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Development of A Miniature Robot for Hearing Aid Implantation

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Abstract— **In this paper, we present a novel robotic assistant dedicated to otologic surgery for an implantable hearing aid system, which is a procedure involving drilling into the lateral skull of the patient. This compact and flexible miniature robot is designed so as to fulfill the requirements of precise bone drillings for hearing aid implantation. It is built from an original five degree-of-freedom (DOF) parallel structure with a motorized end-effector, particularly well suited to otological surgical procedure. The specification, the design and the analysis of the workspace are detailed. A preliminary accuracy evaluation is presented. A rotational accuracy of 0.6 $\pm$ 0.6^o and a translational accuracy of 1.4 $\pm$ 0.5 mm were found.**

I. INTRODUCTION

The surgery in the field of Oto-Rhino-Laryngology (ORL) often requires the surgeon to work at the very limit of human perception and dexterity. Image-guided systems (IGS) and robot-assisted solutions have been identified as effective ways to overcome those natural human limitations. Several studies/surveys [1][2][3][4][5] have suggested that IGS helps increase intra-operative patient safety by assisting the surgeon in navigating through complex anatomy that may be altered or obscured by prior surgery, trauma, neoplasms or extensive sino-nasal polyposis. However, there is also consensus that to date IGS is still not the standard-of-care but indicated for selected clinical situations [1][2]. Despite the great progresses that have been achieved during the past two decades, the widespread use of navigation systems in ORL surgery has been limited by the need for a system which achieves the necessary level of accuracy [6] and at the same time offers the required dexterity and tactile sensitivity [7]. Robot-guided or robot-assisted surgery has recently emerged; providing surgeons with motor-actuated surgical tools, increasing precision, advancing miniaturization and reducing risk of infection.

To date, the most popularly used robotic system is the Da Vinci robot (Intuitive Surgical, US), the first such system with full FDA-approval for clinical use. Da Vinci robot is designed towards generic minimally invasive surgery, involving a surgeon's viewing and control console and three surgical arms for insertion into the patient. The surgeon-operated console is located outside the sterile field. One arm is used to hold the endoscope and the other to manipulate and hold the surgical instruments. A series of sensors provide the surgeon with stabilized robot-assisted motion at the surgical target. Other system, designed to be application specific include the RoboDoc (Integrated Surgical Systems, US) and ACROBAT (Imperial College, London) for orthopaedic surgery, the Pathfinder (Armstrong Healthcare Ltd, High Wycombe) and Neuromate (Integrated Surgical Systems, US) for neurosurgery, and an adapted industrial robot Kuka KR3 for minimally-invasive cochleostomy [11]. Common to all these systems is the design principle behind them: they are all based upon an image-guided computer-controlled robotic arm with target stabilization and/or tracking. Thus, the accuracy achieved by such systems is not up to the level for our purpose. For instance, the study conducted by Morgan et al. [9] demonstrated that the application accuracy of the Pathfinder is on average 2.7 mm. A similar accuracy of 1.95$\pm$0.44 mm was also found for Neuromate [10].

Thus, to fulfill those challenges of ORL surgery, various research groups have come up with different robotic solutions instead of using a robotic arm. Rothbaum et al. [8] introduced a system for robot-assisted stapedotomy and selected micropick fenestration of the stapes footplate for trails evaluating the potential for robotic assistance to improve clinical measurements of surgical performance. They found that robot-assistance significantly improves performance for micropick fenestration in a surgical model of stapedotomy. The SpineAssist (Mazor Surgical Technologies, US) system, initially developed for screw insertion into spinal fusion has recently been adopted for neurosurgery (MARS robot) [12] [13]. Zhang et al. [14] quantified the potential improvement in cochlear implant surgery when a snake-like robot was used. More recently, Brett et al. [15] presented an autonomous robot system for cochleostomy that was able to control penetration of the outer bone tissue of the cochlea without penetration of the endosteal membrane at the medial surface through the detection of a drill break-out.

In this work, we are aiming to develop a compact and flexible miniature robot in otologic surgery for an implantable hearing aid system, which is a procedure involving drilling into the lateral skull of the patient. This paper can be summarized as follows. First, the surgical procedure and possible roles of the robot for hearing aid implantation is discussed. Second, the implemented robot, which is built from an original five degree-of-freedom (DOF) parallel structure with a motorized end-effector, is described. Third, a workspace study and a preliminary accuracy evaluation experiment are performed. Finally, we conclude our paper with discussion and future works.

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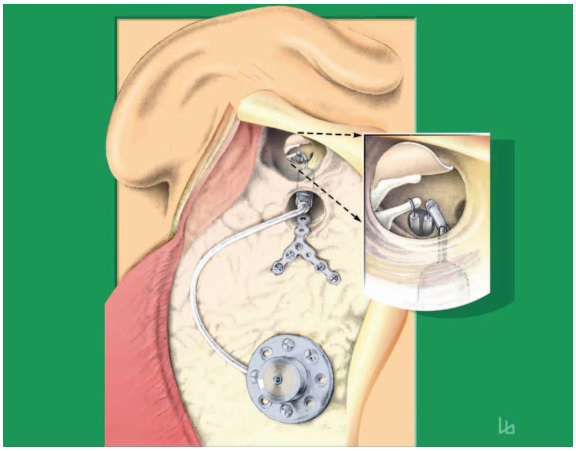

Fig. 1. A schematic view of implanting a Direct Acoustic Cochlear Simulator (DACS) in right ear.

II. Surgical Procedure for Hearing Aid Implantation

Otologic surgery for an implantable hearing aid system is a procedure involving drilling into the lateral skull of the patient (see Figure 1 for an example). The first part of the surgery is to create an exact bed for a long-term stable fixation of the implant electronics. This part has low risk but is time-consuming. The second part of the surgery involves a surgical procedure called mastoidectomy. it is performed to create an access to the middle ear cavity for implanting the rest of the hearing aid system. In this part of the surgery, the operative field has limited viewing angle and the implantation can only be undertaken by an experienced otological surgeon. Thus, a wide surgical exposure is required to identify anatomic landmarks to avoid injury to any critical structures. Even though, protection of adjacent facial nerve in otologic surgery is still a challenge for the surgeon. It was estimated that facial nerve injury in primary otologic procedures are 0.1 - 1.6%, increasing to 4- 10% in revision cases [16]. In addition, human limitations in dexterity and tactile sensitivity further complicate and constrain such a micro-surgical procedure [8].

In such an otologic surgery, a robot could intervene and play roles of assisting surgeon at several stages. The first and simplest role could be that the robot holds an endoscope so that the surgeon can do all the fine manipulations in an enlarged view of the surgical target. The second role could be that the robot autonomously executes the task of milling a hearing aid implant bed in the calotte bone at the lateral skull base, following a milling path that is planned based on pre-operative image data. The third role, which is also the focus of this work, could be that the robot conducts mastoidectomy. We have chosen mastoidectomy as the task for our robot because of its high frequency (conservative estimate of at least 100,000 procedures performed annually in the United States according to a recent study [17]), the unique anatomy involved (vital structure encased in bone which does not deform during surgical intervention), and the surgical technique required (performed using a drill and particularly amenable to robotic application).

III. Description of the Miniature Robot

A. Design consideration

Our miniature robot was designed by taking several clinical application oriented principles into consideration. Therefore much attention was paid to a number of clinically critical issues:

Mounting: An underlying principle of effective robot development is a suitable attachment of the robot system to a base structure. For systems to be deployed in the operating room (OR), it is necessary to attach the robot either directly to the OR-table or to the OR-table and additionally to the ground. Such an attachment is necessary in order to create a highly rigid structure enabling for a high positioning accuracy of the robot within the patient coordinate system. We decided to realize a connecting mechanism consisting of two articulated arms and snap-on connectors for OR tables (see Figure 2 for details). The connectors can be rigidly attached to the table and the articulated arms with the robot can then be positioned arbitrarily. For an even improved rigidity we incorporated two of the articulated arms with their single attachments to the robot base structure placed as far from each other as possible. In Figure 2, one of the arms is depicted in the foreground, where the other one is placed behind the bipod structure. It is intended to apply an additional articulated connecting the robot system to the patient via a dental splint.

Housing: The development of a suitable housing is an integral part of the whole development process. Such a housing addresses a number of issues such as safety concern (both for the system itself as well as for the patient/user), holding of system components such as cable connectors, attachment for additional structures and strict sterilization concern. The overall approach was to develop the housing so that the complete system can be easily covered with sterile drapes.

Electrical aspects: A key aspect of the development is an efficient electrical integration of the sub-components of the robot systems. Thus, stringent measures for electromagnetic compliance have to be taken (the standard IEC601-1-2 provides EMC requirement for medical electrical devices). This is mainly achieved by shielded cabling and by additional shielding elements in the housing parts. The robot electrical system does not apply an information bus system to communicate between the controller and the robot. Therefore, a large number of electrical signals have to be transmitted in parallel (e.g., encoder signals, zero position switches, et al.) for each of the five effective axis.

B. Kinematics of the robot

Our miniature robot is built from an original five degree-of-freedom (DOF) parallel structure with a motorized end-effector (see Figure 2 for details). The four DOF parallel structure is a combination of a bipod structure at the robot

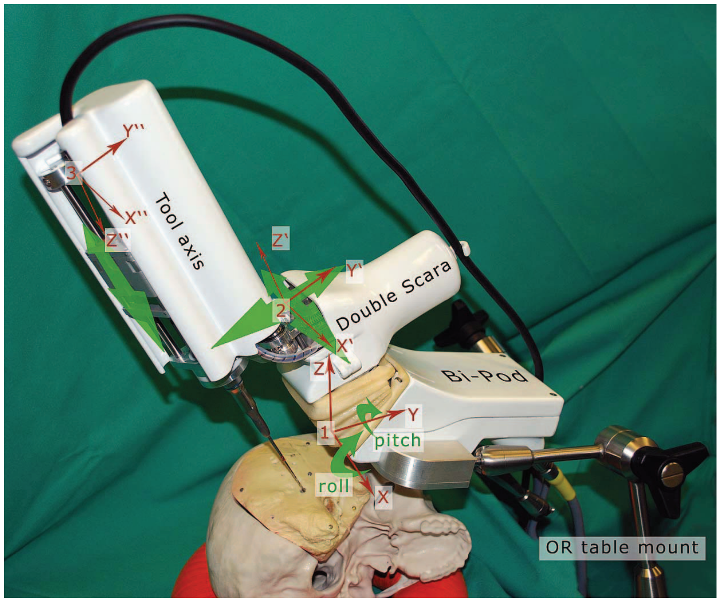

Fig. 2. Prototype of the miniature robot which was designed on an original five degree-of-freedom parallel structure with a motorized end-effector.

base with a double scara structure. The last DOF is along the z-axis for translation of a surgical instrument along its working axis. It allows for direct attachment of a surgical instrument or of a motorized end-effector as shown in Figures 2 and 3.

The base of the robot system is mounted to the OR table using two standard articulated arms as shown in Figures 2 and 3, allowing for arbitrary placement and orientation within the workspace of the robot. The robot base contains the first two axis arranged as a bipod subsystem. It consequently allows the scara subsystem for a two DOF rotational movement (roll and pitch) around a joint mounted to the base plate. Thus, the robot can move along the surface of a circular sphere (i.e. the human head). In the present miniature robot, the range of motion is designed as $\pm 16^o$ for roll and from 35^o to 53^o for pitch. The double scara subsystem provides additional translational motion of the working instrument or end-effector. It consists of two active axis providing effective movements in a plane of size 60×60 mm^2. The z-Axis provides another effective motion along the working axis of an attached surgical instrument or a motorized end-effector (Figure 2). The motorized end-effector consists of a belt driven spindle (p=2mm) together with two slide rails (see Figure 3 for details). Effective motion is 100 mm along the axis allowing for simple removal and installation of the actual surgical hand piece, necessary for sterilization issues.

All five axis are equipped with digital differential encoders (TTL Maxon with resolution 512ticks/rev on 3 channels), zero position switches (Baumer Electric AG, Switzerland) and DC drives (Maxon, Switzerland) for effective real-time control.

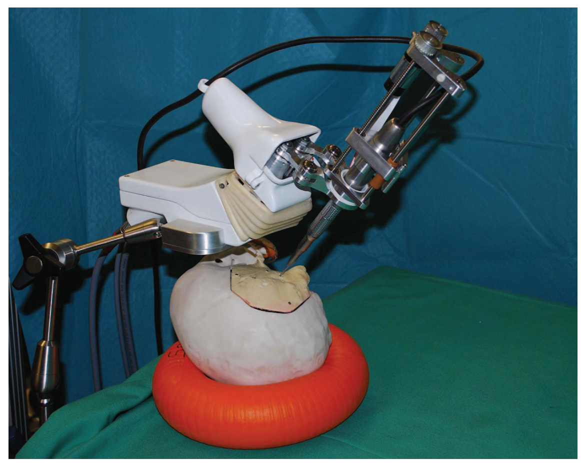

Fig. 3. The detailed structures of the motorized end-effector and of the connection to the mini-robot.

C. Robot Controller

The control system of the robot consists of a real time controller, a set of digital axis controllers and a set of singular axis amplifiers. The real time controller is integrated as a stand alone bare bone system (MSX-Box, AddiData, Germany) running on Linux kernel with a real time extension (RTAI). The controller provides USB and firewire ports and supports TCP/IP interfaces to an image-guided system. Effectively, the controller provides real time calculation of axis values from provided Cartesian positions using the provided kinematics model and vice versa.

The real time control part is connected to a set of digital axis controllers (APCI 8001, Roesch & Walter). The control structure provide positional PID control (f = 800Hz) for

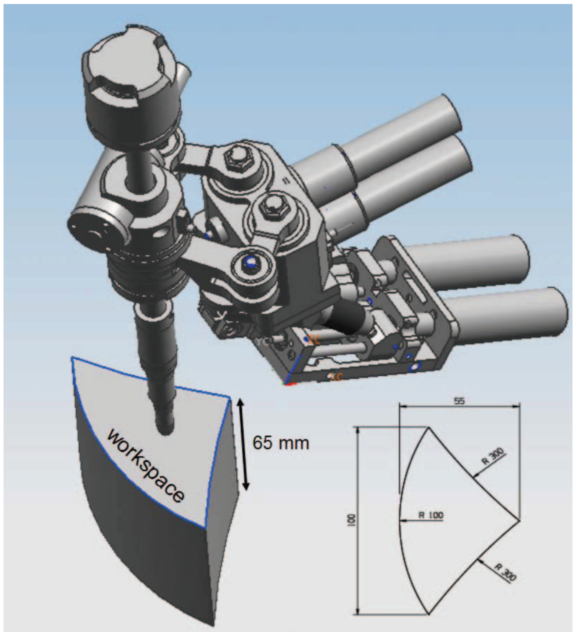

Fig. 4. Workspace of the miniature robot.

every axis. The axis controllers provide a speed proportional voltage signal to the connected drive amplifiers (f = 4KHz) (Elmo Violin, Israel).

IV. Experiments and results

A. Workspace study and results

One basic concern about the miniature robot is whether it can provide sufficient workspace for all steps of hearing aid implantation, though in this work we only focus on mastoidectomy. For this purpose, the workspace of the robot was compared with dimensions of housings of the implant electronics of five commercially available implantable hearing systems. Additionally, we also compared the workspace with dimensions of conventional mastoidectomy which was performed on a real size temporal bone.

The workspace of the miniature robot is shown in Figure 4. Dimensions of all five examined electronic implant housing are smaller than the upper surface of the workspace of the miniature robot. Largest dimensions of the mastoidectomy on the plastic temporal bone (superior-inferior 22.5 mm, anterior-posterior 19.5 mm, proximal-distal 27.5 mm) are significantly smaller than those of the workspace (superior-inferior 100 mm, anterior-posterior 55 mm, proximal-distal 65 mm, see Figure 4 for details). Thus, we conclude that the workspace of the miniature robot is principally sufficient to perform the milling of the bed for the implant electronic of the hearing device as well as for the mastoidectomy.

B. Preliminary accuracy evaluation study and results

We designed and conducted a preliminary accuracy evaluation study on a plastic phantom that was designed to simulate the size and the landscape of a human temporal bone (see the left image of Figure 5 for the shape of the phantom). In this study, we first aligned the base plate of the phantom with the XY plane of the local coordinate system of our robot. We then placed a 5×5 regular grid positions on the central part of the phantom (we actually placed totally 36 grid positions on the surface of the phantom. However, in this study, we decided only to evaluate the accuracy using the 5×5 regular grid positions on the central part of the phantom, which already covered the workspace required for our clinical applications). At each grid position, we planned a trajectory with a known depth for our robot to drill through. Those trajectories were arranged in such a way that when the robot moved from one grid position to another neighboring grid position along the x-direction, the roll angle was reduced with a 3^o of interval while the pitch angle was maintained the same (see the right image of Figure 5 for a side view of the trajectory arrangement). A similar principle was also applied to the robot movement along the y-direction, i.e., when the robot moved from one grid position to another neighboring position along the y-direction, the pitch angle was reduced with a 3^o of interval while the roll angle was maintained the same.

To evaluate the robot-assisted drilling accuracy, we used an active optical tracking system (OTS) (OptoTrak 3020, Northern Digital Inc., CA). A custom-made trajectory digitization probe was designed, which allowed for determination of the position of the end point of a drilled trajectory as well as its axial orientation with respect to a local coordinate system of the test phantom, which was established by attaching a so-called dynamic reference base [18] to the test phantom. Figure 6 shows the setup for trajectory digitization. Using the digitized position of the end point and the orientation of each drilled hole together with its planned depth, we could compute the position of the entry point of the associated hole. When entry points and the axial orientations of all drilled hole were determined, we could further proceed to compute the angular difference between any two neighboring holes along the x or y direction as well as the distance between their entry points. Comparing those values with the planned values, we could then determine the rotational as well as the translational accuracy of our robot.

The rotational errors and the translational errors when the robot was moved along the x axis and the y axis are summarized in Table 1. A rotational error of 0.4 ± 0.3^o and a translational error of 1.2 ± 0.5 mm were found along the x axis. Along the y axis, the rotational error was changed to 0.6 ± 0.7^o and the translational error was changed to 1.6 ± 0.4 mm. An overall rotational accuracy of 0.6 ± 0.6^o and an overall translational accuracy of 1.4 ± 0.5 mm were found.

C. Cadaver study and results

In this experiment, the clinical usability of the system was evaluated on a cadaver head specimen. To avoid the cabling problem, we used a passive optical tracking system (Polaris, Northern Digital Inc., CA). The complete procedure included preoperative CT scanning and planning, execution of the keyhole drilling procedure, a postoperative CT scan-

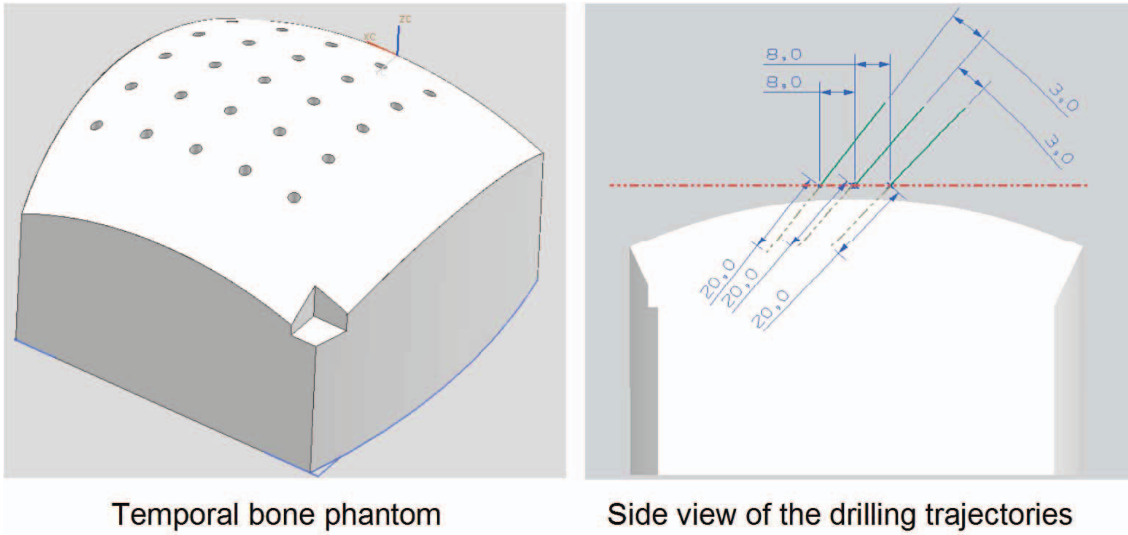

Fig. 5. The test phantom (left) and the arrangement of the planned trajectories for the robot to drill through (right).

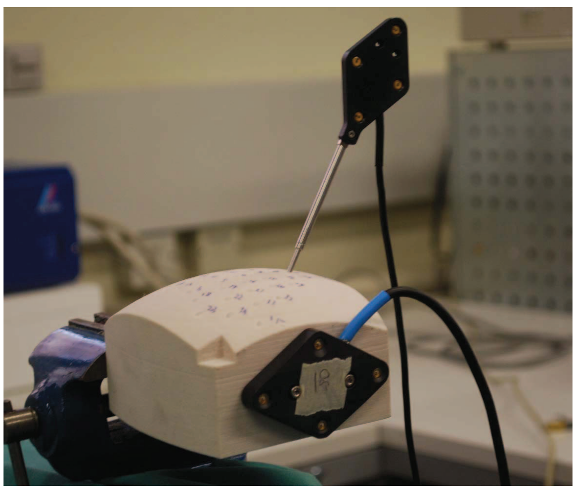

Fig. 6. Setup for the trajectory digitization, where the custom-made probe was inserted into one drilled hole.

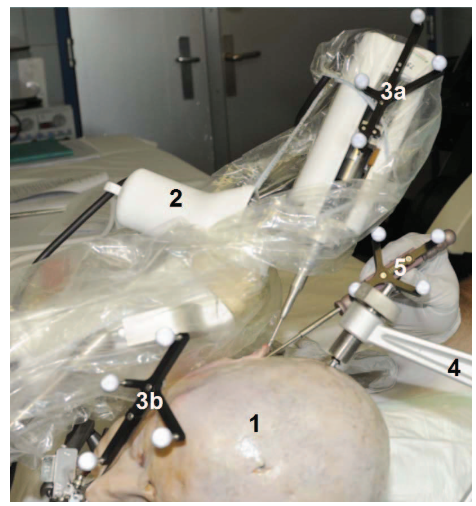

Fig. 7. Experimental setup for the cadaver study. (1) the cadaver head specimen; (2) the navigation references (3a and 3b); (4) the Mayfield clamp for head fixation; and (5) a navigated probe for point digitization.

TABLE I

THE ROTATIONAL ERRORS AND THE TRANSLATIONAL ERRORS OF THE ACCURACY STUDY

Errors	Average	Minimum	Maximum
Rot. Error along x axis (^{o})	0.4 ± 0.3	0.1	0.9
Trans. Error along x axis (mm)	1.2 ± 0.5	0.4	2.7
Rot. Error along y axis (^{o})	0.6 ± 0.7	0.0	3.2
Trans. Error along y axis (mm)	1.6 ± 0.4	0.8	2.4

ning and geometric accuracy analysis. Figure 7 shows the experimental setup.

Figure 8 shows the co-registered pre-operative and post-operative CT scans with the planned trajectory, which is defined by two points: the entry point (EP) and the target point (TP), and the drilled trajectory (DT). Between the planned and the drilled trajectories, a minimal distance of 3.42 mm and an angle of 8.4^o was identified. The effectively drilled trajectory was well behind the external auditory canal (EAC) but striked the facial nerve (FN). This result was confirmed when performing a manual mastoidectomy after the procedure.

V. DISCUSSIONS AND CONCLUSIONS

In this paper, we have presented a compact and flexible miniature robot for hearing aid implantation. This miniature robot was built from an original five DOF parallel structure with a motorized end-effector, particularly well suited to otological surgical procedure. To address the concern of the workspace of our miniature robot, we performed a study to compare the workspace of the robot with the dimensions

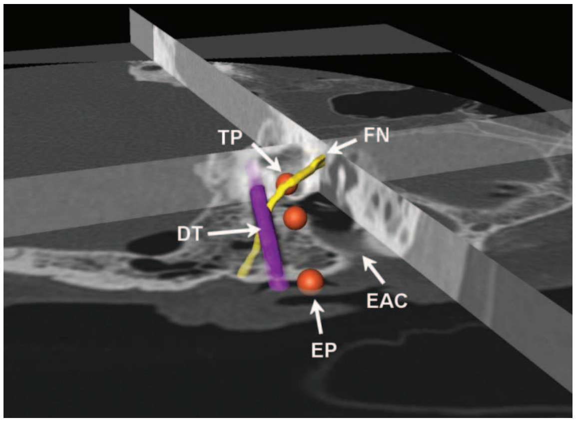

Fig. 8. Comparison of preoperative planning (EP, TP) with the postoperative drilled trajectory (DT).

of housing of the implant electronics of five commercially available implantable hearing systems. Additionally, we also compared the robot workspace with the dimensions of a conventional mastoidectomy which was performed on a real size temporal bone model. Our study results suggest that the workspace of our robot should be principally sufficient to perform the milling of the bed for the implant electronic of the hearing device as well as for the mastoidectomy.

To evaluate the precision of the robotic assistance, we further conducted a preliminary accuracy study on a test phantom. Using an active optical tracking system and custom-designed instruments, we determined the rotational and the translational accuracies. An overall rotational accuracy of 0.6 ± 0.6^o and an overall translational accuracy of 1.4 ± 0.5 mm were found. Although such a translational accuracy is in an equivalent range of other robotic systems such as PathFinder and NeuroMate, we still have a concern that much of the error may come from the measurement method that we used. This was reflected by the fact that some of the holes around the boundary were not drilled deep enough to tightly hold the digitization probe, due to a curved shape of the phantom, affecting the measurement accuracy. However, at this stage, we can not separate the error by the robotic assistance from the error contributed by our measurement method. A more accurate measurement tool such as a coordinate measuring machine (CMM) may be needed for a better determination of the accuracy of our robot.

Our cadaver study demonstrates the successful integration of the present miniature robot with an image-guided navigation system. Such integration is a very important step to close the loop between the robotic assistance and the image-based navigation. Although we found that the size and the weight of the robot was favorable, the differences between the planned and the drilled trajectory were relatively large, which resulted in the damage of the facial nerve. One of the major sources of errors that we identified was the rigidity of the robotic system. This will be improved in future by the use of an additional articulated arm between the base of the robot and the dental splint of the head.

VI. ACKNOWLEDGMENTS

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