

Medical Engineering Faculty of Mechanical Engineering

# Innovative Technology for Smart Therapy

## Director

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# RNTHAACHEN UNIVERSITY



#### Helmholtz-Institute for Biomedical Engineering, RWTH Aachen University

#### 2006

### Introduction

The Chair of Medical Engineering (mediTEC) of the Faculty of Mechanical Engineering of the RWTH Aachen University is especially engaged in basic research issues as well as application oriented aspects of computer assisted and model driven therapy systems engineering. In this context the activities are focused on the following areas: image and information processing as an essential basis for computer assisted therapy planning, biomechanical modelling and simulation, surgical navigation and robotics, sensor-integrated medical instruments ("smart instruments") and ultrasound technology. Furthermore, significant research activities are concerning ergonomics and usability engineering in medicine. Apart from technology oriented R&D partnerships of mediTEC, our Center for Medical Product Usability (CeMPEG) provides Usability Engineering and evaluation services for companies (in the context of development and market approval) as well as for medical partners (looking for a comparative evaluation of the ergonomic quality and usability of medical products). Actual projects in the domain of Orthopaedic and Trauma Surgery, Neurosurgery, General Endoscopic Surgery, Interventional Radiology, Maxillofacial Surgery, Dental Therapy and Rehabilitation are ranging from requirement analysis and market surveys, feasibility studies (proof of concept) and system development to usability analysis and clinical field tests. Among these projects, the OrthoMIT project (minimal invasive orthopaedic therapy) funded by the German Federal Ministry of Education and Research - BMBF (7/2005-3/2010; 25 Partners; overall funding 12,5 M€) currently represents one of the most exciting R&D challenges of mediTEC.

#### Image and Information Processing

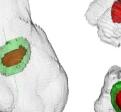
Modeling and employment of a priori knowledge is an essential aspect of medical image processing. Knowledge-driven segmentation algorithms potentially provide an enhanced image understanding, an unsupervised performance and an improved robustness. Segmentation of calvarial tumors from CT image data as a basis for operation planning in neurosurgery is a typical instance for a beneficial application of knowledge-based medical image processing. Calvarial tumors exhibit weak borders posing difficulties if the segmentation is performed with standard algorithms. We implemented and tested an active shape approach guided with a priori tumor probabilities and imagespecific edge information [1,2]. The algorithm has been trained on the images with manually delineated tumors Clinical validation of the results has demonstrated that the automatic algorithm accuracy is in the range of the inter-expert rater variability. Moreover, we developed an automatic parameter scanning and optimization framework, including algorithms for statistical computation of a reference segmentation and parameter selection.

#### Figure 1: Model based calvarial tumor segmentation using active shapes

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Hip resurfacing represents an alternative to total hip arthroplasty particularly relevant for young and active patients. The major objective is the

preservation of the intact femoral





bone that consequently improves the prognosis for future hip surgeries. However, the exact placement of the implant components is time-consuming and requires enlarged surgical access and experience as well as careful handling of the alignment devices. To increase the reliability and to reduce the invasiveness of the implantation procedure, we developed a fluoroscopy based method and system for the identification of the relevant anatomical structures and the subsequent interactive navigation for an optimal implant alignment. In cadaver studies the feasibility and effectiveness of this approach and its implementation in a clinical setting have been demonstrated (Fig. 2, [9]).



Figure 2: Preclinical cadaver study on fluoroscopic navigation for hip resurfacing surgery

# Sensor Based Marker Free X-Ray Calibration

In fluoroscopic navigation calibration is mandatory in order to compensate geometric distortions. Conventional calibration phantoms reduce the effective work space of the C-arm system and rely on overlaying markers in the intraoperative images. Using a tracking system and magnetic field sensors, an online compensation of distortions can be achieved without the need of an intraoperative calibration cage. Based on an initial system calibration (which has to be performed once per system), the model is able to predict the distortions caused by the measured magnetic field vector and to calculate an appropriate dewarping function. In first tests, the model was able to predict and compensate distortions by approximately 80% to a remaining error of 0.45 mm MAX 0.19 mm RMS in less than 1 sec intraoperatively [10].



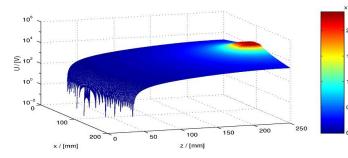


Figure 3: Simulation of the electrical field distribution of an image intensifier

### Individualized Image-Based Modelling of Musculo-Skeletal Deformities

Preoperative analysis of the gleno-humeral joint and the surrounding muscles based on MRI is mandatory for decision making prior to structural and functional surgery of the dysplastic shoulder. Based on deformable morphological and functional modelling using image data, a priori knowledge and other functional information, a patient-specific reconstruction and adaptation of a shape model that describes the gleno-humeral joint deformity together with muscular structures as well as biomechanical functional properties of these specific structures can be generated (Fig. 4). A functional analysis can incorporate the derived morphological properties along with information provided by the consideration of pathological aspects such as joint congruency and unbalanced performance of related muscles. Consequently such individualized models could substantially support the analysis of the potential genesis of the deformity, an individualized pre-operative surgical planning, simulation of the consequences and an estimation of the improvement of the expected functionality [3].

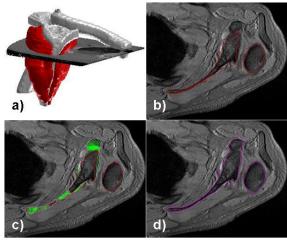


Figure 4: MR image-based individualized modelling of the dysplastic shoulder: a) Reference model, b) Coarse Registration of the reference model with patient image, c) Model adaptation, d) Patient specific model

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#### Biomechanics, Planning and Navigation of Complex Correction Osteotomies

The spatial planning and realization of corrective osteotomies on lower extremities including the correct alignment of the bone fragments require special skills and experience from the surgeon. A new approach towards computer assisted intra-operative biomechanical analysis, planning and navigation is being developed in the framework of the OrthoMIT project. Based on an intraoperative acquisition of relevant anatomical and functional information (X-ray imaging, kinematic analysis, definition of relevant biomechanical parameters, surgical preferences and approaches), the system automatically calculates optimal single- or double-cut oblique osteotomies, including the simulation of an appropriate osteosynthesis. Moreover, the transfer and control of osteotomies and osteosynthesis is supported by navigation tools.

### Evaluation of the CRANIO-System for Computer and Robot Aided Craniectomy

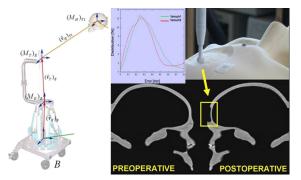


Figure 5: Evaluation of the overall CRANIO system accuracy

The resection of cranial tumors followed by the insertion of prefabricated individual craniofacial implants demands a precise resection of the tumorous skull bone. The CRANIO-system developed at our Institute integrates CT-based planning and navigation modules along with a surgical robot system based on a Stewart-Gough platform and a dedicated safety hardware and software architecture [5,6]. Laboratory phantom studies have been performed to assess the overall system accuracy (e.g. CT resolution, milling path generation, registration etc.). Direct measurements as well as postoperative CT scans of defined remaining bone layers of 1 mm confirmed an overall system accuracy of higher than 1 mm. Spatial overlaps between planned and registered postoperative resection volumes were higher than 95%. Apart from the limited CT-image resolution, patient registration as well as intra-operative tool calibration based on optical tracking technology were identified 2006

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as major sources of error. Therefore, alternative tracking approaches, new algorithms for accurate, robust and minimal invasive registration as well as enhanced precalibrated robot tool adapters, avoiding tool calibration with an optical tracking system, have been further topics of our research. Anatomic studies comprising the entire resection process were successfully conducted in a clinical environment. Moreover, our work on a knowledge-based computer assisted design of craniofacial implants has been continued (see [7] for more details). The approval of the system for first clinical studies is an essential objective of our ongoing work.

### Ultrasound Based 3D-Reconstruction of Intra-Femoral Bone Cement in RTHR

The detection of the 3D cement-bone interface in Revision Total Hip Replacement (RTHR) for the removal of bone cement is a challenging task in Orthopaedic Surgery. In the framework of the OrthoMIT project we implemented an automatic detection and 3D surface reconstruction of the cement-bone boundary using intraluminal A-mode ultrasound. We developed a prototype system of a specialized intra-luminal ultrasound system, capable of full 360° rotation and axial movement inside the femoral cavity, using a miniaturized, high bandwidth mirror probe (Fig.6). For optimizing the ultrasound penetration depth and spatial resolution of the system, coded signal excitation and compression filter signal processing have been considered [4]. First ex vivo trials showed promising results (Fig.4b). An integration of the miniaturized ultrasound probe into the OrthoMIT robotic micro-mill-

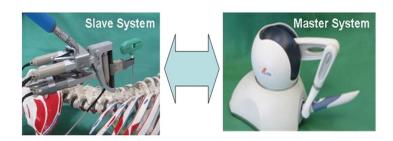
ing module is one topic of our ongoing work.



Figure 6: First lab prototype of the intra-femoral ultrasound device (left) and related ultrasound based 3D-reconstruction of the femoral bone and bone cement

#### **Modular Surgical Mini-Robotics**

In the framework of the OrthoMIT project, the concept of an autoclavable modular mini-robot for different interventions in spine, hip and knee surgery is under development, based on previous hybrid surgical robot systems developed at our Institute. The kinematic structure of the MINARO system is a planar five-bar parallel linkage mechanism with optional linear drives. Starting from this basic kinematic structure, a modular concept for other applications (4-7 DOF) is under development.



#### Figure 7: Initial experimental laboratory set-up of a master-slave system (3 DOF master device to control the motion of a 5-6 DOF slave robot device in different sequences of operation)

One of the main problems of current tele-operated medical robotics is the loss of tactile and haptic information and the change of senso-motoric coordination compared to traditional open surgery. Haptic devices help to extend the medical robot's capability in transmitting sensation (real or simulated) of the surgical site to the surgeon. We investigated different types of control architectures and application scenarios [12]. In the framework of the OrthoMIT project, we investigate the use of a tele-manipulator for CT-guided interventional spine applications (e.g. for biopsy, radiofrequency ablation, vertebroplasty/kyphoplasty and discography) in cooperation with AME/HIA [11]. The aim is to reduce the time-of-intervention and the patient's and physician's exposure to radiation as well as to open the door towards new interventional procedures.

#### Development of Modular Integrated Surgical Work Station

A major objective of our work related to an integrated surgical work station (ISWS) is an enhanced information exchange and workflow within the OR and its clinical environment. Due to an increasing number of technical devices and systems in the OR, the integration and reduction of different human-machine-interfaces and related devices is crucial. An analysis of commercial ISWS systems has been carried out to identify common features, differences and bottlenecks. Based on this analysis a new concept for an integrated modular surgical work system has been developed in the framework of the OrthoMIT project (Fig. 8). Using a serviceoriented architecture (SOA), resources are available as independent services that can be accessed via network, enabling high flexibility for the integration of different surgical modules depending on the individual case and application [8].

# Ergonomic Evaluation and Usability Engineering in Medicine

The usability of medical devices is a crucial factor for patient safety as well as for systems effectiveness and efficiency in daily clinical routine. The development and analysis of surgical assistance systems and robotic manipulator systems is a typical instance for our work in this domain. In the context of endoscopically assisted and microscopic surgery we systematically analysed performance shaping factors (PSFs) such as modes of visualisation (e.g. stereoscopic visualisation with HMDs), the impact of vibration, working postures, man-machine interface devices, work-flow and related boundary conditions. Clinical usability testing of systems is carried out in laboratory setups as well as in field tests in close cooperation with our clinical partners. Apart from the evaluation of existing systems, these findings are used for the development and optimization of new technical concepts and devices [12].

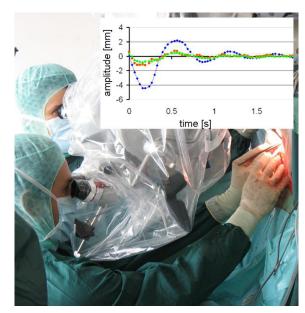
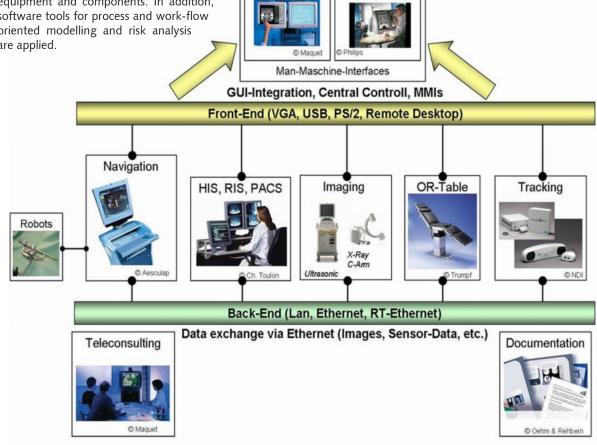


Figure 9: Ergonomic analysis of microscopic devices and related working conditions

CAD based simulation environments and anthropometric man models (Anthropos, RAMSIS) are used for

an early assessment and the optimization of an intraoperative system-design, for the assessment of working posture and patient positioning strategies or the setup of equipment and components. In addition, software tools for process and work-flow oriented modelling and risk analysis are applied.



Central Displays

MMI (e.g. Speech

Recognition)

Figure 8: Concept for the integrated OrthoMIT workstation

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#### Team

