Weight (kg)*	*Dimension LxWxH (mm)*	*DOF*	*Angulation Range (°)*	*Range of Motion (mm x mm)*	*Connection to head*	*Navigation / Tracking*
iSYS1 (iSYS Medizintechnik)	1,42	267x118x76	4	± 31,5	40x40	mayfield clamp	Medtronic S7 optic / EM
NeuroMate® (Renishaw-mayfield)	210	1250x700x1250	5	± 160	r=1000	OR table	integrated arm-based
ROSA™ (Medtech Surgical Inc.)	250	909x664x1554	6	± 170	r=642	-	integrated arm-based (laser)

N...Newton, kg...kilogramm, DOF...Degrees of freedom, EM...electromagnetic

The LCR fka iSYS-1 fka B-RobII ...

Four-axial robotic positioning unit



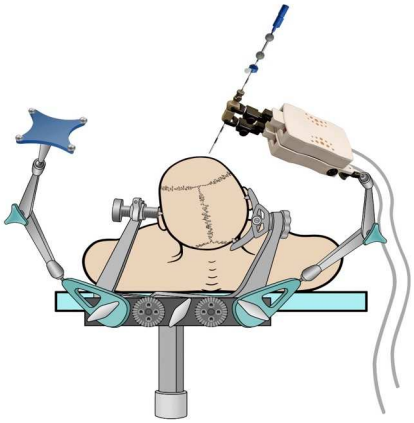
Angulation (±30°) and positioning (±20mm) with submillimertric accuracy

Software Interface

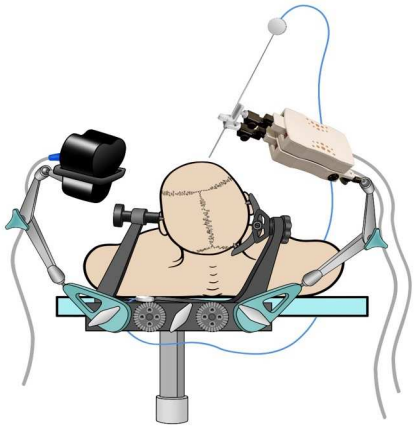
Standard Navigation System

Robot Setup

Optical – Tracking

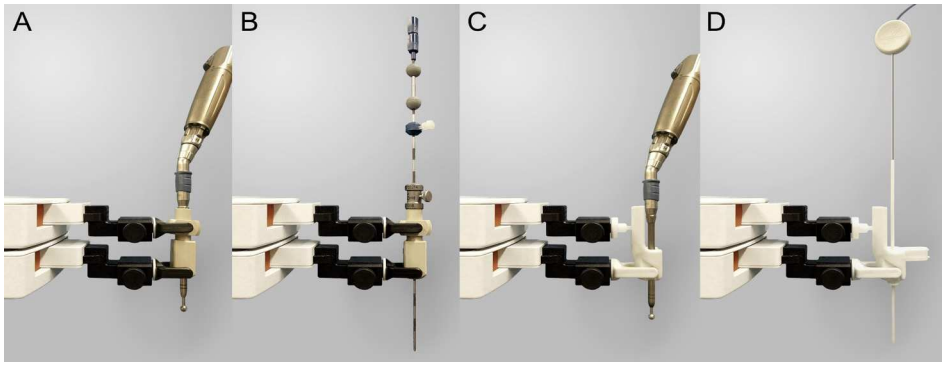


EM – Tracking



Robot Attachments

A. Biopsy – Drill guide
B. Biopsy – Needle guide
C. Catheter – Drill guide
D. Catheter – Catheter guide



Preclinical Study - Biopsy

9 neurosurgeons / 9 biopsy targets
162 biopsies

iSYS-1®
n=81

vs

Manual biopsy arm
n=81

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

Current Applications

+ Burr hole procedures
  + Biopsy
  + Catheter placements
+ Twist drill procedures
  + Biopsy
  + SEEG electrode implantation

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CLINICAL ARTICLE

A novel miniature robotic guidance device for stereotactic neurosurgical interventions: preliminary experience with the iSYS1 robot

Georgi Minchev, MD,[1] Gernot Kronreif, PhD,[2] Mauricio Martínez-Moreno, MD,[1] Christian Dorfer, MD,[1] Alexander Micko, MD,[1] Aygül Mert, MD,[1] Barbara Kiesel, MD,[1] Georg Widhalm, MD, PhD,[1] Engelbert Knosp, MD,[1] and Stefan Wolfsberger, MD[1]

[1]Department of Neurosurgery, Medical University of Vienna, Vienna; and [2]Austrian Center of Medical Innovation and Technology, Wiener Neustadt, Austria

CONCLUSIONS According to the preclinical data, application of the iSYS1 robot can significantly improve accuracy and reduce instrument positioning time. During clinical application, the robot proved its high accuracy, short setup time, and short instrument positioning time, as well as demonstrating a short learning curve.

intracranial catheter placements were performed with robotic guidance to evaluate the feasibility, accuracy, and duration of system setup and application in a clinical setting.

RESULTS The preclinical phantom trial revealed a mean target error of 0.6 mm (range 0.1–0.9 mm) for robotic guidance versus 1.2 mm (range 0.1–2.6 mm) for manual positioning of the biopsy needle ($p < 0.001$). The mean duration was 2.6 minutes (range 1.3–5.5 minutes) with robotic guidance versus 3.7 minutes (range 2.0–10.5 minutes) with manual positioning ($p < 0.001$). Clinical application of the iSYS1 robotic guidance device was feasible in all but 1 case. The median real target error was 1.3 mm (range 0.2–2.6 mm) at entry and 0.9 mm (range 0.0–3.1 mm) at the target point. The median setup and instrument positioning times were 11.8 minutes (range 4.2–26.7 minutes) and 4.9 minutes (range 3.1–14.0 minutes), respectively.

CONCLUSIONS According to the preclinical data, application of the iSYS1 robot can significantly improve accuracy and reduce instrument positioning time. During clinical application, the robot proved its high accuracy, short setup time, and short instrument positioning time, as well as demonstrating a short learning curve.

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Twist Drill Procedure (Biopsy)

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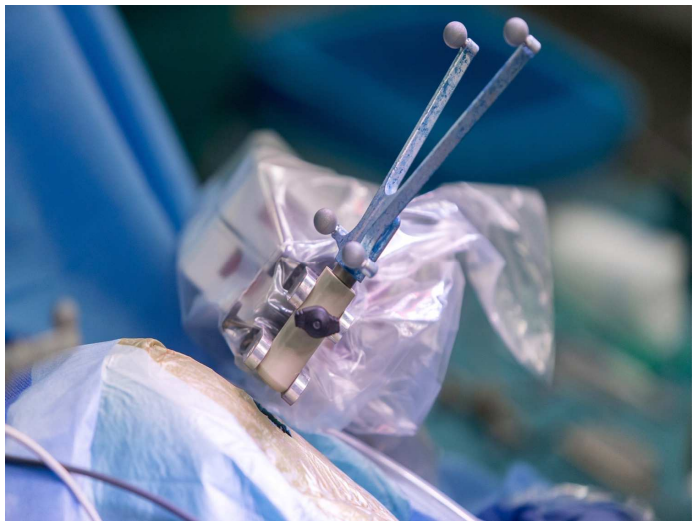
+ Minimally invasive technique with stable bone fixation
+ Originally designed for SEEG
+ Adapted to stereotactic biopsy workflow

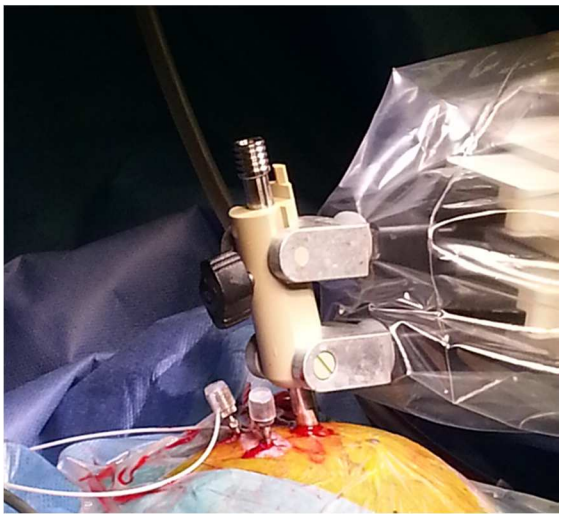


Results – Accuracy and Duration

Indications	*n*
Biopsy	80
Volume (cc)	*median (range)*
Lesion	12.9 (0.1-235.5)
Target	4.8 (0.1-66.9)
Accuracy overall (mm)	*median (range)*
IntraOP Error	
Trajectory alignment error	0.1 (0.0-0.1)
PostOP Real Error (biopsy-OPT)	
At Entry	1.4 (0.2-4.2)
At Target	1.5 (0.0-3.9)
OR Time (Biopsy)	*median (range)*
Setup time (robot fixation - sterile drape)	11.6 (4.2-26.7)
Surgical time (incision - suture)	18.5 (7.0-37.0)
Instrument positioning time (robot positioning - targeting)	7.7 (4.2-12.9)

SD...Standard Deviation, min...minutes, OPT...optical, EM...electromagnetic
preOP...preoperative, postOP...postoperative

Challenging Application: SEEG



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CLINICAL ARTICLE

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

Christian Dorfer, MD,[1] Georgi Minchev, MD,[1] Thomas Czech, MD,[1] Harald Stefanits, MD,[1] Martha Feucht, MD,[2] Ekaterina Pataraia, MD,[3] Christoph Baumgartner, MD,[4] Gernot Kronreif,[5] and Stefan Wolfsberger, MD[1]

[1]Department of Neurosurgery; and Departments of [2]Pediatrics and Adolescence Medicine, and [3]Neurology, Epilepsy Monitoring Unit, Medical University Vienna; [4]Second Neurological Department, General Hospital Hietzing, Vienna; and [5]Austrian Center of Medical Innovation and Technology (ACMIT), Wiener Neustadt, Austria

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 en-

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.

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 ± 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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Conclusion

- Due to its small form-factor we observed a **seemless integration** of the device into these standard neurosurgical procedures.
- According to our preclinical and preliminary clinical data, application of the robot **can improve procedural accuracy without adding significantly to OR time**.
- The adapted minimally invasive instrument set for biopsies **proved high stability, optimization of the workflow and higher procedural accuracy**.

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THANK YOU!

ACMIT Gmbh
Viktor Kaplan-Strasse 2
2700 Wiener Neustadt
Austria

Phone +43 2622 22859-0
Fax +43 2622 22859-55
E-mail office@acmit.at
www.acmit.at