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In-vivo Electrical Impedance Measurement in Mastoid Bone

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Direct cochlear access (DCA) is a new surgical approach to enable minimal invasive cochlear implantation. It aims at replacing the current mastoidectomy by using a robot to drill a tunnel to the middle ear. The trajectory passes at low distance of the facial nerve, which is an important risk for the patient. For facial nerve monitoring (FNM) uses electric signals to determine correlation of current threshold to electrode to nerve distance. This approach has been proposed to increase safety of the procedure, but previous experiments showed that current FNM measurements lacks specificity and sensitivity for accurate nerve detection during drilling. Therefore, the goal of this study is to provide an in-vivo characterization of the electrical impedance of the mastoid tissue.
A sheep animal model was used to measure electrical impedance of the deep mastoid bone. Two custom made probes were inserted into mastoid bone in up to six predefined pairs of drilling trajectories. The electrical properties of the tissue were measured at three frequencies from 10Hz to 1kHz. The resulting impedance measurements could be described by a simple electronic circuit composed of a resistor in series with a constant phase element (CPE). Interestingly, the same set of parameters could be used to describe the behavior of the CPE for all experimental measurements. The results indicate that the measured phase shift could be explained by the impedance at the bone/electrode interface caused by the polarization of steel electrodes. Therefore, our results support the hypothesis that the CPE describes polarization and electrochemical processes happening at the contact interface. On the other hand, the resistor component of the circuit showed a high dependence to the average bone quality and inter-electrode distance.
In conclusion, a simple model can be used to predict the complex impedance of bone solely based on pre-operative imaging.

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Implant for bone expansion as new procedure for generation of vascularised grafts to bridge long bone defects

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The reconstruction of long bone defects after resection of long bone segments after tumor surgery or infection are still challenging. Two of the most common used techniques to reconstruct defects of long bones are the free fibula transfer and the method of segment transportation accompanied by callus distraction. Certainly both procedures are associated with a high duration of treatment and implies high complication rates. In order to bridge long bone defects with an autologous, vital bone graft, which allows a sufficient mechanical stabilization with an intramedullary nail, we developed a combination of callus distraction and free fibula transfer. For the technical implementation the procedure of callus distraction has to be converted into a technique of callus expansion. To demonstrate the feasibility, a fully implantable prototype for animal tests on domestic pigs was created: The prototype consists of a liquid-filled pressure tank connected over a catheter with a proximal electronically controlled solenoid valve and a distal custom-made balloon. In order to expand the diaphysis of the fibula a bone segment with the shape of a halved cylinder is cut from the bone. The balloon is inserted in the medullary cavity of the fibula between diaphysis and separated bone segment. The initial diameter of the balloon amounts 2.4 mm, the final diameter after expansion is 5.4 mm. The expansion process starts after a resting phase of seven days postoperatively with a velocity of 1 mm expansion per day. The control software enables a brief opening of the valve every 20 minutes to expand the balloon. At the end of the procedure a vascularized bone segment with a medullary cavaty diameter of 5.4 mm can be detached and used for transplantation into a long bone defect. The presented procedure constitutes an innovative approach for the reconstruction of segmental defects of long bones.

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Ultrasonic-based Transcutaneous Energy Supply and Signal Transmission for Hermetically Encapsulated Miniature Implants

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Currently, the wireless transcutaneous energy supply and communication of active implants is typically accomplished by electromagnetic transmission. Limits arise if the implant must be very small, the implantation site is remote from the body surface, or if a hermetic metallic housing encapsulates the implant to achieve long-term stability and biocompatibility. In these cases, sufficient efficiency for electromagnetic transmission can only be achieved by implanting a coil subcutaneously, which in turn is connected to the implant via a connection wire - an arrangement laborious to implant and susceptible to faults. Otherwise, signal transmission is hampered and power supply requires a bulky battery, which must be exchanged regularly by surgical intervention. Our development thus aims at a medical implant system including a hermetic, titanium-housed implant, in which transcutaneous energy supply and communication are achieved by ultrasound instead of electromagnetic transmission. For proof-of-concept, we have exemplarily developed an electrostimulation implant for the stimulation of peripheral nerves. It can be sufficiently supplied with energy by ultrasound generated by an extracorporeal unit, and it can suitably communicate with this extracorporeal unit via ultrasound as well. Stimulation parameters can be varied by remote action, and several implant data can be read out wirelessly. In order to allow for secure communication, the communication protocol is encoded by a sophisticated cryptographic technique. Instead of a bulky battery, a small rechargeable cell is used for energy buffering. Thus implant volume is restrained to less than 5 cm^3. Ultrasound passes through the hermetic titanium housing of the implant bidirectionally, and transmission and powering bridges a distance of more than 100 mm in water. Besides greater reach and the capability to penetrate metallic housings, a promising advantage of ultrasound over electromagnetic methods is its potential for localizing deep implants if displaced, and its focusability towards the localized direction to optimize transmission.

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Accuracy investigation of a new mininavigation system for dental implants

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Dental implants are in 96% positioned free hand including a risk of suboptimal placement and adverse events. In order to overcome these limitations, a miniaturized navigation system has been developed with two stereo cameras fixed on the drill guiding implant insertion. The aim of the present work was to determine the tracking precision of the system within its whole working room which should not exceed 0.4mm in order to keep the expected overall submillimetric precision of the system.
A prototype of the navigation system was used to track a highly precise optical marker (visual pattern on a ceramic substrate, 10 x 15 mm in size). The marker was mounted to the measuring head of a Thome coordinate measuring table on which the camera system was fixed as well to perform reference measurements. Coordinates of the measuring table coordinate system (CTCS) and the stereo camera coordinate system (SCCS) were collected along a 3D point array slightly larger than the working room with a resolution of 5 mm. Measurement coordinates were transferred to the SCCS using the optimum transformation. The precision of a working room position was determined as distance between transformed and real measuring table position. The working room size was 47 $8mm^3$, forming a truncated pyramid like geometry. The measured global error in the inner working room was always less than 0.07mm and in the outer working room less than 0.15mm.
The results of the present study give a first impression of the working room size which is sufficient to be used for the dental implantation and the tracking of the marker itself. The precision analysis shows that the precision remains below the minimum precision of 0.4mm. Further tests have to be conducted including the Cone-beam CT based planning in order to determine the overall precision of the mininavigation system.

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Development and evaluation of a cooled RF-lesion electrode which yields increased lesion size and energy delivery

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Stereotactic radiofrequency (RF) lesioning is used to treat dysfunctions of the central nervous system such as movement disorders and epilepsy. RF lesions fall short from a limitation in size and energy delivery which can be achieved with a single trajectory. Combining the RF application with local cooling around the electrode was proposed to induce larger lesions and to increase energy delivery. To test this hypothesis, we designed a bipolar, cooled RF electrode and conducted RF experiments in egg white during video recording of the coagulation process, measuring the spatio-temporal temperature distribution and documenting the application parameters RF-power, impedance and temperature. Experiments were performed for standard RF, continuous cooling and dynamically-cooled RF for which the cooling effect was dynamically controlled by the temperature. Standard RF achieved a volume of 85.75 mm³ coagulated egg white and the energy delivery amounted to 196 J. With continuous cooling, a volume of 127.21 mm³ was reached but an excessive increase of impedance often stopped the application after a few seconds. Dynamically-cooled RF application reached significantly largest lesion size (217.16 mm³) and also provided highest energy delivery (296 J). Our data show that the energy delivery becomes more uniform over time and overall larger with dynamic cooling due to the lack of an excess temperature which otherwise stops the delivery of RF energy for some time without cooling. The impedance over the course of RF application remains stable (70-80 Ω) for dynamic cooling and standard RF but with additional temporary variations right after the stop of RF energy delivery for standard RF. With continuous cooling, the impedance shows a sudden and huge increase (several hundred ohm) due to sustained RF energy delivery, which stops the coagulation. Combining dynamically-cooled and impedance-controlled RF application therefore suggests to further enhance the efficiency of the cooled RF lesion process.

ID: L-OP-09

Design of a Haptic Human-Machine-Interface for Bimanual Control of a Surgical Robot

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Scope of the Project FLEXMIN is the development of a surgical robot for single incision surgery. This surgical teleoperation system is based on a master-slave structure. For best performance during the surgical task, one goal of the project is to provide haptic feedback at the user interface, based on tissue interaction forces at the slave manipulator.

Providing a well-adapted human machine interface as master system requires a detailed analysis of the slave robot.
The slave robots' outline mimics a conventional rectoscope for transanal endoscopic surgery. At its' proximal end, two adverse manipulators are provided. Both manipulating arms are based on parallel kinematic structures. Surgical graspers are provided as end-effectors. The arms are designed with 4 degrees of freedom and a grasp. The 4 degrees of freedom are distriputed as 3 cartesian coordinates and the rotation along the axis of the end effector.

As user interface a hybrid kinematic structure consisting of a passive and an active part, is chosen. As two manipulators have to be controlled, identical structures for the left and right hand are provided. The kinematics of the passive part copy the actual manipulators' main kinematic chains leading to identical joint angles at the slave robot and the input device. Doing so, intuitive control over the robot is assumed. The handle can also be rotated and provides the control mechanism for the grasper. The latter two axes also provide haptic feedback. The active part consists of a delta kinematic 3-DOF device able to produce forces in three Cartesian axes. Altogether, five axes per side can be controlled actively. With the designed system, haptic feedback can be provided with forces up to 20 N in a frequency range up to 1 kHz. The haptic system provides a z-width larger than 20 dB leading to a wide range of presentable properties, measured at the manipulator.

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Fibre optical probe navigation during deep brain stimulation implantation – safety aspects

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The most severe complication in stereotactic deep brain stimulation (DBS) surgery is intracerebral bleeding. Therefor planning of the target site and trajectory is of out most important. Despite accurate planning, trajectories can deviate due to loss of cerebral spinal fluid which is the cause of a brain shift. Intraoperative measurements are therefore an important complement to image based surgical planning.

By using an insertion guide (diameter 2.2 mm, length 190 mm) with forward looking optical fibres and the outer dimension adapted to Leksell® Stereotactic System (Elekta instrument AB, Sweden), laser Doppler flowmetry (LDF, Periflux 5000, Perimed AB, Sweden) can be used to record the cerebral microcirculation and backscattered light reflecting tissue type in front of the guide. The system has been used during more than 120 DBS implantations and typical “bar-codes“ for two common DBS targets, the subthalamic nucleus (STN) and the ventral intermediate (VIM) nucleus of the thalamus previously been defined. The aim of the study was to evaluate patient safety where the LDF was used during DBS implantations (n = 83) at Linköping University Hospital (LiU M182-04, T54-09). Medical record and postoperative radiology were reviewed together with the optical data collected during surgery. 82 trajectories were recorded without adverse events. In one case, a small bleeding was detected by means of the optical systems during surgery. It can be concluded that the microvascular measurements can visualize ventricular and sulci involvement, can also detect small haemorrhages. With the method's forward looking feature in combination with controlled stepwise insertion of the probe, it has a potential to act as a ”vessel alarm” and thus helps further minimizing the risks of bleedings.

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Support System for TNM Classification of Laryngeal Cancer using Bayesian Networks

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Most solid tumors are staged according to the TNM classification characterizing the extend of the primary tumor (T), regional lymph nodes (N), and distant metastasis (M) and have major influence on treatment decision and prognosis. Insufficiencies, in terms of under- and overestimations of the TNM stage, may lead to suboptimal treatment decisions and could deteriorate patients outcome.

Using Bayesian Networks (BN), decisions can be modelled based on guidelines, studies and clinicians' expertise. Based on individual patient's information, the resulting patient specific Bayesian Network (PSBN) may support therapeutic decision making by calculating also unobserved data (e.g. therapy side effects, quality of life, and missing examinations). We modelled the TNM staging of laryngeal cancer manually in a close collaboration between clinicians and computer scientists.

The laryngeal cancer TNM-model consists of 303 variables and 334 direct dependencies. Based on 63 patient cases, we validated the model computer based by using statistical methods as well as a manual review and optimization by a clinician. The TNM model calculated 38 correct answers (60%), compared with the real-life TNM stage. We identified issues are mainly related to data quality, data inconsistency and suboptimal interpretation of diagnostic findings for determination of the TNM-stage. After reviewing and enhancing the data integration process, the model was correct in all 63 cases. Furthermore, a "PSBN-Analyser" was developed as an interactive application to present and to highlight relevant information for the decision support graphically.

The laryngeal cancer TNM-model achieved a high level of precision for the correct calculation of the TNM stage, as expected due to a precise definition. Furthermore, the decision became more transparent, comprehensible and reproducible by Bayesian's inherent graph model. We developed an extended model for treatment decision support of laryngeal cancer for which we expect a more complex verification process. Next, we will conduct a study with clinicians to evaluate the decision support of our model and the PSBN-Analyser. Furthermore, we will combine BN with the HL7 standard Arden Syntax to address semantic data integration.

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Real-time prediction of temperature elevation during bone drilling using the torque and force signal

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Bone drilling is a surgical procedure which is used in many orthopaedic, dental, otolaryngological (head and neck) and other surgeries involving the human skeleton. Production of heat during the drilling process has recently regained a lot of attention. Especially for otolaryngological surgeries, which often involves cutting and drilling around nerves, it is important to assess and reduce the heat of the drilling process to avoid thermal damage. Within this work, we conducted an extensive experimental campaign to investigate and model the temperature elevation during bone drilling using bone tissue with different porosities. Therefore, cortical bovine bone samples were prepared with differently spaced lateral holes in order to mimic the different bone porosities of the human cranium. A custom made test setup, which consisted of a CNC-machine, a thermal camera with a macroscopic lens and a load cell was used to measure the temperature elevation, torque and axial force of the drilling process. Drill bits with two different diameters (Ø1.8mm and Ø2.5mm) were tested on three sets with different bone porosities and repeated eight times. A previously introduced simple thermal model was used and modified to allow direct calculation of temperature elevation from the torque and force signal. The used 1D moving point source model, which is based on a Green function, can be used to evaluate the temperature elevation at any point along the drilling trajectory. The two required calibration constants of the model were identified using the data and the comparison of measured and predicted temperature elevation at multiple drilling depths shows a very good correlation (for Ø2.5mm: R^2=0.92, SEE=0.12°C, $p<0.001$; Ø1.8mm: R^2=0.82, SEE=0.09°C, $p<0.001$). This validation of the proposed model allows the future assessment of drilling temperature elevation as a safety mechanism for surgical interventions that are close to nerves and other delicate structures. Additionally, due to its analytical solutions, the model can be used in real-time and is therefore able to warn the surgeon before temperature rise exceeds the threshold of tissue damage.

ID: L-PP-03

A single port robot with parallel manipulators, latest results

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Single port surgery is the next step in minimally invasive surgery promising to further improve the surgical outcome. Performing surgical procedures through only one incision is a challenging task that can be simplified by using a telemanipulator. To overcome the key issues of the commonly used continuum robots in terms of dexterity, dynamics, stiffness and controllability we have introduced a new single port robot that uses two intracorporeal parallel kinematics manipulators.
So far two manipulators, each having 4 degrees of freedom, have been manufactured and characterised. To enable needle holding and handling, several graspers are designed and integrated into the manipulator's structure. To open and close the grasper, the rotation of a rod is used that is transferred to the tip by several kinematic chains that are attached along the manipulators tripod structure. To avoid jamming, the transfer characteristic of this kinematic chain is analysed and the final design that uses elastic elements is presented. To enable high gripping forces that are needed to handle the needle in a save way, the design of the grasper gears is discussed. During first test, the capability of applying sutures and tying knots is presented.
Furthermore, it is shown, that by using parallel kinematics instead of tendon driven robots the 3D tip force can be determined exactly using distally located force sensors. Measuring the forces and having knowledge of the manipulator's positon the tip force is calculated using the inverse transpose Jacobian matrix. Concerning the footprint of the sensors, signal and supply routing and the sterilizability of the overall robot this approach seems promising in the field of practical surgical robotics. In a next step the so obtained force vector will be used to generate a kinesthetic feedback at the robot's user interface.

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Multiaxial Force Sensor for Tissue Characteristics Measurements

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Comprehensive knowledge of forces/torques at the tip of a surgical instrument during in vivo operation enables the prediction of currently applied stress and strain to the tissue to ensure patient's safety with maximum load limits. This work presents a sensor to measure interaction forces between a medical instrument and organic tissue of a patient during surgery. A handheld multiaxial force sensor device with a maximal diameter ≤ 22 mm is designed, which consists of a tight fit coupling for the usage of multiple surgical instruments (e.g. scalpels, rasps or hooks), a six axis force/torque sensor with piezoelectric silicon strain gauges, sensor electronics and a battery. The forces/torques are measured with eight full-bridge strain gauges (gain-factor ≥ 40, $S_{min} \leq 10^{-6}$) with an edge length of 500 µm on a spoke wheel structure with a diameter of 12 mm. The nominal force in axial direction is 10 N and the nominal torque is 1 Nm in all spatial directions. The sensor electronics board with an 18 bit serial multiplexed analog to digital converter is integrated into the sensor case to reduce noise influence and connected to the measurement bridges via flip-chip bonded flex-circuits. Digital signal processing computation, such as low-pass filtering, calibration matrix transformation and fieldbus communication, is implemented on a microcontroller on the board. The sensing data of the tool-tip forces are transferred via Bluetooth for real-time display on a computer or tablet. All implemented components are temperature-resistant and sealed with protective coating to enable sterilization for clinical usage. A first characterization of the sensor results in a maximal systematic error of 4.92 % and random error of 1.13 %. Future work includes a proof of concept trail of the sensing device with surgeons on medical simulators.

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Marker for estimation of position and bearing of medical devices

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Markers made out of radio opaque material are widely used to increase the visibility of interventional tools for minimal invasive procedures under X-ray guidance. These markers show usually a symmetrical shape. Common types are rings or wires out of metal or plastic compounds. Thus the estimation of the three-dimensional position and bearing of the medical devices e.g. catheters is difficult in a two dimensional X-ray projection. We introduce a new shape of a marker for medical devices, which allows an explicit estimation of the orientation of the medical device in medical imaging.
The new marker has a special shape that can be used specially for tubular devices. Therefore the marker has a half ring in the middle, one flank adjusted in distal direction at the one end of the half ring and one flank adjusted in proximal direction of the device at the other end of the half ring. Thus in a frontal view the half ring is visible on one side of the device. In an axial view the marker is represented in that way that one flank on one side of the device goes in upward direction and one goes on the other side in downward direction. The half ring connects the flanks. After turning the device 90 degrees, both flanks are visualized right under each other, the half ring is only visible on one side.
A prototype made of platinum wires was mounted on a 1,9F catheter and tested under fluoroscopic and radiographic X-ray. To validate the visibility of the marker, a radiopacity test based on DIN 13273-7 was performed. The catheter tip with markers was placed in various directions on an X-ray diffuser.
The marker shape allows a reliable estimation of the position and bearing of the catheter without excessively influencing diameter and stiffness.

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The benefits of latest minimally invasive surgical procedures in degenerative lumbar spondylolisthesis

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Background
The use of minimally invasive surgical (MIS) procedures for the treatment of degenerative lumbar spondylolisthesis is increasing although the outcomes of standard open posterior lumbar fusion surgery remain efficient. The question remains what exactly are the benefits of MIS procedures.
The aim of the study was to determine the difference between latest MiTLIF and open TLIF procedures regarding the clinical outcomes, perioperative parameters, fusion rate and adverse events.

Methods
In the study, 20 patients with the painful, lumbar degenerative spondylolisthesis (Grade I) not responding to conservative treatment were treated with the open TLIF procedure and 20 patients with two different minimally invasive TLIF procedures. Clinical outcomes were assessed before, 6 months and one year after the procedure using the Oswestry Disability Index (ODI) and Visual analogue score (VAS) for back and leg pain, with 15 % improvement in ODI and 20 % in VAS defined as a clinically significant. The perioperative parameters including blood loss, operative times, exposure to fluoroscopy and length of hospital stay were evaluated. The lumbar CT scans of the patients were taken accordingly in order to determine the fusion rate.

Results
There was a significant improvement for back and leg pain according to ODI and VAS score in both groups with no statistically important difference between the two groups. There was less blood loss and faster recovery time in the MiTLIF group but slightly higher fluoroscopic exposure and operative times. The fusion rate after one year was similar in both groups.

Conclusions
All procedures resulted in significant pain reduction and good functional outcome for the patients with better results in the MiTLIF group regarding the hospital stay and blood loss. According to our results and according to the literature reviews there is still not enough evidence to state that one procedure is superior to other however the results are encouraging in proceeding and developing new less invasive techniques.