Chair of Medical Engineering
Faculty of Mechanical Engineering

Innovative Technology for Smart Therapy

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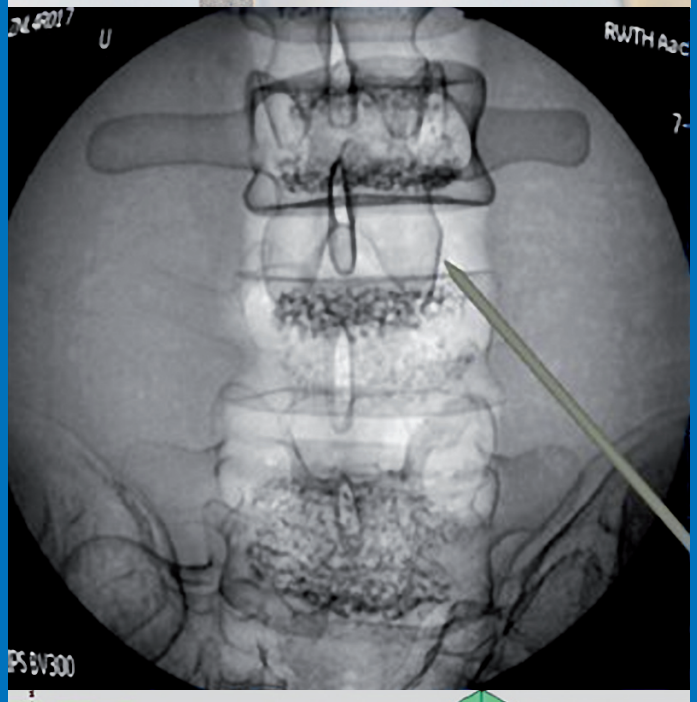

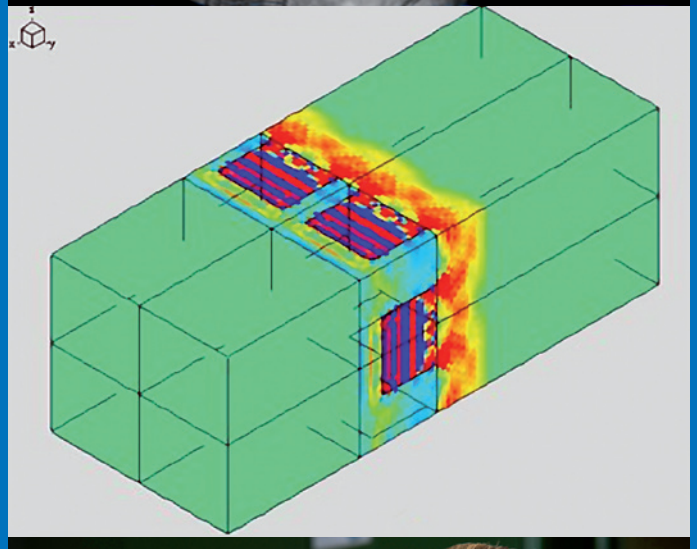

Introduction

The Chair of Medical Engineering (mediTEC) of the Faculty of Mechanical Engineering of the RWTH Aachen University is 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 structured along the following areas: image, signal and information processing as well as biomechanical modeling and simulation as an essential basis for computer assisted model-based therapy planning, surgical navigation and smart mechatronic instruments, devices and robotics, ultrasound and medical shock wave technology 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 analysis and clinical field tests. The OrthoMIT project (minimal invasive orthopedic therapy; 7/2005-6/2011; 24 partners; 14.5 M€ overall funding by the German Federal Ministry of Education and Research - BMBF) in cooperation with the Orthopedic Clinic of the University Hospital Aachen continues to be one major framework of our research activities. This also holds for the BMBF project IDA on the development of an intraoral ultrasound based micro-scanner (Medical Technology Innovation Award 2008) in cooperation with the Department of Prosthodontics and Dental Materials, University Hospital Aachen and industrial partners. Moreover, our activities towards advanced IT concepts for integrated operating room solutions have been enforced by the establishment of the new initiative and project "smartOR" coordinated by our chair (4/2010-3/2013; 8 partners, 2,8 M€ overall funding by the German Federal Ministry of Economics and Technology - BMWi). Additionally, various new research grants related to basic research issues as well as innovative application oriented concepts, patent applications and industrial cooperations have been established. Moreover, in 2010 we saw the market launch and continuing successful market application of several products originally developed in our lab. 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 our new method and software tool mAIXuse for human error risk analysis has been applied with a very positive response in cooperation with various industrial partners. We congratulate Dipl.-Ing. A. Janß of our team, who received the renowned Walter Masing Award of the German Association for Quality (DGQ) for his work in this domain.

Fig. 1: Dipl.-Ing. A. Janß receives the Walter Masing Award 2010.

Image and Model-Based Functional Surgical Planning

Optimized surgical treatment of pathological musculoskeletal deformities and related functional limitations requires customized computational models. These models provide valuable information on morphology and function along with better understanding of the pathology and enhanced biomechanical surgical planning in individual cases. Models can be customized, based on patient-specific imaging data (e.g. MRI/CT).
Within several research projects we focus on the development of model-based approaches for the segmentation and modeling of musculoskeletal structures from medical images. This includes for example the non-rigid adaptation of functional and morphological reference models (CT/MRI/X-ray/US) to patient-specific anatomic data for humeral head (a) and scapula (b), as well as e.g. level-set deformable model segmentation for knee surgery (c) (Fig. 2). Our studies also address the evaluation of biomechanical models (e.g. hip) and their integration for treatment planning (Fig. 3).

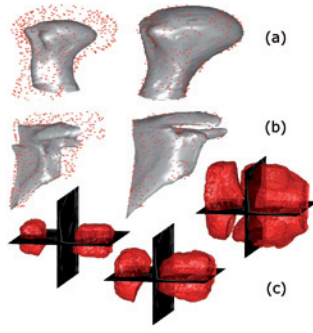

Fig. 2: Non-rigid functional and morphological modeling.

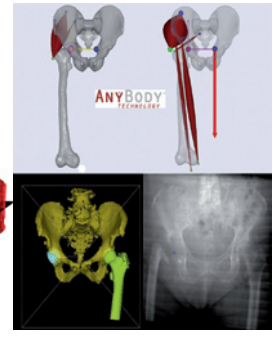

Fig. 3: Image- and model-based evaluation on the hip.

In another project context, model-based image analysis is used for the comparative study of different approaches in (minimal invasive) trauma surgery (Fig. 4).

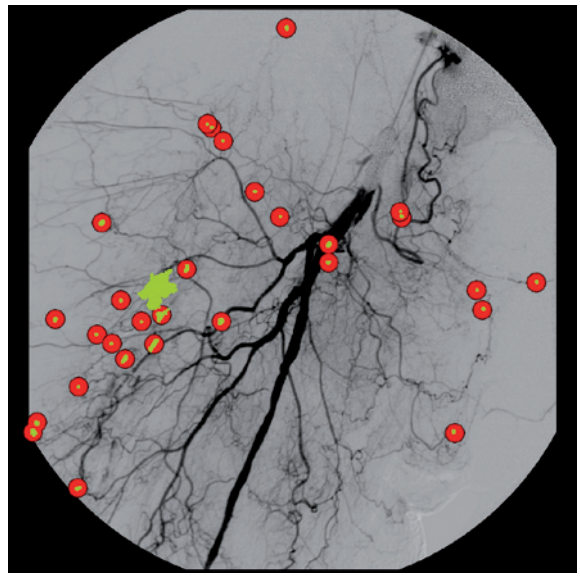
Fig. 4: Analysis of a Digital Subtraction Angiography for the evaluation of organ blood supply after minimal invasive surgery.

Robust Registration in Computer Assisted Surgery

Intra-operative rigid registration is used to establish the spatial relationship between pre-operative images and the surgical site. It relies on reference structures localized in both reference frames. However, the measurement of anatomical landmarks and reference surface structures is prone to anisotropic measurement errors. To increase the robustness of registration algorithms, we developed a novel registration approach accounting for a-priori knowledge on error distributions.

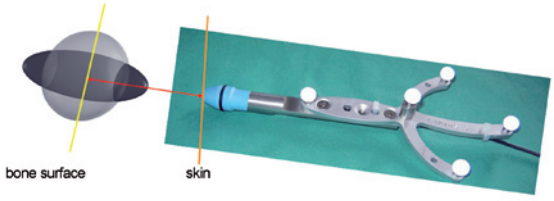

Fig. 5: Consideration of localization uncertainty in transcutaneous registration using A-mode ultrasound.

Smart Instruments and Mechatronic Systems

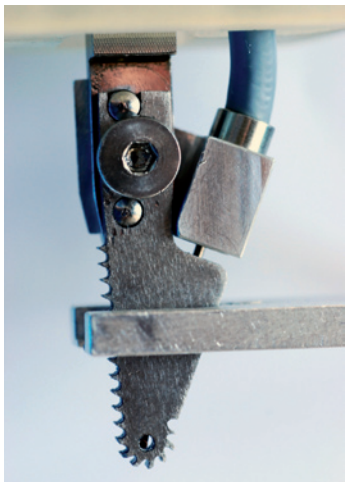

Fig. 6: First prototype of a saw blade with an integrated sensor.

In craniofacial surgery (e.g. trepanation) as well as in spine surgery or sternotomy the preservation of underlying soft tissue is of utmost importance while efficiently cutting the bone. The smartCUT approach combines a novel soft tissue preserving efficient saw with an automatic depth control based on optical and/or ultrasound sensors providing information on the actual penetration depth of the sawblade.

In the context of hydrocephalus therapy, a new extra-ventricular drainage system as well as an implantable iShunt system is developed in cooperation with the Chair of Medical Information Technology at our institute. The system comprises sensors to monitor and actively control the brain pressure. In this framework our team especially addresses the conceptual design and the development of mechanic components.

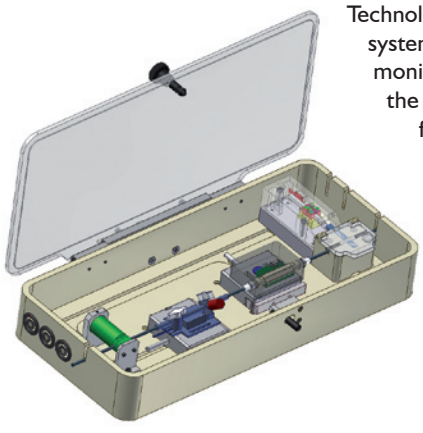

Fig. 7: Functional prototype of an extra-ventricular drainage system.

A Modular Robot System for Knee, Hip and Spine Surgery

In the framework of our OrthoMIT project, the need for miniaturized robotic devices has been identified for different applications in orthopedic surgery. The removal of the periprosthetic bone cement in revision total hip replacement surgery as well as the implantation of a free-form shaped knee implant are two examples of potential applications. Based on the MINARO modular robot architecture application specific robot configurations can be easily assembled by combining basic and application-specific hard- and software modules.

Fig. 8: The modular MINARO robot system [Source: BMBF/PT DLR].

Intraoral Ultrasound-Based Micro-Scanning

Computer-integrated manufacturing of dental prostheses such as crowns, bridges and inlays gains more and more importance due to its high accuracy and time efficiency. The precise intraoral digitization of the tooth preparation is a crucial step of the CAD/CAM process. Ultrasound (US)-based scanning could be an alternative to optical methods since gingiva, saliva and blood have less influence on the accuracy of the digitization process and no powder is needed to compensate for unintentional reflections. Moreover, sub-gingival preparations can be scanned without invasive exposure of the preparation boundary. The objective of the interdisciplinary IDA-project is the development of an US-based intraoral micro-scanner, replacing the conventional casting process without the drawbacks of current optical scanners.

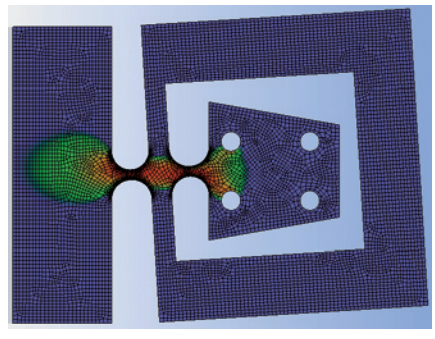

Fig. 9: FEM-Simulation of a micro-positioning device for a miniaturized US-scanner.

Contrast Enhanced Ultrasound-Based Analysis of Compartment Syndrome

In traumatology, the compartment syndrome is one of the most common complications during bone fracture healing with serious consequences for the patient. However, no objective non-invasive diagnostic methods exist. In cooperation with the Department of Orthopedics and Trauma Surgery of the University Hospital Aachen elastography and contrast enhanced ultrasound measurement of the microcirculation are used to analyse micro perforations and inner pressure of the muscle. To extract clinically reliable data, a software framework has been developed.

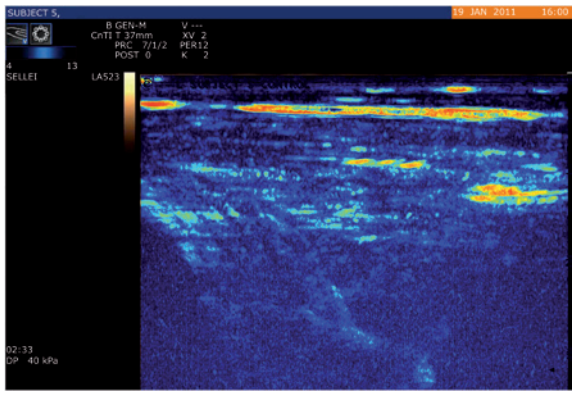

Fig. 10: Ultrasound-based monitoring of muscular structures.

Immediate Cardiac Vitality Diagnosis Using Ultrasound-Based Strain Analysis

An exact differentiation between vital and non-vital myocardial tissues of patients with a restricted left ventricular ejection fraction has a great relevance for diagnosis and therapy as only vital myocard benefits from a coronary revascularization. 2D strain analysis is an innovative echocardiographic method enabling diagnostic evidence on myocardial vitality comparable to MRI. In the framework of the project CardioFusion (funded by the German Research Foundation - DFG) in cooperation with the Cardiology Department of the University Hospital Aachen, we are developing a system for the fusion of 2D strain-US analysis and X-ray based biplanar coronary angiography, providing intraprocedural spatial correspondence between the stenosed coronary arteries and the vitality of related myocardial segments. Based on this information, a decision on an intervention (PCI) could be made immediately without delays due to MR imaging.

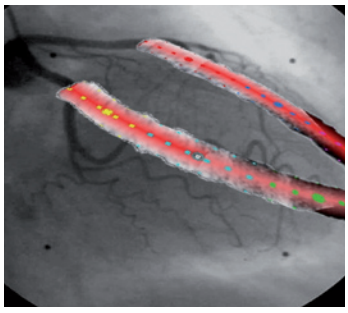

Fig. 11: Fusion of 2D-US-strain analysis and fluoroscopic images.

Simulation and Optimization of Medical Shock Wave Applications

Physical reasons of the destructive character of shockwaves have been studied during the last decades. However, the causes for the therapeutic effects still remain unclear. Depending on the shockwave device used (method of shock-wave generation) and the device settings, different mechanical stimuli act on the target tissue. Based on profound knowledge about the correlation between the shock wave generation patterns and strategies, on the mechanical stress/strain caused by the resulting shock wave and on the biological response, new target-oriented treatments would become possible. To better understand the cause-effect relation of shockwaves and biological responses a simulation model of the non-linear shockwave propagation has been implemented as well as two simplified models for the shockwave treatment – one for cell culture flasks and one for isolated rat hearts. During simulation the normal and shear stress and strain caused by the shockwave can be calculated at each time step. In our ongoing experimental evaluation the model will be iteratively validated and optimized by experimental data and correlated to verified biological findings.

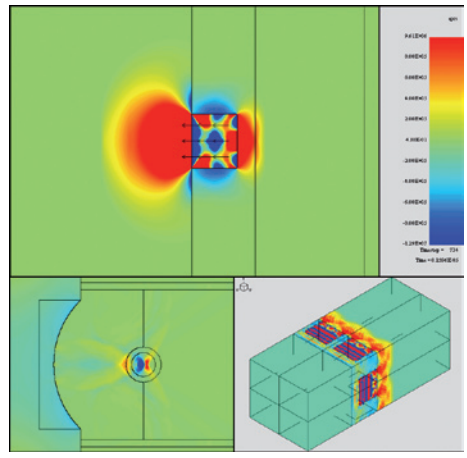

Fig. 12: Simulation of piezoelectric shockwave generation and non-linear propagation.

Zero-Dose C-Arm Navigation

The Zero-Dose C-Arm Navigation approach developed in our institute, offers a radiation free, model-based preview of the expected X-ray image in real-time during C-arm alignment. Apart from a significant reduction of radiation due to the elimination of initial "pilot shots", the acquisition of optimal X-ray projections increases the safety and reliability of fluoroscopically guided interventions. Especially in spine surgery (as well as in trauma surgery on the pelvic ring), the placement and control of e.g. screws should be based on adequate X-ray projections. After a successful demonstration of the

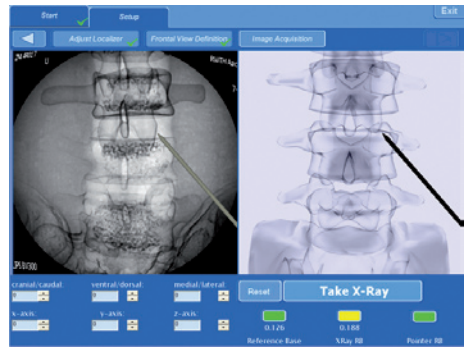

Fig. 13: Zero-Dose X-ray preview (right), corresponding X-ray image (left).

principle of the Zero-Dose C-Arm Navigation Module for interventions on the hip and lower extremities, a spine module as well as enhanced modes of visualization have been developed providing a more realistic preview of the relevant structures (anatomy, OR-table components, instruments visible in the relevant projection). Additionally, the module can be used for educational purposes when relevant anatomical structures like nerve roots, facet joints or vertebral discs are highlighted within the spine model. In-vitro studies have proven that the radiation exposure can be significantly reduced by using the system.

Modular Integration of Surgical Worksystems

In the framework of the OrthoMIT project, a modular and flexible integrated surgical work system based on the Service Oriented Architecture (SOA) concept has been developed and realized in a first prototype. The smartOR project uses these concepts as a basis for further development of standardized protocols and interfaces, security concepts for plug-and-play integration of medical devices, innovative and standardized man-machine-interaction and risk-management of adaptable integrated operating room systems.

Fig. 14: Laboratory setup and evaluation of integrated OR-components [Source: BMBF/PT DLR].

SensoPAL - Sensor Integrated Patient Support

In cooperation with SurgiTAIX AG, Aachen, the Chair of Medical Information Technology and several clinical partners, we are developing a sensor integrated patient support which could be applied in emergency cots, transportation and positioning systems or OR tables. Capacitive ECG enables the diagnosis of heart activity without fixing adhesive electrodes, even through the clothing. The build-in tracking equipment allows for easy and distortion-corrected electromagnetic position tracking while the design enables X-ray imaging without interferences. The SensoPAL project is supported by the European Union and the State of North Rhine-Westphalia (Ziel2/EFRE program) and was elected as Project of the Month March 2010 by the Ministry of Economic Affairs of the State of North Rhine-Westphalia.

INKA – An Integrated Workstation for Head Surgery

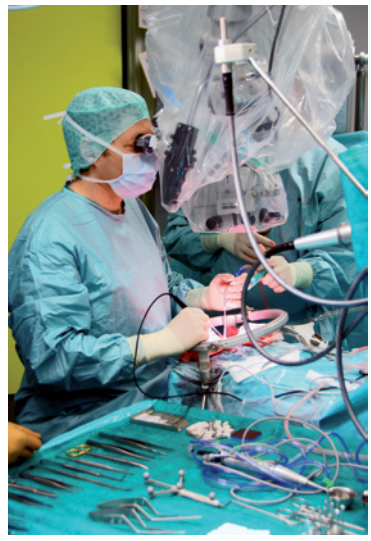

Fig. 15: A typical set-up in neurosurgery.

Today, Neuro- and ENT-Surgery depend on multimodal information as well as multiple technical devices and systems to be integrated in the operating room. Based on an in-depth analysis of workflows and related necessary and sufficient information or technical assistance respectively, a novel concept of an integrated work station is developed in cooperation with a consortium of four clinical and three industrial partners. Apart from the integration of tracking and navigation devices, enhanced concepts of man-machine-interaction as well as modular mechatronic assistance systems are main aspects of our work. Standardized interfaces based on a Service Oriented Architecture (SOA), provide a modular and flexible integration and extension of the workstation.

Human Risk Analysis and Usability Engineering

According to international standards such as IEC 62366 and ISO 14971 systematic usability engineering and risk management processes are required during the complete product development as well as in the marketing phase in order to increase usability and reliability of medical products. In medical applications the analysis and evaluation of risks for human error are of increasing importance as more and more complex technical equipment is introduced into clinical as well as home care applications. In this context, the mAIXuse approach for human risk analysis (awarded in 2010 by the German Association for Quality (DGQ), see Fig. 1) has been successfully introduced into industrial application. The method can be used from early developmental stages up to validation of existing prototypes as well as in preclinical and clinical studies. Moreover, comparative evaluation of the usability of different products in a given clinical context of use is another scenario for the application of mAiXuse.
Workshops and seminars on usability and risk evaluation methods as well as on the conduction of user based studies (e.g. with the mAIXuse method) have been successfully implemented for medical device manufacturers and hospitals.
Our CeMPEG usability laboratory provides facilities for comprehensive user-centered interaction tests and

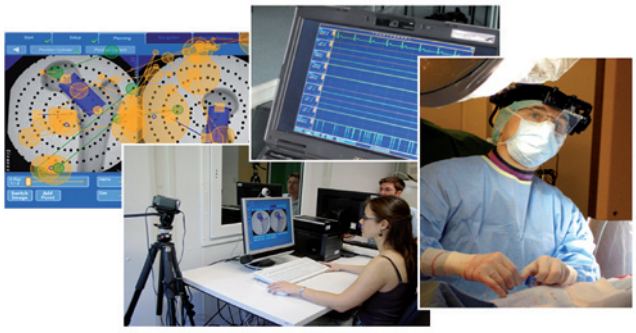

Fig. 16: Ergonomic evaluation in our CeMPEG usability lab and in the OR.

workflow assessment, video-based task, workflow and working posture analysis, including the logging of relevant physiological data (e.g. EMG, ECG, EDA, breathing frequency) and eye-tracking in lab settings as well as in clinical field tests.

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- the German Research Foundation (DFG)
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Awards

- Dipl.-Ing. Armin Janß: Walter Masing Award of the German Association for Quality (DGQ)

Selected Publications

[1] Cunha-Cruz, V.; Follmann, A.; Popovic, A.; Bast, P.; Wu, T.; Heger, S.; Engelhardt, M.; Schmieder, K.; Radermacher, K.: Robot and Computer Assisted Craniotomy (CRANIO): From Active Systems to Synergistic Man-Machine Interaction – J.Engineering in Medicine, Vol. 224, pp. 441-452, 2010.

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Team