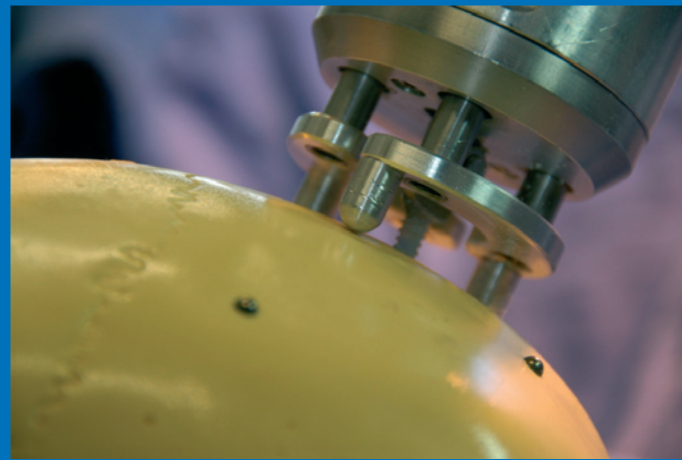
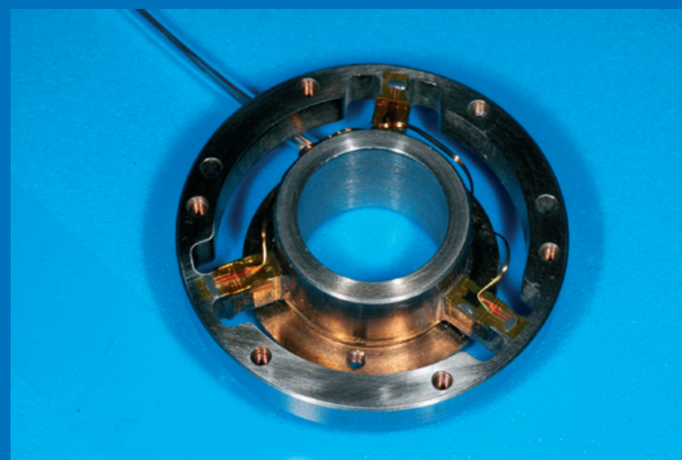
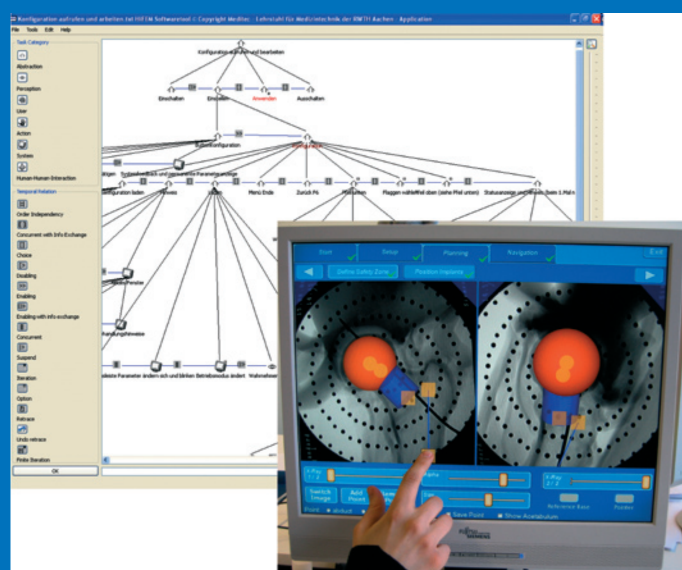
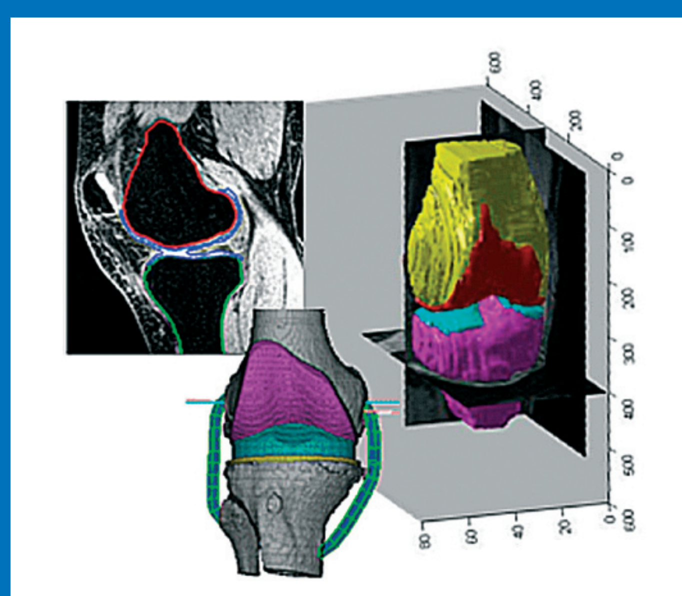
Chair of Medical Engineering
Faculty of Mechanical Engineering

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 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. Research activities of our Center for Medical Product Usability (CeMPEG) focus on ergonomics and usability engineering in medicine. Actual projects in the domain of Orthopaedic and Trauma Surgery, Neurosurgery, General Endoscopic Surgery, Cardiology, 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 analyses 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 14M€) passed a very positive peer midterm review resulting in a substantial funding upgrade. Moreover, the STS-project (development of a safety trepanation system for neurosurgery), which received the Medical Technology Innovation Award of the BMBF in 2007, has been launched. Our team also received the Medical Innovation Award 2008 of the BMBF for the development of a novel ultrasound-based intraoral scanner system.

Biomechanical Modelling & Simulation

For optimal planning of orthopaedic interventions on the musculoskeletal system, the individual morphological as well as the functional situation of the patient has to be considered. In order to enable a comprehensive quantitative view on all relevant functional (e.g. posture, gait, kinematics and joint reaction forces) and morphological (e.g. implant position and orientation, target geometry definition) parameters, we integrate multi-body-simulation into the clinical planning procedure. This approach has been used in the context of correction osteotomies. Here, the major objective is to restore the physiological joint load by correcting the respective bone geometry and related soft tissue. The integration of multi-body-simulation into the computer-based planning process enables a quantitative evaluation of functional parameters for relevant everyday's activities such as standing, walking or stair climbing.

MRI-based Modelling, Planning and Navigation in Computer Assisted Orthopaedic Surgery

Image-based preoperative planning and intraoperative navigation using individual templates both require the design of patient-specific 3-D templates that uniquely match the surface geometry of individual bony structures and serve as guiding tools for cutting planes and surgical drills during surgery. Intraoperatively no computer or tracking system is needed and our earlier clinical studies demonstrated enhanced accuracies and reduced times of intervention. This approach, originally developed at our institute in the early 90s, actually enjoys increasing popularity world-wide for different types of interventions (e.g. including total knee and hip arthroplasty). However, in contrast to the original CT based approach, MR based planning enables the consideration of articular cartilage and avoids the exposure to radiation which might be especially important e.g. in the case of periacetabular osteotomies in younger patients. The degeneration of knee cartilage volume is the most obvious indicator that characterizes the progression of knee osteoarthritis. Therefore the evaluation of cartilage volume and thickness is required for a better diagnosis and surgical planning. However, an efficient segmentation of relevant structures is of utmost importance for clinical routine use. Against this background, we focus on the development of automatic segmentation and modelling tools together with optimized protocols for MR-imaging. Apart from hip and shoulder surgery, total knee arthroplasty is one major application. (Fig. 2). The evaluation of the modelling accuracy along with the overall evaluation and optimization

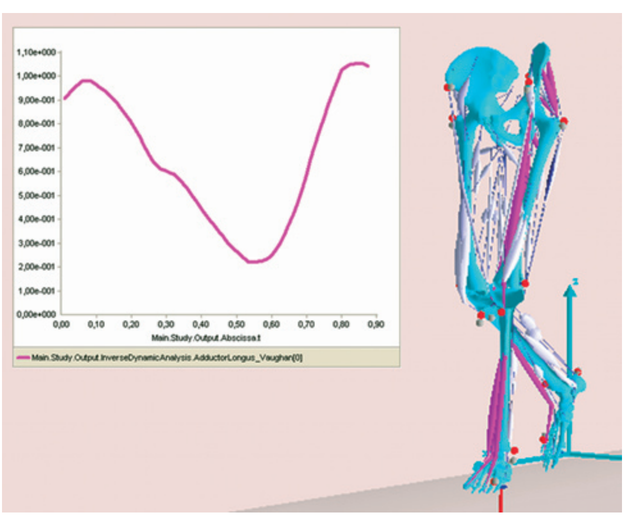


Fig. 1: Simulation of musculoskeletal activities.

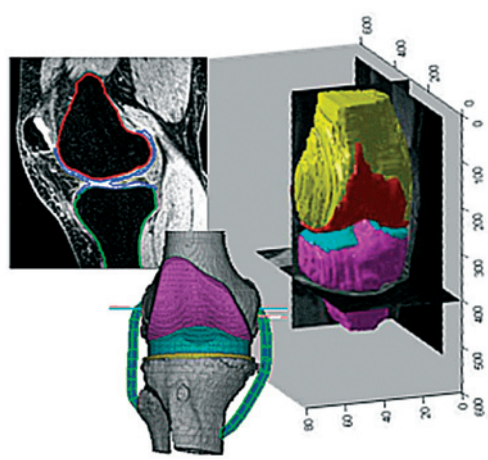


Fig. 2: MRI-based modelling and planning.

Medical Engineering

of the MRI-based planning approach are aspects of our ongoing research.

SmartTrepan - Sensor Guided Trepanation System for Safe and Efficient Craniotomy

During trepanation, a neurosurgical procedure to open the skull, the protection of the underlying dura mater and a minimized loss of bone are major concerns. A concept for a novel trepanation system has been developed, based on a soft tissue preserving cutting tool and an autonomous control of the cutting depth (patent pending). The semiautomatic instrument is manually maneuvered by the surgeon and the cutting depth is adapted automatically by the control system corresponding to the actual skull thickness, combining computer-related accuracy with the surgeon's know-how and cognitive capabilities. The skull thickness information can be acquired by using preoperative CT-Data and position tracking as well as through integrated sensors (e.g. ultrasound)

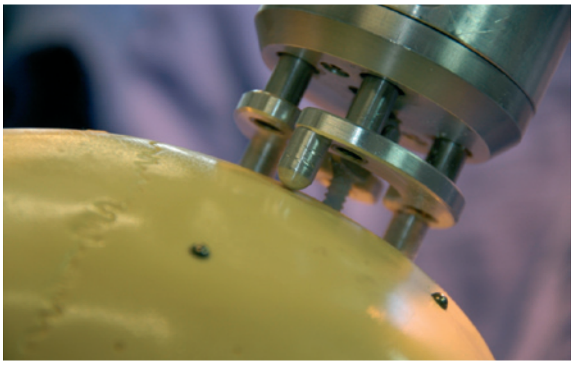


Fig. 3: The Sensorized Trepanation System (STS).

respectively. This project received the "Medical Technology Innovation Award 2007" of the German Federal Ministry of Research and Education (BMBF).

Tracking Technology

Tracking, i.e. the 3D localization of patient and surgical tools is one of the key technologies in computer assisted surgery. The accuracy of these systems is an important parameter for the outcome of the operation. The accuracy of optical tracking systems, actually representing the state of the art in most surgical applications, has been investigated in comparative studies revealing significant differences between actual systems. The development of hybrid systems incorporating inertial sensors and optical / electromagnetic tracking (EMT) to overcome disadvantages of the single systems is another major aspect of our research. Electromagnetic tracking offers several advantages in practical use such as independence of the line-of-sight and miniature markers, but it is highly susceptible to field distortions caused by metallic items within the measurement area. Therefore, we have developed novel approaches for real-time compensation of these distortions (patent pending). The combination of calibration devices and specific correction algorithms will allow the use of EMT in complex clinical environments.

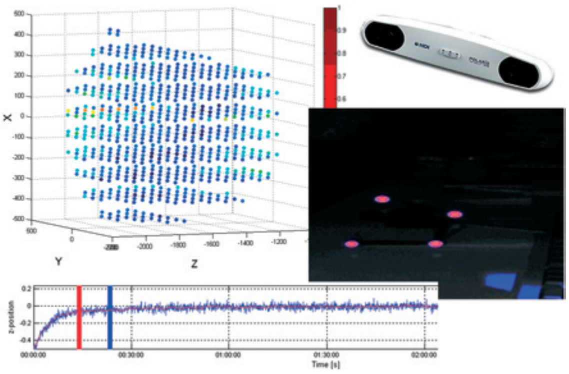


Fig. 4: Experimental evaluation of hybrid tracking systems.

Intraoral Data Acquisition Using Ultrasound Micro-Scanning

At present, crowns and bridges are produced by use of conventionally casted gypsum plasters. In practice, this method is time-consuming and leads to non-conformities. CAD/CAM technologies and digital casting offer higher efficiency and accuracy in the production of fixed prostheses. However, intraoral optical digitization is limited to supra-gingival geometries of prepared teeth and is influenced by saliva, soft-tissue and blood. A miniaturized intraoral ultrasound micro-scanner eliminates these drawbacks (patent pending). The key technology including high frequency ultrasound hard- and software as well as the intraoral micro-scanning system is developed within the IDA project ("Medical Technology Innovation Award 2008" of the German Federal Ministry of Research and Education (BMBF)).

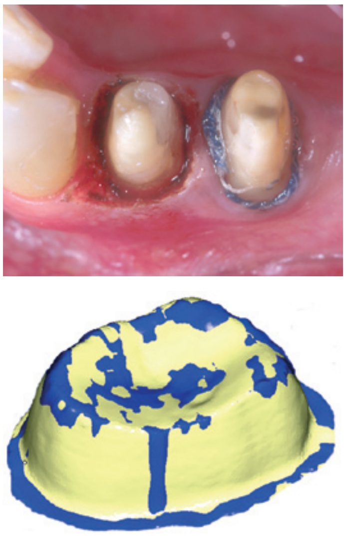


Fig. 5: Prepared teeth for conventional casting (top), matched ultrasound (blue) and optical (yellow) digitization of a prepared tooth.

Minirobot Based Ultrasound Geometry Scanning in Orthopaedic Surgery

Automatic detection and precise removal of intra-femoral bone cement in revision total hip replacement (RTHR) is challenging and time-consuming. Robot assisted automatic cement milling may be a solution but still requires precise knowledge of the cement's geometry and its location. Within the OrthoMIT project a miniaturized ultrasound module which can be easily adapted to our hybrid 6 degree of freedom (DOF) minirobot MINARO is being developed and evaluated for precise cement detection. The robot integrated ultrasound module eliminates the need for optical tracking as well as error-prone patient registration. Furthermore, ultrasound produces no radiation and the hardware is very cost efficient. However, refraction and wave mode conversion at the cement boundaries are influencing the detection accuracy. In order to minimize those artefacts, we optimized signal processing as well as scanning strategies as a function of DOF supported by the mini-robot. A trade-off between system complexity and detection accuracy is reached if the scanning strategy at least includes 3 DOF (Fig. 6).

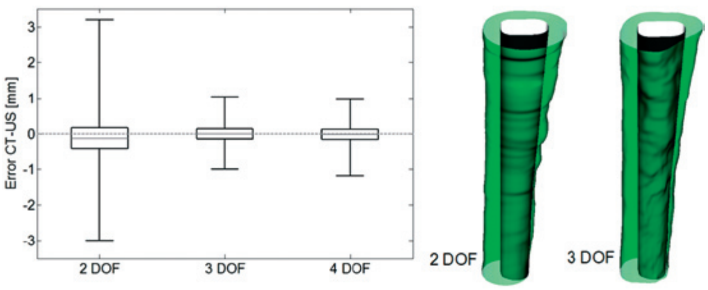


Fig. 6: Accuracy of ultrasound based bone cement detection as a function of DOF (l), 3D reconstructions of the detected cement-bone interface (green) and the cement cavities (grey).

Smart Knee-Surgery with genALIGN

Successful reconstruction of the mechanical axis (Mikulicz-line) as well as appropriate ligament balancing are crucial elements in knee replacement surgery.

The genALIGN concept is based on a direct measurement of instabilities and forces in the knee (patent pending). For these measurements, a new autoclavable force-torque-sensor (Fig. 8) is integrated into the navigation instrument (Fig. 7). Conventional rigid body references and tracking systems are no longer necessary.

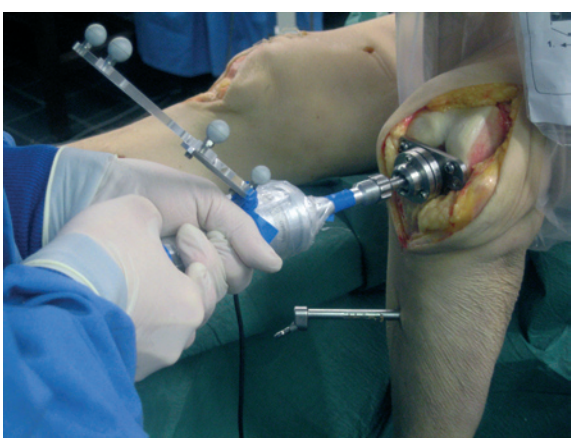


Fig. 7: The genALIGN system during application in cadaver study (rigid bodies for optical tracking are used for evaluation purpose only).

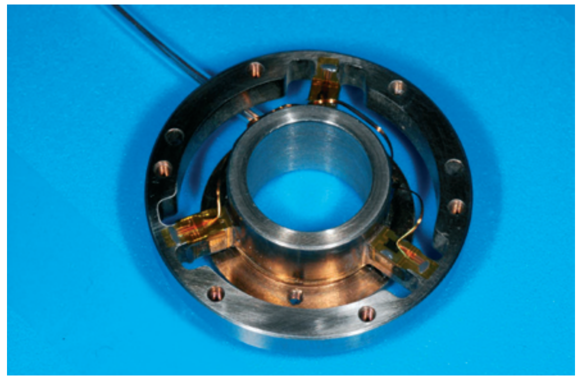


Fig. 8: Autoclavable 6 DOF force-torque mini-sensor.

The respective patent application has been awarded the "Inventors Award" at a statewide competition of universities in North-Rhine-Westphalia.

In addition to this device we are developing a sensor-integrated tibial inlay for application during the ligament balancing procedure. An array of six force sensors provides information about the intraarticular loads enabling the surgeon to appraise the ligamentous guidance of the joint and to adjust the ligamentous structures according to the individual requirements. The sensorized inlay has been tested and characterized in first laboratory set-ups (Fig. 9) and will be implemented in initial pre-clinical trials soon.

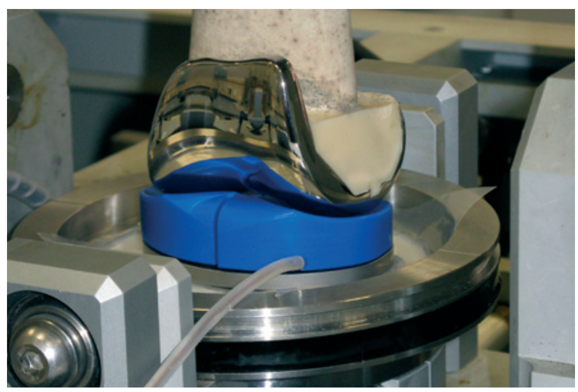


Fig. 9: Laboratory set-up for tibial inlay testing.

Haptic Feedback in Computer Assisted Surgery

The placement of a needle in "Pin-Point" interventional radiology is nowadays achieved by frequent needle adjustments and updated CT-scans. 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 and physicians and to optimize the workflow, a tele-manipulator controlled from the outside of the CT suite is being developed. However, using a tele-manipulator, the direct interaction and haptic feedback is lost. In order to overcome this problem, the tele-manipulator is controlled by a master device with force feedback (Phantom 1.5 6-DOF High-Force) allowing the physician to control the motion of

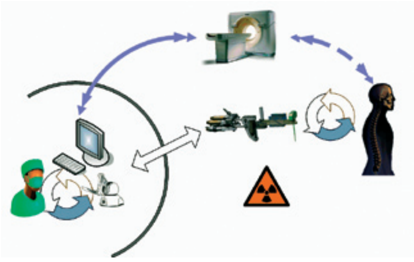


Fig. 10: Tele-manipulated interventional radiology.

the slave manipulator on the basis of image based navigation and to sense the interaction of the needle with the tissue. Hence, repeated CT-scans potentially could be avoided.

A 6 DoF manipulator has been equipped with miniaturized calibration cage for automatic CT-registration (Fig. 8).

Ergonomic Quality and Safety

To enhance quality and safety in medical work systems, usability and reliability of human-device-interaction are crucial. International standards such as IEC 60601-1-6 and IEC 62366 have defined a comprehensive usability engineering (UE) process including usability specification and obligatory usability validation with intended user groups. In this context model- and guideline-based as well as user-centred usability assessment methods and tools are developed at our Centre for Medical Product Ergonomics and Usability (CeMPEG). Our usability lab is equipped with modules for synchronized video- and screen-recording, ontology-based workflow documentation and logging of relevant physiological data (e.g. EMG, ECG, EDA, breathing frequency,…). Stationary and mobile eyetracking devices are used to assess, document and analyze visual interaction with user interfaces in the lab as well as in the OR.

In the framework of the INNORISK project a software tool has been developed together with several industrial partners to support the application of prospective usability assessment for complex medical devices. The software tool uses formal, normative models to predict the user and system behaviour in order to estimate the usability of a new or redesigned system. The general approach towards prospective usability analysis and the corresponding software tool have already been evaluated in comparison to conventional risk assessment and usability evaluation methods in cooperation with medical device manufacturers and other industrial partners.

The aim of the project is to provide tools for designers and developers, especially in small and medium-size enterprises (developing and manufacturing medical devices), in the early stages of the developmental process of risk sensitive human-machine-interfaces, in order to ensure ergonomically-designed and safe systems for both, patients and physicians.

In cooperation with the CeMPEG e.V. training courses on usability engineering and usability assessment services are offered to medical device manufacturers as well as to hospitals.

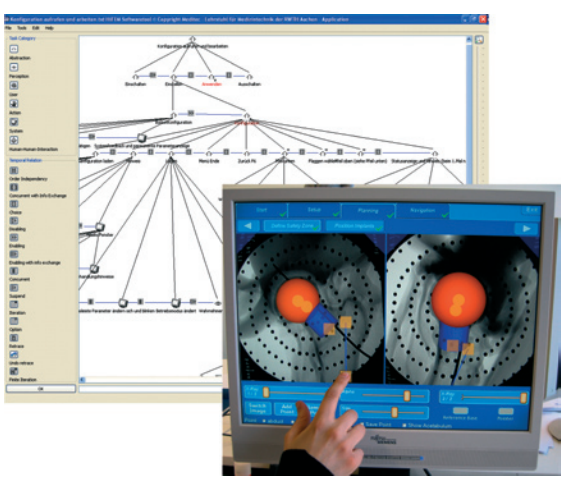
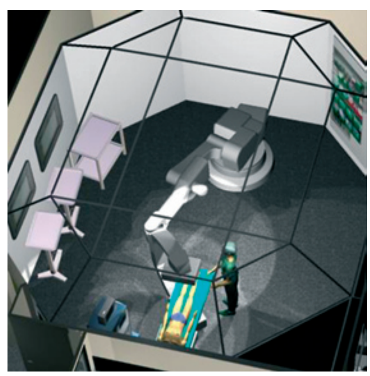


Fig. 11: Usability analysis for an intraoperative surgical planning and navigation system.

Simulation for Robot Integrated Imaging

Within the OrthoMIT project a virtual Evaluation OR was set up modelling the real demonstrator OR in the University Hospital Aachen. This simulation comprises the entire standard OR equipment as well as different anthropometric man models (ANTHROPOS, RAMSIS) which are e.g. used for ergonomic assessment of working postures. Newly developed components are integrated into the virtual OR in an early stage to visualize, discuss and prospectively assess the resulting settings. As one application, the integration of a robotic X-ray C-arm handling system into the OrthoMIT OR is investigated together with industrial and clinical partners. The specific intervention workflows can be simulated to analyze and minimize potential risks of interaction between the OR-personnel, the patient and the robotic imaging device in Orthopaedic Surgery.



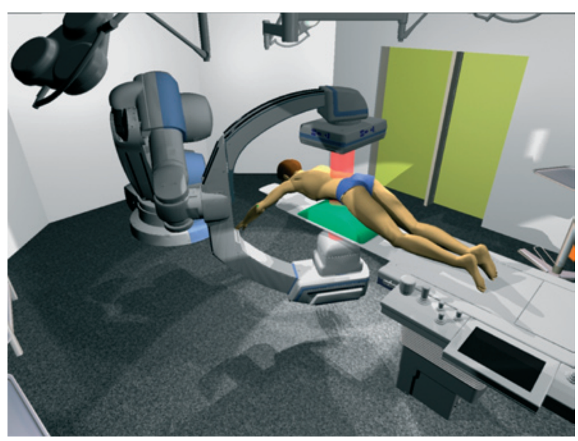


Fig. 12: Simulated integration of the robotic X-ray C-arm (Siemens Artis Zeego) into the OrthoMIT OR.

Integrated Surgical Work Systems

Within the OrthoMIT project, a modular and flexible integrated surgical work system based on the Service Oriented Architecture (SOA) paradigm is in development. In the context of modular system architectures, risk management is the most important aspect. Our concept has been officially accepted as a usecase of the upcoming IEC 80001 standard (on the application of risk management for IT-Networks incorporating medical devices).

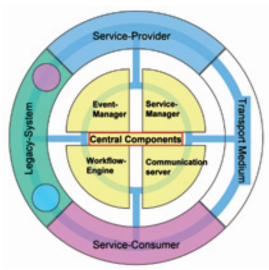


Fig. 13: SOA concept of the OrthoMIT Integrated Surgical Work System.

The integration and inter-system communication opens the door towards new strategies and functionalities of advanced surgical work systems. This includes the use of new tracking system concepts, reduced radiation due to advanced C-arm navigation modules as well as more efficient patient positioning strategies and systems.

Acknowledgements

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Awards

- S. Heger, A. Tinschert and K. Radermacher: Innovation Award for Medical Engineering 2008 of the German Federal Ministry of Education and Research (BMBF) for the project "Intraoral Data Acquisition (IDA) Using Ultrasound"

Selected Publications

[1] Gravius S, Belei P, Fuente M de la, Müller-Rath R, Radermacher K, Wirtz D, Mumme T: Functionality and Accuracy of a Fluoroscopic Navigation System in the Placement of the Femoral Component for Hip Resurfacing - A Cadaver Study. Z Orthop Unfall. May 2008; 146(3): 357-363.

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