



Chair of Medical Engineering
Faculty of Mechanical Engineering

Innovative Technology for Smart Therapy

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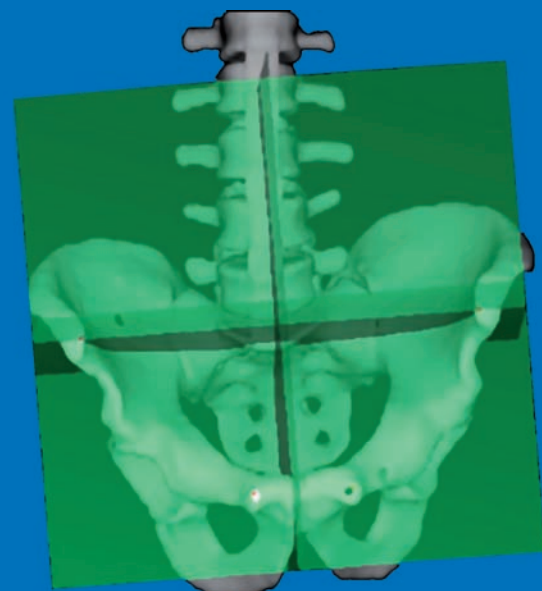
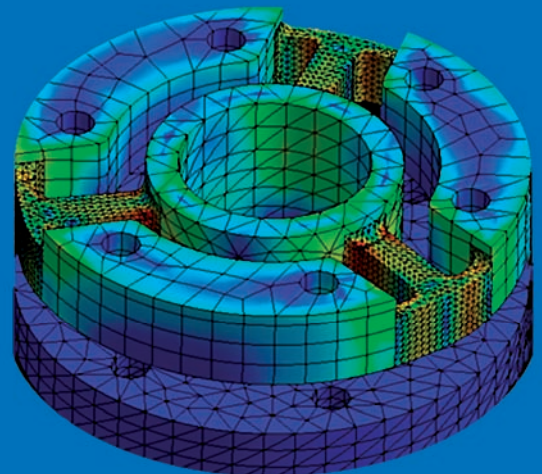
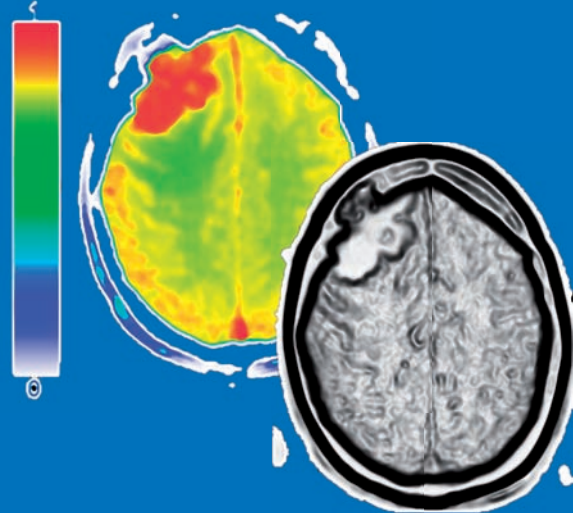
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Introduction

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"), ultrasound technology, man-machine interaction and risk management in medical systems. Actual projects in the domain of Orthopaedic and Trauma Surgery, Neurosurgery, General Endoscopic Surgery, Cardiology, Interventional Radiology, Maxillofacial Surgery, Dental Therapy and Rehabilitation Engineering 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 (7/2005-6/2010; 25 Partners; overall funding ca. 15 M€) currently represents one of the most exciting R&D challenges of mediTEC. In addition to 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).

Individualized Modelling of the Dysplastic Shoulder

Reconstructive surgery in severe upper limb nerve injuries in children requires exact MRI (Magnetic Resonance Imaging) based planning. Preoperative model based

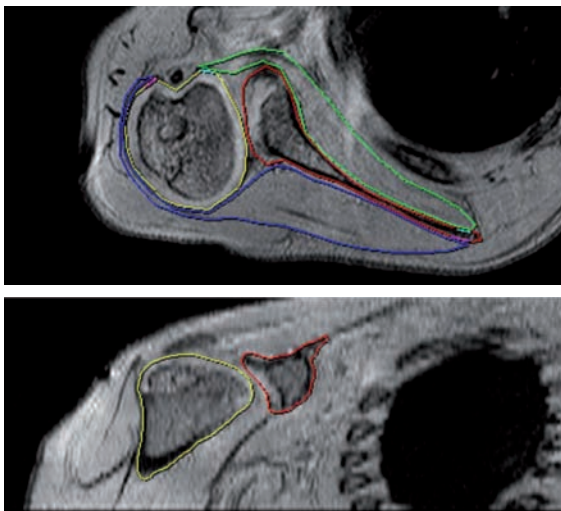


Fig. 1: MRI-based patient-specific modelling of deformities

analysis of the individual gleno-humeral joint and the surrounding muscles is mandatory for decision making prior to structural and functional surgery of the dysplastic shoulder. The essential step towards a patient-specific biomechanical model is the reconstruction of a deformable shape model that describes the gleno-humeral joint morphology and deformity. This is the basis for subsequent functional analysis incorporating the derived morphological properties along with model based information on muscle activities and pathological aspects such as joint congruency and the unbalanced performance of the related muscles.

Computer and Robot Assisted Individual Craniofacial Reconstruction

The performance of the CRANIO-System for resection of cranial tumors and the insertion of prefabricated implants have been evaluated in ongoing laboratory and cadaver studies. Force-control has been implemented to increase system safety as well as efficiency and accuracy.

A-mode ultrasound permits the non-invasive intra-operative registration of pre-operative CT data. New robust surface-based registration algorithms have been implemented and tested. Furthermore, tools for time efficient probe alignment have been developed and tested in cadaver studies. To extend the scope of operation of the CRANIO system further modules e.g. for milling of cochlea implant cavities and other milling operations have been implemented and tested. Moreover, a novel synergistic approach towards a robot supported craniotomy has been developed. The resection of the bone flap is performed hands-on by the surgeon using a robot-mounted craniotome. Force and position control is provided by the system adapting to the surgeon's commands.

The use of CT data and CAD/CAM systems for the reconstruction of skull defects is already established. However, the related procedures are both time-consuming and cost-intensive.

A surgical planning module for knowledge-based reconstruction of skull defects has been developed. The novel semi-automatic approach to individual implant design is based on patient specific reference models. Even for bilateral skull defects an implant can be efficiently generated based on skull geometries derived from case data bases, adaptive registration and deformable modelling approaches. The method has been successfully evaluated by simulating the reconstruction of the artificially generated defects.

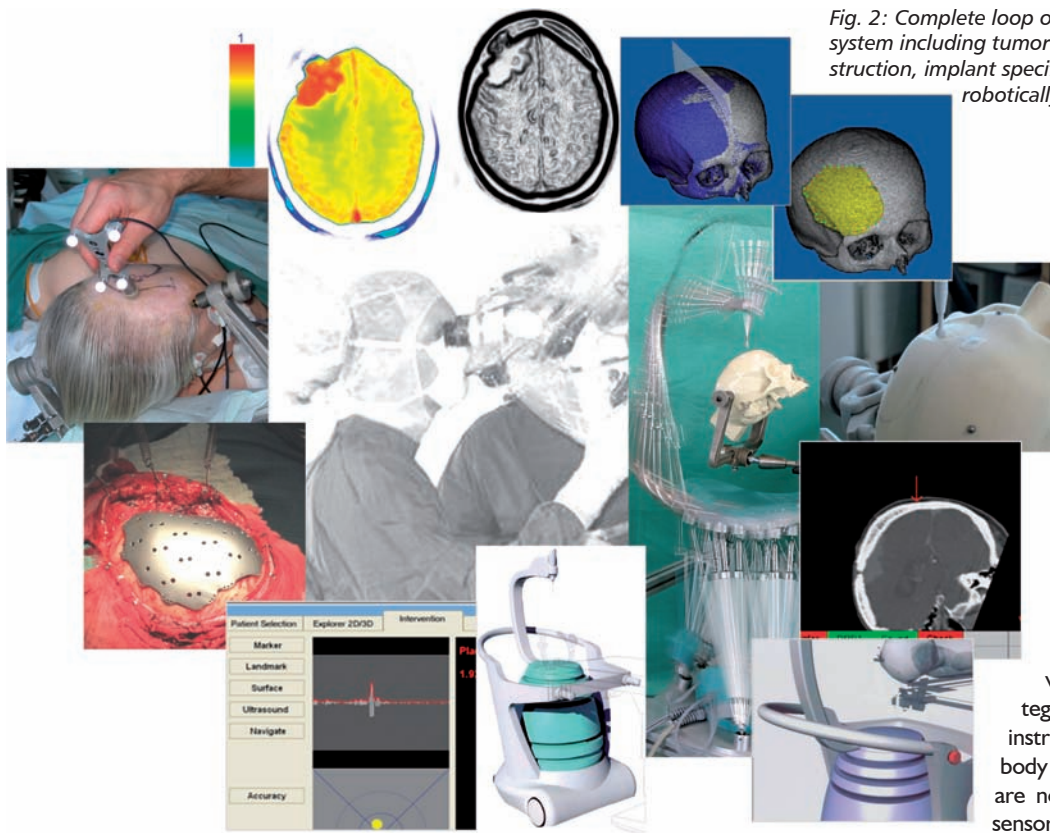


Fig. 2: Complete loop of application of the CRANIO system including tumor segmentation, surface reconstruction, implant specification, patient registration and robotically assisted milling

GenAlign – A New Approach to Smart Knee- Surgery

Successful reconstruction of the mechanical axis (Mikulicz-line) as well as appropriate ligament balancing are crucial elements in knee replacement surgery. The genAlign (Patent pending) system concept is based on direct measurement of instability and forces in the knee. A new autoclavable force-torque-sensor is integrated into the novel navigation instrument. Thus, conventional rigid body references and tracking systems are no more necessary. Moreover, a sensor-integrated tibia inlay provides intraoperative information for effective ligament balancing according to the individual requirements.

Model Driven Functional Planning in Lower Limb Surgery

Advanced surgical planning of interventions on the musculoskeletal system not only requires the consideration of individual morphological models. Adaptive functional modeling for patient specific therapy planning on the basis of image data and biomechanical analysis is crucial in less invasive effective orthopedic surgery. The combination of static and dynamic functional outcome simulations prior to and during surgery provides important information for the definition of an optimal surgical strategy. Biomechanical evaluation of the influence of different operative strategies on joint reaction forces as well as on soft tissue structures provide early feedback related to the potential functional outcome, rehabilitation strategies as well as potential impacts on implant life time.

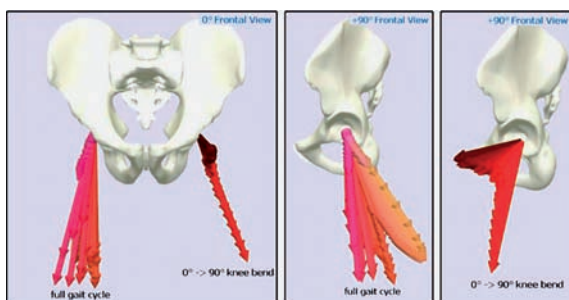


Fig. 3: Joint reaction forces calculated from different body movement simulations

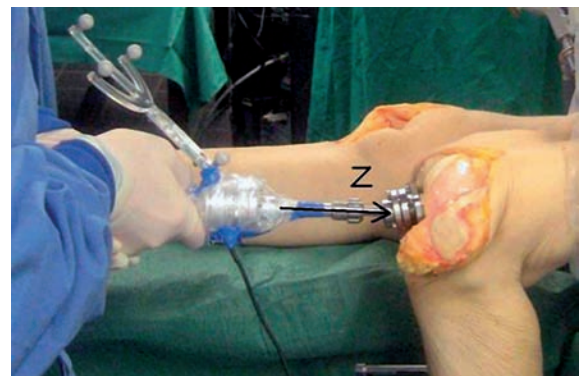


Fig. 4: GenAlign system during application in cadaver study (rigid bodies for optical tracking are used for evaluation purpose only).

Fig. 5: Prototype of the Sensor-Integrated Tibia Inlay



Intraoral Data Acquisition (IDA) Using Ultrasound

Today, crowns and bridges are produced by use of gypsum plasters which are conventionally casted. In practice, this method needs a lot of time and leads to non-conformities. CAD/CAM technologies and automatic geometry

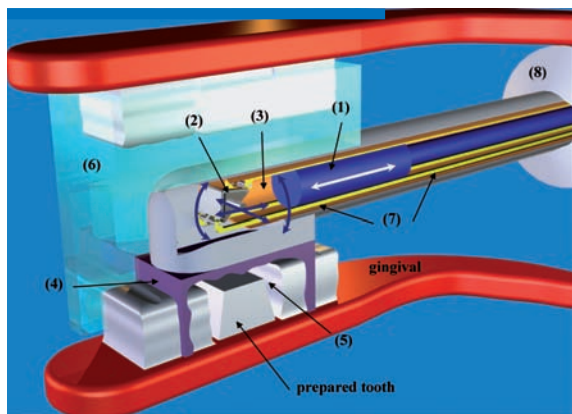


Fig. 6: Intraoral microscanner: probe (1), mirror (2), water supply (3), connection (4), gel coupling (5), bite splint as counter bearing (6), micro-mechatronics (7,8)

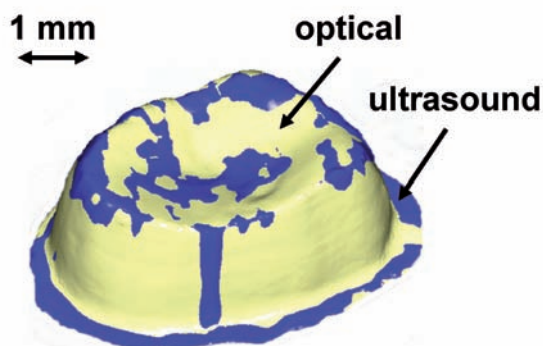


Fig. 7: Prepared tooth digitized optically and by ultrasound

digitization offer higher efficiency and accuracy in the production of fixed prostheses. However, intraoral digitization using optical systems is limited to supra-gingival geometries of prepared teeth and is also influenced by saliva, soft tissue and blood. A miniaturized intraoral ultrasound scanner potentially eliminates these drawbacks in a cost efficient way. Initial feasibility studies have been conducted successfully with our clinical partners. Key technology of this new approach developed in our lab includes specialised ultrasound hard- and software as well as an intraoral micro-scanner system. (Patent pending)

Efficient Dose Reduction in C-Arm Based X-Ray Imaging and Navigation

In conventional surgery and x-ray image based navigation, a huge number of x-ray images taken during surgery can not be used due to insufficient visibility of the target structures. Common reasons are the lack of targeting aids and the limited direct view on structures that are visible by x-ray only. Furthermore, in 2D-fluoroscopic navigation the achievable accuracy strongly depends on the orientation and the correlation between the acquired multiplanar images.

Using a simple and rough registration of the local anatomy, for example by palpation of three anatomical landmarks

and a non-uniform matching of a statistical model of the target structure, a virtual x-ray preview image can be displayed in real-time without the use of x-ray radiation by measuring the relative position of the structure to the x-ray device. Initial studies showed a potential dose reduction of 40-80% depending on the type of operation.

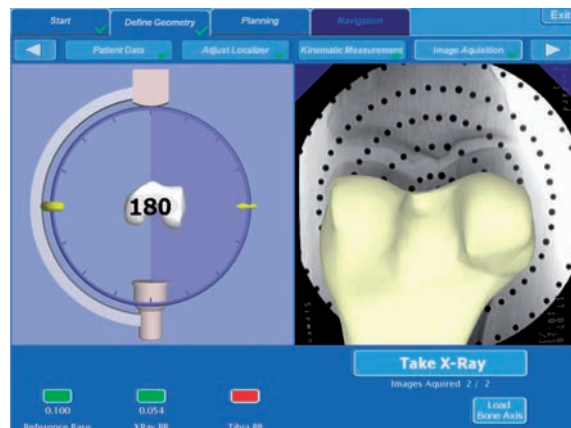


Fig. 8: X-ray dose reduction based on statistical model (r.) and C-arm navigation graphics (l.).

MINARO - A Modular, Flexible Minirobot for Surgery

During the last 20 years various robots for surgical applications have been introduced to the operation room. Those robots were mostly based on off the shelf rail industrial robots (e.g. SCARA) with considerable changes for increased

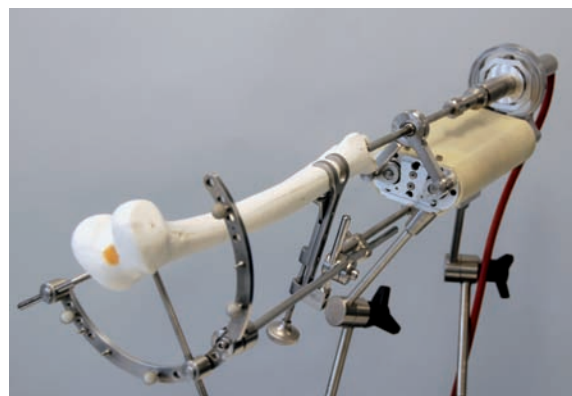


Fig. 9: MINARO minirobot milling femoral cavity for implant in total hip arthroplasty (lab setup)

robot safety and special medical requirements. However, the change from conventional towards robot-assisted surgery made little progress because these systems often showed disadvantages regarding usability, function and costs. On the other hand many different tailor-made systems for specific surgical applications have been introduced. In contrast, MINARO represents a new modular concept enabling a very easy, low-cost and flexible adaptation of a basic 5 DOF mini-robot system to different surgical applications, such as milling of bone cement in revision total hip replacement, joint surface shaping in total knee arthroplasty or tele-manipulation of instruments and endoscopes e.g. in laparoscopic surgery.

Man-Machine-Interfaces for Neurosurgery

As video-based analyses of neurosurgical interventions have shown that up to 20% of the operation time is consumed by manual positioning of the microscope a digital surgical microscope ("exoscope") manipulator and an endoscope mini-manipulator have been developed. In this framework a stereoscopic Head-Mounted Display (HMD) is used for visualisation of the respective video images. Freehand operation of the manipulator systems is provided by a novel combination of headtracking and voice control. In this context the ergonomic quality and safety of the complex mul-

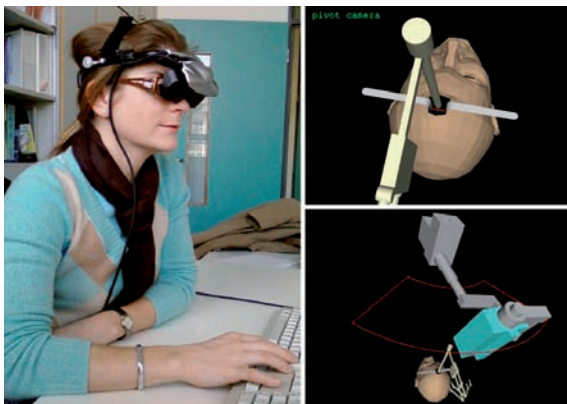


Fig. 10: User test involving representation of virtual scene via HMD (l.), simulated surgical task including endoscope and exoscope manipulator (r.)

timodal man-system-interaction is one of the key issues to be addressed. In order to support the flexible development and evaluation of optimized interaction concepts a virtual reality simulation has been implemented. It allows for investigation of system performance during view adjustment tasks with systematic variation of the control parameters. The simulation-based analysis of objective and subjective performance and task load determined in user tests showed significant differences between certain parameter settings and supported the optimization of these parameters.

Knowledge-Based OR Table Positioning Assistant

Unsuitable static working postures are generally considered to be a crucial factor for most work-related musculoskeletal disorders. Non-ergonomic working postures lead to additional stress, strain and increased risk for patient and operating personnel. Based on a video-supported timeline-analysis of different orthopaedic interventions, specific work- and posture-phases together with dedicated task-specifications were identified. The working postures were rated with regard to their potential level of induced stress using standardized posture scales (OWAS, RULA). Based on these findings, an expert-system for individualised task-, surgeon- and patient-specific positioning of the OR-table was developed and realized in a labtype. This 'virtual ergonomic assistant' provides the surgeon with suggestions regarding situatively optimized positioning of the OR table. If the suggestion is accepted, the



Fig. 11: Non-ergonomic static working postures in orthopedic surgery

system automatically moves the OR table to the calculated position under permanent control by the surgeon.

Approach Towards Open and Modular Integrated Surgical Workstations

In the framework of the OrthoMIT project, a concept of a modular and flexible integrated surgical work system based on the service oriented architecture (SOA) paradigm is currently developed. Using SOA, resources are available as independent services which can be accessed via network, enabling high flexibility for the integration of different surgical modules depending on the individual case and application. Due to the intended interconnection of originally independent medical devices risk-analysis and -management are of crucial importance during the development and realization of such an integration architecture for medical applications. The upcoming IEC 80001 standard (on the application of risk management for IT-Networks incorporating medical devices) specially focuses on these problems. The OrthoMIT concept has been officially accepted as a proposed example of use for IEC 80001.

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Awards

- M. Engelhardt, A. Follmann, K. Radermacher and K. Schmieder: Winner of "BMBF-Innovationswettbewerb Medizintechnik" with the contribution "Intelligent Sawing Tool for safe Trepanation" (together with Clinic for Neurosurgery, Ruhr-University Bochum)
- R. Elfring and K. Radermacher: Third Place in the Competition "Hochschulwettbewerb Patente Erfinder" for the Invention "genALIGN".

Selected Publications

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Team

