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Minimally invasive mastoidectomy approach using a mouldable surgical targeting system.

A proof of concept.

Abstract:

Hearing restoration using a cochlear implant requires a surgical access to the inner ear. In order to enhance patient safety, reduce trauma, and shorten the patient's time under anaesthesia current research focusses on minimally invasive cochlear implantation surgery by drilling only a single bore hole. This demands a highly accurate surgical assistance device to guide the drill along a predetermined trajectory planned in patient's image data.

In this study a recently developed surgical targeting system was evaluated for the first time in a human cadaver trial. After screwing a reference frame on a temporal bone specimen and imaging of both, a trajectory through the facial recess was planned in order to reach the middle ear. Based on this plan a patient specific surgical template including a linear guide for the surgical drill was composed utilizing bone cement. After the hardening of the bone cement the surgical template was mounted on top of the reference frame.

The drilling could be performed as previously planned without harming facial nerve and chorda tympani. The deviation of the actual drill hole to the planned trajectory was 0.17 mm at the level of the facial recess. The minimal distance of the drill hole to the facial nerve was 0.59 mm.

This proof-of-concept study demonstrates the feasibility of performing the access to the middle ear in a minimally invasive manner using the mouldable surgical targeting system. The presented process allows the patient specific individualization of a drill guide under sterile conditions. This might facilitate its integration into clinical routine.

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1 Introduction

A cochlear implant (CI) is a neuroprosthesis which serves to restore hearing in patients suffering from severe hearing loss or deafness. Hearing restoration can be achieved by electric stimulation via an electrode array implanted into the inner ear (cochlea). This requires surgical access to the cochlea, a spiral-shaped hollow organ embedded deep within the temporal bone. The current surgical procedure, known as mastoidectomy posterior tympanotomy approach (MPTA), requires large resection of the mastoid bone using a hand-held surgical drill while identifying and preserving contained vital structures, in particular the facial nerve and chorda tympani which frame the facial recess.

In order to enhance patient safety and reduce trauma current research aims at minimally invasive cochlear implantation surgery—characterized by drilling a single bore hole from the surface of the skull directly down to the basal turn of the cochlea. Due to the invisibility of the embedded target organ and nearby risk structures manual execution of the drilling is impossible. Instead, the minimally invasive approach demands individual imaging and an accurate surgical assistance device to guide the drill exactly along a predetermined trajectory. Different concepts of micro-stereotactic frames have been developed for this challenging task over the past ten years [1–6]. Common features are their rigid fixation on the patient's skull by use of bone screws and their patient specific manufacturing. Systems differ in the manner how this individualization is realized: they are manufactured in 3D printing facilities [1], milled using a CNC machine [2], or assembled by use of a 3D Cartesian robot [3].

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While experimental results with these devices are promising it would be beneficial to overcome the need for expensive machines in or close to the operation room (OR). In this spirit the authors are developing surgical targeting systems which are simpler to manufacture or to finalize directly under sterile conditions inside the OR [4–7]. Recently, we have introduced a new micro-stereotactic frame for which bone cement is used to fix the individual pose of a drill guide within few minutes [6]. All components can be delivered sterile to the OR, are easy to use and enable a rapid procedure. In addition, bone cement is a well-known and well-established surgical material and therefore suggests high clinical acceptance—presupposed necessary accuracy can be achieved. While a promising positioning accuracy with 0.3mm ± 0.25mm was reported earlier [6] this is the first report of a drilling experiment in a temporal bone specimen with that system.

2 Materials and Methods

2.1 Specimen preparation, imaging and trajectory planning

This first feasibility study was performed using one anonymised human temporal bone specimen under approval of the authors' institutional review board (number 3627-2017). Prior to imaging a uniform reference and supporting frame (Fig. 1) was fixed to the specimen using three self-tapping bone screws (Max Drive Drill Free 2.0x9, KLS Martin Group, Tuttlingen, Germany). Due to the number of bone anchors this reusable part of the micro-stereotactic frame is referred to as ‘Trifix’ in the following. Two dowel pins at the upper side of the Trifix enable mounting of the patient-specific surgical template in a well-defined position without clearance and serve in addition for the definition of the reference coordinate system $\{CS\}_{3fix}$. Four spherical registration markers on the sides of the reference frame enable identification of the same coordinate system in the images. The actual positions of these titanium spheres with respect to $\{CS\}_{3fix}$ were determined by use of a portable coordinate measurement machine (CMM, Romer Absolute Arm Compact 7312, Hexagon Manufacturing Intelligence, Wetzlar, Germany).

The specimen with the attached Trifix was scanned in a cone beam computed tomograph (CBCT) (xCAT, Xoran, Ann Arbor, MI) with an isotropic voxel size of 300µm. Manual segmentation of the cochlea, facial nerve and chorda tympani was performed using MITK Workbench (release 2016.03, German Cancer Research Center (dkfz), http://mitk.org) and the resulting objects were saved to STL files.

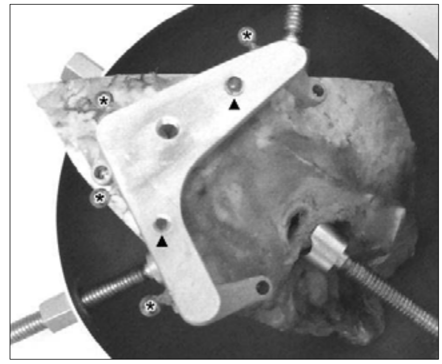

Figure 1: Bone-anchored Trifix reference frame with four spherical reference markers (*) and two dowel pins (▲) for mounting the individual surgical template.

A custom planning program was developed using Insight Segmentation and Registration Toolkit (ITK), The Visualization Toolkit (VTK) as well as Qt. It was used for all following steps of planning and evaluation in the experiment. After loading of the image data semi-automatic sphere detection was used to precisely locate the markers of the reference frame in the DICOM images. Their position was registered with the coordinates (in $\{CS\}_{3fix}$) of the spheres known from the CMM measurement in order to calculate the coordinate transformation. Fiducial registration error was calculated and checked. Afterwards a safe trajectory was planned that avoids damage to adjacent structures starting at the surface of the skull and targeting the inner ear while passing through the facial recess (Fig. 2). A larger safety margin was assigned to the facial nerve than to the chorda tympani following the difference in relevance of the two nerves for the patient. Although the trajectory was directed to the cochlea’s basal turn, the drill was planned to stop after reaching the middle ear. The coordinates of the trajectory (defined by the start and the target point) were exported using $\{CS\}_{3fix}$.

2.2 Building the surgical template

The manufacturing of the surgical template according to the planned trajectory was performed using a prototype alignment device, called Jig Maker, with six passive prismatic joints (Fig. 3). By altering the length of these struts the pose of the upper platform can be set with respect to a central alignment pin which represents the planned trajectory. The specific lengths were determined using a parametric

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CAD model (Inventor Prof. 2015, Autodesk, San Rafael, CA, USA), which is controlled by the exported coordinates of the previously planned start and entry point. After updating the model to these specific parameters, the corresponding lengths are provided in the CAD model and were used to adjust the prismatic joints.

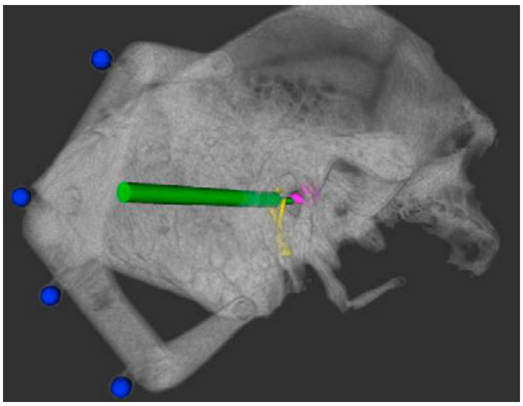

Figure 2: Semi-transparent visualization of the temporal bone specimen and the attached Trifix with detected registration markers (blue spheres), manually planned trajectory (green), segmentation of both facial nerve and chorda tympani (yellow) as well as of the cochlea (pink).

The upper platform replicates the reference frame's top plane with the identical configuration of dowel pins. This enables the transfer of the surgical template to the bone-anchored Trifix after its manufacturing. This individual component of the micro-stereotactic frame was built up using three disposable parts made of polyamide (PA) by use of selective laser sintering. After placing these parts in the Jig Maker and therefore aligning them in the patient specific configuration this pose was secured using the already mentioned bone cement (Palacos MV, Heraeus Medical GmbH, Wehrheim, Germany) (Fig. 3c).

2.3 Performing the drilling experiment

After hardening of the bone cement the surgical template was mounted on top of the Trifix attached to the temporal bone specimen. Before drilling, the deployed twist step drill bit was equipped with a set collar for a mechanical limitation of drill depth. The necessary length was also taken from the CAD model by measuring the distance between the desired target point and the top plane of the outer drill bushing. The custom made twist step drill bit was 1.8 mm and 4.0 mm in diameter. Following the guidance of the drill bushings inside the surgical template the access to the middle ear was drilled manually by use of an ordinary cordless drill/driver tool (GSR 10,8 V-LI-2, Robert Bosch GmbH, Stuttgart, Germany). Drilling was preformed slowly applying only slight thrust to minimize the risk of deflecting the drill tip when touching the bone surface. During the procedure the drill bit was irrigated with water. Drilling stopped when the set collar touched the upper drill bushing.

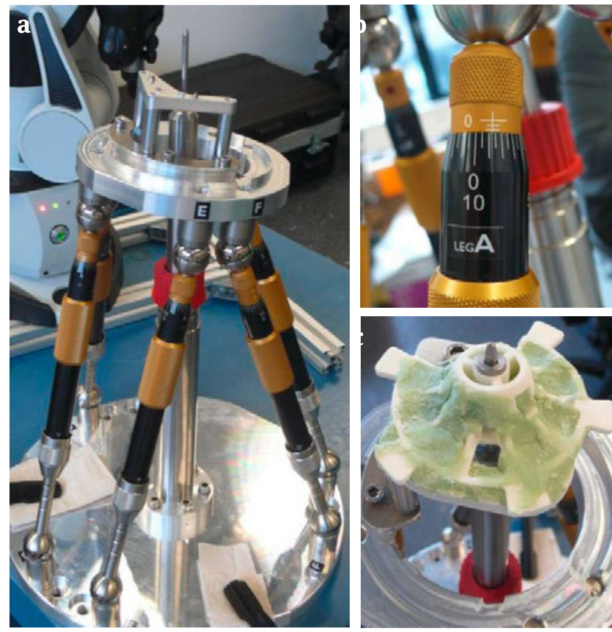

Figure 3: (a) Jig Maker. **(b)** Passive prismatic joint (comparable to micrometer screws) of the hexapod. Its length can be adjusted manually. **(c)** Surgical template on top of the upper platform during hardening of the bone cement.

2.4 Evaluation

In order to analyse the accuracy of the drilling a second CBCT scan was acquired with a titanium pin inside the drill canal. The position of the actual bore hole was registered to the planned trajectory using the registration markers visible in both images. Finally the deviation between planned and drilled trajectory was measured at the level of the facial recess.

3 Results

Minimally invasive MPT approach could be performed without damaging facial nerve and chorda tympani. The minimal distance of the drill hole to the facial nerve was 0.59 mm (Fig. 4). The deviation of the drill canal to the planned trajectory was 0.17 mm at the level of the facial recess.

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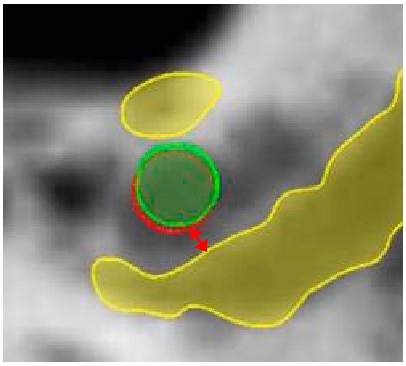

Figure 4: Path-of-Flight view showing the planned trajectory (green), the position of the drill hole (red) and the segmented nerves (yellow) at the level of the facial recess. The red arrow depicts the measured distance to the facial nerve.

4 Discussion

Within that study a previously introduced mouldable surgical targeting system was tested for the first time using a temporal bone specimen. The mastoid process of the temporal bone is characterized by a great number of air filled spaces (mastoid cells). Drilling in bone is the most realistic experiment compared to test bench testing using virtual targets [6,8] or artificial bone material [9] and was expected to cause additional deviations due to that inhomogeneity of the mastoid. However, the measured deviation of the trajectory at the facial recess was well below the safety margin to the facial nerve. This allowed a safe passage.

The most crucial step is manual setting the length of the struts in the Jig Maker which requires great care to avoid errors. An automatic adjustment of legs using an active hexapod would simplify the procedure and reduce the risk of human errors. However, this would introduce additional costs and regulatory requirements what's why we prefer this manual solution, but requires further experiments to thoroughly investigate the reliability of the whole system.

The presented process allows a simple patient specific individualization of a drill guide under sterile conditions. This might facilitate its integration into clinical routine and is considered as improvement over previously described systems.

5 Conclusion

Within the presented proof of concept experiment the feasibility of a minimally invasive MPTA using a recently developed mouldable surgical targeting system could be demonstrated. While this preliminary result is encouraging further experiments are necessary to thoroughly investigate the reliability of the system.

Author Statement

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References

[1] Warren FM, Balachandran R, Fitzpatrick JM, Labadie RF. Percutaneous cochlear access using bone-mounted, customized drill guides: demonstration of concept in vitro. Otol Neurotol 2007;28:325–9.

[2] Labadie RF, Mitchell J, Balachandran R, Fitzpatrick JM. Customized, rapid-production microstereotactic table for surgical targeting: description of concept and in vitro validation. Int J Comp Assist Radiol Surg 2009;4:273–80.

[3] Kratchman LB, Fitzpatrick JM. Robotically-adjustable microstereotactic frames for image-guided neurosurgery. Proc. SPIE, vol. 8671, 2013, p. 86711U.

[4] Vollmann B, Müller S, Kundrat D, Ortmaier T, Kahrs L a. Methods for intraoperative, sterile pose-setting of patient-specific microstereotactic frames. Proc. SPIE, vol. 9415, 2015, p. 94150M.

[5] John S, Rau TS, Lexow GJ, Lenarz T, Majdani O. Target error evaluation of a minimal invasive cochlear implant strategy using a patient specific miniature stereotactical frame. CEUR Workshop Proc., vol. 1477, 2013.

[6] Rau TS, Lexow GJ, Blume D, Kluge M, Lenarz T, Majdania O. Micro-stereotactic frame utilizing bone cement for individual fabrication: An initial investigation of its accuracy. Prog. Biomed. Opt. Imaging - Proc. SPIE, vol. 10135, 2017.

[7] Kobler JP, Nuelle K, Lexow GJ, Rau TS, Majdani O, Kahrs LA, et al. Configuration optimization and experimental accuracy evaluation of a bone-attached, parallel robot for skull surgery. Int J Comput Assist Radiol Surg 2016;11:421–36.

[8] Balachandran R, Mitchell JE, Dawant BM, Fitzpatrick JM. Accuracy evaluation of microTargeting platforms for deep-brain stimulation using virtual targets. IEEE Trans Biomed Eng 2009;56:37–44.

[9] Lexow GJ, Kluge M, Majdani O, Lenarz T, Rau TS. Phantom-based evaluation method for surgical assistance devices in minimally invasive cochlear implantation. Prog. Biomed. Opt. Imaging - Proc. SPIE, vol. 10135, 2017.

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