

# Accuracy of Drill Depth Control of an Image-Guided Micro-Stereotactic Targeting System Dedicated to Cochlear Implantation Surgery

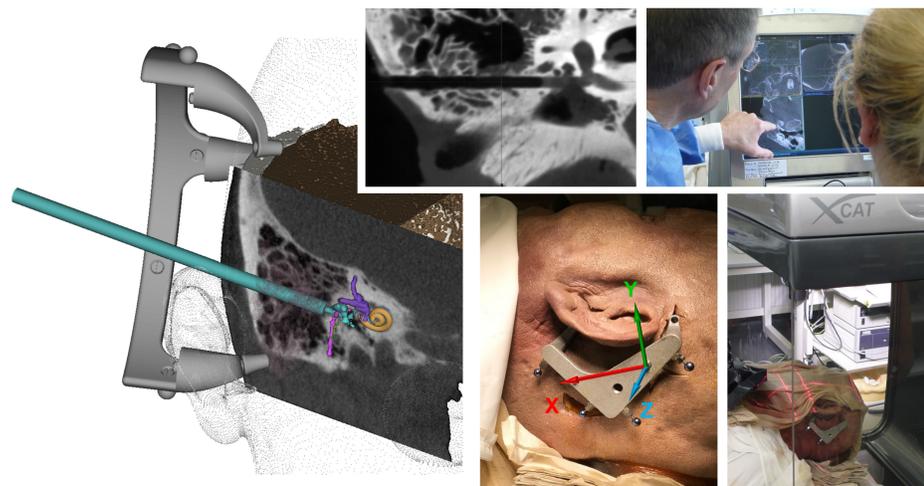
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## Motivation

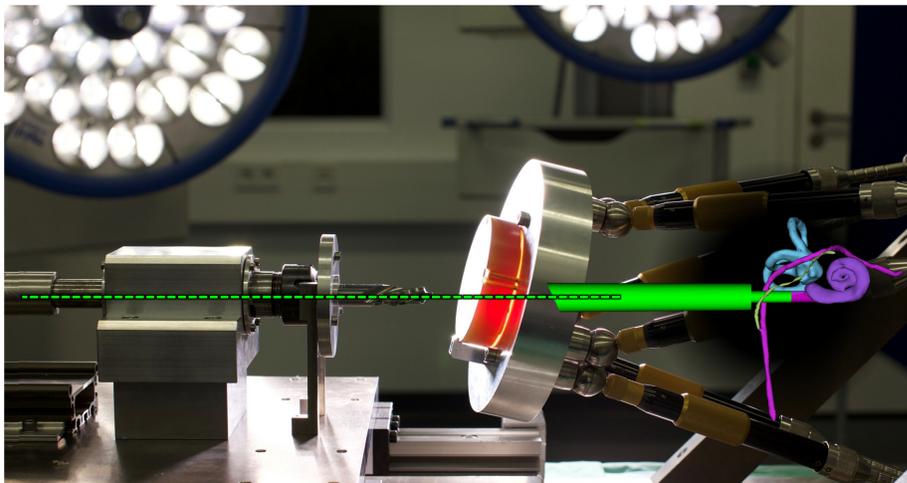
In the future, cochlear implantation surgery will require significant simplification in order to handle the strongly growing numbers of patients who could benefit from a cochlear implant (CI). The increasing demand is caused e.g. by a continuously extension of indication criteria due to improved implant design, an increasingly ageing population, as well as establishing cochlear implantation as a treatment modality for hearing loss in the developing world.



▲ Imaging and planning of the drill path after fixation of the bone-anchored reference frame.

## The RoboJig System

In order to simplify the surgical procedure, reducing the duration of surgery, and thus decreasing the overall costs of the procedure while keeping the high safety standards, we have been developing a micro-stereotactic targeting system for minimally invasive cochlear implantation surgery. An intraoperatively customized drilling jig enables accurate drilling through the bony lateral skull base to gain access to the inner ear for CI electrode array insertion.

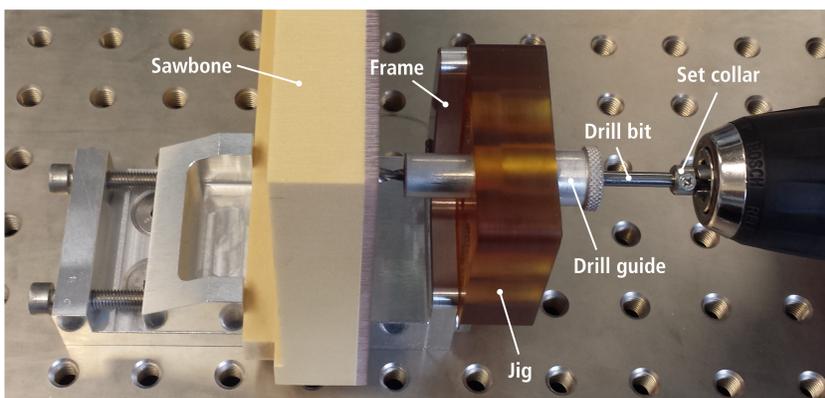


▲ Intra-operative customization of the jig by drilling one counterbore hole inside a blank which is in alignment with the previously planned trajectory based on the individual anatomy of the patient.

## Material and Methods

In total 30 drillings were conducted in order to calibrate and evaluate the accuracy of the system, with special focus on depth control of the drilling. Drilling depth was varied between 25.1 mm and 29.6 mm (range of the typical distance from the skull surface to the inner ear). After fabrication of the jigs, drilling was performed in a homogenous block made of synthetic bone substitute (Sawbone Europe AB, Malmö, Sweden) using a custom-made twist step drill bit. Deviations from the planning were measured using a highly accurate portable coordinate measuring machine (CMM, Romer Absolute Arm Compact 7312, Hexagon Manufacturing Intelligence, Wetzlar, Germany).

The mean deviation between actual and planned depth of the first 20 drillings was used to calculate a correction factor, which was expected to be necessary in order to compensate for manufacturing tolerances of the device used for customization of the jigs. This value was implemented in the planning procedure for the last 10 drillings in order to assess the drill depth accuracy. Drill depth should be adjustable with an accuracy of  $\pm 0.2$  mm.



▲ Experimental setup. The set collar limits forwarding of the custom-made drill bit at a fixed length. Drilling depth can be adjusted by the location of the plane of the counterbore hole inside the jig.



▲ The individual drilling jig is mounted on the bone anchored frame and enables highly accurate drilling of the mastoid as well as tool-based insertion of the electrode array.



▲ Schematic drawing and pictures of the measurement method for evaluation of drill depth accuracy.

## The Results

The first 20 drillings yielded the calibration term which was found to be  $0.34 \text{ mm} \pm 0.09 \text{ mm}$  (range: 0.04 mm to 0.43 mm). Lateral deviation of the drilling in comparison to the planned trajectory was  $0.19 \text{ mm} \pm 0.11 \text{ mm}$ . After calibration of drill depth control, the desired depth has been reached with an accuracy of  $0.07 \text{ mm} \pm 0.04 \text{ mm}$  (range: 0.00 mm to 0.13 mm).

## Conclusion and Outlook

In this study, accurate control of the drilling depth using the developed system could be proven. The remaining inaccuracy in depth control can be easily compensated by a safety margin in the planning and seems to be non-critical for the desired application. The accuracy measured makes the method feasible for precise opening of the inner ear. Thus, highly accurate image-guided cochlear implantation surgery with residual hearing preservation seems to be feasible.

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**Conflict-of-Interest:** The authors Th. Rau, M. Kluge, S. John, T. Ortmaier, O. Majdani, and Th. Lenarz declare being limited partners of HörSys IP GmbH & Co. KG that holds a financial stake in OtoJig GmbH, a German company that owns related IP and further develops a similar technology.

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