



Chair of Medical Engineering  
Faculty of Mechanical Engineering

# Innovative Technology for Smart Therapy

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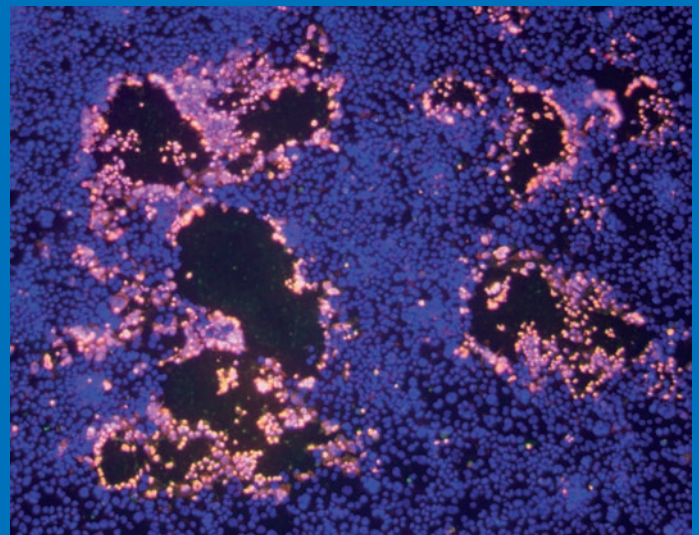
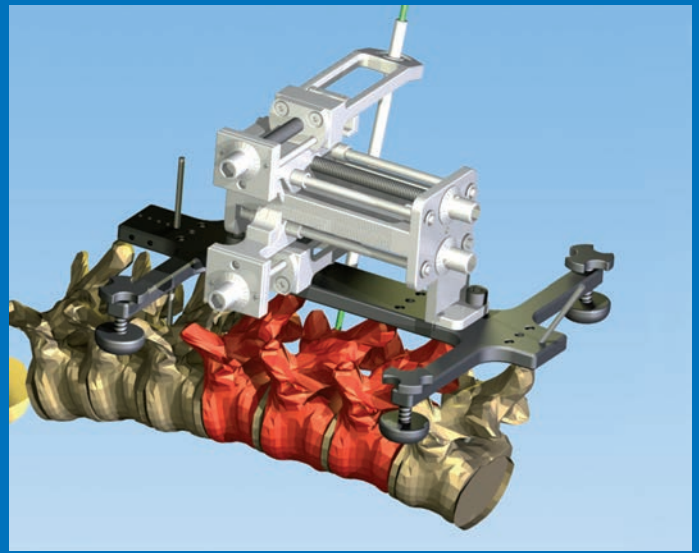
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## Introduction

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 diagnosis and model guided therapy systems engineering. In this context the activities are concentrated on the following areas: image, signal and information processing as an essential basis for computer assisted model-based therapy planning, biomechanical modeling and simulation, surgical navigation and robotics, smart mechatronic instruments and devices, ultrasound technology and medical shock waves as well as ergonomics and safety in medicine.

Actual projects in the domain of Orthopedic and Trauma Surgery, Neurosurgery, General Endoscopic Surgery, Cardiology, Interventional Radiology, Maxillofacial Surgery, Dental Therapy and Rehabilitation are ranging from feasibility studies (proof of concept) and system development to usability analyses and clinical field tests. The OrthoMIT project (minimal invasive orthopedic therapy; 7/2005-6/2010; 24 partners; 14.5 M€ overall funding by the German Federal Ministry of Education and Research – BMBF) continues to be one major framework of our research activities. Additionally, various new research grants and industrial cooperation related to basic research issues as well as innovative application oriented concepts and patent applications have been established. As in 2007 and 2008, in 2009 our team again received the *Medical Technology Innovation Award* of the German Federal Ministry of Education and Research (BMBF) for a novel approach in computer assisted surgical instrument control.

Based on our long-standing research activities on ergonomics in medicine, we established a portfolio of tools and methods for usability engineering of medical products. Especially the application of our new method and software tool mAIXuse for human error risk analysis received a very positive response in cooperation with various industrial partners.

## Individualized Biomechanical Modeling

Surgical treatment of pathological deformities and functional limitations of complex musculo-skeletal structures such as the shoulder or the hip requires a reliable and customized preoperative analysis of the joint morphology and functionality. Currently, in many cases intervention planning is performed based on X-ray projections. Consequently, many clinically established biomechanical models are based on 2D X-ray imaging. However, the transfer of 2D-model parameters from individual image sets into 3D-biomechanical analysis is critical. Clinical surveys with medical experts demonstrate a high variability in visual identification of individual model parameters in X-ray images (Fig. 1). Associated mathematical analyses show a significant influence of these inaccuracies on the model output and hence on the quality of the planning result. Due to these findings, the development of more reliable approaches for the identification of individual parameters and their transfer into individualized biomechanical 3D-models is one major objective of our work.

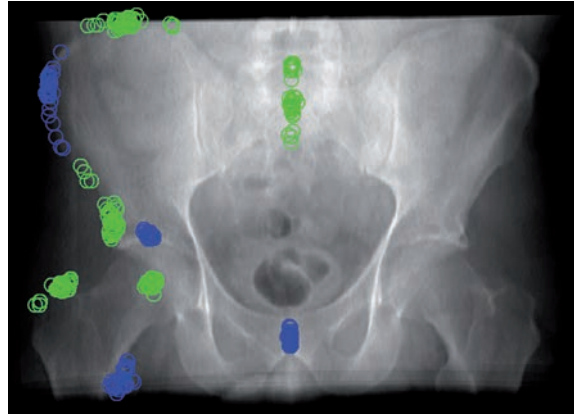


Fig. 1: Variability analysis in parameter identification on 2D-X-ray images.

Apart from CT- and ultrasound-based approaches, dedicated methods using magnetic resonance imaging data have been developed for the customization of musculo-skeletal 3D-models. Individualized patient-specific models derived from these data potentially deliver valuable morphological and functional preoperative feedback and allow for an estimation and optimization of the surgical outcome (Fig. 2).

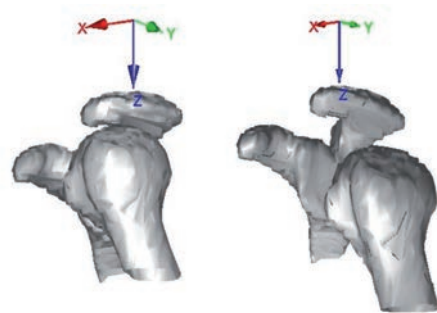


Fig. 2: Model-based biomechanical morphing simulating shoulder deformities.

## A Novel 6DOF Fixateur Externe System for Gradual Corrections of Long-Bone Deformities

Gradual corrections are an established method in order to correct long-bone deformities and to restore physiological biomechanical joint load conditions. In the framework of a feasibility study, an alternative design concept for a Fixateur Externe system has been realized. Therefore, the requirements of the main clinical applications in trauma

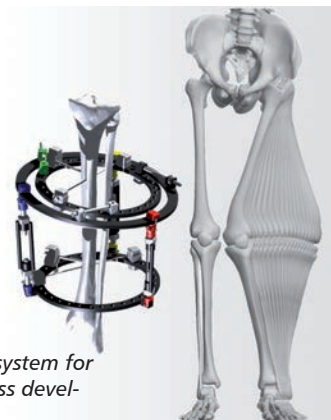


Fig. 3: Fixateur Externe system for gradual corrections in less developed countries (LDCs).



and orthopedic surgery, the biomechanical constraints of long bone gradual corrections as well as the specific boundary conditions regarding manufacturing in less developed countries (LDCs) have been taken into account. In these countries, common systems often are not available due to their high costs. As a consequence the main objective of this project was the development of a novel versatile system that can be manufactured under simple, low-cost conditions.

## Smart Spine Navigation

Based on our Zero-Dose X-ray navigation approach an efficient dose reduction can be achieved in computer assisted navigation systems by using patient individualized deformable models. After a successful evaluation of the system on lower extremities, our efforts now have been extended towards spine applications, with an even higher potential for efficient dose reduction and increased safety.

Due to higher anatomical complexity and the presence of sensible structures nearby, new registration methods and dedicated user guidance are necessary. The new Zero-Dose spine module will be an essential basis for the upcoming SpinePilot project starting in 2010.

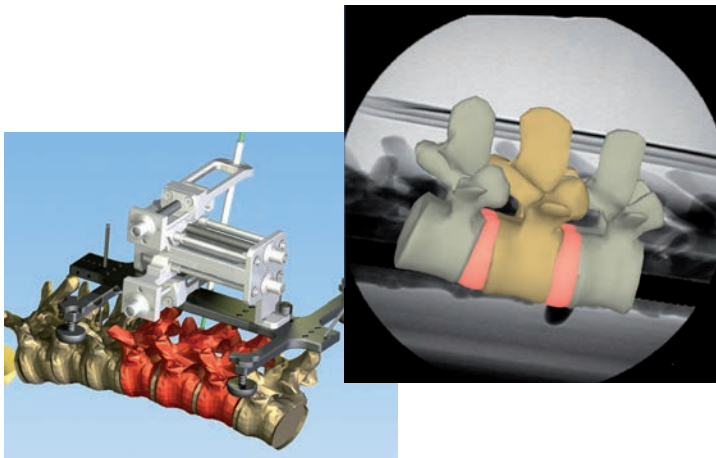


Fig. 4: Concept study of a mechatronic system for spine surgery using the Zero-Dose X-ray navigation approach.

## Protection of Dura Mater Using a Smart Trepan

A semiautomatic trepanation system (Smart Trepan) based on a new soft tissue preserving saw and an autonomous control of the cutting depth has been developed for minimal invasive skull surgery.

The protection of the dura mater and a minimized cutting gap are the major objectives of this project. The synergistic control concept of the Smart Trepan System (STS) combines the accuracy and time efficiency of a computer controlled device with the surgeon's experience and cognitive capabilities.

Usability and safety of the semiautomatic handheld device are of utmost importance. Therefore, prospective risk and usability analysis based on our mAIXuse technique have

been carried out. Additionally, user-centered usability tests have been performed.

Furthermore, an extensive parameter study of the sawing process was carried out. In laboratory trials the impact of these parameters on the soft tissue preserving capabilities of the saw, the cutting efficiency and the manual control of the instrument were systematically investigated.

Based on the results of these studies the STS-system was built up consisting of the planning system, the real-time control unit and the semiautomatic instrument itself. Ongoing research is focused on preclinical and clinical studies demonstrating the system's overall performance.

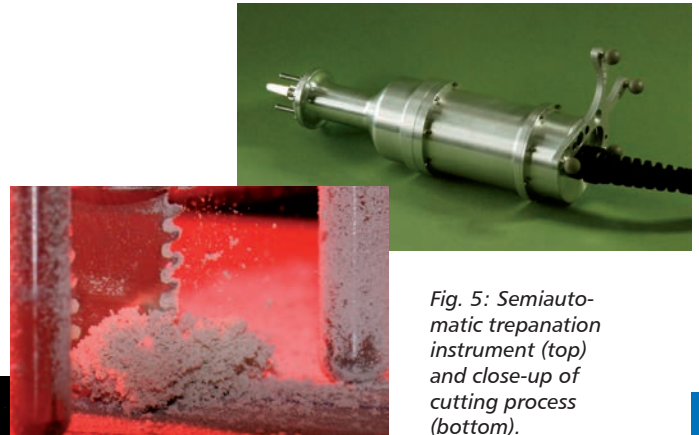


Fig. 5: Semiautomatic trepanation instrument (top) and close-up of cutting process (bottom).

## Modular Minirobot

Surgical instruments have to meet strict hygienic demands. Hence, specific sterility requirements as well as potential risks related to hygienic reprocessing have to be considered regarding the instrumental design.

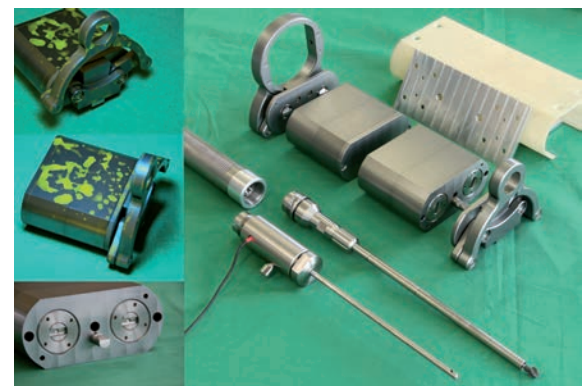


Fig. 6: Modular structure of the MINARO-System with basic modules, application-specific kinematic modules and two instrument modules (right) and modules "contaminated" with a fluorescent fluid during cleanability study (left).

At the Chair of Medical Engineering a fully sterilizable modular minirobot (MINARO) is developed. The modular structure allows for easy adaptation to different orthopedic as well as non-orthopedic applications. During the design of the system the influence of reprocessing on

the robotic functions and the reliable cleanability were reviewed.

To analyze its cleanability the robot was “contaminated” by a fluorescent fluid and cleaned in a standardized automatic decontamination process. As a result of the evaluation potential hygienic risks related to the robot design could be identified.

## iShunt – an Intelligent Mechatronic Implant for the Therapy of Hydrocephalus

The human brain is surrounded by an aqueous fluid. In case of hydrocephalus, the inner fluid chambers are enlarged and the intracranial pressure is severely raised, leading to brain damage if untreated. The common therapy is the implantation of so called shunt systems, which regulate the intracranial pressure by controlled drainage of liquor. Until now there are no mechatronic shunt systems available that allow for automatic adjustment of drainage to physiological conditions. Thus, over- and under-drainage often occur due to false opening pressures leading to brain damage and pain for the patient. The major objectives of the iShunt project, initiated by the Chair of Medical Information Technology of our institute, are the development and evaluation of new concepts for mechatronic shunt systems. In the context of this project, our team is especially responsible for the development of the mechatronic valve systems and components.

to avoid complications and to ensure an appropriate treatment, an early and reliable diagnosis is essential. Until now, there are no objective and reliable non-invasive diagnostic methods available. In the context of this research project, new non-invasive methods for the diagnosis of an imminent compartment syndrome are developed and evaluated.

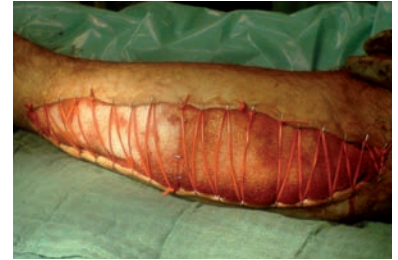


Fig. 8: Fasciotomy in case of a compartment syndrome.

## IDA – Intraoral Data Acquisition Using Ultrasound Micro-Scanning

The conventional manufacturing process of dental prostheses based on casted gypsum plasters is error-prone, time consuming and expensive. CAD/CAM based optical scanners have been launched for extra-oral or intra-oral digitization of prepared teeth promising high accuracy and more comfort for the patients. Nevertheless, sub-gingival preparations cannot be scanned by optical systems without the exposure of the preparation boundaries, and blood and saliva influence the accuracy of the digitization. Moreover, unintentional reflections, e.g. from the dentin layer, have to be compensated by applying powder on the teeth which yields additional error sources and expenses.



Fig. 9: First laboratory study of the IDA concept.

The objective of the interdisciplinary IDA-project is the development of an ultrasound-based intraoral micro-scanner, replacing the conventional casting process without the drawbacks of current optical scanners.

Ultrasound is able to pass soft tissue, blood as well as saliva and does not use ionizing radiation. The patented concept of the micro-scanner consists of a cost-efficient high frequency transducer and a mechanically mounted five degrees of freedom (DOF) micro-reflector. The kinematic design, the ultrasound hardware as well as the signal and image processing are major foci of the project. The IDA-project is the winner of the “Medical Technology Innovation Award” (2008) funded by the German Federal Ministry of Education and Research (BMBF).

## Haptics in Computer Assisted Surgery

CT-based pin-point procedures in the spine area require high accuracy and human expertise. The success of these procedures mainly depends on visual and haptic cues and is strongly related to the individual experience and skills of the physician. To reduce radiation exposure of the patients

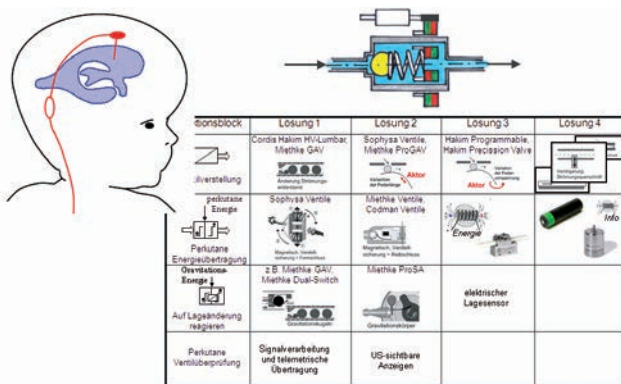


Fig. 7: Principle of an implanted shunt valve together with conceptual studies on potential design solutions.

## Non-Invasive Diagnosis of an Imminent Compartment Syndrome

The compartment syndrome, an enormous pressure increase in a muscle compartment, is one of the most common traumatological complications in case of fractured extremities, leading to a severe blockage of microcirculation. Common therapy consists of a fasciotomy, where the affected member is surgically opened on its whole length and kept open until the pressure has decreased (Fig. 8). In order



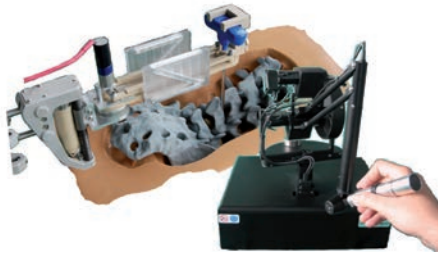


Fig. 10: CT-based pin-point tele-haptic manipulator.

and physicians as well as to optimize the workflow, a miniaturized master-slave tele-manipulator for interventional radiology is currently being developed. The slave-manipulator is controlled by a master device with force feedback (Phantom 1.5 6-DOF High-Force) enabling a hybrid image- and force-based navigation and motion control of the slave manipulator during needle placement. Hence, repeated CT-scans potentially can be avoided.

## Myocardial Vitality Assessment

For patients with low left ventricular ejection fraction, a precise differentiation of vital and avital myocardial tissue is therapeutically and prognostically very important. At present, cardiac MRT is the gold standard of this process. However, its clinical application is limited due to time loss, high costs and limited availability. In a pilot study, the feasibility of using cardiac shock waves to activate hibernating myocardial tissue and the use of 2D-Strain Ultrasound analysis to detect the change of cardiac contraction is analyzed in in-vitro experiments in cooperation with the Clinic for Anesthesiology, Clinic for Internal Medicine I (both University Hospital Aachen) and the Shock Wave Laboratory Aachen.

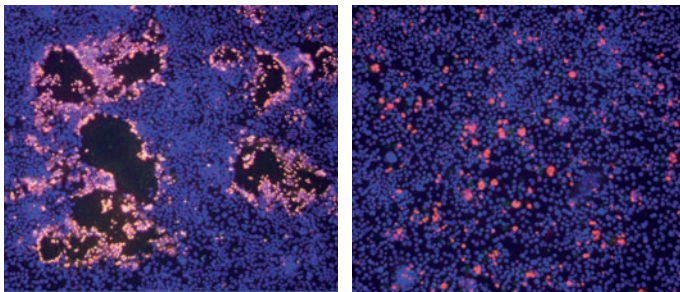


Fig. 11: Fluorescence microscopy following shock wave application.

## Risk Management of Integrated Surgical Work Systems

In the OrthoMIT project, a concept of a modular and flexible integrated surgical workstation based on the service oriented architecture (SOA) paradigm has been developed. In the context of modular system architectures, risk management is the most important aspect. The exemplary application of our concept according to IEC 80001 has been published as a VDE application recommendation for risk management in medical IT-networks.

Fig. 12: VDE application recommendation: risk management for IT networks incorporating medical devices in operating theatres.



## Model-Based Usability- and Risk Analysis

Various studies concerning critical events in the medical context have proven that in most of the cases use deficiencies are the cause for human failure, especially when new and complex technical equipment is involved. International standards such as IEC 60601-1-6 and IEC 62366 have defined a comprehensive usability engineering (UE) process for market approval of medical devices including usability specification and mandatory usability validation with intended user groups.



Fig. 13: Model-based usability evaluation with the mAXuse tool for a commercial planning and navigation system.

In the framework of the BMWi-funded AiF / FQS INNORISK project a novel method for the design and risk assessment of Human-Machine-Interfaces (HMI) was developed and evaluated together with several industrial partners. Based on these results, the related software tool was further developed and evaluated in the framework of the OrthoMIT project. The new software tool (mAXuse) enables a formal-analytical usability evaluation and HMI-related risk analysis already at an early stage in the developmental process. mAXuse can be used prospectively in the context of the design process as well as for the analysis, redesign or validation of existing HMIs.

Based on a formal task modeling approach with an integrated error analysis (based on taxonomies of human failure) interactive use process sequences are characterized and their potential impact on the overall HMI process can be investigated.

The application of dedicated assessment algorithms enables an efficient and reliable analysis and provides an automated documentation of the evaluation results according to normative and regulatory standards.

On the basis of these techniques and tools, training courses as well as the conduction of usability and risk assessment studies (e.g. with the mAlXuse method) are offered

in cooperation with the CeMPEG e.V. as a service for medical device manufacturers and hospitals.

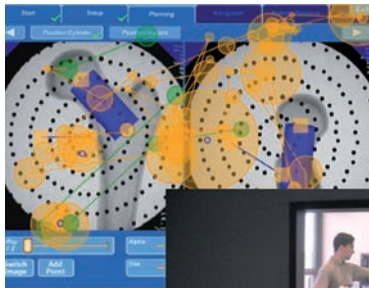


Fig. 14: Ergonomic assessment of planning systems for orthopedic interventions: gaze path based on eyetracking data (l.) and evaluation in the usability lab (r.).

Within our recently expanded usability laboratory comprehensive user-oriented interaction evaluation and workflow assessment regarding medical devices can be performed. Synchronized, video based task and working posture analysis as well as logging of relevant physiological data (e.g. EMG, ECG, EDA, breathing frequency...) can be provided in lab settings as well as directly in the OR environment. Remote and mobile head-mounted eye-tracking devices are used to document and analyze gaze data during human interaction with specific user interfaces or complete interventional processes.

## Acknowledgements

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## Awards

- Fieten, L., Pikkemaat, R., Leonhardt, S., Radermacher, K.: Medical Innovation Award 2009 of the German Federal Ministry of Education and Research (BMBF)
- Heger, S., Fieten, L., Mumme, T., Wirtz, D.-C., Radermacher, K.: Best Technical Poster Award 2009 of the International Society of Computer Assisted Orthopedic Surgery

## Selected Publications

- [1] Bruners, P., Penzkofer, T., Nagel, M., Elfring, R., Gronloh, N., Schmitz-Rode, T., Günther, RW, Mahnken, AH.: Electromagnetic Tracking for CT-guided Spine Interventions: Phantom, Ex-vivo and In-vivo Results. In: European Radiology, Vol. 19 (4), pp. 990-994, 2009.
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## Team

