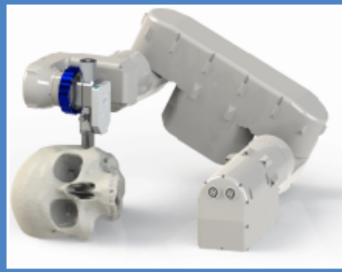
HearRestore

IMAGE-GUIDED MICRO SURGERY FOR HEARING AID IMPLANTATION



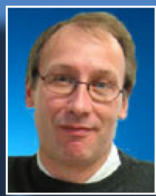
Prof. Stefan Weber, UniBE

PD Dr. Philippe Büchler, UniBE

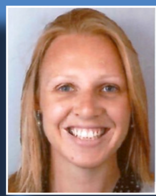
Prof. Marco Caversaccio, InselSpital

Dr. Olivier Chételat, CSEM

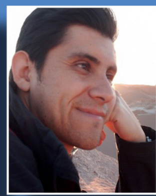
Dr. med. Patrick Dubach, InselSpital



Mr. Edo Franzi, CSEM



Dr. Kate Gerber, UniBE



Prof. Mauricio Reyes, UniBE

Prof. Andreas Stahel, BFH

Prof. Philippe Zysset, UniBE

What it's about…

Developing novel surgical and robotic technologies to drastically reduce the invasiveness and improve the outcome of hearing implant surgery.

Context and project goals

Hearing impairment or loss is among the most common reasons for disability. Worldwide, 27% of men and 24% of women above the age of 45 suffer from hearing loss of 26dB and more. Meaning that the person concerned can only hear sounds with a volume higher than 26dB, where whispering, quiet talking and loud radio music have sound pressures of 30dB, 50dB and 80dB respectively. In absolute numbers 80 to 100 million humans in the EU are suffering from hearing impairment.

While steady and extensive research is carried out to further improve and extend cochlea implant technology, the traditional surgical approach, foremost its invasiveness has not changed over the last three decades. In other surgical domains, the advancement of minimally invasive procedures advanced with the introduction and availability of suitable endoscopic and instrument and ultimately computer technology. Additionally, free-hand image guided surgery (IGS) and surgical robotics have been around since more than one decade increasing the surgeon's spatial orientation and thus reduction of uncertainty during surgical and interventional procedures. IGS is currently established as standard of care in Neuro-, head and orthopedic surgeries. While the propagation of such technologies into the aforementioned surgical disciplines is saturated, other clinical disciplines (i.e. abdominal) and interventions on a smaller geometric scale, so called as microsurgical procedures – have yet to be investigated.

Thus, in this project we will systematically explore and investigate approaches for micro-scale surgical image-guidance by utilizing the latest advancements of modern implants, imaging technology, as well as signal processing and computational power. The complex task of cochlear implantation is a prime example of a multi-scale system where research together with dedicated efforts in system integration can make a significant improvement in treatment options. Additionally, this scenario focuses on a relevant medical problem with an everincreasing importance due to the rise of the developed world. Unlike in the well-explored 'macro-surgical' application scenarios, the utilization of IGS in microsurgery requires extensive research far beyond existing knowledge. Thus, the project consortium intends to investigate a number of recent and promising research approaches that suggest feasibility and suitability for the mentioned application scenario, such as:

- Tracking of surgical instruments using nanometer scale tracking technology;
- Computer based planning of the implantation procedure using anatomical, physiological, and functional information derived from high resolution (80 µm) medical image data;
- Sub-millimeter accurate, reproducible and minimally-invasive patient-to-image registration;
- Numerical modeling of the drilling process for precise drill pose estimation;
- Utilization of Neuromonitoring to allow for safe and functional image guidance;
- Development of suitable clinical models and benchmarks in which efficacy and safety of image-guided cochlear implantation are demonstrated.

To enable such a project, a consortium of experts in nano-meter scale tracking, surgical robotics, medical image analysis, biomechanics, numerical bioengineering and clinical medicine has been created.

How it differentiates from similar projects in the field

This project is set apart from the competition in its approach to accuracy, safety and redundancy. The surgical robot is a platform technology which allows precise performance and monitoring of different stages of the surgery. Machining forces, integrated nerve stimulation/neuromonitoring, temperature prediction models and image-guidance uncertainty predictions/calculations all culminate in an information rich environment to help provide a safe and rich machine-surgeon collaboration.

Quick summary of the project status and key results

Substantial progress has been made in all subtasks. The major highlight of the project is the successful transfer of the base technology to clinical use. The project has obtained regulatory clearance for a first in man clinical trial. The system has undergone final safety verification with the trial beginning in August 2015.

The clinical trial will include patient data collection for tasks in several work packages for verification and optimization of algorithms and models developed in 2014.

Additionally, the consortium was able to conduct a live animal study with collaboration from all of the four partner institutions. The study offered a unique opportunity for each of the project partners to make individual in-vivo measurements with direct impact on their individual sub-tasks. Extensive electromyography measurements were conducted with varying and controlled stimulation protocols along with both in-situ impedance measurements and drilling temperature measurements. The work has resulted in a number of recently submitted publications.

Success stories

Awards:

A presentation of the scientific challenges and findings from the robot project was awarded with the “Hamlyn Medical Robotics Award 2013” during the prestigious Hamlyn Symposium on Medical Robotics, held at the Royal Society of Engineering in London in 2013.

Also, Mr. Juan Anso (PhD student at ARTORG center) received the distinction of ‘Best Master’s Thesis’ from the Biomedical Engineering department of the University of Bern for his work on facial nerve monitoring.

Second best paper award was also awarded to S. Weber et al for the submission entitled “Minimally invasive, robot assisted cochlear implantation” at the 3rd joint Workshop on Computer / Robot Assisted Surgery, Verona – Italy, 2013.

Presence in the media:

TV: Euronews “High Tech”: The project was showcased in a report on the spaceCoder technology.

Patents

B. J. Bell, T. Williamson, and S. Weber, “System and Method for estimating the spatial position of a tool within an object,” EP12168772.72012. This patent on process-based pose estimation was submitted previously, and was recently awarded. This patent is one of the foundations of a safety warning system which can alert the surgeon of impending contact between the drill and the facial nerve or other structures.

"6D positioning system using a shadow sensor”, US application number 14597434, filed 15-Jan-2015

“Positioning system using a constellation of light sources”, EP15151233, filed 15-Jan-2015

Main publications

J. Ansó, B. Bell, N. Gerber, T. Williamson, K. Gavaghan, M. Caversaccio, S. Weber, Feasibility of Detection of the Facial Nerve Using EMG During Robotic Direct Cochlear Access, In International Journal of Computer Assisted Radiology and Surgery, Volume 8, Supplement 1 (pp. 101–107).

J. Ansó, C. Stahl, N. Gerber, T. Williamson, K. Gavaghan, K.M. Rössler, M-D. Caversaccio, S. Weber, B. Bell, Feasibility of Using EMG for Early Detection of the Facial Nerve During Robotic Direct Cochlear Access, Otol Neurotol. 2014 Mar;35(3):545-54. doi: 10.1097/MAO.0000000000000187.

J. Ansó, T. Wyss, M. Caversaccio, S. Weber, B. Bell, High Accuracy Functional Neuromonitoring to Preserve the Facial Nerve during Robotic Direct Cochlear Access using a custom made Concentric Stimulating Probe, 30th International Conference of Clinical Neurophysiology: Abstracts of Poster Presentations – Poster Session 8 – Intraoperative monitoring 1.

J. Ansó, T. Wyss, P. Büchler, A. Stahel, S. Weber, M. Caversaccio, B. Bell, Intraoperative Neuromonitoring of the Facial Nerve during Minimally Invasive Cochlear Implantation: A custom made Stimulating Probe, 13th International Conference on Cochlear Implants and Other Implantable Auditory Technologies.

B. Brun[1], T. Williamson[1], M. Caversaccio2, S. Weber[1], B. Bell[1], Validation of custom active markers for use with a high accuracy tracking system, CURAC 2013.

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. doi: 10.1007/s11548-013-0908-5.

B. Bell, N. Gerber, T. Williamson, K. Gavaghan, S. Weber, M. Caversaccio, Minimally Invasive Robotic Cochlear Implantation Surgery, 13th International Conference on Cochlear Implants and Other Implantable Auditory Technologies.

N. Gerber, P. Senn, M. Vischer, B. Bell, C. Jolly, S. Weber, M. Caversaccio, Preliminary Clinical Evaluation of Surgical Planning for Cochlear Implantation Surgeries, 13th International Conference on Cochlear Implants and Other Implantable Auditory Technologies.

W. Wimmer, F. Venail, T. Williamson, M. Akkari, N. Gerber, S. Weber, M. Caversaccio, A. Uziel, B Bell, Semiautomatic Cochleostomy Target and Insertion Trajectory Planning for Minimally Invasive Cochlear Implantation, BioMed Research International, 2014 Hindawi Publishing Corporation 10.1155/2014/596498.

B. Bell, T. Williamson; N. Gerber, K. Gavaghan, W. Wimmer, M. Kompis, S. Weber, M. Caversaccio, An image-guided robot system for direct cochlear access, Cochlear implants international : an interdisciplinary journal, 15(Suppl 1), S11-S13. Maney 10.1179/1467010014Z.000000000192.

W. Wimmer, B. Bell, M. Huth, C. Weisstanner, N. Gerber, M. Kompis, S. Weber, M. Caversaccio, Cone Beam and Micro-Computed Tomography Validation of Manual Array Insertion for Minimally Invasive Cochlear Implantation, Audiology & neuro-otology, 19(1), pp. 22-30. Karger 10.1159/000356165.

T. Williamson, X. Du, B. Bell, C. Coulson, M. Caversaccio, D. Proops, P. Brett, S. Weber, Mechatronic feasibility of minimally invasive, atraumatic cochleostomy, BioMed research international, 2014, p. 181624. Hindawi Publishing Corporation 10.1155/2014/181624.

F. Venail, B. Bell, M Akkari, W. Wimmer, T. Williamson, N. Gerber, K. Gavaghan, F. Canovas, S. Weber, M. Caversaccio A. Uziel, Manual Electrode Array Insertion Through a Robot-assisted Minimal Invasive Cochleostomy: Feasibility and Comparison of Two Different Electrode Array Subtypes, Otol Neurotol. 2014 Apr 7, doi: 10.1097/MAO.0000000000000741.

“How could you develop such a robot and I don’t know about it!”

Renowned ENT surgeon
Prof. Dr. med. Olivier Sterkers, Paris