Accuracy and Feasibility of a Dedicated Image Guidance Solution for Endoscopic Lateral Skull Base Surgery

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Compliance with Ethical Standards

All of the authors have read and approved the manuscript.

Funding: This work was partially funded by the CTU-grant Nr. 2017-01 (University of Bern) allocated to Lukas Anschuetz.

Conflict of interest: The authors declare no conflict of interest.

Research involving human participants: All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional, regional and national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent: For this type of study, formal consent is not required.

Key words: image guided therapy; navigation; lateral skull base; endoscopic ear surgery; endoscopic lateral skull base surgery

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Abstract

We aimed to design, build and validate a surgical navigation system which fulfills the accuracy requirements for surgical procedures on the ear and the lateral skull base, and which integrates with the endoscopic workflow and operating room set-up.

The navigation system consists of portable tablet computer (iPad Pro, Apple Computer, USA) and an optical tracking system (Cambar B1, Axios3D, Germany), both connected via a wireless Bluetooth link and attached directly to the OR table. Active optical tracking references are rigidly fixed to both the patient and surgical tools. Software to support image import, registration and 2D/3D visualization has been developed. Two models were used for targeting accuracy assessment: a technical phantom model and an ex-vivo temporal bone model. Additionally, workflow integration and usability of the

navigation system during endoscopic lateral skull base procedures was investigated in ex-vivo experiments on 12 sides of cadaver head specimens.

The accuracy experiments revealed a target registration error in the technical phantom model of 0.20 ± 0.10 mm (n=36) and during the ex-vivo assessment of 0.28 ± 0.10 mm (n=21). Navigation was successfully carried out in n=36 procedures (infracochlear, suprageniculate and transpromontorial approach), with navigated instruments usable without interference with the endoscope. The system aided in the successful and accurate identification of vital anatomical structures.

Useful surgical navigation is, to large extent, a result of sufficiently accurate tracking technology. We have demonstrated sufficient accuracy and a potentially suitable integration for surgical application within endoscopic lateral skull base procedures.

Key words: image guided therapy; navigation; lateral skull base; endoscopic ear surgery; endoscopic lateral skull base surgery

Introduction

The anatomy of the temporal bone is highly complex. The middle ear and the petrous bone contain crucial structures such as the facial nerve (FN), the vestibulocochlear nerve (VCN), the labyrinth, the internal carotid artery (ICA) and the jugular vein bulb (JB). Moreover, the dura and central nervous structures such as the cerebellopontine angle (CPA) are at close range. The preservation of the integrity and function of these structures is crucial to the surgical outcome and to avoid morbidity. This requires extended surgical expertise and experience.

Stereotactic image guidance may improve spatial orientation and allow the surgeon to identify crucial anatomical structures by instrument navigation. This is achieved by mapping of the real-world situs and its three-dimensional (3D) Cartesian points to a virtual 3D model, typically created from medical imaging data, most commonly computed tomography (CT) or magnetic resonance imaging (MRI). The acquired image model acts as a 3D map of the surgical object, displayed as a virtual image, upon which surgical instrumentation can be displayed in real-time. Provided sufficient accuracy, image-guidance may lead to more efficient procedures (higher accuracy, shorter procedural durations) while improving patient safety (reduced invasiveness, reduced adverse events) [1].

Despite the rigid structure of the temporal bone, which facilitates the application of stereotactic image guidance, it is not routinely used in this region. This is mainly due to the accuracy requirements, which are significantly higher than in other surgical fields [2]. The effective targeting accuracy required for image guidance on the lateral skull base was described to be in the sub-millimeter range [3].

Recent advances in minimal-invasive transcanal endoscopic lateral skull base surgery [4-6] lay the foundation of potentially interesting uses of stereotactic image guidance systems on the lateral skull base in the future. Compared to traditional surgical approaches, where a wide skin incision and extended bone works are required, these emerging techniques access the lateral skull base through the external auditory canal (EAC). The diminution of the access size, the conical workspace and operating in a tunnel challenges spatial orientation and may therefore be a suitable application for image guided surgical navigation.

We hypothesize that sufficiently accurate image guidance improves spatial orientation and instrument manipulation during endoscopic lateral skull base surgery. Thus, this work investigates whether a custom-made image guidance system designed specifically for lateral skull base procedures provides for effective target precision in an ex-vivo model. Furthermore, this work investigates the potential utilization of the system during applicable OR workflows during endoscopic approaches at the lateral skull base.

Material and Method

Image guidance system

The system consists of a tracking camera (Cambar B1, Axios3D, Germany) with a tracking accuracy of 0.05 ± 0.025 mm [7] with a Bluetooth Interface (via a connected micro controller), a tablet computer (iPad Pro, Apple Computer, USA), running a custom-made image guidance software. Instrument and patient tracking is provided through active tracking and by utilizing previously developed dynamic reference bases [7]. The patient marker is rigidly attached to the patient's lateral skull through a single bone anchored fiducial screw (8mm length, M-5243.08, Medartis, Switzerland). A custom-made pointer instrument is used as the primary tool (200 mm length) during guidance (Figure 1). Preprocessing software converts and optimizes the planning data from custom-made surgical planning software [8] for further use on the tablet. The image guidance software consists of relevant modules for real-time metrology communication, DICOM image loading, patient-to-image registration and visualization of image guidance information directly with the native 2D medical image data or 3D surface models of the anatomy. The software guides the user through a fiducial based registration process and enables real time tracking of surgical instruments relative to a patient reference marker. Patient-to-image registration is achieved via fiducial screws (2.2mm ∅ × 5mm length, M-5243.05, Medartis, Switzerland).

Validation of effective targeting accuracy

Effective image guidance accuracy is highly dependent on the resolution and geometric precision of the underlying image modality, the method of choice for patient-to-image registration and the accuracy of patient and instrument tracking and instrument calibration, among other factors. The target registration error (TRE) represents a clinically applicable method to determine a given systems effective image guidance accuracy [9,10]. In this study, TRE was determined using a technical phantom (Figure 2) and an ex-vivo model.

The technical phantom model consists of 10 larges (2.2mm ∅ × 5mm length) and 12 smaller fiducial screws (not relevant for this study) as well as four spherical markers for calibration (see [11] for further details on the phantom). A coordinate measurement machine (FaroArm Platinum, FARO Technologies) was used to determine spatial ground truth of all available fiducial markers. Four surgical plans [8] were emulated using sets of four randomly selected screws for registration and sets of three screws for determining TRE. Per accuracy assessment, the plan was transferred to the navigation system, the phantoms fiducial positions were digitized by averaging n=50 instrument positions. Subsequently, patient-to-image registration was computed using an iterative closed point (ICP) algorithm [12]. Per measurement attempt, positions of each of the three remaining fiducial screws were measured by averaging n=250 positional measurements acquired in five independent and distinct orientations. Altogether, n=36 TRE measurements were carried out: 3 target screws × 3 camera positions × 4 plans.

The ex-vivo model consists of three human cadaveric specimens (temporal bone, Thiel embalming). Preoperatively and per specimen, titanium surgical screws were implanted (for registration on the mastoid surface and for artificial targets in the middle ear and lateral skull base), and a CT scan was acquired (0.15 × 0.15 × 0.2 mm^3, SOMATOM Definition Edge, Siemens, Germany). Fiducial positions were automatically computed [11] and the image data transferred to the system. For each specimen patient-to-image registration was performed with the four fiducial screws on the mastoid surface. Each fiducial screw in the middle ear cavity was digitized by averaging n=50 instrument positions. A total of n=21 TRE measurements were performed: 7 artificial targets × 3 camera positions.

Investigation of usability

The local review board granted approval to perform the present study. The image guidance system was used during cadaveric dissection of six human cadaveric specimens (whole head, Thiel embalming). Preoperatively and per specimen, 2 × 4 titanium surgical screws were implanted (four per side). Similar to the ex-vivo model for accuracy assessment, a CT scan was acquired ($0.15 \times 0.15 \times 0.2\ mm^3$, SOMATOM Definition Edge, Siemens, Germany). Fiducial positions were automatically computed [11] and the image data transferred to the system. Endoscopic steps were performed using a 0° endoscope (3mm diameter, l=150 mm) connected to a HD 3 CCD System (Karl Storz AG, Germany). The experimental set-up is shown in Figure 1.

Per side, three different minimal-invasive exclusively endoscopic approaches to the lateral skull base were performed and validated:

1. Infracochlear approach: The tympanic cavity was accessed through a circumferential tympano-meatal flap. After identification of the main landmarks an infracochlear route with identification and exposure of the ICA, the JB and the third portion of the FN was performed in order to reach the inferior petrous apex. In this approach, the cochlea is entirely preserved [4].
2. Suprageniculate approach: After performing a wide atticotomy the incus and the malleus were removed. Thereafter, the middle cranial fossa (MCF) dura was exposed above the geniculate ganglion from the lateral semicircular canal posteriorly to the great superficial petrous nerve (GSPN) anteriorly [4].
3. Transcanal transpromontorial approach: The stapes was removed to expose the vestibule and the spherical recess. The basal, middle and apical turn of the cochlea were identified and removed to access the fundus of the IAC [5].

Accuracy was assessed by identifying specific surgical landmarks in the CT scan and compared to the intraoperative position of the pointer instrument (Figure 3).

Results

Target registration error in the technical phantom model and in the ex-vivo model was measured to be 0.20 ± 0.10 mm (n=36) and 0.28 ± 0.10 mm (n=21) respectively, using fiducial screws as a reproducible means for localization both in image and in the patient space.

The navigation system was tested in a total of n=36 procedures (6 specimens × 3 procedures × 2 sides). Identified landmarks from external to internal auditory canal were: promontory, first, second and third portion of FN, geniculate ganglion, cochleariform process, JB, ICA, MCF dura, Eustachian tube orifice, lateral semicircular canal, IAC fundus and IAC porus. Neither the guidance system itself nor its components interfered with the endoscope during the procedures. After attaching the reference marker on the patient's head and registering to the image data, the guidance system did not conflict either with the surgical technique or the conventional workflow for any of the performed approaches. Both the patient marker and the pointer instrument, including the cables can be sterilized. The tablet can be draped (eShield™, Whitney Medical Solutions) and remains functional even with surgical gloves.

Discussion

This study describes the development and ex-vivo validation of an image guidance system specifically for endoscopic lateral skull base surgery. In contrast to other surgical domains, effective sub-millimeter accuracy is imperative for a clinically valid and safe implementation. In this study, we demonstrated a TRE of 0.2 ± 0.1 mm in a technical phantom model and a TRE of 0.28 ± 0.1 mm during ex-vivo assessment. These measurements exceed that of available navigation systems. A previous accuracy evaluation by Labadie et al. reported TRE values for Brainlab^{TM} (1.31 ± 0.87 mm), InstaTrak^{TM} (2.77 ± 1.64 mm) and LandmarX^{TM} (1.97 mm) [2], while a system built specifically for the lateral skull base (Fiagon GmbH) reported a TRE = 0.8 mm [13]. Recently, Komune at al. demonstrated a navigation accuracy of 0.49 ± 0.05 mm using seven fiducial screws for patient registration [14]. In another study, the error margin was described 0.2 ± 0.6 mm for bone anchored fiducials during a transcanal retrocochlear approach to the IAC [15]. However, the authors report in this study the accuracy at the fiducials and not the procedural TRE. Moreover, no information is provided how these values were assessed. Nevertheless, the conclusion of the authors, that combining the panoramic views offered by the endoscope with a high precision surgical navigation provides adequate spatial orientation and approximation of critical anatomical structures [15]. For example, the author's state, that the bone covering the cochlea or the ICA in the infracochlear approach is thinned to as much as 0.5 mm, emphasizing the need for high-accuracy stereotactic navigation. However, no practical conclusions about clinical benefits of the navigation system or the investigated minimal-invasive approaches may be drawn from the present cadaveric studies. Moreover, if during clinical application uncovering of a structure is required (e.g. dura, ICA), the accuracy may drop at the structure due a shift caused by the intracranial or blood pressure respectively. Anyway, as long as the bony encasement of the anatomical structures, such as the labyrinth, FN, ICA and JB is preserved, the TRE will remain stable. In addition, the clinical benefit of this dedicated navigation system for the lateral skull base has yet to be investigated in future studies.

At this point, we wish to emphasize, that no navigation system is able to replace dedicated surgical training and exact anatomical knowledge of the performing surgeon remains unquestionable. While the navigation system enables visualization and identification of anatomical structures with submillimeter accuracy, it cannot and will not replace the surgeon's knowledge and experience.

The navigation system was designed based on two major concepts: high accuracy and ease of integration. In order to fulfill the demanding requirements associated with the surgical situation, the developed navigation system utilizes specialized hardware components as compared to previously developed systems [2,14,15]. Instead of the standard tracking camera (NDI Polaris), a more compact tracking system (Axios CamBar B1) was integrated. This system can be directly mounted to the surgical table, not requiring a separate stand. Although the camera workspace is limited, it was sufficient to perform all approaches without any spatial limitations. The close placement to the working field means that many of the line of sight issues typically associated with optical tracking are avoided. Systems which utilize electromagnetic technology for tracking also avoid many of these issues and recent developments show that electromagnetic tracking becomes feasible for lateral skull base surgery, with reported TRE values around 0.5mm [14,15]. However, environmental effects and the effect of instruments and equipment close to the system workspace must be also considered when utilizing systems of this type.

Furthermore, instead of displaying the navigation software on a large touchscreen some distance away from the surgical site, the complete software executes on a tablet. Wrapped in a sterile casing, the tablet can be used directly on the surgical table by the surgeon wearing surgical gloves, enabling effortless integration into the existing setup. The system is lightweight and the components small and therefore simple to handle and integrate. Thus, the system would also be suitable on small or mobile ORs.

All image guided navigation systems need accurate techniques to effectively complete the patient to image registration procedure. The presented system allows patient-to-image registration based on fiducial screws. While this enables high levels of accuracy, the implantation of fiducial markers requires local anesthesia if placed preoperatively or generally increase the overall operation time if implanted intra-operatively [16]. This should therefore be considered as the main limitation of the presented system. High accuracy surface matching as previously described [17] using the mastoid surface as a reference is promising. However, for endoscopic approaches, the exposure of the mastoid is not an option, since external incisions can be avoided with this technique. Thus, the investigation of alternative registration solutions represents a major direction of future investigation.

Endoscopic approaches minimize the morbidity of surgical interventions whereas the navigation system ensures the patient's safety [1]. The combination of the endoscope and the navigation system was demonstrated to be useful and efficient in this study. Most endoscopes provide a 2-dimensional perception of the anatomical structures' surface, whereas the navigation system allows the user to see below the surface. During the dissection, this additional visual feedback was useful to plan the surgical path, to adjust the surgical technique and to double check on crucial anatomical structures to ensure the patient's safety. In some cases, vital anatomical structures such as for example the ICA and the JB are close together (Figure 4), which would represent a relative contraindication to endoscopic lateral skull base surgery. In these cases, the navigation system may be particularly useful to reach the petrous apex of the temporal bone. The use of a highly accurate navigation system on the lateral skull base could expand the present indications for minimal-invasive surgery. This technology may offer the surgeon new possibilities to perform minimal invasive approaches inside a highly complex anatomical area.

Conclusion

The developed navigation system achieves the accuracy requirements for lateral skull base surgery, while seamlessly integrating into existing workflows and setups. The combination of navigation and endoscopic techniques allows a good view of the anatomy and pathology even if the surgical access is only a small tunnel. Although endoscopes provide only a 2-dimensional view of the site, this can be compensated through the use of the navigation system. The described methods potentially allow minimally invasive approaches for procedures that currently require large incisions or the removal of significant amounts of bone tissue, and may lead to more widespread use of minimally invasive endoscopic techniques by lateral skull base surgeons in general.

Compliance with Ethical Standards

All of the authors have read and approved the manuscript.

Funding: This work was partially funded by the XX-grant Nr. 2017-01 (XX) allocated to XX.

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References

1. Kohan D, Jethanamest D, Image-guided surgical navigation in otology, Laryngoscope Volume 122 Issue 10 October 2012 Pages 2291–2299
2. Labadie R, Davis B, Fitzpatrick J, Image-guided surgery: what is the accuracy? Curr Opin Otolaryngol Head Neck Surg. 2005 Feb;13(1):27-31.
3. Williamson T, Gavaghan K, Gerber N, Weder S, Anschuetz L, Wagner F, Weisstanner C, Mantokoudis G, Caversaccio M, Weber S., Population Statistics Approach for Safety Assessment in Robotic Cochlear Implantation, Otol Neurotol. 2017 Jun;38(5):759-764.
4. Marchioni D, Alicandri-Ciufelli M, Rubini A, Presutti L. Endoscopic transcanal corridors to the lateral skull base: Initial experiences. Laryngoscope. 2015;125 Suppl 5:S1-13.
5. Marchioni D, Alicandri-Ciufelli M, Rubini A, Masotto B, Pavesi G, Presutti L. Exclusive endoscopic transcanal transpromontorial approach: a new perspective for internal auditory canal vestibular schwannoma treatment. J Neurosurg. 2017 Jan;126(1):98-105.
6. Presutti L, Alicandri-Ciufelli M, Bonali M, Rubini Alessia, Pavesi G, Feletti A, Masotto B, Anschuetz L, Marchioni D. Expanded transcanal transpromontorial approach to the internal auditory canal: pilot clinical experience on 10 cases. Laryngoscope. 2017 Mar 8. doi 10.1002/lary.26559. [Epub ahead of print]
7. Caversaccio M, Gavaghan K, Wimmer W, Williamson T, Ansò J, Mantokoudis G, Gerber N, Rathgeb C, Feldmann A, Wagner F, Scheidegger O, Kompis M, Weisstanner C, Zoka-Assadi M, Roesler K, Anschuetz L, Huth M, Weber S.

Robotic cochlear implantation: surgical procedure and first clinical experience. Acta Otolaryngol. 2017 Apr;137(4):447-454.

8. Gerber N, Bell B, Gavaghan K, Weisstanner C, Caversaccio M, Weber S, Surgical planning tool for robotically assisted hearing aid implantation, Int J Comput Assist Radiol Surg. 2014 Jan;9(1):11-20.
9. Widmann G, Stoffner R, Bale R. Errors and error management in image-guided craniomaxillofacial surgery, Oral Surg., Oral Med., Oral Pathology, Oral Radiol. Endodontics. 2009; May,107(5): 701–715.
10. Caversaccio M, Zulliger D, Bächler R, Nolte LP, Häusler R. Practical aspects for optimal registration (matching) on the lateral skull base with an optical frameless computer-aided pointer system. Am J Otol. 2000 Nov;21(6):863-70.
11. Gerber N, Gavaghan KA, Bell BJ, Williamson TM, Weisstanner C, Caversaccio MD, Weber S. High-accuracy patient-to-image registration for the facilitation of image-guided robotic microsurgery on the head, IEEE Trans. Biomed. Eng. 2013; 60(4): 960–968.
12. Veldpaus FE, Woltring HJ, Dortmans LJ. A least-squares algorithm for the equiform transformation from spatial marker co-ordinates. J Biomech. 1988; Jan:21(1): 45–54.
13. Kristin J, Mucha D, Schipper J, Klenzner T, Registration Strategies for the Application of the Navigation System Fiagon at the Lateral Scull Base, Laryngo-Rhino-Otol 2012; 91(05): 306-310.
14. Komune N, Matsushima K, Matsuo S, Safavi-Abbasi S, Matsumoto N, Rhoton AL Jr. The accuracy of an electromagnetic navigation system in lateral skull base approaches. Laryngoscope. 2017 Feb;127(2):450-459.

15. Kempfle JS, Fiorillo B, Kanumuri VV, Barber S, Edge ASB, Cunnane M, Remenschneider AK, Lee DJ, Kozin ED. Quantitative imaging analysis of transcanal endoscopic Infracochlear approach to the internal auditory canal. Am J Otolaryngol. 2017 Sep - Oct;38(5):518-520.
16. Selesnick S, Kacker A, Image-guided surgical navigation in otology and neurotology, Am J Otol. 1999 Sep;20(5):688-97.
17. Zhou C, Anschuetz L, Weder S, Xie L, Caversaccio M, Weber S, Williamson T, Surface matching for high-accuracy registration of the lateral skull base, Int J Comput Assist Radiol Surg. 2016 Nov;11(11):2097-2103.

Figure Legends

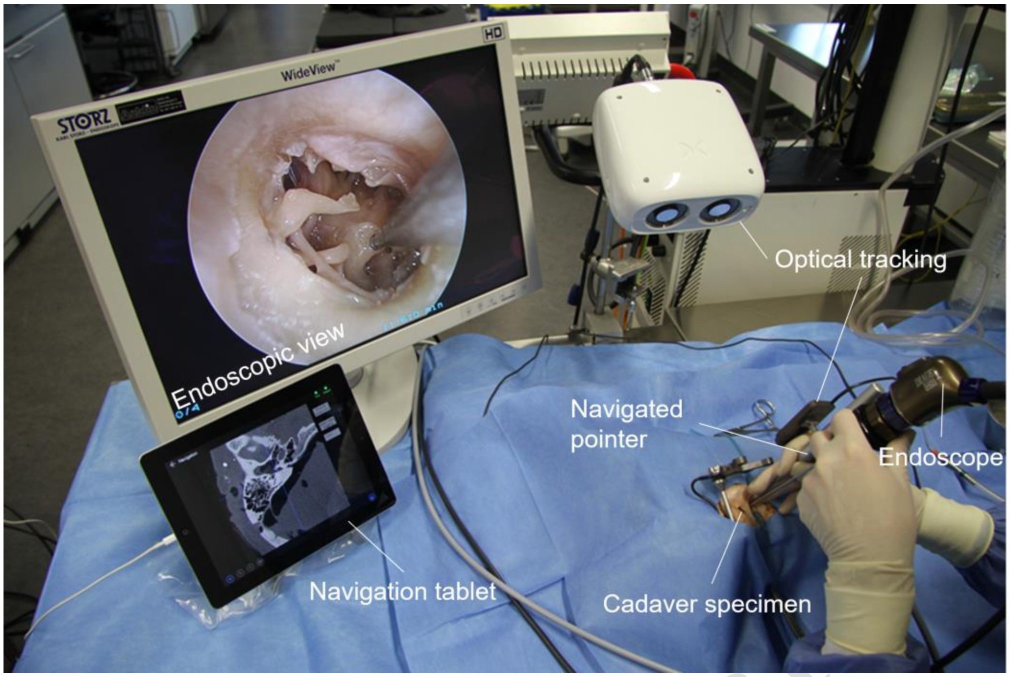

Figure 1: The lightweight navigation system: optical tracking camera (Cambar B1, Axios3D, Germany), tablet computer (iPad Pro, Apple Computer, USA), custom made instrument and patient tracking and bone anchored fiducial screws. (Medartis, Switzerland).

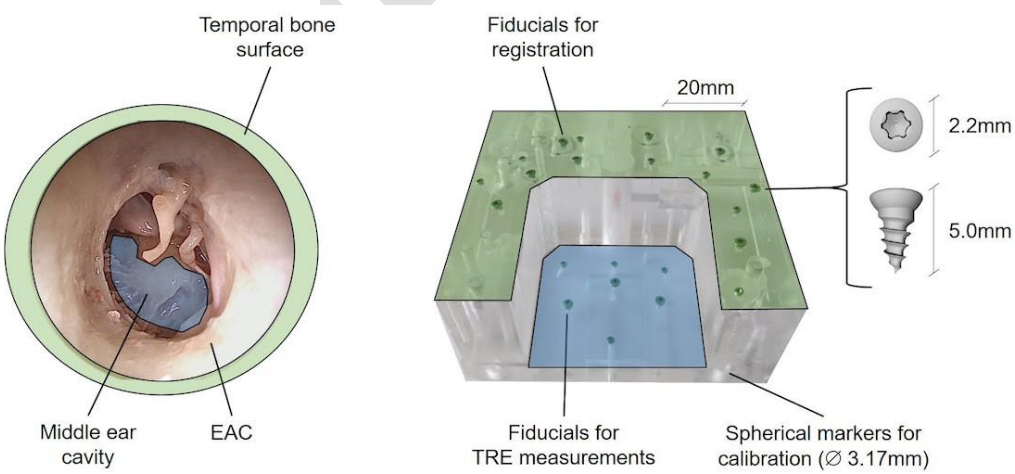

Figure 2: Target registration error was determined using an ex-vivo temporal bone and a technical phantom. We measured mean target error of 0.20±0.10 mm (n=36) in the phantom and 0.28±0.10 mm (n=21) in the temporal bone.

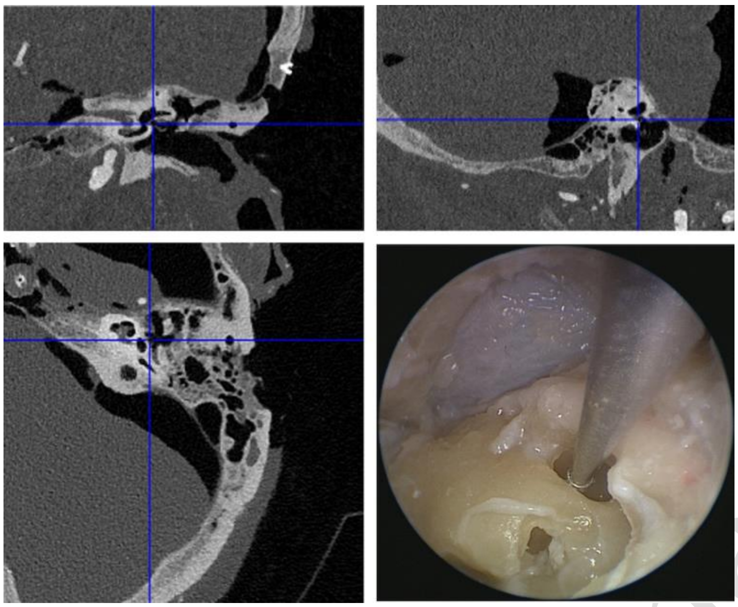

Figure 3: The accuracy is assessed during the ex-vivo validation study. Here the oval window with the vestibule is shown after removal of the stapes during a transcanal transpromontorial approach to the internal auditory canal.

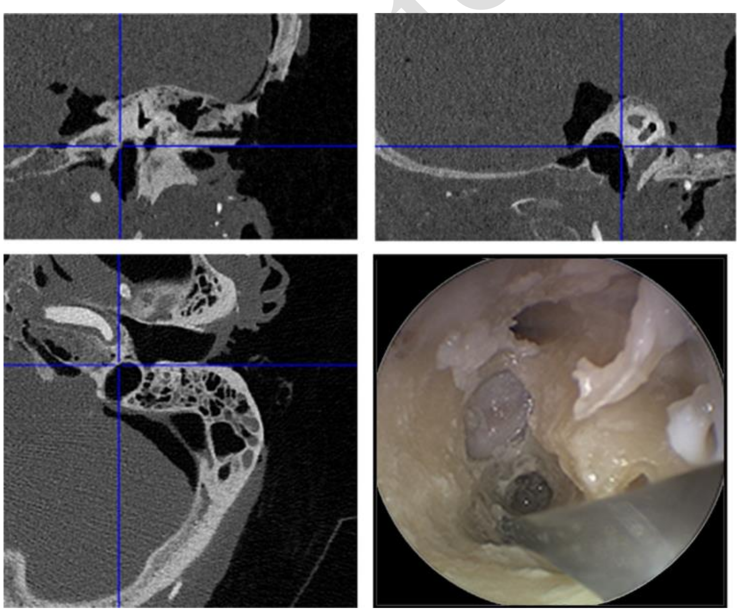

Figure 4: A high jugular bulb is considered a contraindication to endoscopic approaches to the inferior petrous apex. Here the navigation system allows to identify the inferior petrous apex between the jugular vein and the internal carotid.