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Innovative Technology for Smart Therapy

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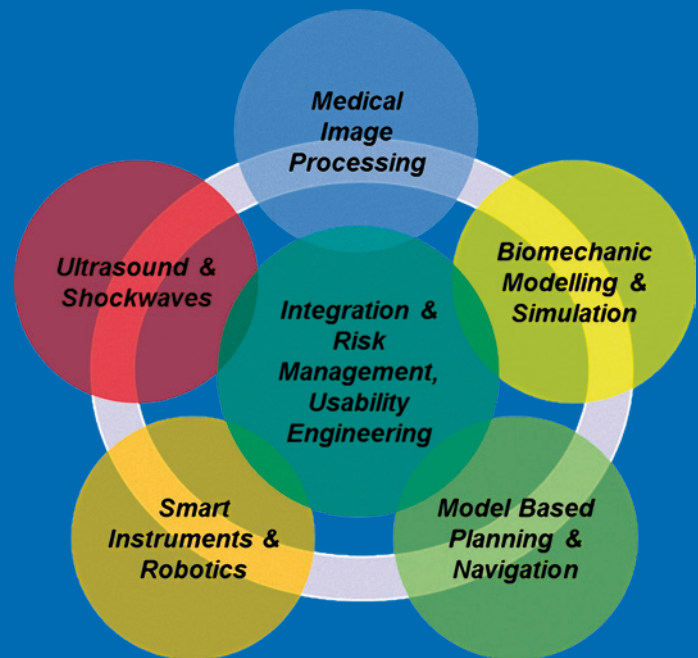
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Introduction

The team of the Chair of Medical Engineering of the Faculty of Mechanical Engineering of the RWTH Aachen University (mediTEC) is engaged in basic research issues as well as in application-oriented aspects of computer assisted diagnosis and model-guided therapy systems engineering. For more than two decades our work has been focused especially on computer assisted therapy with activities ranging from image, signal and information processing, to biomechanical modeling and simulation for computer assisted personalization of model-based therapy planning and surgical navigation, smart mechatronic instruments and surgical robotics. Moreover, since 2005 we established an ultrasound and medical shock wave lab and related research activities. Considering the increasing technical complexity of medical work systems, the integration, risk management and usability engineering of medical work systems represent another focus of our research. Actual projects in the domain of Orthopedic and Trauma Surgery, Neurosurgery, General Endoscopic Surgery, Cardiology, Interventional Radiology, Maxillofacial Surgery, Dental Therapy and Psychiatry are ranging from feasibility studies (proof of concept) and system development to usability analysis and clinical field tests.

The successful presentation of the final integrated smart-OR demonstrator system (smart medical IT networks for modular integrated OR systems; 4/2010 -3/2013; 2.8 M EUR overall funding by the German Federal Ministry of Economics and Technology (BMW); Coordination: mediTEC) on the conhIT 2013 trade fair and conference in Berlin exemplifies our continuing activities for the optimization of surgical work systems. Consequently the OR.NET Project funded by the German Ministry for Education and Research (BMBF) with an overall budget of 18,5 M EUR (2012-8/2015) (co-coordination mediTEC; 54 full partners and more than 30 associated partners from industry, academia, clinics and associations) is essentially based on the results of the smartOR-project. It enables us to continue our work on a broader and sustainable basis.

In 2013 we were able to present very successfully another final demonstrator system in the framework of the BMBF project IDA (development of an intraoral ultrasound based micro-scanner; Medical Technology Innovation Award 2008, 4 Partners, 1,2 M EUR, Coordination: mediTEC). In the context of the final status symposium at Vaalsbroek Castle, Vaalsbroek, NL we presented the concept and final results of the IDA project to the participants representing major international players in dental medicine and industry. The feedback and discussion was very positive, new cooperative projects could be established. Based on the success of the IDA project, a spin-off initiative has been set forth.

Apart from other projects funded by the state of North-Rhine Westphalia and by the European Union as part of the European Regional Development Fund, the RapidGEN project on personalized modeling and rapid manufacturing of individual knee implants (2,3 M EUR; 7 Partners, Coordination: mediTEC) is another example of our actual flagship projects. Additionally, various new research grants related to basic research issues as well as industrial co-operations in the context of medical shockwaves and mechatronic devices have been acquired by our team. The



Fig. 1: IDA Symposium 2013.

continuing successful market application of several products originally developed in our lab as well as the increasing number of successful international patent applications confirm our general concept of combining basic as well as problem oriented medical engineering research and application development, being also an essential basis for the sound education of our students.

Last but not least, we congratulate our soccer team mediÄTTÄCK, the RWTH University indoor soccer champions 2013 (2011 and 2009)!



Fig 2: RWTH soccer champion 2013: mediTEC soccer team mediÄTTÄCK.

Selected Projects

Personalized Biomechanical Modelling

The therapeutic outcome in joint surgery highly depends on the consideration of the individual morphologic and functional situation. Today's procedures are generally based on X-ray imaging, CT or MRI. The 3D-reconstruction of soft and hard tissue for biomechanical modelling and surgical planning is cumbersome and not established in clinical routine. However, a-priori knowledge can be used for generic biomechanical modelling including statistical modelling of tissue morphology.

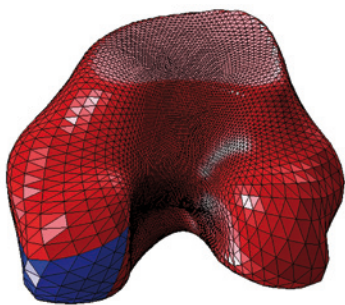


Fig. 3 (left): Statistical model of the distal femur computed from 30 CT data sets.

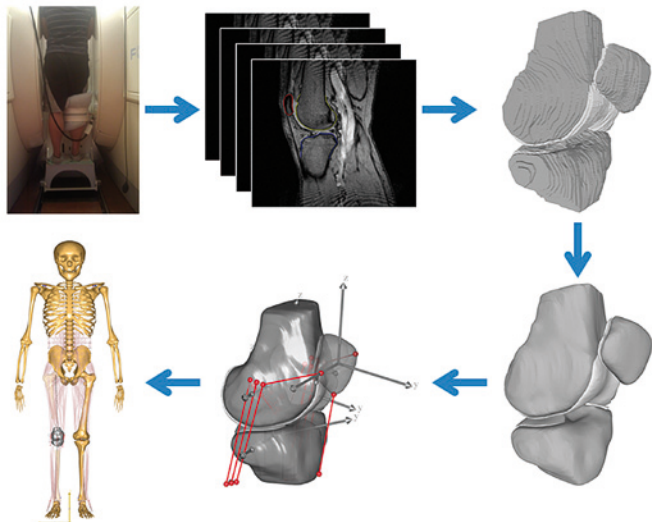


Fig. 4 (below): Experimental workflow for the comparison of in-vivo kinematics (Upright MRI based motion analysis) and corresponding simulated kinematics.

The acquisition of limited patient specific information based on 3D imaging such as upright MRI, 3D-X-ray or ultrasound and its fusion with a-priori model data, enables efficient functional modelling and surgical simulation. The development and validation of biomechanical models for surgical planning and rehabilitation are key objectives of our ongoing research.

RapidGEN - Personalized Design and Rapid Manufacturing of Individual Knee Implants

So far patient specific implants are considered to be relatively expensive due to the additionally necessary CT-imaging and the time-consuming conventional manufacturing.

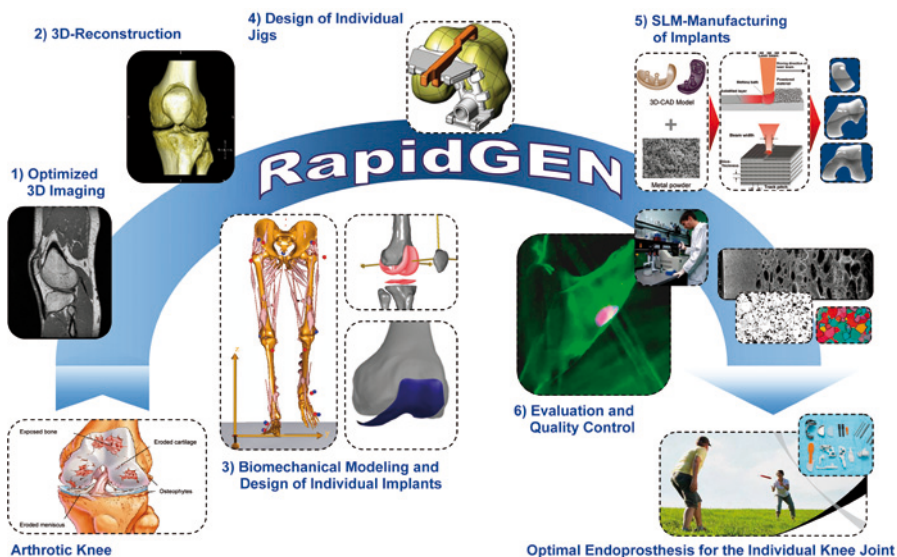


Fig.5 (left): RapidGEN: personalized modeling and rapid manufacturing of patient-specific knee implants.

By the application of an optimized 3D imaging, and an image- and model-based planning of personalized implants, radiation exposure can be reduced or even avoided and functional design of personalized knee implants can be supported. Due to an integration of the optimized design and manufacturing process, including innovative additive manufacturing technology such as selective laser melting (SLM), the overall costs can be significantly reduced.

Shoulder Biomechanics

Insights into individual shoulder biomechanics are of high clinical relevance. With our newly developed 6DOF shoulder test rig for experimental human cadaver tests together with computer based multi body simulation models of the shoulder, we established a sound basis for our actual research on shoulder biomechanics in cooperation with



Fig. 6: Shoulder test rig.

our clinical partners (Clinic for Orthopedic Surgery, RWTH Aachen). Besides model validation, parameter studies related to surgical planning and implant design are major objectives of our work.

Ultrasound in dental implantology

Dental implants are well-established in modern dentistry. However, progressive peri-implant bone loss may lead to failing implants. Conventionally, jawbone thickness is monitored using x-ray imaging or digital volume tomography. Ionizing radiation as well as imaging artifacts caused by metallic implants and superstructures are major drawbacks.

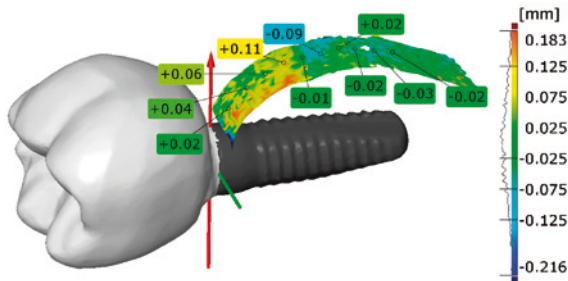


Fig. 7: High frequency 3D ultrasound micro-scanning of the jawbone surface (color coding: reconstruction error).

Ultrasound, as a patient friendly and cost efficient technology may be used to overcome this problem. Because bone is an inhomogeneous and highly attenuating medium surrounded by soft tissue, the physical interaction between ultrasound and bone is complex. Model based signal processing strategies and scanning concepts based on high frequency ultrasound surface scanning have been developed and are currently integrated into an intraoral IDA ultrasound scanner.

Shockwave Therapy

Since the 1980's shockwaves are used in different clinical fields e.g. the destruction of urinary stones, treatment of different musculoskeletal conditions and healing of chronic wounds. Nevertheless, it is still unknown why the sound waves have this influence especially on living tissue. To enhance understanding, various in-vitro and in-vivo experiments are conducted in cooperation with different clinical partners and the department of Anatomy and Cell Biology (RWTH Aachen). Amongst others, we investigate the effect of shock waves on wound healing in cooperation with the Department of Oral and Maxillofacial Surgery (RWTH Aachen). In a skin flap mouse model the VEGF-expression at the wound edge of shockwave treated and control animals is measured by luminescence and histology is examined.

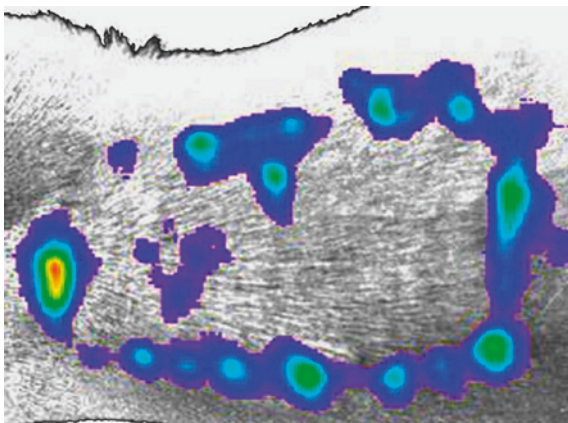


Fig. 8: Luminescence due to VEGF-expression at the wound edge in a mouse-model after shockwave treatment.

Modelling field distortions in EMT

Electromagnetic tracking (EMT) is of high interest for minimal invasive therapy. However, active disturbances as well as distortions of the electromagnetic field caused by ferromagnetic materials can result in serious errors. This especially holds in case of interventions in neurosurgery or neuroradiology requiring high precision tracking (such as e.g. aqueductoplasty). In the project NeuroEMT a method for model based distortion correction has been developed in cooperation with the Institute of High Frequency Technology (RWTH Aachen).

Modelling of the intervention scenario includes the anatomy of the human head (soft and hard tissue) as well as the surgical set-up including e.g. the Mayfield clamp and the operating table.

The evaluation revealed a strong correlation between measured tracking errors in the lab setup and simulated deviations. This provides the basis for automatic EM field distortion correction.

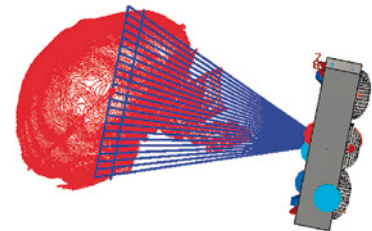


Fig.9: Experimental vs. simulation setup. Institute of High Frequency Technology, RWTH Aachen

Smart Instruments

The connection of the computer based planning and its accurate transfer into the operating site is one major objective in computer assisted surgery (CAS). However, the high cost-to-benefit ratio of multi-DOF surgical robots only for adjusting cuttings guides or drilling sleeves with respect to bone, hinders its broad clinical application. Our new Smart Screw Driver (SSD) approach is addressing this problem. It provides a link between the computer and simple passive screws for the x-DOF adjustment e.g. of a cutting guide for knee surgery. Each screw is automatically identified and adjusted according to the surgical plan. The system has been integrated and tested successfully.



Fig. 10: Interactive computer controlled adjustment of a cutting guide for Total Knee Arthroplasty.

Integration and Risk Management

The smartOR project provided an innovative solution for the integration of medical devices and IT-systems in operating rooms. The development of an open surgical communication bus (OSCB) and interfaces for a platform and vendor independent solution on the basis of a service oriented architecture (SOA) are key elements of the concept. The presentation of smartOR partners on the conhIT 2013 trade fair and conference in Berlin found a very positive response.

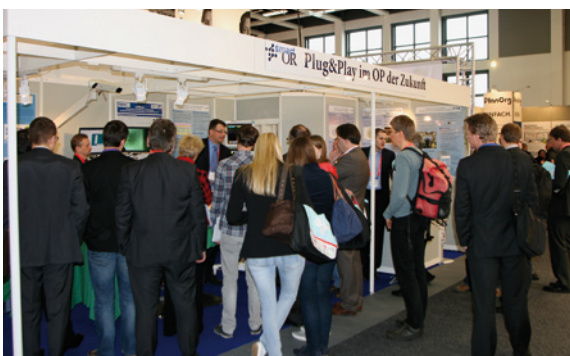


Fig. 11: smartOR @ conhIT 2013, Berlin.

The results of the smartOR project are an essential basis for the BMBF project OR.NET aiming at a secure dynamic networking of medical devices and IT systems in the OR and clinic.

Apart from innovative technical aspects, the development of highly sophisticated methods for risk management and the accreditation of device combinations and modular sub-systems with open interfaces are major objectives of the project work.

In the context of the risk management process, manufacturers and clinical operators must be able to (semi-)automatically integrate the risk analysis and control of individual components into an overall risk management according to ISO 80001. Therefore, new tools and standards have to be developed, particularly regarding the modular integration of human-machine-interaction processes.

The general concept and related issues of the OR.NET project have been the subject of a round table organized by Prof. Radermacher on the Medica Health IT Forum 2013 in Düsseldorf with very positive public response.



Fig. 12: Medica Health IT Forum: OR.NET round table.

Neurofeedback for home application

The EEG-based neurofeedback training provides an alternative treatment opportunity for attention deficit hyperactivity disorder (ADHD). While EEG-sensors measure the brain activity, the patients control the height of a figure on a screen by deliberately concentrating and relaxing in turns. By this, they learn to control specific parts of their brain activity. In order to offer training sessions more frequently and thereby optimizing the therapy, it is the main objective of this project to transfer the training from specialized doctor's offices to the living environment of the patient.



Fig. 13: Principle of the EEG-based Neurofeedback and conceptual design of the headset.

Therefore a new neurofeedback system with an innovative therapeutic as well as patient user interface, including a headset to attach electrodes and amplifier, is currently being developed with industrial and research partners in order to improve the usability for home application.

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- European Space Agency (ESA)
- ERS@RWTH Aachen
- START program of the medical faculty of the RWTH Aachen

Selected Publications

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Team

