Medical Engineering

Faculty of Mechanical Engineering

Innovative Technology for Smart Therapy

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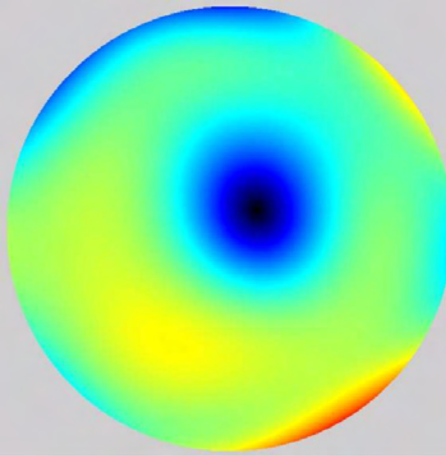
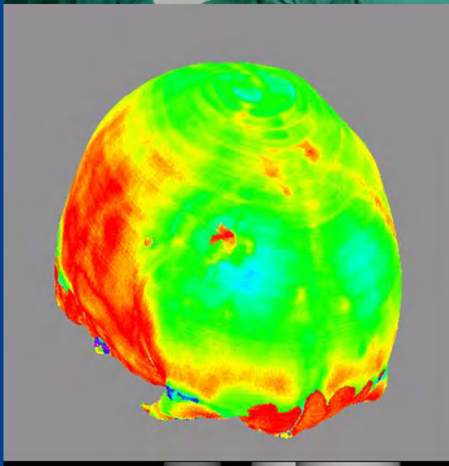
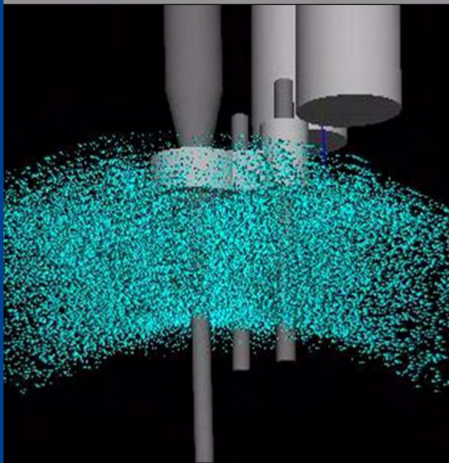
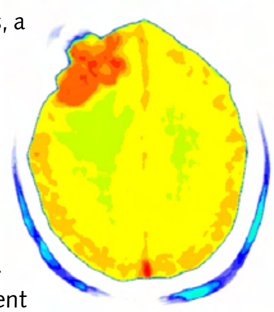


Introduction

Since 1992 the Helmholtz-Institute for Biomedical Engineering Aachen (HIA) has established research activities in surgical therapy technology with a special focus on minimal access surgery, on the fast evolving field of medical robotics and computer assisted surgery as well as on the related aspects of man-machine interaction and ergonomics. In 2005 these activities have been integrated to the newly established Chair of Medical Engineering (*mediTEC*) at the Faculty of Mechanical Engineering at the RWTH Aachen University as an integral part of the new, restructured HIA.

Within the broad spectrum of medical technology research and development, activities of *mediTEC* focus on fundamental as well as on application-oriented aspects in computer-assisted therapy systems engineering, particularly including image and information processing, navigation and robotics, biomechanical modelling for planning and simulation, sensor-integrated instruments ("smart instruments") and ultrasound technology. Apart from indispensable medical basics and the development and application of modern technologies and engineering methods, a special emphasis is put on aspects of ergonomics and safety in the course of the research and development of integrated medical work systems.



Projects - ranging from feasibility studies (proof of concept) and system development to usability studies and clinical field tests - are defined and conducted in close cooperation with medical as well as industrial partners. Actual activities are related to Orthopaedic and Trauma Surgery (incl. Care and Rehabilitation), Neurosurgery, General Endoscopic Surgery, Maxillofacial Surgery and Dentistry.

Apart from basic research on ergonomics and usability engineering in medicine, our **Ce**nter for **M**edical **P**roduct **E**r**G**onomics and usability engineering (*CeMPEG* - **Ce**ntrum für **M**edizin**P**rodukt-**E**rgonomie und **G**ebrauchstauglichkeit) provides professional usability engineering and evaluation services e.g. to industrial partners (in the context of development and market approval) as well as to clinics and medical partners who are looking for a comparative evaluation of the ergonomic quality and usability of medical products.

Based on long-lasting international cooperation e.g. in the framework of large EC-projects and multiple, bilateral R&D activities as well as in education and training, *mediTEC* has access to an international network of clinics, research labs and industrial partners (especially SMEs) in the Aachen region, Europe, Israel, Asia, Australia, New-Zeeland and America (especially US, Canada, Brasilia).

Image and information processing

Advances in medical imaging and sensor technology have lead to a dramatic increase in the amount of information available to clinicians as a basis for planning, delivery and control of therapeutic procedures. The extraction of relevant information for the specific clinical application, followed by interpretation, merging, and visualization has become an important topic especially in computer-aided surgery.

Automatic contour extraction from X-Ray projections is an exemplary issue addressed e.g in the context of bone cement removal in Revision Total Hip Replacement (RTHR) [4], for modelling and registration in fluoroscopically navigated hip resurfacing surgery or in the case of computer assisted repositioning osteotomies [2]. Today, fluoroscopic images are usually calibrated using a three-dimensional calibration cage fixed in front of the X-ray image intensifier. To enable a marker- and cage-free intraoperative use of the C-arm a new model based calibration approach has been developed reducing the maximal resulting error within the field of view [3].

Figure 1: Segmentation of calvarial tumors

In the field of neurosurgery, segmentation of calvarial tumors is based on image-data combined with apriori knowledge gained from clinical case data of previous patients. Clinical validation refers to accuracy, robustness, reliability and reproducibility issues as well as to user-interaction. Approaches based on a combination of various algorithms and statistical considerations have been developed and evaluated [8, 9].

Ultrasound based registration of anatomical structures

Figure 2: Intraoperative registration with 3D tracked A-mode ultrasound in cranial surgery

Individual anatomical structures have to be registered e.g. with image and planning information or for direct interactive instrument control. This step essentially influences the effectiveness e.g. of tumor resection in cranial surgery. 3D tracked A-mode ultrasound as a non-invasive virtual pointing tool enables transcutaneous palpation and registration of points dislodged from the operating site. An interactive user interface informs about the estimated transducer position and guides the surgeon during palpation. For an optimal adaptation of the ultrasound probe to the soft-tissue interface a special forerun has been developed. Ex-vivo and in-vivo optically tracked Amode ultrasound registrations for cranio applications have been successfully performed [6,13]. Various other applications of A-mode ultrasound are under investigation.

Individual implant modelling

The reconstruction of skull defects requires careful preoperative planning to achieve good functional and aesthetic results. Computer-aided design and manufacturing of customized implants has been established, however, the workflow involving clinicians and CAD/CAM technicians needs to be optimized not only in terms of time and cost efficiency but also with regard to the quality of the resulting implants. In the framework of the CRANIO project we are currently developing an approach towards semiautomatic modelling and individual adaptation of complex reconstructions using anatomic knowledge and clinical reference case databases in the context of an integrated manufacturing process.

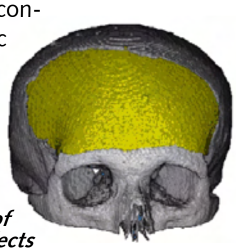
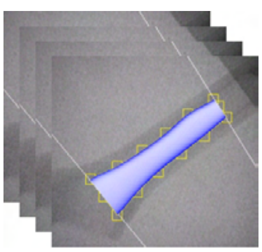


Figure 3: Knowledge based semiautomatic reconstruction of bilateral skull defects

CRANIO - robot assisted craniosurgery



The aim of the CRANIO project is to develop a system that integrates the entire surgical process, from planning, customized implant manufacturing to intraoperative navigation and robot-assisted craniotomy. Particularly in the case of a tumor infiltration into the bone, a stepwise milling of the affected areas is necessary since a craniotome can not be used. In this case a robot dispenses the surgeon from time-consuming and strenuous bone milling and provides an accurate fit of the customized implant. Based on the analysis of the specific workspace requirements a hexapod structure and a new intraoperative robot setup incorporating a modified Mayfield head clamp have been developed. The system's safety architecture including redundant sensor systems, fail-safe brakes and the introduction of an autonomous safety hardware, has been implemented on the basis of a process-oriented computer-assisted risk analysis.

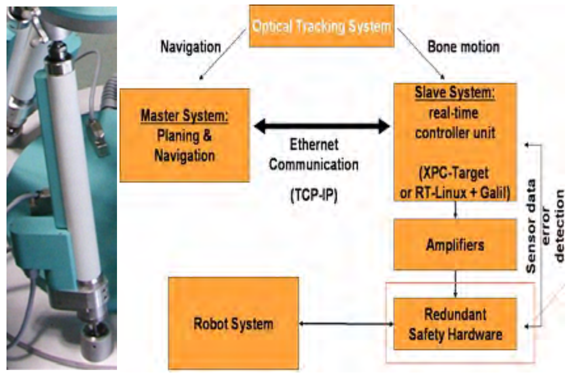


Figure 4: a): Detail of the CRANIO hexapod robot system with 6 linear DC drives, fail-safe brake systems and redundant position sensors; b): CRANIO system control architecture

MINARO - navigated miniaturized robot system for revision total hip replacement

In RTHR, the removal of the distal femoral bone cement can be a time consuming and risky operation due to the weakened cortical wall and the difficulty in determining the 3D boundary of the cement. In the framework of the MINARO project an intraoperative 3D reconstruction of the cement volume is realized by back projection of segmented contours from multiplanar X-ray projections of the femur. Apart from an optional freehand navigation module of the milling tool, a concept of a bone mounted robot system for the machining of the bone cement has been developed. The robot system is based on a 3 degree of freedom (DOF; optional 5 DOF) modular hybrid kinematic structure. First trials with the compact robotic device on anatomic bone models have demonstrated the feasibility of the concept.

Figure 5: a) 3D reconstruction of the femoral bone cement is based on 4-6 X-ray projections; b) intraoperative automatic generation of the tool path, collision detection and optimal navigated pre-positioning; c) miniaturized bone mounted hybrid robot system for cement removal

Exoscope manipulator platform

The objective of this project is to provide adequate assistance systems for endoscopically assisted neurosurgery. The combination of an endoscope and a digital surgical microscope ("exoscope") as well as the specific boundary conditions of micro-neurosurgical interventions has motivated the development of specialized master-slave robotic assistance systems. Based on a detailed analysis of technical and user-requirements concerning workspace, motion characteristics, safety issues and OR-integration a semi-robotic platform-concept is under development [15]. Figure 6 shows a first prototype of the exoscope system mounted on a specialized multi-functional arch on the operating table. For the individual presentation of the images Head-Mounted-Displays (HMD) are used. The platform is operated by the surgeon using speech control for mode selection and head-tracking for motion control for the fine-adjustment of the camera perspective onto the operating field. This approach has been evaluated in cooperation with clinical partners [14].

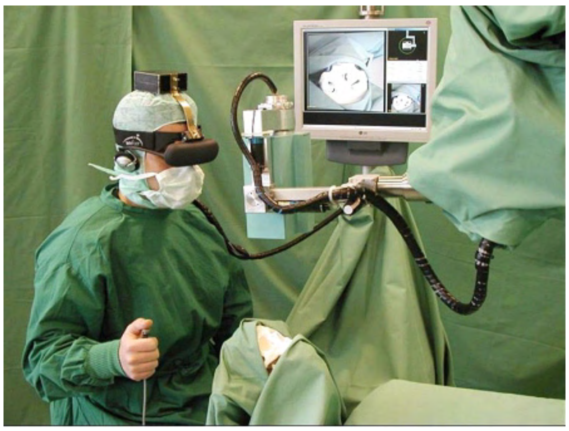


Figure 6: MINOP Telemanipulator platform for an electronic surgical microscope

Ergonomics and medical product usability evaluation

The complexity of especially computer based medical products has continuously increased in the last 10 years. This also applies to surgical therapy technology including computer assisted planning, navigation and robotics. The evaluation of these new surgical technologies is likewise becoming an increasingly important research issue and an essential basis for the ongoing technical evolution. *CeMPEG* has established a portfolio of software tools and methods for risk analysis, guideline- and user-based evaluation as an integral part of usability engineering and medical product quality assurance procedures. An initial computer based risk analysis is used for the identification of critical task-sequences involving the user as an essential part of the overall system. In a next step, a guideline-based evaluation is done by ergonomic experts of *CeMPEG* using a database of concrete requirements and criteria derived from standards, guidelines and literature. For a user-based evaluation, target group participants are asked to perform steps of a preoperative and/or intraoperative procedure, e.g. within a model OR setup, while being monitored by an evaluator. After going through a standardized introduction, the task goals can be displayed on a separate computer screen and the test persons are able to consult an online tutorial. The time of performance and the quality of the working results are recorded and assessed. The criticality of errors is analysed and rated by the observing evaluator depending on their impact on the final result. Moreover, the overall learnability can be assessed by directly comparing test persons with different levels of experience (Fig. 7). Last but not least, questionnaires are used for a subjective assessment of error tolerance, learnability and user satisfaction.

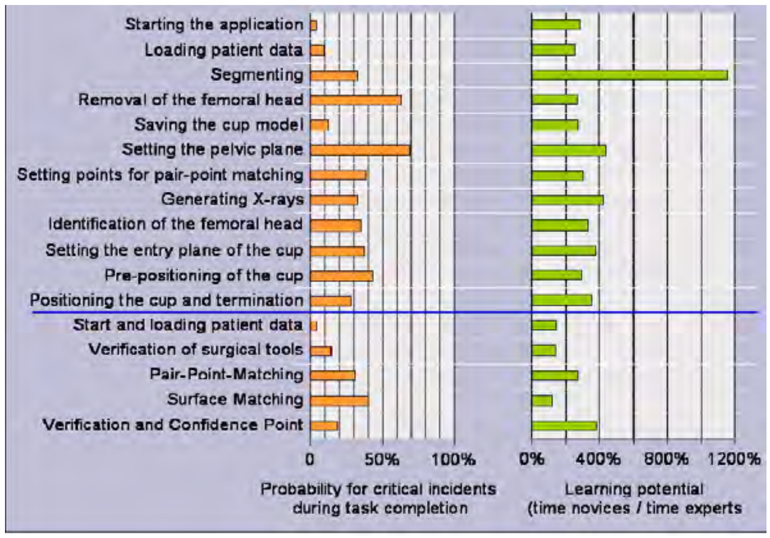


Figure 7: User based evaluation of a commercial planning and navigation system: comparison of error probability vs. learning potential for typical task sequences

Figure 8 shows an experimental set-up of a study on an eye-hand coordination for different HMD configurations [12]. This study has been conducted at the HIA in cooperation with the Chair and Institute of Industrial Engineering and Ergonomics, RWTH Aachen University and has been funded by the Holste foundation.

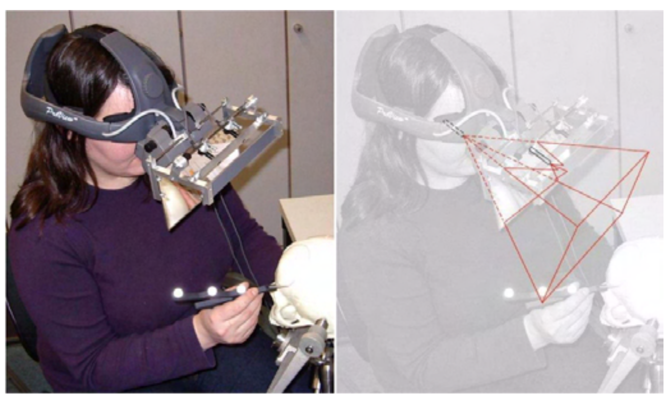


Figure 8: User based evaluation of eye-hand coordination in case of different video-see-through HMD system configurations

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