An alternative concept for template-guided minimally-invasive cochlear implantation surgery

Thomas S. Rau[1,2], *G. Jakob Lexow*[1,2], *Marcel Kluge*[1], *Thomas Lenarz*[1,2], *Omid Majdani*[1,2]

[1] Department of Otolaryngology, Hannover Medical School, Hannover, Germany
[2] Cluster of Excellence Hearing4all, Hannover Medical School

`contact: rau.thomas@mh-hannover.de`

Abstract:
Minimally-invasive cochlear implantation surgery requires appropriate surgical tools to enable the surgeon to drill a single borehole from outside the skull directly down to the basal turn of the cochlea. A new concept for proving a customized surgical template, also known as micro-stereotactic frame, is described. Bone cement is utilized to fix the individual pose of the template. The design of a first prototype is presented. Additionally, an alignment device was constructed, to temporarily fix the single components of the template until the bone cement is cured. The positioning error was measured by marking target points in a vinyl sheet with a pointed spike. A microscope was used to measure the position of these marks and compare it with the planned target points. In total 10 samples of the new micro-stereotactic frame were used in the experiments. Mean error at the target point was 0.22mm with a standard deviation of 0.09mm.

Keywords: micro-stereotactic frame, template, bone cement, minimally-invasive, cochlear implant, image-guided surgery

1 Introduction

Minimally-invasive cochlear implantation surgery is characterized by drilling a single bore hole from the surface of the skull directly down to the basal turn of the cochlea. This small access to the inner ear may replace the conventional mastoidectomy approach in the future. Its clinical implementation depends on whether it becomes possible to provide the surgeon with suitable tools to support him in the drilling of the borehole through the bone. These tools are necessary for two main reasons: First, the minimally-invasive drilling is a blind process. As the cochlea is embedded in bone deep inside the skull base, the surgeon cannot see the target point and therefore is not able to guide the surgical drill manually. For that reason, a system is required which incorporates patient-specific planning based on individual images into the surgical workflow. Second, the access to the inner ear requires high accuracy. Within the mastoid (the bone behind the ear) facial nerve and chorda tympani are embedded. There is only a narrow space between both structures, the facial recess, which has to be passed to reach the cochlea under an angle appropriate for cochlear implantation. Therefore tolerances for such a surgical assistance device are very low: only few tenth of a millimetre.

Recently, different concepts have been described to overcome this challenge. These concepts include robots used as master-slave systems [1] as well as in combination with image-guided surgery systems (IGS) [2–4], head mounted robot systems [5,6] as well as different designs of micro-stereotactic frames (MSF) [7–10]. Common features of these micro-stereotactic frames are: they are directly fixed on the patient's skull and are individually fabricated or adjusted. There are systems which are 3D-printed [7], individually milled using a CNC machine [8], or having at least three legs whose shape needs to be customized to align the frame to the individual trajectory: Kratchman et al. described a system with legs consisting of several parts, with each is assembled in a specific configuration by use of a 3D Cartesian robot and finally fastened using superglue [9]. Vollmann et al. introduced a method to produce the legs under sterile conditions using silicone hoses which are filled with bone cement [10]. Aside from cochlear implantation surgery, surgical templates are already well established in dental implantation [11,12].

However, most of these approaches require expensive equipment and a specially trained technician in the operation room to run the device [1–5,7,8], need an additional surgery for placement of bone anchors [7] or require time consuming sterilization during surgery [8]. In contrast, the presented approach is driven by the aim to provide an inexpensive and easy to use technology for the fabrication of the template during surgery under sterile conditions. That's why bone cement is utilized as a sterile material, which is well-known to the surgeon, easy to use, and hardens within few minutes. In this paper a new micro-stereotactic frame is described, including an alignment device for pose-setting as well as a method for accuracy measurement. Finally, first results are presented and compared with other initial studies.

2 Materials and Methods

2.1 General concept and considered workflow

For the proposed micro-stereotactic frame a reference frame has to be attached to the patient's skull as a first step of surgery. Its current shape and overall dimension are based on a study of anatomical variability of the lateral skull base [13]. The reference frame is referred to as "Trifix" (see Fig. 1) as it requires three small bone screws for sufficient bone fixation (Max Drive Drill Free 2,0x9, KLS Martin Group, Tuttlingen, Germany). They can be inserted manually or by use of a battery powered screwdriver (BOS Driver, KLS Martin Group) with torque control. The top of the Trifix forms a reference plane with a definite mechanical interface. It allows for precise mounting (and demounting) of the patient-specific moulded component of the whole micro-stereotactic frame. In this first prototype the interface is realized by use of two dowel pins (for accurate positioning without clearance) and an additional screw (for rigid fixation of the position throughout the following process).

After mounting the reference frame on the patient's head, a three-dimensional (3D) image needs to be acquired by use of an intra-operatively CT or DVT scanner, for example the xCAT device (Xoran Technologies, LLC, Ann Arbor, MI, USA). Within this image the reference frame will serve as a fiducial for image-to-physical registration [14]. Within the same image the desired trajectory can be planned. Doing so, the planned trajectory is described in the master coordinate system (MCS) defined by the Trifix.

As the reference frame is designed to suit to most patients, the whole micro-stereotactic frame requires an adjustable component, which will guide the surgical tools strictly along the planned trajectory. Therefore, a linear guide needs to be fixed in the desired pose relatively to the base plate, whose lower surface forms the counterpart to the mechanical interface on top of the reference frame. For this initial accuracy study a simple drill bushing served as linear guide. The bushing is stuck into a drill bushing holder. Its top plane can be used as stopper for depth control (not necessary in this study). The rigid fixation between the base plate and the drill bushing holder can be realized by moulding bone cement between both parts. In the current design a subcarrier is added for stability reasons. The spoked shape was chosen to allow the bone cement to enclose and connect all single components of the surgical template.

The reference frame is made of aluminium. The other components are produced by use of rapid prototyping technologies (voxelwerk GmbH, Berlin, Germany) and all but the base plate made of polyamide (PA). As stiffness of the base plate is considered as a crucial aspect for the accuracy of the micro-stereotactic frame, this part was sintered using a glass-filled polyamide powder (PA 3200 GF). All these parts are designed for single use.

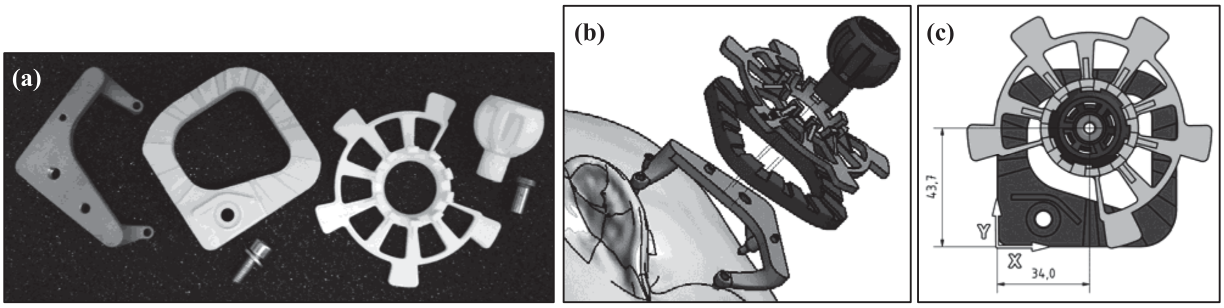

Fig. 1: (a) Single components of the proposed surgical template including reference frame (Trifix), base plate, fixation screw, subcarrier, drill bushing holder and drill bushing. **(b)** Schematic drawing of the micro-stereotactic frame, showing its desired location behind the pinna. **(c)** Top view indicating the right-hand master coordinate system at the corner of the reference frame. In this example the starting point of the trajectory is P_s = [34.0; 43.7; 0.0].

2.2 The Jig-Maker: An alignment device for temporary pose-setting

For individualization of the surgical template (or jig) a device is necessary which enables accurate adjustment of the component parts with respect to the planned trajectory. This configuration has to be fixed temporarily by the device until the aligned parts are permanently fixed by the bone cement. The developed tool, which is referred to as "Jig-Maker", is based on a commercially available passive hexapod (X1med3D, SchickDental GmbH, Schemmerhofen, Germany). Originally, the hexapod was designed for customization of surgical templates for dental implantation [11,12]. Each of its legs is designed comparable to a micrometer screw. Thus, the orientation and location of the upper platform of the hexapod can be adjusted to the desired pose by manually setting the length of each leg. The top of the upper platform was equipped with a mounting plate featuring the same mechanical interface as the reference frame. Consequently, also the master coordinate system of the reference frame (visible in image data) is transferred to the Jig-Maker. Using this mechanical interface the base plate of the template can be fixed in the same position and orientation as on the reference frame. An alignment pin, whose diameter fits to the chosen drill bushing of the template, is mounted above the upper platform and is used to adjust the pose of the drill bushing relatively to the base plate according to the individually planned trajectory. Fig. 2a shows the alignment tool. Its upper platform is loaded with the component parts of the surgical template after their fixation with bone cement. In the future, the Jig-Maker will be covered by a sterile drape to enable intraoperative use. However, sterile conditions haven't been necessary for this experimental evaluation and were therefore omitted in this study.

The specific configuration of the Jig-Maker is calculated using a CAD model (Inventor Professional 2015, Autodesk, San Rafael, CA, USA) of the whole assembly, which is controlled by configurable parameters. These parameters are the coordinates of the start and target points of the desired trajectory. These values are stored in an Excel file (Excel 2010, Microsoft Corporation, Redmond, WA, USA) and readout to drive the pose of the CAD representation of the upper platform. Accordingly, the lengths of the legs within the CAD model are updated. Using these data, the lengths of the legs of the "physical" JiG-Maker can be adjusted.

2.3 Test bench for accuracy measurement

The method for determination of the accuracy of the experimental device is inspired by the work of Dillon et al. [15]. Here, the test bench is a greatly simplified replication of the spatial relations at the patient's skull base. On top, there is a mounting plate representing the reference frame and featuring the identical mechanical interface. A target plate is mounted directly on top of the ground plate of the test bench (Fig. 2b). It represents the target region within the skull. Its surface is 64 mm below the reference plane of the mounting plate. This means that targets at a depth of approx. 89 mm to 94 mm (measured from a depth control stop at the guiding aid) can be simulated using the introduced test bench. The target plate is made of PVC to enable the creation of an indentation at the actual target point using a pointed spike (Fig. 2c), which is guided by the template. Consequently, the mark in the target plate documents the actual pose of the respective template. On the surface of the target plate drilled blind holes form a quadratic grid of reference markers with an intermediate distance of 10 mm. These bores (having a diameter of 0.5 mm) are inserted during fabrication of the target plate by a highly accurate CNC milling machine. The mounting plate and the target plate of the test bench are accurately aligned and fixed relatively to each other using dowel pins as well as additional CNC milled assembly parts. Doing so, deviations of the test bench, related to fabrication and assembling of its parts, was minimized as much as possible and should be in the range of a few micrometers.

2.4 Performing the experiments

The reference markers served also for planning of targets points for the experimental evaluation of the micro-stereotactic frame within the CAD model of the test bench. In total 10 samples of the surgical template were planned. The starting points $P_{s,i}$ of the desired trajectories were spread over the possible workspace of the base plate and defined in the xy-plane of the master coordinate system of the reference frame (consequently $z_s = 0$). Some of these target points were planned along a line running from the origin through the center of the base plate to investigate the influence of the displacement of the linear guide from the fixation screw. In this first study only vertical configurations of the template were considered, therefore the target points $P_{t,i}$ are defined as $x_t = x_s$, $y_t = y_s$ and $z_t = -64\text{mm}$. If the presented guiding device works perfectly accurate, the actual location of the target point (marked with the pointing needle) has to be in alignment with the planned (virtual) target.

Using the planned target points the corresponding lengths for the legs of the Jig-Maker were calculated using the described CAD model. This enabled setting the pose of the upper platform of the hexapod. The base plate was assembled on the mounting plate of the Jig-Maker by screwing the fixation screw hand tight. The subcarrier as well as the drill bushing holder with the bushing inside were put on top of the base plate. Finally, the alignment pin was lowered and pushed through the drill bushing.

Mixing of the bone cement (Palacos MV, Heraeus Medical GmbH, Wehrheim, Germany) was done manually by use of a plastic bowl and a spatula until a homogenous and doughy consistency was reached. Due to its medium viscosity the bone cement could be used for moulding the template immediately after mixing. No additional waiting time was observed. First the bone cement was applied using the spatula and roughly distributed over the parts of the micro-stereotactic frame. During that time the bone cement started setting until it reached the point where it did not longer adhere to the rubber gloves. Therefore, in the second part of the moulding process the bone cement was further spread and pressed using the fingers to ensure that it infiltrated the relevant cavity of the prefabricated parts.

After hardening of the bone cement the finished template was demounted from the Jig-Maker and transferred to the accuracy test bench. It was fixed on top of the test bench using the mechanical interface and the pointed spike was pushed through the drill bushing until it reached the target plate. The target point was marked with a slight hammer blow. This procedure was repeated for all ten samples.

2.5 Determination of the target error

The target plate was captured using a reflected-light microscope (Leica APO Z6, Leica Microsystems GmbH, Wetzlar, Germany) with full apochromatic optic (objective 0.5× Apo, Z6/Z16, f =187 mm) and equipped with 5 Mpx CCD camera (DFC 420, Leica Microsystems GmbH, resolution: 2,592 × 1,944 pixels). Magnification and resulting image section was chosen in such way, that the target point and four surrounding reference points were visible at the same time. The well-known distances (due to the CNC-based manufacturing of the target plate) between each two reference points and the corresponding distances measured within the image were used for highly accurate image calibration. Additionally, the distances between the target point and all four reference points were measured. The values for the position of the target point in x- and y-direction were averaged and compared with the desired location. The target error was calculated by the Euclidean distance between planned and measured target point. This procedure was repeated for all 10 target points of the trial to calculate the average error and standard deviation as well.

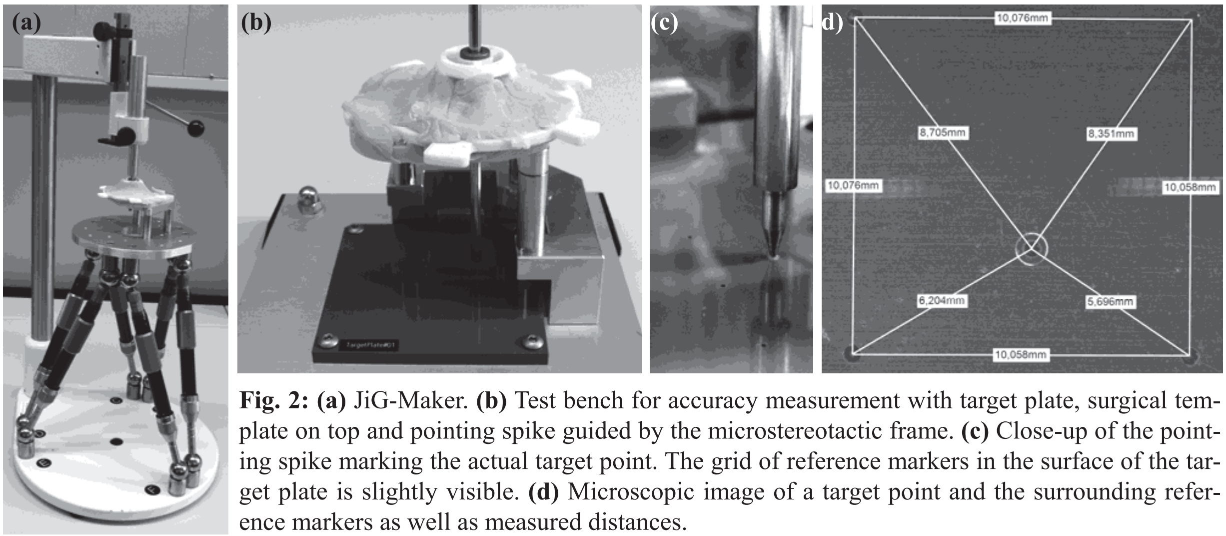

Fig. 2: **(a)** JiG-Maker. **(b)** Test bench for accuracy measurement with target plate, surgical template on top and pointing spike guided by the microstereotactic frame. **(c)** Close-up of the pointing spike marking the actual target point. The grid of reference markers in the surface of the target plate is slightly visible. **(d)** Microscopic image of a target point and the surrounding reference markers as well as measured distances.

3 Results

All samples could be produced without unexpected difficulties. Fabrication took about 20 min. This includes setting the length of the hexapod's legs and the hardening of the bone cement. Mean error at the target point was 0.22 mm with a standard deviation of 0.09 mm. Fig. 3a depicts the deviations of the marks in the target plate compared to the respective planned target point. There was one outlier with an inaccuracy of 0.43 mm. In Fig. 3b the target error is plotted against the distance between the trajectory's start point P_s and the origin of the master coordinate system.

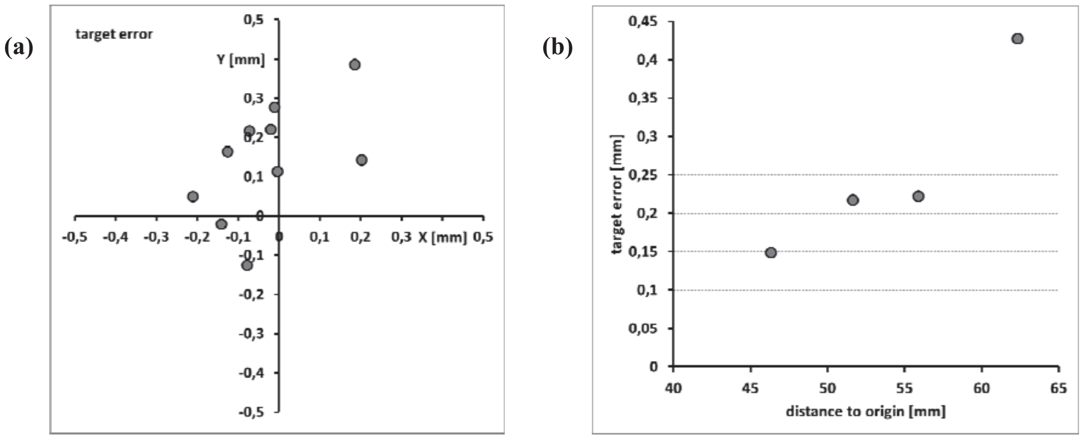

Fig. 3: **(a)** Deviation observed in this initial trial. Each measurement is normalized by the planned target point which coincides with the coordinate origin. **(b)** Relation between accuracy and distance to the origin of the reference frame for

four samples. These target points were planned along a line running from the origin through the center of the base plate. All values are in mm.

4 Discussion

In this study a new method for intraoperative fabrication of a micro-stereotactic frame was presented for the first time. The findings of this initial study are encouraging: the whole procedure (assembling the component parts of the surgical template in the Jig-Maker, adjusting the legs of the hexapod, moulding the template) was easily performable and does not require special skills of the user. The use of bone cement and moulding of the template is comfortable and quickly doable. The measured accuracy of 0.22 mm ± 0.09 mm is within the necessary submillimetre range for minimally-invasive cochlear implantation surgery. It is comparably low to the microtable—another micro-stereotactic frame, which has already proven its usability in a clinical trial [17]. In Table 1 our result is compared to over studies investigating the accuracy of devices designed for the minimally invasive approach to the inner ear. For a fair comparison only studies on phantoms or test bench are included. This means, as in this study, only the positioning error has been considered excluding other potential deviations as e.g. caused by drilling in the inhomogeneous bone. These initial results will be used for a systematic error analysis and deviation of further improvements. Doing so, further enhancements can be expected as, for example, the development of the robot system of the Berner group shows: in their initial trial error was 0.56 mm ± 0.41 mm in [18]—contrast in recent publications an excellent drilling error of 0.08 mm ± 0.05 mm have been reported [2]. Our comparably good initial results are a good reason to continue the research on mouldable surgical templates. This includes further investigations of the device regarding the positioning error in non-vertical configurations to describe the error distribution within the whole working space of the micro-stereotactic frame. Additionally, drilling within inhomogeneous bone needs to be investigated as it typically causes additional deviations.

Table 1: Targeting accuracy (positioning error) of different devices.

Technology	**n**	**mean ± SD [mm]**	**max [mm]**	**Ref.**
MSF (cement legs)	19	0.75 ± 0.63	—	[10]
MSF (StarFix)	8	0.45 ± 0.15	0.81	[16]
MSF (Microtable)	5	0.37 ± 0.18	0.61	[8]
Roboter	4	0.24 ± 0.11	0.37	[3]
MSF (**this study**)	10	0.22 ± 0.09	0.43	—
MSF (FreezeFrame)	10	0.14 ± 0.13	0.24	[9]

Further investigations also have to investigate the stiffness of the bone cement moulded surgical template to resist deviations caused by process forces. An improved design or other materials for separate parts may become necessary. Therefore, an advanced version of the test bench is going to be developed which allows for fixing test blocks made of a bone surrogate material with artificial mastoid air cells [6,15]. If these preliminary findings can be confirmed we will go for experimental trials using human temporal bone specimens. In these experiments the presented micro-stereotactic frame has to compete with other devices which are already tested using artificial bone material [6] or temporal bone specimens [1,2,4,19].

5 Conclusion and future work

The promising results of this preliminary study endorse further research on that new micro-stereotactic frame. Its accuracy has to be evaluated in a more systematic and extensive manner. For clinical use a user-friendly planning software will required which provides tools for (semi-)automated segmentation, trajectory planning and detection of the reference frame in the patient-specific images as well as an algorithm for calculating the settings for the Jig-Maker.

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