three-dimensional spatial configuration. A standard ultrasound system with a 2–5 MHz abdominal probe is connected to the computer, displaying real-time ultrasound images on its screen. A pose sensor is mounted on the ultrasound probe enabling the system, after a proper calibration, to identify the exact 3D location and orientation of each ultrasound pixel in space. In order to obtain the ultrasound images to determine fetal head position and fetal station some human manipulation is required.

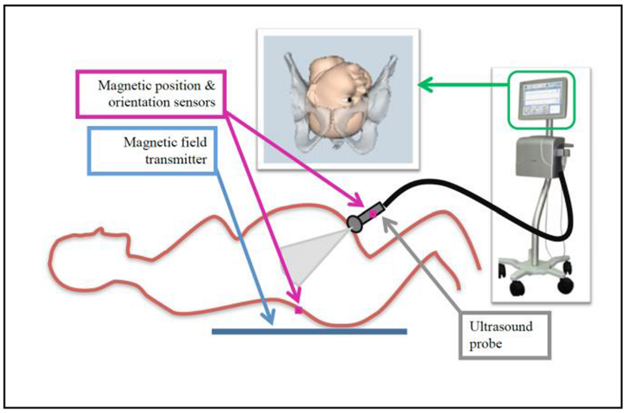

Fig. 1 Schematic representation of the system

For in vitro evaluation, we design a bench test with a fetal head and a maternal pelvis. A robot is used to position the fetal head with respect to the pelvis (Fig. 2). Station was measured for 12 different settings with 3 different trained specialists. For every setting, each operator measured the station as routinely done and registered the station provided by LaborPro System. Measurements were performed in several sessions over several days for each operator. For each set of measurements, we calculated the mean value, with standard deviation, and subsequently the coefficient of variation. Each parameter was used for intra- and inter-operator variability.

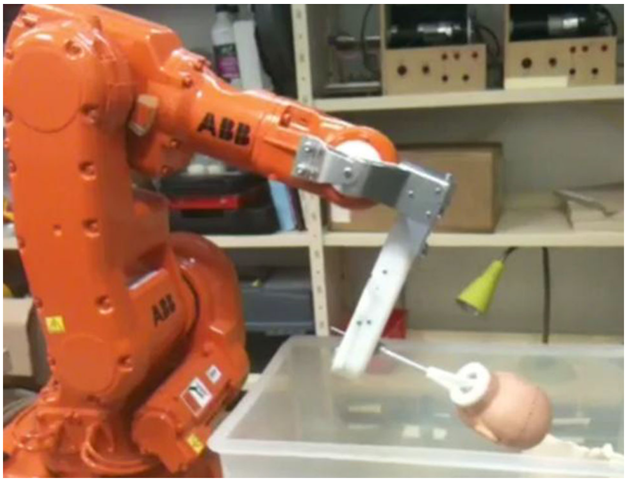

Fig. 2 Picture of the final system

Results

The in vitro data show that fetal head station determination using the automatic mode of the LaborPro has very little (less than 5 %) intra- and inter-operator variability in a fixed robotic model. This information completes clinical data from the literature. This is the first time these new tools were tested on models where the fetal head is positioned by a robot programmed for predetermined fetal head positions and stations. This setting limits the possible variability that could be observed when several operators performed consecutive measurements, since fetal head could move during time, and according to uterine contraction. Moreover, operators performed the whole process of measurement for each data, since the robot positions the head back in the neutral position every time. This limits the theoretical artifact when all operators work on recorded images or volumes. The overall very small variability is encouraging for the development of non-invasive systems for station monitoring when all other parameters are controlled. Systems such as the one described here, with a robotic model for fetal head position and station, should help progress the development of non-invasive tools to monitor fetal head descent and station during labor.

Conclusion

The system described in this section, which combines ultrasound and a position-tracking system, was developed using bone morphing of the maternal pelvis. This bone morphing and the accuracy of distance measurements were validated on models, which do not take into account the accommodation phenomenon occurring during birth. Nevertheless, the in vitro validation of the intra- and inter-operator variability was good.

References

[1] Dupuis O, Silveira R, Zentner A, Dittmar A, Gaucherand P, Cucherat M, Redarce T, Rudigoz RC (2005) Birth simulator: reliability of transvaginal assessment of fetal head station as defined by the American College of Obstetricians and Gynecologists classification. Am J Obstet Gynecol 192:868–874.
[2] ACOG Technical Bulletin No. 218, December 1995 (replaces no. 137, December 1989, and no. 157, July 1991). (1996) American College of Obstetricians and Gynecologists. Int J Gynaecol Obstet 53:73.
[3] Trig Medical LtD http://www.trigmed.com

Ensuring the safety of minimally invasive image guided cochlear implantation

T. Williamson[1], N. Gerber[1], C. Rathgeb[1], W. Wimmer[1], J. Anso[1], M. Caversaccio[2], S. Weber[1], K. Gavaghan[1]
[1]ARTORG Center for Biomedical Engineering, Bern, Switzerland
[2]Bern University Hospital, ENT Head and Neck Surgery, Bern, Switzerland

Keywords Robotics · ENT · Direct cochlear access · Safety

Purpose

Over the last decade numerous attempts at an image guided technique for gaining minimally invasive access to the inner ear have been made. Replacing a conventional mastoidectomy approach with a drilled tunnel only slightly larger in diameter than the implant electrode array (1.5–1.8 mm), minimally invasive cochlear implantation (MICI) poses numerous advantages, including the preservation of mastoid tissue and potentially reduced surgical and recovery times. A preliminary clinical study demonstrated the feasibility of the approach [1] however resulted in facial nerve damage in one of seven cases, thereby highlighting the need for an optimized and highly controlled drilling process. Additionally, with the critical need for high drilling accuracy, standard image guidance registration calculations and feedback prove to be insufficient. To this end, an image guidance robotic system with a multi-layer safety mechanism based on registration accuracy and external sensor information was designed to ensure drilling accuracy and patient safety. Integrated into an existing image guided for robotic minimally invasive cochlear implantation the safety mechanisms were implemented and verified in a study on cadaveric temporal bone samples.

Methods

A drilling protocol designed to optimize the safety of the procedure was proposed and integrated into a custom planning software and robotic system [2]. Software allows the segmentation of the structures within the mastoid and the definition of the trajectory, with optimization of the drilling path completed based on the distances from the trajectory to surrounding critical anatomy. Once optimization is complete, the trajectory is automatically divided into multiple segments. The first segment commences at the mastoid surface and terminates 3 mm distally to the level of the facial nerve; the segment is assigned a drilling protocol (2 mm intervals) designed to provide sufficient thermal control whilst optimizing drilling time. During drilling of the first segment the forces observed at the tip of the drill are recorded and comparison of these forces with sampled surrounding bone density profiles allows the estimation of the tool pose independently from registration error [3]. Intraoperative cone beam CT imaging is performed prior to commencing the second segment which passes the close lying nerves. Based on the acquired images, the projected distance at which the current drill trajectory will pass anatomical structures, in addition to the drilling error, is calculated automatically using custom software. For distance calculations, a titanium rod inserted into the drill tunnel is automatically segmented and registered to the preoperative plan using a mutual information registration. The second segment terminates 3 mm past the level of the facial nerve and defines a region in which a heat sensitive drilling protocol, previously determined experimentally [4], is to be employed (0.5 mm drill intervals) to ensure thermal damage of the surrounding nerves is avoided The final segment completes the drilling to the middle ear cavity at the original drilling parameters as the drilling returns to a less critical region.

The effectiveness of safety measures were assed in minimally invasive drillings performed on 16 temporal bone specimens. Registration of the specimen to the pre-operative images was required to meet heuristically determined error thresholds of FRE < 0.04 mm and a maximum Euclidean difference from a leave-one-out registration test at the planned target < 0.5 mm. Trajectories were drilled by the robotic system according to the planned protocols and safety measurements were performed on completion of the drilling of the first segment. Accuracy of the drilling, intraoperative image based safety calculations and force-density tool pose calculation as well as the preservation of anatomical structures were assessed on high resolution CT (xtremeCT, Scanco Medical, CH).

Results

Minimally invasive access to the middle ear, targeting the round window of the cochlea, was successfully performed in all 16 cases. Inability to assess one case on the postop CT lead to its exclusion from subsequent analysis. Registration accuracy thresholds resulted in the detection of a fiducial that had been mistakenly removed and returned to the same hole after preoperative imaging. The procedure was successfully performed after the acquisition of a second image. A drilling accuracy of 0.15 ± 0.07 mm was observed at the target on the round window and accuracies of 0.08 ± 0.04 mm and 0.12 ± 0.05 mm were observed on the surface of the mastoid and level of the facial nerve respectively. In all specimens the preservation of the facial nerve and chorda tympani was confirmed on postoperative high resolution CT images; in one case the chorda tympani was sacrificed due to a narrow facial recess. The drilling error predicted at the level of the facial nerve at the round window target point, based on the acquired intraoperative images were calculated with accuracies of 0.14 ± 0.1 mm and 0.19 ± 0.11 mm respectively. The distance from the drill to the facial nerve was estimated with an accuracy of 0.04 ± 0.04 mm, suggesting the major segmentation and prediction errors did not occur in the direction towards the nerve. The force-density algorithm predicted the actual tool path at 3 mm before the facial neve with an accuracy of 0.22 ± 0.14 mm (Fig. 1).

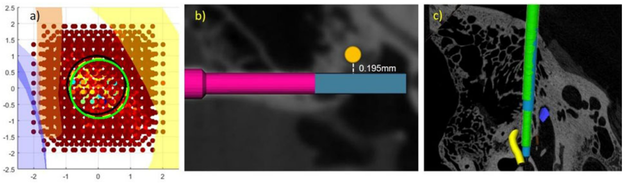

Fig. 1 Drilling safety mechanisms using (a) force and density data, and (b) image data (b), were assessed on post-operative microCT images (c)

Conclusion

Presented above is a drilling protocol and safety mechanisms designed to ensure the safe completion of minimally invasive cochlear implantation procedures. The described mechanisms are designed to prevent both mechanical and thermal damage to the structures of the facial recess and were evaluated on a total of 16 human temporal bone specimens; in all cases the structures of the facial recess remained intact according to the pre-operative plan.

References

[1] Labadie RF, Balachandran R, Noble JH, Blachon GS, Mitchell JE, Reda FA, Fitzpatrick JM (2014). Minimally invasive image-guided cochlear implantation surgery: First report of clinical implementation. Laryngoscope, 124(8), 1915–1922.

[2] Bell B, Gerber N, Williamson T, Gavaghan K, Wimmer W, Caversaccio M, Weber S (2013). In Vitro Accuracy Evaluation of Image-Guided Robot System for Direct Cochlear Access. Otology & Neurotology, 34, 1284–1290.

[3] Williamson TM, Bell BJ, Gerber N, Salas L, Zysset P, Caversaccio M, Weber S (2013). Estimation of tool pose based on force-density correlation during robotic drilling. IEEE TBME, 60(4), 969–76.

[4] Feldmann A, Anso J, Bell B, Williamson T, Gavaghan K, Gerber N, Zysset P (2015). Temperature Prediction Model for Bone Drilling Based on Density Distribution and In Vivo Experiments for Minimally Invasive Robotic Cochlear Implantation. Annals of Biomedical Engineering. [Epub ahead of print]

Ex-vivo evaluation of a chorda tympani prediction model for minimally invasive cochlear implantation

C. Rathgeb[1], K. Gavaghan[1], C. Dür[2], O. Scheidegger[3], T. Williamson[1], L. Anschütz[2], M. Caversaccio[2], S. Weber[1], N. Gerber[1]
[1]University of Bern, ARTORG Center for Biomedical Engineering Research, Bern, Switzerland
[2]Inselspital Bern, Department of ENT, Head and Neck Surgery, Bern, Switzerland
[3]Inselspital Bern, Department of Neurology, ENMG-Station, Bern, Switzerland

Keywords Chorda tympani · Prediction model · Minimally invasive · Cochlear implantation

Purpose

Minimally invasive cochlear implantation (MICI) requires the definition of an access tunnel from the surface of the mastoid to the cochlea, passing through the facial recess. Bounded by the facial nerve, chorda tympani, the medial aspect of the external auditory canal and the incus, the definition of a safe drilling trajectory requires the accurate calculation of distances to these close lying structures to ensure sufficient safety margins are respected. Previously described planning systems calculate distances using automatically or semi automatically segmented anatomy from preoperative CT images.