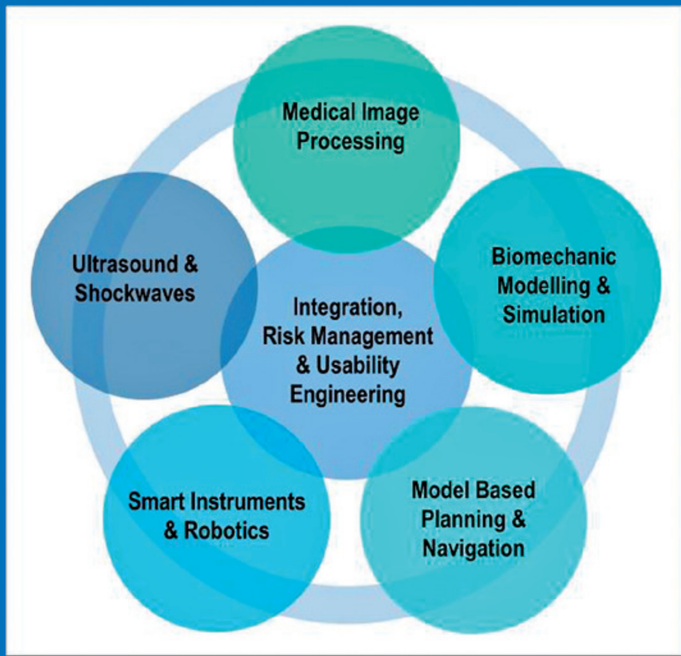
Chair of Medical Engineering
Faculty of Mechanical Engineering

Innovative Technology for Smart Therapy



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Introduction

The main objective of our work is to promote engineering science modern technologies and innovations supporting better health care. Apart from the development of innovative technical solutions and products, basic engineering research or an application and optimization of advanced engineering methodologies e.g. for process analysis, risk management and quality assurance of complex human-technology systems, can be the key in some cases. Actual trends towards personalized medicine (including e.g. patient specific implants) or open medical networks ("internet of things") are based on modern technologies such as 3D-imaging, image processing and generative manufacturing ("3D-printing") or modern sensor and communication technologies. However, in many cases technical solutions remain worthless without an in-depth understanding of related physiological or pathological boundary conditions, requirements, clinical processes and workflows. Against this background, our activities cover different aspects linking basic research with application-oriented development and evaluation, reaching from the acquisition, segmentation and reconstruction of relevant information, its registration and integration for patient specific modelling and planning, to adequate technical means for model guided therapy. Last but not least, risk management and usability engineering within the clinical context of use are major aspects of our work.

In 2015, the coordination of the OR.NET project on secure dynamic integration of modular OR-systems, a flagship project of the German Ministry for Education and Research (BMBF) with an overall budget of 18,5 M€ (2012-8/2015), 54 full partners and meanwhile more than 40 associated partners from industry, academia, clinics and associations, represented a continuing major challenge. Apart from very encouraging results concerning international standardization and approval strategies, technical demonstrator systems have been successfully presented in Lübeck, Leipzig and Aachen.

Based on the results of our initial BMBF project IDA (development of an intraoral ultrasound based micro-scanner; Medical Technology Innovation Award 2008 of the BMBF), members of the mediTEC team founded the whitesonic GmbH and received substantial funding of the Federal Ministry of Economic Affairs and Energy (BMWi) for the transfer of our basic research and development results to its clinical application.

Personalized biomechanical modelling, design and generative manufacturing of patient specific knee implants have been major objectives of our RAPIDGEN project (2,3 M€ co-funded by the state of North-Rhine Westphalia and by the European Union as part of the European Regional Development Fund; 7 Partners, Coordination: mediTEC) successfully concluded in 2015. The projects results are a substantial basis for continuing research and developments in cooperation with our medical and industrial partners. Additionally, various projects related to basic research issues (e.g. funded by the German Research Foundation (DFG)) as well as industrial co-operations in different focus areas have been continued or started by our team. International cooperations, publications of our research, the market applications of products originally developed in our lab as well as international patent applications continuously confirm our general concept of combining basic as well as problem oriented medical engineering research and application development, also assuring a sound basis for the education of our students.

Selected Projects

Patient specific biomechanical modelling for computer assisted wrist surgery

For the therapy of wrist injuries and degenerative diseases of the joint system, it is essential to understand wrist joint biomechanics. A musculoskeletal model for therapy planning in wrist joint surgery has been developed and evaluated in cooperation with the Department of Plastic Surgery, Hand and Burns Surgery of the University Hospital Aachen (Prof. Pallua). Apart from generic morpho-functional modelling of the wrist joint, the integration and optimization of image based patient specific model adaptation into standard clinical workflows and use scenarios has been a major objective of this project. Based on a multi body simulation (MBS), the model enables a simulation of individual wrist motion and outcome prediction in case of changing kinematics due to e.g. ligament ruptures or different surgical measures. Therefore, patient-specific models seem to be valuable tools for surgeons in therapy planning, implant placement and orientation, and planning of rehabilitation, respectively. Further evaluation and optimization are objectives of our ongoing work.

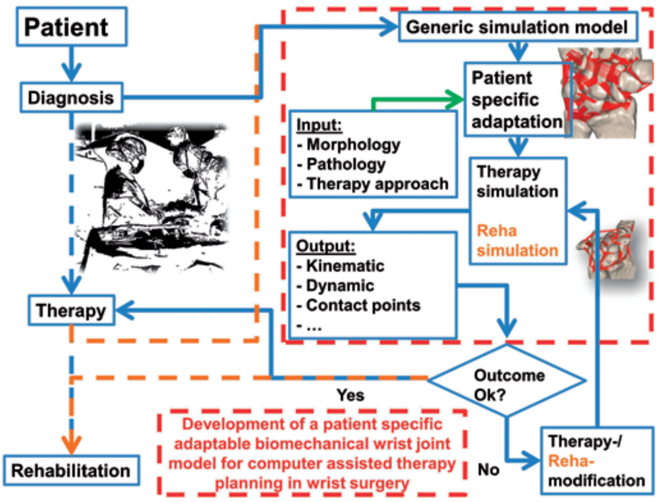

Fig. 1: Patient specific musculoskeletal modelling scheme for planning and rehabilitation.

Patient specific modelling of the hip

In the context of the implantation of a hip endoprosthesis the positioning of the components is generally seen as a factor strongly related to the risk of failure. The malpositioning of the acetabular component increases the risk of failure of the prosthesis caused by dislocation or edge-loading. The determination of a patient-specific optimal orientation as well as a patient-specific safe zone of the acetabular component therefore remains a major issue.

A generic musculoskeletal MBS model of the lower limb has been adapted and personalized on the basis of individual motion capture data and morphological data obtained by computed tomography. The model was validated using in vivo data of a one-legged stance with physiological knee flexion from the OrthoLoad database (www.orthoload.com).

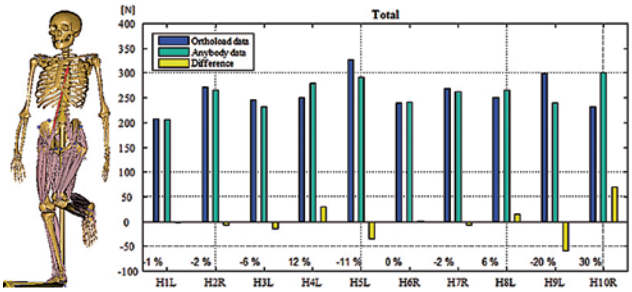

Fig. 2: Evaluation results for the patient-specific model performing a one-legged stance (left). The difference of the resulting hip reaction force between simulation and in-vivo data for ten subjects (right).

In-silico and in-vitro parameter studies for the optimization of knee implant designs

Experimental in-vitro testing on knee-simulators play an important role in the understanding of the complex biomechanics of the human knee and offer great opportunities to perform parameter studies and evaluate new implant designs. We think, that experimental ex-vivo parameters studies with our PCA-Knee Simulator are an essential complementary mean for the verification of our in-silico model based biomechanical simulations and parameter optimization studies.

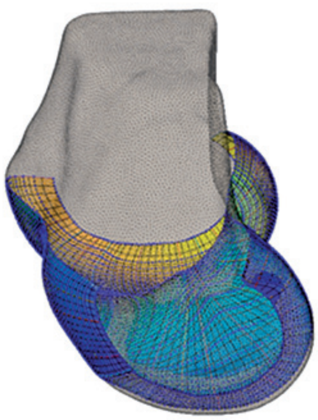

Fig. 3: Automatic in-silico parameterization of the distal femoral morphology.

For extensive parameter optimization, both methods should enable fast and easy biomechanical analysis with various implant geometries. However, whereas in-silico parameter variation is easy and cheap, manufacturing of CoCr implants for experimental ex-vivo studies is very costly and time consuming. Therefore, a comparative study including different rapid prototyping ("3D-printing") technologies, processes and implant geometries has been launched. A high surface quality and shape accuracy, as well as low friction are very important requirements and currently analyzed. Preliminary results are very promising.

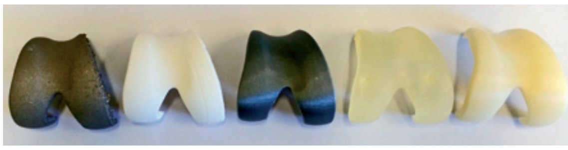

Fig. 4: Experimental knee implants manufactured with different materials and processes.

Biomechanical modelling of craniospinal fluid-dynamics

Normal Pressure Hydrocephalus (NPH) has become a common disease in the elderly presenting itself in the typical symptoms of dementia, gait ataxia and incontinence. However the pathogenesis of NPH is still not understood. Therefore a concept for an experimental in-vitro as well as in-silico phantom model of the craniospinal hydrodynamics has been developed. The model enables sensitivity analysis to investigate parameters and morpho-functional changes and related hydrodynamics.

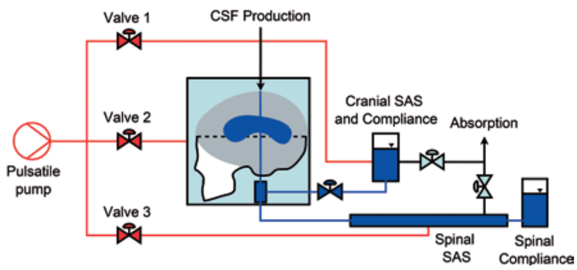

Fig.5: Conceptual design of the NPH simulation phantom.

Automatic removal of osteophytes on bone surfaces of the knee

In the case of total knee arthroplasties (TKA) a better outcome may be achieved by using patient-customized implants. The implant design is based on the actual bone surface obtained from medical imaging. Due to the degeneration of bone and cartilage, osteophytes may develop which show up in the acquired images and thus in the segmented surface data. The removal of these osteophytes (to be removed by the surgeon during operation) is necessary for implant design and is cumbersome and time consuming. Therefore, we developed a method for automatic osteophyte removal. From a set of manually segmented bone surfaces as well as their original surfaces we annotated a mean shape with average sites of osteophytes. Osteophytes can then be automatically removed from a new unknown shape by morphing the annotated mean shape into the target shape while omitting sites of osteophytes. Due to the underlying regularization in the morphing procedure, these areas are virtually interpolated and thus the osteophytes are removed.

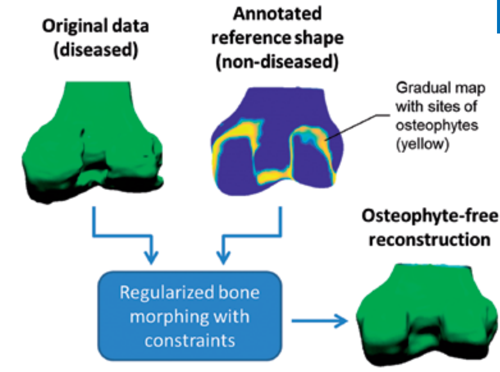

Fig. 6:
Automatic osteophyte removal through bone morphing of an annotated mean shape.

Modular framework for 2D/3D registration

In many fields of computer-aided surgery, combining multi-modal image data such as 3D volume data and 2D projections can improve the accuracy and efficiency of the procedure. 3D data provide detailed information of the patient's anatomy while 2D images maybe more easily available in clinical routine and can be useful for extracting functional data such as joint orientations in a weight bearing situation or the positions of the patient and the surgical instruments in the operating room. Due to the variety of applications using

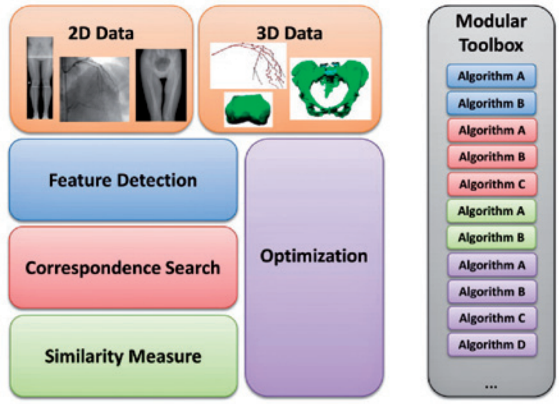

Fig. 7: Modular mediTEC framework for 2D/3D registration.

2D/3D registration in the field of for example orthopaedics or cardiology, a modular framework has been developed. Different types of input data can be registered to each other using modular algorithms. This also allows fast adaptation of new algorithms and new applications.

SICOSI – Smart Impedance Controlled Osteotomy Instrumentation

The transection of bone, while preserving adjacent sensitive soft tissue structures such as nerves or vessels, is a crucial task in many surgical interventions. In this context craniotomy and re-sternotomy, which are standard approaches to create surgical access to intra-cranial or intra-thoracic structures, are of high relevance. Conventionally the procedures bear high risk of unintended damage of the soft tissue underneath the bone. However, approaches based on robot-assistance using pre- or intraoperative imaging data require additional steps, making the integration into the standard workflow complex and time consuming. The SICOSI project (funded by the German Research Association (DFG)) aims to investigate the feasibility of a novel hand guided, sensor integrated instrument based on online bio-impedance measurements during the cutting process. Thus, no additional imaging or tracking information is needed. Therefore, first concepts for real-time cutting depth control were developed. Furthermore, sensor integration into a synergistic surgical device has been demonstrated and evaluated in first feasibility tests on fresh bovine bone specimen. Moreover, usability of different saw blade designs and manufacturing approaches have been investigated. Results of mono- and bipolar measurements show, that the transition of different layers of bi-cortical bone and bone breakthrough lead to characteristic impedance patterns that can be used for process control.

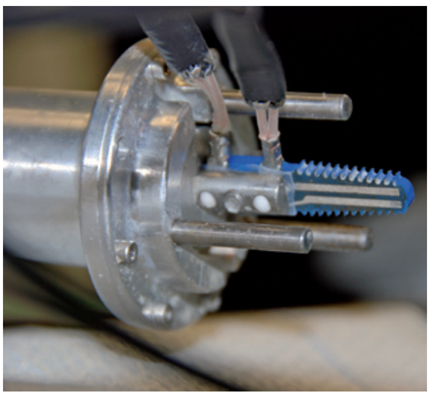

Fig. 8: Ceramic saw blade with integrated electrodes.

Optimization of shockwave lithotripsy

Shockwaves have been used clinically for the disintegration of kidney stones since the 1980's. The sonic pulses are coupled to the skin of the patient and focused on a target point inside the human body. The positioning of the focus on the stone is achieved with the help of imaging technologies such as ultrasound or x-ray. However, until now the optimal temporal as well as spatial distribution of the pressure waveform, leading to the most efficient fracturing with the least side effects, is unknown.

Fig. 9: Shockwave treatment of an artificial kidney stone leads to fracturing of the stone. The fracture pattern can then be compared to the simulated tensions.

To enhance understanding of the fracture mechanisms and optimize the pressure distribution for an improved disintegration, we conduct FEM simulations of the effect of different setups, protocols and related sound fields on kidney stone fragmentation and compare them to the in-vitro stone disintegration with artificial kidney stones.

IDentUS - Intraoral Dental scanning using Ultrasound

Dental impressioning is often affected by soft-tissue, blood and saliva regardless whether using compound impression techniques or digital optical scanning methods. In contrast, ultrasonic waves are able to non-invasively penetrate gingiva, saliva and blood leading to decisive advantages as cleaning and drying of the oral cavity becomes needless. The application of ultrasound may facilitate the detection of subgingival structures without invasive surgical preparation. The objective of the BMWi EXIST project IDentUS is the development and evaluation of an ultrasound-based intraoral micro-scanner for dental applications. In addition, suitable business models and strategies for a market entry have been developed. Moreover, the launch of the RWTH spin-off whitesonic GmbH, founded in August 2015, represents another essential milestone of the EXIST II grant dedicated to finalize the product for the market.

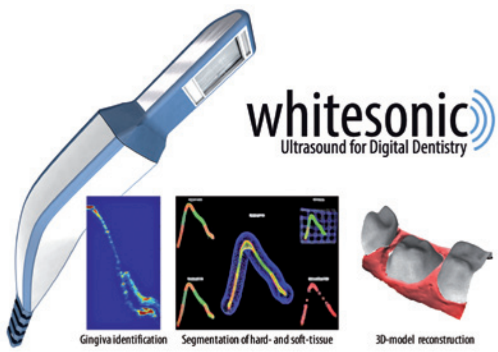

Fig. 10: whitesonic intra-oral microscanner and processing steps in ultrasound-based digital impressioning of tooth-preparations.

Integration, risk management and approval of open MedDev-IT networks in the OR and clinic

Risk management and approval of open IT networks with integrated medical devices is one major challenge of the BMBF-Project OR.NET (on secure dynamic integration of modular OR-systems, a flagship project of the German Ministry for Education and Research (BMBF) with more than 90 partners from academics, clinics, associations and industry, coordinated by mediTEC). These activities are essentially based on our research on technology, approval strategies, risk management and usability of integrated OR-systems.
In 2015 we implemented and demonstrated a fully integrated OR demonstrator system for spine surgery in cooperation with the Clinics for Neurosurgery (Prof. Clusmann), Orthopaedics (Prof. Tingart) and Anaesthesiology (Prof. Rossaint) of the University Clinic in Aachen based on open communication standards. In cooperation with more than 20 industrial partners the modular integration of a large number of different medical devices and IT components could be shown in the context of podium presentations and hands-on workshops, October 2015 in Aachen. The main focus of our research has been on the development of new concepts for a safe and usable modular integration of human-machine-interaction for both, surgeons and anaesthesiologists. We developed a surgical workstation and a modular user interface with numerous device panels for different devices, use cases and scenarios. Moreover, the integrated system provided direct access to clinical KIS and PACS systems. Due to modularity, the system architecture provides higher flexibility and access or integration on demand to the OR team with a lot more autonomy and might help to optimize workflows and reduce handling errors. OR.NET demonstrators with different technical or clinical foci have been successfully presented to the public in Lübeck, Leipzig and Aachen and will also be shown on the conhIT exhibition in April 2016 in Berlin.

Fig. 11: Podium presentations and hands-on OR.NET demonstrator evaluation workshops, October 2015, AC

The use of open standards for device communication in the OR opens up new opportunities for device handling. At present, many devices and corre-sponding functions in the OR have to be released via input devices such as e.g. through footswitches. However, in neurosurgery, up to 10 different footswitches may be installed at a time for human-machine interaction. The surgeons find themselves confronted with a conglomeration of footswitches of different size and kind, hidden behind drapes under the OR table. Unintentional displacement or confusion of footswitches may cause adverse events. In order to overcome these use deficits, we developed a prototype of a universal footswitch with a corresponding user on-screen interface of the surgical workstation. The surgeon can release different functions of various devices with the same footswitch, whereby the configuration changes depending on the specific requirements of the intraoperative workflow. An initial usability evaluation in cooperation with industrial and clinical partners showed very promising results.

Fig. 12: Graphical user interface (upper) and first labtype of the integrated universal footswitch.

Moreover, strategies and tools as well as device- and service-profiles to enable risk management and approval of modular OR systems including modular human-machine interfaces have been developed.
Extended medical device profiles contain inter alia additional profiles regarding the extended intended use, network communication risks (manufacturers' responsibility) and network requirements (clinical operators' responsibility) as well as user interface descriptions. The extended medical device and service profile complements the standardization activities in the OR.NET project e.g. regarding the ISO 11073 extensions for the data model and especially for safety aspects of medical device communications. Medical Device User Interface Profiles (MDUIP) have been developed in order to extend the technical device profile, enabling an automatic optimized selection and composition of various user interfaces and an integrated human risk analysis in terms of quality assurance in human-machine interaction. Until now, the MDUIP concept has been implemented and evaluated for the integration of an endoscopy system, an OR-table, an ultrasound dissector, a high frequency cutting device, a 3D X-ray C-arm and a surgical microscope.

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- European Space Agency (ESA)
- ERS@RWTH Aachen

* **Note:** In this report we can only provide a short overview of selected activities. For further information on the related projects, our cooperating partners, funding agencies and sponsors, please visit our website ***www.meditec.rwth-aachen.de*** or contact us directly.

Selected Publications

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Team

Fig. 13: mediTEC-Team members at winter-school 2015, Mayrhofen, Austria (upper) and at entreprise running challenge 2015, Aachen