Application of a new computer-assisted robotic visualization system in cochlear implantation—Proof of concept

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Abstract

Background: Over the last decades conventional cochlear implant (CI) surgery has remained essentially unchanged. Nevertheless, alternative implantation techniques to further improve patient outcomes such as endaural implantation or robot-assisted surgery have been proposed in recent years. However, none of these have gained acceptance in clinical routine, thus confirming a demand for new developments.

Methods: Cochlear implant surgery was performed in two mastoid bones obtained from body donors using a novel hands-free exoscope. Advantages and disadvantages of the system were evaluated.

Results: In all cases, implantation of the electrode was feasible. The system allowed for hands-free movement and adjustment of the exoscope by the head-mounted display. Network connectivity of the system leaves room for improvement.

Conclusion: The RoboticScope is an innovative tool and can be used supportively in conventional CI surgery in the experimental setting. Although operating the device requires a certain learning curve, the usability is intuitive for every ear surgeon.

Keywords
cochlear, computer-assisted surgery, ENT, head and neck, imaged guided surgery

1 | INTRODUCTION

In the late 20th century, new developments in otology included the use of a microscope in surgery the invention of the cochlear implant (CI)—the first technological replacement for a lost human sense.1 The success story of many satisfied CI-patients shows that the procedure is widely considered to be safe and effective. CI is the biomedical device most successfully used for hearing impairment, and it has become a common medical treatment of deafness and protecting residual hearing.2 Over 4 decades after the first description by House et al. conventional CI surgery remains essentially unchanged.3

Until today, complete mastoidectomy with facial recess exploration and posterior tympanotomy is the gold standard. While this surgical approach is invasive, it is also known to be the safest approach in trained hands as it allows for identification and preservation of critical structures, especially in the case of distorted anatomy. Nevertheless, alternative implantation techniques to further improve patient outcomes, including reduced mastoidectomy under

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endoscopic supervision and endaural implantation techniques, have been proposed in recent years.\textsuperscript{4,5} Minimally invasive approaches, including a key-hole tunnel drilled through the facial recess, have been introduced and demonstrated in adults.\textsuperscript{6,7–9}

In Otolaryngology-Head and Neck Surgery (OHNS), robotic systems are mostly used for the treatment of oropharyngeal cancers.\textsuperscript{9–11} Several efforts have been made to transfer the benefits of robot assisted surgery to ear surgery: in 2017, Caversaccio et al. reported on a minimally invasive access to the cochlea. Based on preoperative images, a drilling tunnel targeting the round window was planned and drilled by a robotic system. Electrode array insertion was then manually achieved under microscope visualization. The procedure was performed without complications, and all surrounding structures, like ossicles, facial nerve, chorda tympani and the equilibrium organ, were preserved.\textsuperscript{4} In 2019, the group presented the robotic middle-ear access for cochlear implantation.\textsuperscript{5} In 2020, Wang et al. published the results of the robotic cochlear implantation of a perimodiolar electrode.\textsuperscript{2} In the same year, Top-askal et al. compared surgical techniques and robotic techniques for cochlear implantation in terms of the trajectories toward the inner ear, in silico.\textsuperscript{12} Schneider et al. demonstrated the feasibility of robot-assisted drilling of trajectories for cochlear implantation in human body donor mastoid bones.\textsuperscript{13} All authors describe, that the main challenges with robot-assisted electrode insertion are the deviation of the drilling canal in the mastoid bone and the increased operating time. Therefore, none of the available robotic systems have yet gained acceptance in clinical routine, thus confirming a demand for new developments in the field of robotic systems assisting conventional surgery.\textsuperscript{14}

Recently, exoscopes—remotely positioned high-definition cameras that project a three-dimensional (3D) image—have been applied to skull-base surgery. In the context of cochlear implantation, the utility of an exoscope may allow for a more rapid surgery as it allows for the surgeon to avoid having to make microscopic adjustments or worry about passing instruments around the microscope.\textsuperscript{3} In this article, the advantages and limitations of an innovative hands-free exoscope are described for cochlea implantation in a pre-clinical cadaver study. The system is currently being developed for a variety of surgical procedures in the fields of ear, nose, throat, plastic surgery and neurosurgery, but can also be used for microscopic procedures in other fields.

2 | MATERIAL AND METHODS

2.1 | Experimental setup

Two formalin-fixed human temporal bones were used for preclinical evaluation. The experiments were approved by the local ethics committee (IRB # 390/20). All experiments were performed by an attending OHNS faculty (RR). The regular anatomy of the specimens was intact. The skin was removed and the temporal bone was fixed on a retainer with clamps (Figure 1). The RoboticScope was placed in front of the surgical table and covered with a plastic drape to protect the camera from dust. Mastoidectomy and posterior tympanotomy were performed in the usual manner with standard drills. The round window membrane was exposed and opened (Figure 2). A ‘Slim Straight’ cochlear electrode (Cochlear) was inserted via the round window approach. The different features of the RoboticScope were tested during the surgical procedure.

2.2 | RoboticScope

The RoboticScope (BHS Technologies GmbH) is an exoscope, which consists of a robotic arm which can be navigated with an accuracy of 0.02 mm and a maximum velocity of 25 mm/s. The robotic arm holds a 3D-camera with 4112 × 1542 stereo resolution. A screen is attached to the pillar of the system. The system also includes a foot pedal and a head-mounted display (HMD), which is integrated in a headset with eyepieces (Figure 3). By tapping the foot pedal, a menu is started on the HMD and on the system screen, which allows the surgeon to operate a variety of system features. The menu is controlled by the surgeon’s head movements, which are registered by the HMD. The menu consists of an inner and an outer ring (Figure 4). The inner ring contains the primary functions, which are most frequently used during the operation.

The inner ring consists of four different functions. ‘Free view’ (1.1) allows the change of view of the operation field within the horizontal plane. Using the ‘Orbit view’ (1.2), the surgeon can fix a point and view it from any number of perspectives. The focus level remains the same. ‘Focus’ (1.3) means, that the camera is fixed to the respective working distance. However, it can be moved along the line of sight to focus at different depths. The working distance remains the same throughout the entire process. Choosing the ‘Zoom’ (1.4), surgeons can choose from eight zoom levels in each of the three movement modes.

The outer ring contains secondary functions, which are used less frequently. With the ‘Lift HMD’ function (2.1), the eyepieces can be lifted off the HMD to obtain a view of the surrounding. Using the function ‘Store position’ (2.2) means, that the position of the robot arm and all settings used are saved. This allows the return to this position later. ‘Media tool’ (2.3) provides the possibility to take a picture or start a video record of the operating field. Recorded photos and videos can be saved on a selected mobile storage medium. In addition, one can record the operation time and view recorded files. Choosing ‘Light intensity’ (2.4) allows selection of the desired illuminance. With the help of the ‘Imaging mode’ (2.5), settings of the eyepieces can be modified for special situations, including very narrow viewing points. Instead of the standard 3D setting, a 2D view can be chosen to achieve a sharper view. The working distance can be changed between 300, 450 and 600 mm (2.6).

3 | RESULTS

3.1 | Feasibility

In both temporal bones, the approach and intervention were feasible in terms of visualization and accessibility. Following extensive and structured instruction in the handling of the RoboticScope, the sub-steps of a cochlear implantation were performed. In contrast to conventional CI surgery, the first steps of mastoidectomy were performed with the RoboticScope and not macroscopically. Important landmarks of the mastoid, including the dura, lateral semicircular canal, short incus process, dura and facial nerve were visualized. Finally, a SlimStraight electrode was inserted via a round window approach. The position and movement of the robotic arm are completely controlled hands-free by the surgeon by small head movements. The operation field is only defined by the camera position, while the surgeon's field of vision is independent of the head posture. The robotic arm can be provided with a sterile cover. An external monitor connected to the robot arm enables viewers to follow the course of the operation in real time.
3.2 | Orbit view

In the ‘orbit view’-mode the robot arm swivels over the situs following the surgeon’s head movements. The focused anatomical structure is shown from different angles without the need to use the hands or change the position of the temporal bone.

3.3 | Magnification and colouring

With the RoboticScope, eight degrees of magnification can be chosen. Figure 5 shows an example of the possibilities of magnification by looking at the round window. Compared to reality, the colours look a little faded. However, because the colouring in a fixed human temporal bone petrous is naturally rather pale, this is not comparable to living human tissue during surgery.

4 | DISCUSSION

Contemporary microscopes, currently still the mainstay of ear surgery, are a product of many generations of refinement in optics, illumination and mechanical systems. Recently, endoscopes have become increasingly popular in ear surgery, as they offer an improved view into difficult to access recesses. However, their implementation is limited, because holding the endoscope with one hand prevents the surgeon from bimanual control, as is frequently required for delicate otological surgical manoeuvres.

Cochlear implantation is a fine and complex procedure, which requires extensive clinical experience. The operative microscopic gold standard still consists of the classic procedure with the sub-steps: mastoidectomy, visualization of typical landmarks, posterior tympanotomy, opening of the round window membrane or cochleostomy and electrode insertion. Depending on the type of CI and the individual surgical procedure, an implant bed is drilled. The operation
includes steps with and without using the microscope and a frequent change of instruments. Different drills and suction cups in various sizes are required. Focus as well as zoom of the microscopic visualization must be frequently adapted to the circumstances that change during the course of the operation. In addition, the surgeon’s point of view must be modified by changing the position of the patient’s head and the position of the microscope. This means that instruments have to be returned to the surgical nurse. At least one hand is required for adaptation on the microscope. This involves a considerable amount of time, and the smooth flow of the procedure is disrupted, resulting in a loss of concentration during the surgical procedure. We, therefore, understand that there is a need for tools that enable hands-free surgical work combined with the best possible image resolution—ideally combined with ergonomic work conditions for the surgeon. In view of a process optimization by the hands-free technique, the use of the RoboticScope as part of a cochlear implantation appeared reasonable.

4.1 | Variety of treatment options

In the present study, we demonstrated the feasibility of cochlea implantation with the RoboticScope system in a pre-clinical cadaver study. This may provide the prospect of a possible transfer to surgical treatment of other ear pathologies. It is conceivable to extend the application of the RoboticScope to all otological interventions associated with a retroauricular approach or a mastoidectomy. The orbit mode can be a useful additional feature, for example, in cholesteatoma surgery, particularly after previous operations or in the case of extensive expansion when orientation is difficult. It is doubtful whether the RoboticScope will offer decisive advantages over conventional microscopes in ear surgery with an endaural approach.

4.2 | Advantages and disadvantages of the RoboticScope system

Traditional microscopic ear surgery is performed while viewing the images through the microscopic eyepieces, namely in a heads-down position. This heads-down surgery increases the risk for musculo-skeletal fatigue and injuries of the neck and back, because surgeons are bound to the eyepieces during the surgery. Heads-up surgery, which is performed watching a monitor, is considered to be ergonomically better. The RoboticScope allows heads-up surgery, because the position of the surgeon’s head is independent from the focused structure in the mastoid cavity. Working is potentially more comfortable and gentle on the back. As reported by Eckardt et al. heads-up surgery has even more advantages than the surgeon’s comfort. They reported comparison data between 3D heads-up surgery (TrueVision Visualization System) of 20 volunteers who lacked experience with a microscope, they found, that significantly fewer mistakes were made with the heads-up method than with the microscope method.

Instruction on how to use the RoboticScope (activation via foot pedal and then by head movements) requires little time. The use of the menu is intuitive. As part of their training, otolaryngologists are familiar with wearing forehead wreaths with integrated light sources and magnifying glasses, such that they do not feel disturbed by it. At 485 g, the HMD is comfortable to wear.

A noteworthy advantage of the RoboticScope is the ability to work with both hands during the entire operation, because all settings are controlled completely hands-free. The frequent change of surgical instruments and the necessity of adaption when using the microscope is time consuming. Moreover, the workflow of a surgical intervention is disrupted. With the RoboticScope, such a continuous
flow is possible, the hands and surgical instruments remain on the patient. Furthermore, the eyepieces of the head set shields the surgeon’s field of vision from the surroundings. A distraction, for example, by people entering the operating room, is almost impossible.

4.3 | Limitations

However, there are some limitations to the use of the RoboticScope. From modern microscopes, videos and images are normally digitally transferred onto external storage devices. Although this feature is in development, it was not yet available for our study. Instead, the external monitor of the RoboticScope was photographed in order to obtain pictures. This explains the sub-optimal image quality of the figures used in the present publication.

The significant difference between microscopic surgical manipulation and manipulation with the RoboticScope is the relationship between the visual line and the surgical site: in microscopic manipulation, the visual line is directed towards the surgical site. When using the RoboticScope, the visual line does not necessarily point towards the surgical site, which is, at first, an unusual situation for the surgeon. Furthermore, the experimental setup itself offers a variety of options with regard to optimal exposure of the surgical site: changes to the temporal bone itself via repositioning of the ball joint on the device (corresponding to changes in the head and body positioning of the patient) are possible. Furthermore, changes of the working distance, zoom, focus, lighting intensity and orbit mode can be performed to a degree, which may not be possible during a surgical procedure in a clinical setting.

Compared to the conventional microscope used in ear surgery, the use of the RoboticScope requires a certain re-thinking. The robotic device should be exploited to its full capacity. This will result in a decreased need for changing the patient’s position. The learning curve will vary from person to person and it can be assumed that this will not only depend on surgical expertise or age. Acknowledging the differences and difficulties of a cadaver study (e.g., altered tissue properties by formalin fixation, suboptimal state of drills, dislocation of temporal bones), improved conditions can be expected in a clinical in vivo-setting.

5 | CONCLUSION

The RoboticScope is an innovative tool and can be used supportively in conventional CI surgery in the experimental setting on formalin-fixed human temporal bones. Although handling of the system is intuitive, it requires a certain learning curve. In addition to the performed cochlear implantation, the range of applications can be expanded to include all conventional ear procedures involving a retroauricular approach. Furthermore, clinical implementation on patients should be planned to define and verify the possible advantages of the use of the RoboticScope over the microscopic standard procedure.

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CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

AUTHORS CONTRIBUTION

Ricarda Riepl performed experiments and wrote manuscript; Jens Greve designed research and provided figures; Leon R. Schild assisted with experiments; Felix Böhm prepared samples and experimental setup; Eva Goldberg-Bockhorn analysed results; Thomas K. Hoffmann analysed results; Patrick J. Schuler designed research and wrote manuscript. All authors have revised and approved the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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