iSYS1® Robotic Frameless Brain Biopsies for Intracranial Tumors: A Prospective, Single Center, Exploratory Pilot Study to Evaluate Feasibility, Accuracy and Safety

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CNS 2018 ANNUAL MEETING HOUSTON, TEXAS OCTOBER 6-10, 2018

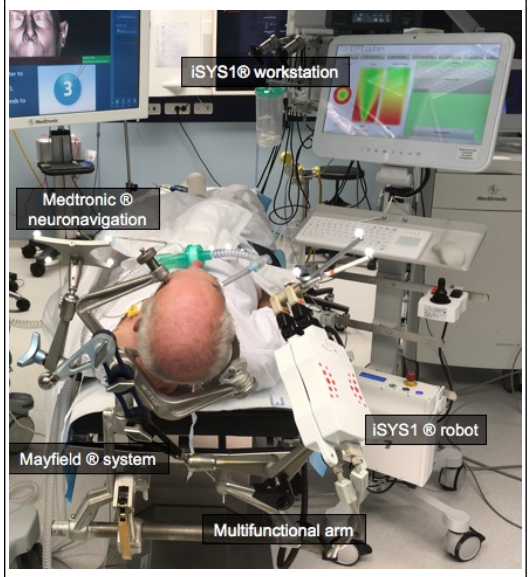
Introduction

Needle biopsies are amongst the most common procedures in cranial neurosurgery and submillimetric precision is essential. Despite MRI and CT based stereotactic guidance, accurate alignment of the biopsy needle with the preplanned trajectory is still associated with inaccuracy. Frameless robotic surgery could increase accuracy and enhance the safety and efficacy of these procedures.

Methods

Clinical and surgical data of all patients undergoing frameless stereotactic biopsies using the iSYS1 robotized system from October 2016 to December 2017 have been prospectively collected and analyzed. Facial surface registration has been adopted for optical neuronavigation.

OPERATING ROOM SET-UP



Clockwise: iSYS1 workstation, iSYS1 robot, Multifunctional arm, Myfield system, Medtronic Neuronavigation system, Stealth, S7.

Results

Feasibility: The procedure of biopsy was feasible in 38 out of 39 patients.

Procedure and complications: The medium length of the trajectory was 50,6 mm (range 34.3-74.9 mm), and median operating time was 20 minutes (range 9-45 minutes, mean time 23,5 minutes). No patient developed permanent new neurological symptoms or signs. No robotic device-related adverse effects were observed. Mean length of hospital stay was 1.5 days, median 1 day (range 1-7 days).

Diagnostic yield: Diagnostic tissue was obtained in 38 of the 39 consecutive biopsies carried out, with a diagnostic yield per procedure of 97,4%. In one patient, harboring a patchy lesion in the splenium of the corpus callosum, the first biopsy was inaccurate (TE >3 mm) and not diagnostic, while a second procedure resulted in a primary central nervous system lymphoma diagnosis. In another patient, tissue samples were not deemed as diagnostic at an initial pathological assessment, even if postoperative scans had confirmed that the biopsy was obtained at target. A further pathological review disclosed a final diagnosis of glioblastoma. The diagnostic yield per patient was 100%.

Accuracy: The mean error at the cranial entry point was 2 mm (median 2 mm, range 0,2-3.8mm, ± 1 SD). The mean TE was 1,06 (median 1 mm, range 0.1-4.0 mm, ± 0,83 SD).

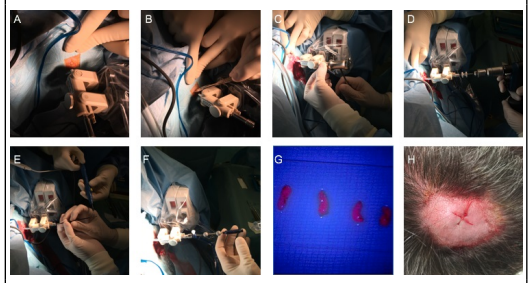
Conclusions

In this preliminary patient series intraoperative frameless robotic iSYS1® assisted biopsy was safe and resulted in high target accuracy and diagnostic yield. Larger studies are necessary to further evaluate the full potential of this device.

Learning Objectives

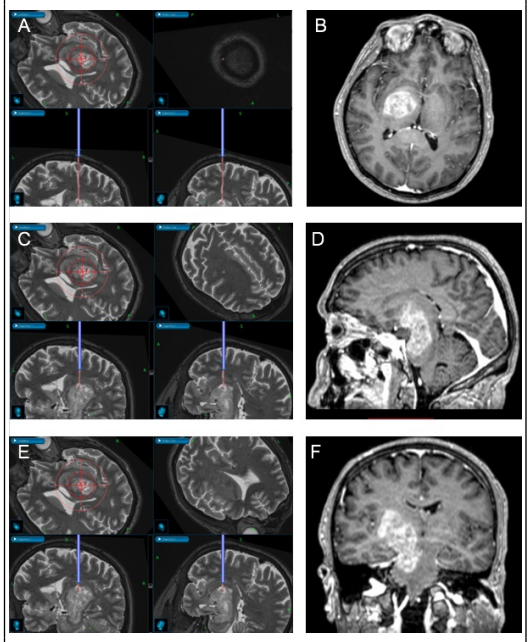
To determine the role of robotic minimally invasive bioptic surgery in patients harbouring a brain tumor not amenable for surgical resection

SURGICAL WORK-FLOW



Surgical workflow of a robot-assisted stereotactic biopsy of an intracranial lesion using the iSYS1. The robotic guidance device is driven to the planned entry point, which is marked with a sterile pencil (A). After 1 cm skin incision with a sharp blade (B), a drill guide is hammered to the external theca in order to provide a stable platform to hold and direct surgical probes (C). There is a small amount of movement allowed when the drill is within the drill guide, ensuring no trajectory deviation. The cranial theca is penetrated with the use of a twist drill (2.2 mm diameter) (D). The dura is coagulated and punctured with a custom made sharp probe coupled with monopolar cautery (E). Biopsy specimens are obtained rotating the side cutting navigated Nashold needle at the target point at different angles (F). Tissue samples of MRI contrast-enhancing lesions are checked under violet-blue illumination for fluorescence (G). The surgical wound is closed with a single absorbable stitch (H).

ACCURACY CALCULATION



Left column: high accuracy stereotactic biopsy of the lesion has been performed with the iSYS1, as showed by trajectory's view T2 MRI images obtained at the cranial entry point (A), halfway to the target (C) and at the planned target (E), which corresponds to the effective one. Right column: Axial (B), sagittal (D), coronal (F) T1 contrast-enhanced MR images showing heterogeneously enhancing lesion within the basal ganglia area and the brainstem, suggestive for high-grade glioma.

References: 1.Minchev G, et al A novel miniature robotic guidance device for stereotactic neurosurgical interventions: preliminary experience with the iSYS1 robot. J Neurosurg. 2017; 2.Barnett GH, et al. Frameless stereotaxy with scalp-applied fiducial markers for brain biopsy procedures: experience in 218 cases. J neurosurg. 1999. 3. Formenko A, et al . Robotic stereotaxy in cranial neurosurgery: a qualitative systematic review. Neurosurgery. 2017.