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A method for image-guided positioning of cochlear specimens in insertion test benches using 3D printed stands.

Abstract: Cochlear implants include an electrode array (EA) which needs to be inserted into the cochlea. Insertion tests using artificial cochlear models (ACM) or ex vivo specimens are widely used methods during EA development to characterize EA design properties, including insertion forces. Measured forces are directly linked to the orientation of the cochlear lumen with respect to the insertion axis of the test bench. While desired insertion directions in ACM experiments can be predefined by design, specimens are individually shaped and the cochlear lumen is embedded invisibly. Therefore, a new method for accurate, individual specimen positioning is required.

A key element of the proposed method is a customizable pose setting adapter (PSA) used to adjust the specimen's fine positioning. After rigid fixation of the specimen to a holder featuring spherical registration markers and subsequent cone beam computed tomography the desired insertion direction is planned. The planned data is used to calculate the individual shape of the PSA. Finally, the PSA is 3D printed and mounted between force sensor and specimen holder to correctly align the specimen to the test bench's insertion axis.

All necessary hard- and software have been developed including the specimen holder, a software for registration and trajectory planning, and a custom Matlab script whose output drives a parametric CAD file of the PSA. Positioning accuracy was determined in a first trial using 10 virtual trajectories and was found to be 0.23 ± 0.12 mm and $0.38 \pm 0.17^\circ$.

The presented stereotactic positioning procedure enables high repeatability in future ex vivo insertion experiments due to accurate, image-guided control of the insertion direction.

Keywords: cochlear implant, insertion forces, image-guided surgery, stereotactic procedure, pose setting, 3D printing.

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1 Introduction

The implantable part of a cochlear implant (CI) system includes a receiver-stimulator and an electrode array (EA). The EA consists of multiple platinum electrode contacts embedded into a thin, elongated silicone body and needs to be inserted into the inner ear (cochlea) to electrically stimulate the auditory nerve in patients with profound to severe hearing loss or deafness.

Insertion tests using artificial cochlear models (ACM) or ex vivo cochlear specimens are widely used evaluation methods during EA development. Design factors of the EA strongly affect the forces acting during the insertion, which are considered as an important indicator for intracochlear injury linked to the loss of residual hearing. Therefore, accurate and systematic investigation of insertion forces caused by different EA designs is a valuable step in developing improved EA. This can advance treatment options and will help to develop a deeper understanding of how design factors, the insertion process and insertion trauma are correlated.

In a typical test setup, an ACM or a cochlear specimen is placed atop a force sensor while the EA is (manually or) automatically fed into the cochlear lumen coming from above and following a vertical axis. The main axis of the force sensor and the insertion axis of the linear stage are often aligned coaxially (Figure 1). It is crucial in such experiments that measured forces are directly impacted by the spatial relation of the insertion axis of the test bench with respect to the orientation of the cochlear lumen. Therefore, the “insertion direction” (referred to as trajectory in the following) needs to be controlled for comparable insertion experiments. While desired trajectories in ACM experiments can be predefined by design (Figure 1c), ex vivo specimens are individually shaped and the cochlear lumen is embedded invisibly (Figure 1d). To

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ensure comparability of measured forces between different cochlear specimens, or for a systematic investigation of the correlation between insertion direction and forces, an accurate method of individual specimen positioning is necessary.

Figure 1: (a) Schematic drawing and (b) image of an insertion test bench. (c) Insertion axis of the test bench (blue arrow), main axis of the force sensor (red), and insertion trajectory into the cochlear lumen (yellow) are coaxially aligned. (d) For specimens, the cochlear lumen is invisibly embedded and therefore its pose is not visually adjustable.

Positioning of a specimen along a previously planned trajectory with respect to the main axis of the insertion test bench would represent the inverse as the traditional positioning of the moving surgical tool with respect to the target, i.e. the cochlea. Nevertheless, the resulting task is the same. Therefore, methods from computer-assisted surgery can be applied in this context. The use of stereo-optical cameras for alignment of the specimens is already described [1], but here we propose a method that does not require an expensive image-guided surgery (IGS) system. This may facilitate distribution of this method in other research centres, as only a consumer-level 3D printer is necessary.

2 Material and Methods

A key element of the proposed method is a customizable pose setting adapter (PSA) used to adjust the specimen's fine positioning. After its individual fabrication, it is mounted below the specimen to control the specimen's pose (= orientation and position, in total six degrees of freedom) within the insertion test bench (Figure 2).

Figure 2: Schematic drawing of the positioning method. (a) Without the pose setting adapter (PSA) only rough alignment of the desired insertion trajectory (yellow line) with the main axis of the test bench (blue line) is possible as only natural landmarks can be used for visual pose setting. (b) Incorporating the PSA into the setup enables precise pose setting.

2.1 Methodology of pose setting

A temporal bone is trimmed down to the inner ear section to minimize its weight and comply with the small nominal load of highly sensitive load cells. As artificial landmarks are known to provide higher accuracy [2], a special registration and specimen carrier (RSC) was designed. The RSC should

- contain at least three spherical registration markers;
- have a low weight as it adds load to the force sensor;
- provide a tight but detachable connection to the specimen to allow its re-use.

The proposed design of the RSC depicted in Figure 3 includes four titanium spheres encircling the specimen. The latter is glued onto a disposable, 3D printed dish. Guided by anatomical landmarks (e.g. round window opening), a rough initial alignment can be achieved during gluing. LEGOTM plates fixed to both the RSC and the dish enable a precise but detachable connection allowing the re-use of the RSC.

To define a desired insertion trajectory within the specimen, a volumetric data set of the specimen on top of the RSC is needed, e.g. captured by cone beam computed tomography (CBCT). Imaging is followed by marking the fiducials and definition of the trajectory. In our laboratory, a custom planning software is used for these tasks featuring semi-automated sphere detection and tools for manual trajectory planning. The fiducials of the RSC are used for registration, which transfers the coordinate system (CS) of the physical RSC into the images, based on the exact position of the spheres (CS_{RSC}). To exclude inaccuracies from

manufacturing of the RSC, the coordinates of the sphere centres were determined using a coordinate measurement machine (CMM: XM-1200, KEYENCE, Osaka, Japan).

Figure 3: (a) CAD rendering of the RSC and dish. (b) Assembly of the RSC with a porcine cochlear specimen.

Planning requires definition of three points: two describing the desired insertion direction and a third one to define the curling direction of the cochlea – as the orientation of the EA relative to the central axis (modiolus) of the cochlea is of relevance. Finally, coordinates of all three planning points (in CS_{RSC}) are exported to enable computation of the PSA geometry. This is implemented in Matlab (R2021a, The MathWorks Inc., Natick, USA). For this purpose, four CS are of relevance (Figure 4):

- CS_{BASE} : Defines the bottom centre of the PSA, with z_1 is equal to the main axis of the load cell;
- CS_{RSC} : Located at the connection between RSC and PSA; defines the geometry of the top surface of the PSA with z_2 as its normal vector;
- CS_{INS} : Placed at the round window opening of the cochlear specimen; with z_3 indicating the insertion direction and x_3 the curling direction of the cochlea;
- CS_{ITB} : Located on the main axis of the insertion test bench with z_4 as insertion axis and x_4 describing the orientation of the EA.

The aim of the calculation is to express the origin vectors of CS_{RSC} (x_2, y_2, z_2) within CS_{BASE} , as this relation directly yields the geometry of the individualized PSA. Therefore, it is necessary to determine the homogeneous transformation matrix ${}^{BASE}T_{RSC}$ (cf. Figure 4). The specimen is considered to be correctly aligned, if CS_{INS} and CS_{ITB} are equal, which is why the searched transformation matrix can be calculated in a simplified way (see eq. 1).

$${}^{BASE}T_{RSC} = {}^{BASE}T_{INS} {}^{INS}T_{RSC} = {}^{BASE}T_{INS} ({}^{RSC}T_{INS})^{-1} \quad (1)$$

${}^{RSC}T_{INS}$ is provided by the mentioned registration step and ${}^{BASE}T_{INS}$ can be determined from a calibration measurement of the test setup using the CMM. The resulting origin vectors from the calculation are then forwarded to a computer-aided-

design software (Inventor Professional 2019, Autodesk, San Rafael, USA) to control a parametric model of the PSA. Finally, the finished PSA can be 3D printed, which also includes printing an interface to a LEGOTM plate glued to the bottom side of the RSC.

Figure 4: Overview of the coordinate systems and the homogeneous transformation matrices of the test setup in the aligned condition.

2.2 Experimental evaluation

Positioning accuracy of the proposed PSA method was first determined with ten virtual trajectories planned above the RSC in the typical region of an added cochlear specimen. In addition, one porcine specimen was used to test the suitability and reliability of the whole procedure. For all cases the previously described procedure was executed including CBCT scan (xCAT, Xoran Technologies LLC, Ann Arbor, Michigan; 300 μ m voxel size) and 3D printing of the PSA (Ultimaker 2+, Ultimaker, Geldermalsen, Netherlands). After mounting the RSC on top of the individual PSA inside the test setup, the positions of the RSC's spheres were measured again using the CMM. By registering the actual pose of the RSC to the planning data, the deviation of the adjusted insertion trajectory to the insertion axis of the test setup could be evaluated. The pose setting error was calculated considering the Euclidean distance at the level of the round window opening and the angle between these two axes. For the porcine specimen an additional CBCT image was acquired to visualize the quality of the alignment.

3 Results

Table 1 shows the achieved accuracy of the positioning process after evaluation of the virtual trajectories. The image data of the trial with the porcine cochlear specimen showed that the insertion axis of the test setup is located right above the RW and entrance to the cochlea (Figure 5). Pose setting error in case of the porcine specimen was 0.21 mm and 0.31°.

Table 1: Accuracy of the alignment method.

Trajectory	Euclidean distance [mm]	Angular deviation [°]
#1	0.23	0.36
#2	0.30	0.53
#3	0.14	0.12
#4	0.13	0.30
#5	0.27	0.15
#6	0.20	0.59
#7	0.48	0.54
#8	0.29	0.54
#9	0.09	0.32
#10	0.13	0.36
Mean	0.23 ± 0.12	0.38 ± 0.17

4 Discussion

The presented stereotactic positioning procedure enables accurate alignment of the cochlear lumen following a planned trajectory to the insertion axis of the test bench. In nine of ten virtual trajectories, the pose setting error was less than 0.3 mm, which is considered as benchmark value of the accuracy required for atraumatic opening of the cochlea [3]. However, even the maximum error of 0.48 mm seems to be sufficient for insertion experiments using an already opened cochlear specimen, as the EAs are flexible and compensate slight misalignments. Furthermore, translational errors could be further minimized by adding an XY micrometer positioning stage in the setup below the force sensor. The visible opening of the cochlea allows moving of the specimen by visual control until the tool's tip is perfectly aligned with the entry point.

More critical is the angular deviation, which was found to be remarkably low in this first setup prototype. Angular alignment accuracy using our proposed procedure is superior compared to only visual alignment by the experimenter, which was previously found to be limited to $7^\circ \pm 1.5^\circ$ by experienced CI surgeons [4]. Therefore, we conclude our new stereotactic positioning method enables higher reproducibility in ex vivo

insertion experiments due to the highly accurate image-guided specimen alignment. This enables systematic investigation of the insertion trajectory as an important parameter affecting insertion forces.

Figure 5: (a) Aligned porcine specimen. (b) CBCT data from the aligned porcine specimen.

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References

- [1] Hügl S, Henke M, Kahrs L et al. Entwicklung eines Versuchsstandes für die Insertionskraftmessung bei präziser Ausrichtung von Präparaten mittels stereooptischer Navigation. *Laryngo-Rhino-Otologie* 2019; 98(S02): 286-7.
- [2] Majdani O, Leinung M, Lenarz T, Heermann R. (2003): Navigation-Supported Surgery in the Head and Neck Region. *Laryngo-Rhino-Otol* 82:632-644.
- [3] Rau TS, Kreul D, Lexow J, Hügl S, Zuniga GM, Lenarz T, Majdani O (2019): Characterizing the size of the target region for atraumatic opening of the cochlea through the facial recess. *Comp Med Imag Graph* 77:101655.
- [4] Torres R, Kazmitcheff G, Bernardeschi D, De Seta D, Bensimon JL, Ferrary E, Sterkers O, Nguyen Y (2016): Variability of the mental representation of the cochlear anatomy during cochlear implantation. *Eur Arch Otorhinolaryngol* 273:2009-18.