

# Preclinical Evaluation of a Micro-Stereotactic Surgical Targeting System for Minimally Invasive Cochlear Implant Surgery.

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## Abstract

*In the past we have developed a micro-stereotactic targeting system to enable an image-guided, minimally invasive access to the inner ear in order to reduce intraoperative trauma to the patient in cochlear implant (CI) surgery. The system consists of a reusable, bone-anchored frame and a customized drilling jig. Recently, a profound preclinical evaluation of the system has been started regarding accuracy, handling, and safety issues. Full head cadaveric specimens are used in order to test the whole surgical procedure. In the following, preliminary results after the first five specimens are presented.*

**Keywords:** image-guided surgery, micro-stereotactic frame, drill guide, drilling accuracy, direct cochlear access.

## 1 Problem

A minimally invasive approach to the inner ear requires drilling of a single bore hole from the surface of the skull down to the cochlea. The straight path typically passes the facial recess—a narrow region between the facial nerve and its branch chorda tympani. Therefore, high accuracy is mandatory. As the average diameter of the facial recess is only approx. 2.5 mm [1] the safety margins to the nerval structures as well as the allowable diameter of the bore hole and are limited. In addition, the size of the surgical access to the inner ear needs to be large enough to perform the insertion of the electrode array of a cochlear implant (CI). It is known from previous studies by Labadie et al. [2,3], that sufficient accuracy can be achieved using customized micro-stereotactic frames, which are rigidly fixed to the bony skull. Such a system serves as a drill guide, constraining the drilling direction to a predetermined trajectory, which is planned using patient-specific image data. A major drawback of the existing concepts is that neither 3D-printing of the STarFix [2] nor milling of the Microtable [3] allow for rapid customization under sterile conditions.

In order to overcome these limitations, we developed a two-part micro-stereotactic concept [4] that is driven by the aim to enable patient-specific fabrication during the surgery under sterile conditions. Thus, the customization procedure is simplified: Now, only a single counterbored hole needs to be drilled into a blank in order to finish a patient-individual jig. This drilling jig is deployed onto a bone-anchored carrier frame to establish a rigid fixation with the patient's head. A standardized mechanical coupling interface links both parts of the micro-stereotactic system. The carrier frame serves also for image-to-patient registration and, therefore, is equipped with four spherical markers. Up to now, only the accuracy of fabricating the individual drilling jig was investigated and was found to be  $0.11 \text{ mm} \pm 0.04 \text{ mm}$  [5]. However, determination of the overall drilling accuracy including all clinically relevant steps of the procedure (see Figure 1) is still missing, which was aim of the presented study.

In the following, preliminary results of the first evaluation study in a preclinical setting using full body donors are presented. This study was motivated by the following questions and issues: Is it possible—using that system—to drill through the facial recess without unexpected damage to vital structures? Which accuracy can be achieved when drilling is performed in the inhomogeneous bone material of the mastoid? Furthermore, we wanted to collect practical experience and surgical feedback for the further development of both hard- and

software components of the system; especially regarding the bone anchoring, imaging quality, and path planning. A minimum of 12 trials are planned. Preliminary results of the first five trials are reported in the following.

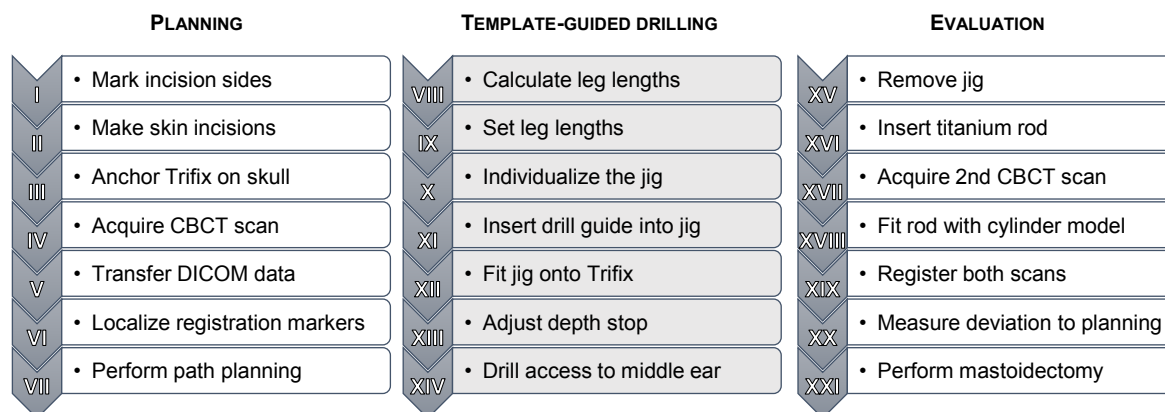


Figure 1: Flowchart of steps involved for preclinical evaluation.

## 2 Material and Methods

For preclinical evaluation five Thiel-fixed [6], anonymized, donated human bodies were used under approval of the authors' institutional review board. Only the left side of each head was used within this study. At the beginning of the procedure, the reusable reference frame, referred to as 'Trifix' in the following, had to be fixed to the skull using three self-drilling and self-tapping bone screws (see Fig. 2a, including steps I-III described in Fig. 1). The position of the Trifix was chosen by the surgeon just behind the pinna with respect to the expected drill path. Afterwards, imaging was performed (Fig. 2b, step IV) using a mobile, intraoperative cone beam computed tomograph (CBCT, xCAT, Xoran, Ann Arbor, MI, USA) with an isotropic voxel size of 300  $\mu\text{m}$ . All scans were checked for proper bone fixation of the screws and visibility of the complete reference frame including all four spherical registration markers.

Approved image data were transferred (step V) to MacBook Pro and loaded into 3DSlicer 4.8.1 with custom-made extensions for semi-automated sphere detection (VI, Fig. 2d)) as well as path planning (VII, Fig. 2c). Using these tools, a safe trajectory was planned manually passing through the facial recess without violating surrounding vital structures of the temporal bone. Special focus was set on preservation of the facial nerve and a drill path which keeps the bony wall of the outer ear canal intact. In one case—due to a narrow facial recess—chorda tympani was sacrificed in order to keep a sufficient safety margin to the facial nerve. Drilling was planned to stop after reaching the middle ear. Start and entry point of each trajectory, relative to the carrier frame, were used to compute the inverse kinematics of the 'Jig Maker' (see below).

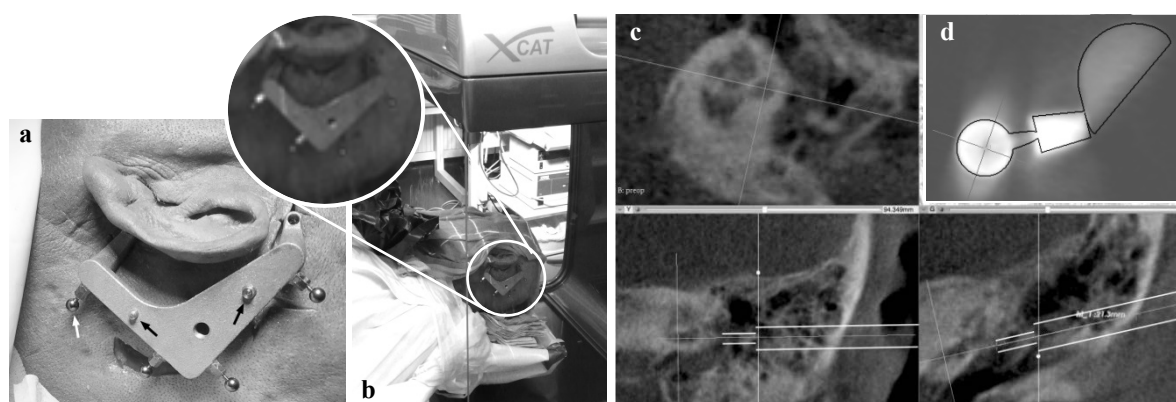


Figure 2: **(a)** Trifix attached to the patient's skull just behind the pinna. Two dowel pins (black arrows) on its surface allows connecting the jig to the reference frame in a free-of-play manner. Four spherical markers (white arrow) serve for image-to-patient registration. **(b)** Patient's head with mounted reference frame (white circle) inside the xCAT CBCT scanner. **(c)** Screenshot of the trajectory planning using a custom-made 3DSlicer plug-in. **(d)** Detected position of the registration marker indicating low fiducial registration error.

The individual part of the micro-stereotactic system was fabricated out of a blank (ULTEM 1000 resin) using a self-constructed device, referred to as Jig Maker in the following (Figure 3a, [5]). In that device, the blank is temporarily fixed using the same mechanical coupling interface, which is identical to the one on the surface of the Trifix. Adjustment of position and orientation in a patient-specific manner is conducted by use of a pose setting mechanism, which is a Stewart-Gough-Platform (Hexapod) with 6 degrees of freedom. The lengths of all six legs of the hexapod were manually adjusted (step IX) using values provided by the planning software (VIII) written in Python using the libraries NumPy [7] and Plotly. After length setting the main axis of the drill bit is in coaxial alignment with the planned trajectory. A special polymer drill bit was designed which enables drilling a counterbored hole with (12.5 and 15.0 mm in diameter, Fig. 3b) in a single-shot process. The drilling machine was manually advanced (step X).

Afterwards the jig was removed from the Jig Maker and equipped with a drill guide (step XI) suiting custom-made twist step drill bits with a diameter of 4.0 mm at the base and 1.8 mm at the tip. The whole assembly was mounted onto the Trifix (XII, Fig. 3c). The twist drill bit was equipped with a set collar for mechanical limitation of the drilling depth (XIII, Fig. 3d). The distance from the drill's tip to the set collar was measured during trajectory planning. Using the guidance of the jig, the access to the middle ear was drilled by the surgeon (XIV, Fig. 3d). Drilling was performed slowly applying only slight thrust and under continuous irrigation with water. The drilling stopped when the set collar, attached to the drill bit, reaches the upper drill bushing.

After drilling, the surgical jig was unplugged from the reference frame (step XV) in order to get access to the bore hole. It was flushed to remove bone dust. Following, a titanium rod with the same two-tier diameter like the drill bit was inserted (XVI, Fig. 4a) to improve visualization of the bore hole in radiological imaging. Afterwards, a second CBCT scan was acquired (XVII) to assess the actual drill path represented by clearly visible titanium rod. Therefore, the titanium rod was manually fitted to a cylinder model with the correct diameter of 4 mm (XVIII). Planning and drilling were compared by registration of both scans (XIX) using the spherical registration markers of the Trifix. The deviation between the planned and drilled trajectory was measured (XX, Fig. 4b) as the distance between the two center lines at the depth of the planned target point. Finally, preservation of facial nerve and chorda tympani was assessed under the microscope after conventional mastoidectomy (XXI).

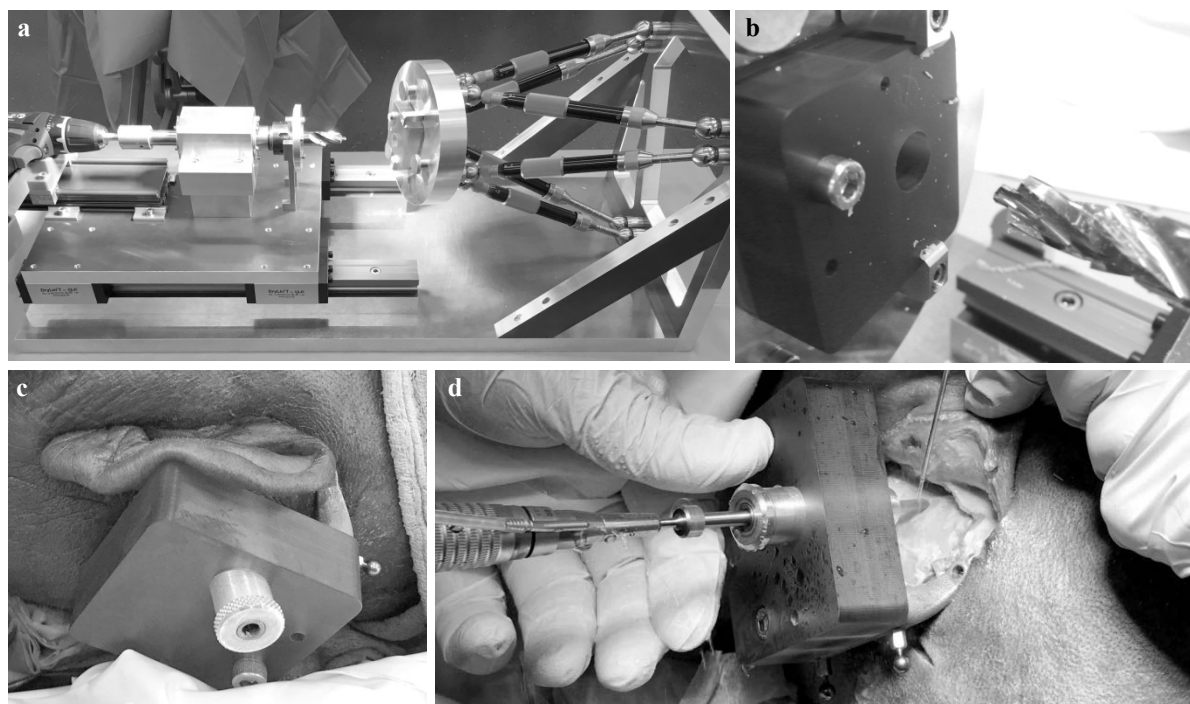


Figure 3: **(a)** Jig Maker with the manual operated drilling machine on the left side and an opposite hexapod-based mechanism for pose setting of the surgical jig. **(b)** Finalization of the blank by drilling a patient-specific counterbored hole whose axis matches the planned trajectory. The hole serves as mounting port for surgical instruments. **(c)** Jig mounted on top of the Trifix with inserted drill guide. **(d)** Drilling the minimally invasive canal down to the middle ear under permanent irrigation.

In the last specimen, feasibility of inserting a commercially available electrode array was evaluated. In order to perform manual insertion using only common otological instruments, a tympanomeatal flap was created through

a retroauricular incision. This enables access to the promontory and allows for visual control using a conventional microscope. A Flex<sup>20</sup> electrode array (MED-EL corporation, Innsbruck, Austria) was threaded through the drill canal and advanced into the cochlea.

### 3 Results

Minimally invasive mastoidectomy approach could be successfully performed in all five patients demonstrating the feasibility of this approach (Figure 4). The facial nerve was preserved in all cases. Chorda tympani was sacrificed in one case as accepted during planning. The difference between the planned and the drilled trajectory was found to be  $0.40 \text{ mm} \pm 0.30 \text{ mm}$  including one case with a deviation of approx.  $0.94 \text{ mm}$ . During the trials, we could immediately identify a human error in setting the length of one leg of the hexapod as the reason for this unexpected difference. After calculating the target error without the human component in adjusting the Jig Maker, the drilling accuracy in that specimen would be  $0.09 \text{ mm}$ . Without that outlier the average accuracy in this study was  $0.27 \text{ mm} \pm 0.05 \text{ mm}$ .

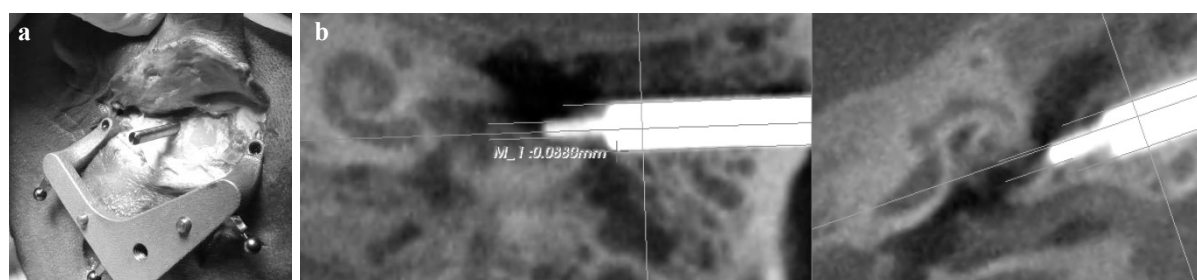


Figure 4: **(a)** Bore hole with inserted titanium rod after removing the surgical jig. **(b)** Images from the second CBCT scan showing good compliance between the drilled canal and the originally planned trajectory.

Table 1: Results of comparing the planned trajectory with the drilled one. Target error was measured as the distance between the two center lines at the planned target point. Average value marked with asterisk (\*) is calculated without specimen #03. FRE: fiducial registration error; SD: standard deviation.

specimen	FRE [mm]	drill depth [mm]	target error [mm]
01	0.077	18.7	0.24
02	0.068	22.4	0.31
03	0.030	22.8	(0.94)
04	0.047	25.9	0.22
05	0.069	23.7	0.31
mean $\pm$ SD		$22.7 \pm 2.6$	$0.40 \pm 0.30$ ( $0.27 \pm 0.05$ )*

One specimen showed an unusual thick skin flap. Due to the limited length of the Trifix's legs bone fixation was not possible through small skin incisions. Instead, a large retroauricular incision was conducted in order to exposure the bone behind the pillar for sufficient fixation of the reference frame.

It was possible to push the electrode array through the minimally invasive drill canal into the middle ear and further through the round window membrane into the inner ear using standard instruments. Post-experimental CBCT imaging confirmed correct location of the electrode inside scala tympani (Figure 5).



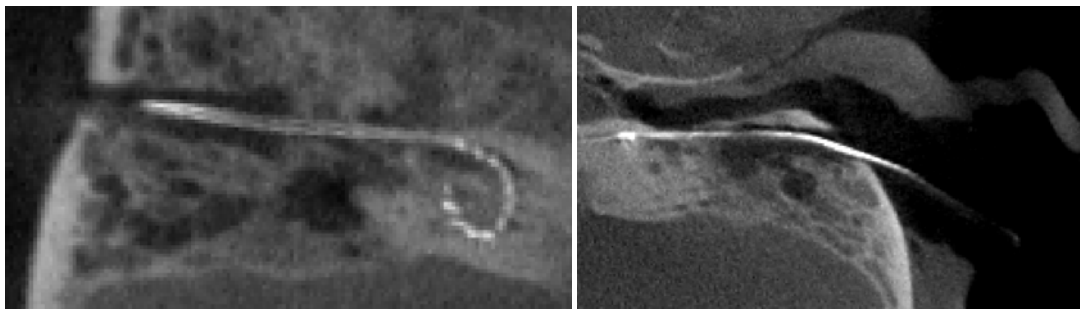


Figure 5: Radiographic images showing the intra-cochlear position of the lateral wall electrode array as well as its lead running through the drill canal.

## 4 Discussion

The presented trials are part of a first preclinical evaluation of the micro-stereotactic surgical targeting system in order to investigate its usability in human cadaveric temporal bones. This study covers the whole surgical workflow including preoperative imaging and planning, manufacturing of the surgical jig, drilling the minimally invasive tunnel through the mastoidectomy posterior tympanotomy approach (MPTA), and finally cochlear implant electrode insertion.

The complete workflow was feasible for all specimens (excluding electrode insertion which was performed in only one case). Facial nerve could be preserved in all cases, which was evaluated both, in post-experimental CBCT imaging, as well as histological evaluation using a conventional mastoidectomy. Apart from one outlier, the deviation between planning and drilled trajectory was sufficient good for minimally invasive cochlear implantation using the MPTA. Accuracy is in the same range as of the Microtable ( $0.31 \pm 0.10$  mm, [8])—another, already clinically evaluated micro-stereotactic system [3].

More detailed analysis of the outlier discloses a human error during manual length setting of the legs of the Jig Maker. Further quality measures, like multi user readings, as they are common in the clinical routine, can be implemented easily to limit such human errors. However, the other trials showed that manual length setting is feasible with high precision.

Overall, the whole process seems to be very robust. Cases where a leg of the frame showed insufficient contact to the skull surface (i.e. due to soft tissue in between the base and the skull surface) were clearly identified in radiological images. Based on these findings it was decided to revise bone fixation in two cases to ensure maximal stability of the bone anchorage. The critical steps of manufacturing the surgical jig using the Jig Maker, and drilling inside the inhomogeneous temporal bone contributed very little to the total error. The average error being smaller than the resolution of the CBCT images showed that deflection of the thin drill bit does not seem to be a problem in the hard cortical and mastoid bone.

At the current stage the most time-consuming steps of the whole procedure are planning and electrode insertion. For clinical implementation, a user-friendly planning software, providing tools for (semi-)automated segmentation and trajectory planning, is under development. In addition, we are working on insertion tools [9] to further simplify the process by waiving the tympanomeatal flap.

## 5 Conclusion

Preliminary results demonstrate the feasibility of a minimally invasive mastoidectomy approach using the developed micro-stereotactic frame. One crucial step is bone anchoring of the carrier frame as one has to ensure that all three bone screws are sufficiently fastened in the skull. This seems to require some amount of experience and practice. Another security relevant issue is manual adjustment of the hexapod's legs, which is a potential source of individual errors. However, this can be overcome either by automatization of the hexapod or by additional security measures of the jig.

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## Conflict of Interests

The authors TR, MK, SJ, TO, TL and OM declare being limited partners of HörSys IP GmbH & Co. KG that holds a financial stake in OtoJig GmbH, a German company that owns and further develops the described technology.

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