Robotic-guided minimally-invasive cochleostomy: first results

Martin Leinung1*, Stephan Baron2, Hubertus Eilers2, Bodo Heimann2, Sönke Bartling3, Ralf Heermann4, Thomas Lenarz1, Omid Majdani1

1Medizinische Hochschule Hannover, Klinik und Poliklinik für Hals-Nasen-Ohrenheilkunde, Hannover, Germany
2Leibniz Universität Hannover, Institut für Robotik, Hannover, Germany
3Medizinische Hochschule Hannover, Abteilung für Neuroradiologie, Hannover, Germany
4St. Franziskus-Hospital, HNO-Klinik, Münster, Germany

Abstract

Due to increasing claims on high precision surgery, robotic assistance is becoming an emerging and highly demanded technology. Especially in surgical procedures in regions with complex anatomy mechatronical devices could help prevent iatrogen damaging of risk structures. In Otolaryngology particular cochlear implantation is a procedure characterized by a high degree of complexity and required accuracy. This surgery, which is accepted to be the most suitable solution for recovery from deafness, demands a exactly localized opening of the cochlea and an atraumatic insertion of a stimulating electrode array within the scala tympani.

This paper presents a new minimally-invasive method for the preparation of the implant’s slot using a combination of high resolution imaging, stereo-optical navigation and a robotic manipulator. In this contribution, we introduce the hardware components of the system as well as its software structure and present first experimental results of a robot assisted minimal invasive cochleostomy.

Keywords: cochlear implant surgery, navigation, robotic assistance device, minimally invasive surgery, high precision surgery

Introduction

Cochlear Implant (CI) surgery for treatment of deafness is performed by implanting a stimulating multielectrode array device into the inner ear. Since there are many functionally important anatomical structures in the temporal bone area, e. g. facial nerve and sigmoid sinus, prior to the opening of the cochlea (cochleostomy) the relevant structures need to be exposed by the surgeon, thus they serve as landmarks for correct positioning of the cochleostomy. The landmark identification is necessary in conventional cochlear implant surgery to securely expose the facial recess between the canal of the facial nerve and the chorda tympani. After tympanotomy at this position the promontory, the round window niche and the stapes can be identified. The cochleostomy is performed right at the round window niche or anterior to it [1]. Through a 0.5-1 mm drilled hole the CI electrode is directed into the scala tympani in the cochlea. An ideal positioned cochleostomy should be placed with a deviation under 0.3 mm [2] in order to avoid damages to the internal soft tissue structures of the inner ear. Perforation of the basilar membrane and dislocation of the electrode into the scala vestibuli results in

*Corresponding author: Dr. med. Martin Leinung, Medizinische Hochschule Hannover, Klinik und Poliklinik für Hals-Nasen-Ohrenheilkunde, Carl-Neuberg-Str.1, 30625 Hannover, Tel.: 0511/532-9877, Fax: 0511/532-8876, eMail: leinung.martin@mh-hannover.de
loss of residual hearing which is of increasing importance with regard to current therapy concepts as combined Electro-Acoustic Stimulation. In this time-consuming exposition nerval structures run the risk of being damaged by the surgical procedure.

In principle, a minimally invasive CI surgery could be performed by targeting the inner ear from the retroauricular region of the cochlea by drilling a single canal through the temporal bone without damaging relevant structures. Using this approach, the operation time could be reduced leading to a reduction of costs. Furthermore, a more precise insertion of the CI electrode could help to retain the residual hearing [3].

Methods

The experimental robot assisted surgery system built up in the laboratory consists of three main parts: A computer tomography of the temporal bone specimen was acquired preoperatively as 3D imaging is indispensable for surgical planning and intraoperative navigation. Preliminary test have shown that the imaging’s detail resolution is the most decisive factor for navigation accuracy: In particular a flat panel volumetric CT (fp-VCT) grants the needed resolution for a high precision positioning of the robot, the second important part of the system. In order to eliminate the robot’s absolute positioning error an external measurement device consisting of a stereo camera is used.

Fp-VCT

The imaging was done using a prototype flat panel Volume CT system (fp-VCT) (GE Healthcare, Lawrence, MA, USA). Recent fp-VCT based volume data can provide ultra high isometric resolutions in all three dimensions ([4], [5]). Bartling et al. have shown the diagnostic use of fp-VCT volume data compared to the present multi-slice CT technique especially for high-contrast structures in the temporal bone [6].

For the experiments presented in this paper imaging was done with a fp-VCT prototype which has no approval for human beings so far. Two flat-panel detectors with a matrix of 1024 x 1024 detector elements, each representing 200 µm, are used. The minimum isometric resolution is about 200-250 µm. The resulting voxel size in the dataset was 176 x 176 x 176 µm³ due to interpolation [4], [7].

Industrial robot Kuka KR3

The experiments were carried out using an industrial robot Kuka KR3, mounted on a lightweight rack, so it can be moved easily. Figure 1 shows the KR 3 robot used the for the first experiments: A common surgical drill (Aesculap, Tuttingen, Germany) was mounted on its endeffector. The drill was taught in as a robot tool to control the position and orientation of the tool directly from the control cabinet. A 3 marker star allows to acquire the position and the orientation of the tool tip via the tracking system (see below). The original software working in the control cabinet was equipped with KUKA’s Remote Sensor Interface (RSI) and furthermore the Ethernet Remote Sensor Interface (ERSI) as well known as corob: ERSI provides interfaces to an external computer to communicate directly with the motion system of the control cabinet via an ethernet link. Thus an external computer is allowed to dynamically control the current motion of the robot. Furthermore it has the ability to stream data to the external computer in real-time. The RSI Program enables to integrate optional sensors into the robotic control and is almost arbitrarily adaptable and expandable by the linkage of flexible objects for new sensors. By means of RSI-instructions objects are created as well as their characteristics are changed. RSI is structured modularly and merged into the KUKA Robot Language (KRL). The actual application is realized in KRL, the ERSI is meant for realization of external sensor objects, e.g. if the arithmetic performance of the control cabinet (KRC) is not sufficient or it appears too complex, to realize a desired control strategy as a RSI object in the real time core. So it is possible to perform a cyclic data transfer of robot information in real time to an external system. With a fixed pattern data like position, angle between axes and operating mode can be transferred. Data exchange is done via an ethernet connection between the control cabinet and an extern computer via the TCP/IP protocol. The following handshake protocol guarantees realtime behaviour of the robot control: The KRC acts as a client and connects to an external server. The structure and contents of the package is specified by an XML document, to become a fixed pattern in each transfer. The KRC introduces data exchange sending a data package. From now on the data exchange occurs in a 12 ms cycle. The external system must answer to every single packet within 4 ms before an error is reported and the communication has to be restarted.
Navigation system

The sensory system used for position finding essentially consists of a Polaris stereo-camera (NDI, Waterloo, Ontario, Canada) and the reference markers which are attached to the relevant navigation objects (patient’s head, drilling device) as rigid as possible. Reference markers consisted of infrared light reflecting spheres in an unique configuration for every different navigation object. The tracking system is capable of calculating the tool’s position and orientation via camera coordinates using geometrical triangulation. The position of a marker in the tracking area can be determined with a remaining error of less than 0.35 mm (manufacturer’s datasheet). The Polaris camera is connected to a computer via a serial interface. The computer, driven by a real-time operating system requests the camera data in a 60 Hz cycle, which is the fastest data rate the camera can provide. For further information on tracking technology we refer to technical literature.

Software

For data acquisition and processing real time capabilities are needed to handle the data transfer to the KR 3 ethernet interface. Moreover, deterministic system behavior is presumed in live critical environments. The computers in this experiment are equipped with the Linux Real time Environment (LiRE) developed at the Institute of Systems Engineering (RTS) in Hannover. This software structure
is designed as a small embedded Linux distribution with realtime capabilities. It is based on the open source software RTAI (Real Time Application Interface for Linux, see http://www.rtai.org) and provides hard real time capabilities in a standard Linux environment by changing some features in the kernel to make it fully preemptive. To obtain timing correctness behaviour and system determinism, RTAI makes some changes in the kernel sources, i.e. in the interrupt handling and scheduling policies.

In order to simplify and arrange a large software structure clearer, it can be divided into smaller compact units. For this task the Institute for Systems Engineering (RTS) of the University of Hannover and at the Institute for Robotics (IfR) developed the Distributed Realtime Communications (DRC) concept. It offers real time programming, remote procedure calling and therefore cross-linking of different systems. All subsystems consist of so-called modules which exchange data packages among themselves via mailboxes. The structure of these modules is standardized and essentially alike. They differ only by a module specific part. Around the basic functions the programmer has only to care for the specific code. The framework is supplied by the DRC. In the presented setup the main software parts are a module for the KUKA KR 3, a module for the Polaris stereo camera and a controller module.

The planning of the necessary trajectory for a minimal invasive cochleostomy was done using the iPlan® ENT 2.5 software (BrainLAB, Feldkirchen, Germany, see Figure 2). The target coordinates were manually positioned in the region of the round window niche. The entry coordinates in the retroauricular region were varied successively adjusted in the image data so that the corresponding straight line between these coordinates a) has a maximum distance to the adjacent vital parts, b) does not harm the posterior wall of the auditory canal and c) enters tangentially the basal turn of the cochlear. Transfer of the preoperative planning data including segmentation and trajectory was performed via VVLink-Interface (BrainLAB) of the navigation system.

Figure 2: KUKA KR3 equipped with a medical drill device from Aesculap® and a reference object for passive optical navigation

Anatomic specimen

The key experiment was performed on a human cadaveric temporal bone obtained post mortem from a voluntary body donor. In order to perform long-term experiments the specimen had been fixated using a standard formalin solution. Before imaging the temporal bone was furnished with 5 titanium osteosynthesis screws which served as artificial landmarks for registration purposes.
Results

After setting up the system, importing the CT data and surgical planning, registering the cadaver specimen and calibrating the KR 3 robot the experiment was accomplished successfully. The robot drilled a canal towards the cochlea. During the test the position and orientation was tracked and recorded by the Polaris camera. A closed loop position and orientation control was not implemented so far. The mean value of the deviation error $e$ to the preoperatively planned trajectory is about 0.5 mm, which results from robot calibration errors and a initial navigation error at the drilling start position. This error can be compensated by a closed loop control and will be integrated in the next future. The drilled specimen was scanned by a conventional multi slice computer tomograph. Figure 3 shows the drilled temporal bone with the preoperatively planned trajectory overlayed. The drill has reached the target structure in an acceptable way. A closer look at the data showed that no vital parts had been harmed. The specimen has to be analyzed further to quantify the placement error of the drilled canal.

![Figure 3: Coronal reformation of postoperative MSCT: The drilled canal (dc) for mastoidotomy and cochleostomy deviates slightly from the planned trajectory (t). The distal part of the canal follows the mastoid in direction towards the basal turn (bt) of the cochlea, after passing the level of the tympanic membrane (tm) it enters the middle ear (me). sc: semicircular canal.](image-url)

Discussion

The first experimental results of a robot assisted cochleostomy have been presented. The minimally-invasive therapy concept allows performing CI surgery without the exposure of critical anatomical structures and anatomical landmarks in the mastoid and at the posterior tympanotomy and therefore has the potential to decrease the surgical risk for the patient.

To date the intervention takes place with the restriction of a static and rigid operation environment because of missing current state feedback during the process. There is no consideration of possible specimen movements such that the approach is only viable for surgical interventions on rigid and
fixable body parts. Therefore, a patient tracking was not implemented so far. The interaction possibilities with respect to the surgeon are limited. Once the coordinate frames are registered, the process takes place automatically which is not suitable for interventions with unexpected incidents.

In order to describe the navigation correctness several error definitions have been introduced in the past [8]: Amongst them the so-called target registration error (TRE) is the most relevant as it denotes the localization quality within the operational site and includes all other errors caused by misalignment of coordinate systems, unexact identification of registration within the imaging dataset and many more. The limited resolution of the underlying 3D imaging is the predominant influencing factor on the TRE. Newer tomographs use high resoluting flat panel detectors whose detail resolution is limited to somewhat less than 250 µm or about 25 lp/cm respectively. They are used in digital subtraction angiography and rotational tomography (often referred to as Digital Volume Tomography). It has been shown, that improved detail resolution correlates with a statistically significant increase in navigation accuracy [6]. Other preliminary studies demonstrated the feasibility of a manually performed, navigation guided mastoidotomy and cochleostomy in principle, when fp-VCT imaging was applied [9]. Thus fp-VCT seems to be a suitable tool for minimizing TRE. Unfortunately fp-VCT scanners are so far non-approved for human use. The current technical development will provide the necessary solutions for proper human use and an approval will happen soon.

The methods of calibration and registration used in this experiment as well as the technical accuracy of the navigation system have to be improved. The optimization of accuracy in our experimental setting requires the optimization of referencing (fixation and marking of the temporal bone, so that it is recognizable to the navigation system) and registration (alignment of virtual imaging anatomy and real anatomy). The presented experiment has to be understood as a feasibility study. Further temporal bones have to be analyzed.

As our efforts not only envision a mechatronic drilling tool for high-precision milling but an innovative and entirely minimally-invasive concept for CI surgery several problems have not been solved yet and are subject of our current work in progress: The two most important amongst them are correct intracochlear electrode placement and handling of medical risks:

- The insertion of the electrode into the cochlea via the narrow access path requires a special tool which is in conception stage.
- Methods have to be developed in order to handle persistent bleeding out of the bony canal.

Conclusions

Current navigation technology did not provide navigation accuracy less than 1 mm so far. The use of high-resoluting fp-VCT opens the door to significantly more accurate navigated procedure. The combination of a localization system with an elaborated active assistance device as it was realized by use of an industrial robot equipped with a medical drilling system enables high precision surgery in areas of complex anatomy with diverse vital structures.

As an example of a high-precision robotic guided surgical intervention we performed a minimally-invasive mastoidotomy and cochleostomy which has to be understood as a key experiment within the framework of a feasibility study. In the future several challenges have to be coped in order to realize the therapy concept, which we explained in this paper. Nevertheless the operating principle has proven to be efficient and offers enormous potential for other applications with similar demands.

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