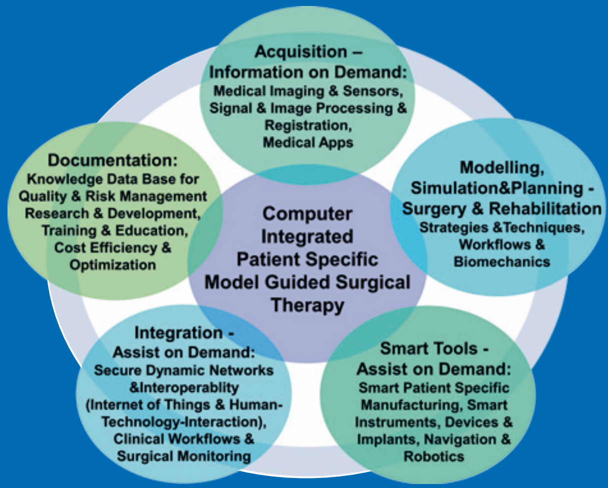
Faculty of Mechanical Engineering

Engineering Science and Innovation for better Health Care



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Introduction

The mission of the Chair of Medical Engineering (mediTEC) of the RWTH Aachen University is to provide an active link between interdisciplinary basic sciences and application oriented engineering research and development of innovative solutions for a better health care. Apart from international publications and a practical transfer and implementation of scientific findings, the education of our students from different disciplines and specialties is a major objective. As a complementary partner of clinicians and industry, our aim is to analyse the issues in health care systematically using engineering methodology and to identify, develop, implement and evaluate most appropriate solutions based on and beyond the state of the art of science and technology. Therefore interdisciplinary cooperation is crucial:

- With clinical experts – for the identification and analysis of the clinical challenges and boundary conditions, the need-oriented development and the evaluation of the cost-to-benefit ratio of technical developmental products and methods.
- With industrial partners – for the development of innovative lab-types and its efficient transfer into clinically as well as commercially attractive products. This can be implemented in cooperation with established industrial partners and/or industrial spin-offs of our chair.

Fig.1: *Impressions from CAOS2017*

In 2017, 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. The continuous success of the BMBF flagship project OR.NET coordinated by mediTEC in the years 2012-2016 (18,5 M €; more than 90 partners) is one outstanding example. Based on the achievements of the OR.NET project, the new standard IEEE 11073-10207 for “Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication” has been approved by the international IEEE standards association. Moreover, the concerted activities with our partners in the framework of the OR.NET association (www.ornet.org) resulted in new projects assuring the sustainability of our work. As president of the International Society for Computer Assisted Orthopaedic Surgery 2016/17, Prof. Radermacher coordinated the CAOS2017 Annual Meeting in Aachen (Fig. 1). During 4 days more than 300 international researchers from clinics, industry and research presented and discussed latest developments in the field. International co-operations, 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. Last but not least, this also provides a sound basis for the education of our students.

Selected Projects

In-vitro simulation of cranial arteriovenous blood flow affecting CSF dynamics

Age-related changes of viscoelastic properties of arteries affect the intracranial pressure (ICP) as well as the cere brospinal fluid (CSF) dynamics and might lead to neurological disorders like normal pressure hydrocephalus. For the in-vitro simulation of related effects we designed a cam disk driven piston pump, which is connected to an in-vitro model of the cranio-spinal system. It enables an easy simulation of different physiologic as well as pathologic arteriovenous flow characteristics and the influence of the cerebral blood vessel pulsation on the CSF dynamics. The setup includes a drive, piston and cylinder unit (Fig. 2). The core piece of the unit is the cam disk which is driven by a stepping motor. Due to its outline, the cam disk forces an arteriovenous flow on the system. By adapting and exchanging the disk, various changes of the blood dynamics can be investigated. We established an integrated digital workflow for the automatic generation of 3D-printed cam disks from clinical flow profiles. The piston pump is a cost efficient alternative to using a voice coil.

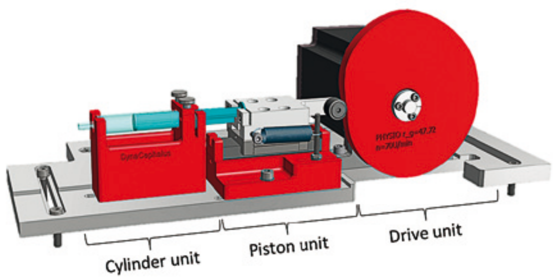

Fig.2: *CAD model of the cam plate driven piston pump.*

Medical Engineering

Patient Specific Target Zone for Implant Placement in Total Hip Arthroplasty

During total hip arthroplasty planning, suitable parameters for implant placement (position and orientation) are determined based on certain criteria such as good fit to the bony anatomy and leg length equality. More complex criteria such as a sufficient range of motion and adequate resulting hip forces are not systematically planned and are only considered based on the surgeons experience. During surgery, the parameters might need to be adapted due to intra-operative findings which might have an effect on the overall result. We developed a framework and algorithm to automatically calculate optimized set of parameters for a specific patient based on all relevant criteria derived from literature and to provide an intraoperative decision support system for the analysis of effects if certain parameters are changed

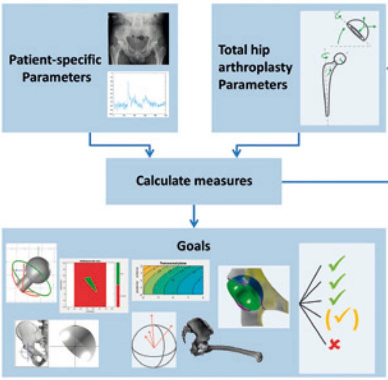

Fig. 3: Framework and clinical workflow for the optimization of patient-specific total hip arthroplasty.

The loading of the implant during activities of daily living is among the most important factors for the lifetime of the prosthesis. Since morphology and motions patterns are inter-individually different, the alignment of the prosthesis should be planned patient-specifically to avoid adverse loading conditions during activities of daily living. Within a clinical workflow the simulation time has to be minimized and the number of required input parameters should be reduced to avoid additional time-consuming and expensive data acquisition. Therefore, the development and validation of integrated morpho-functional models that can be efficiently personalized for each patient on the basis of standard clinical information is one major objective of our work.

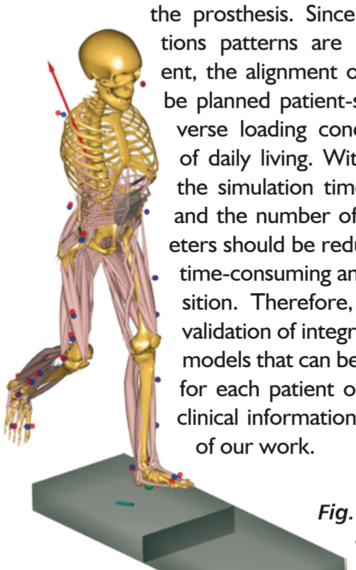

Fig. 4: A patient-specific adapted model for the approximation of the hip joint force during level walking.

Biomechanical Investigation of the Shoulder Joint

Understanding of shoulder joint biomechanics is of major importance for surgery as well as for shoulder arthroplasty design. We developed an ex-vivo shoulder simulator with an innovative "teach-in" function. This allows us to investigate the behaviour of the shoulder in any assigned free spatial movement without the need of any external or pre-set input. The experiment can be conducted using both cadaver and the artificial joint. With the use of additive manufacturing (3D printing), various shoulder joint geometries can be designed and tested, enabling us to conduct parameter studies and perform biomechanical evaluation of different shoulder implant designs. Furthermore, the experimental results are also useful for the verification of multi-body in-silico simulations.

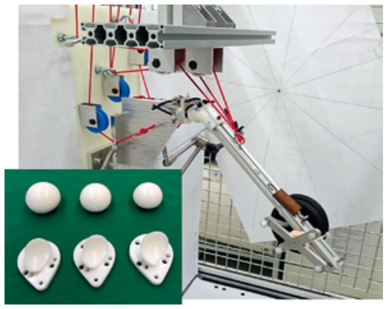

Fig. 5: In-vitro analysis of the impact of a variation of different implant design parameters using the Aachen shoulder simulator

Morphological analysis of the native knee

In total knee replacement, the clinical outcome is significantly influenced by the implant design. Different concepts of gender-, race- or patient-specific designs have been developed. This is based on reported anatomical differences in the knee shape (morphology), as reported in literature. However, little is known whether these differences originate from phenotypic differences between men and women or different ethnicities, or e.g. overall body size, and thus can be eliminated by a simple scaling. Therefore, we develop parametric models to quantify the knee morphology. This includes fully automatic methods for landmark recognition and feature extraction. Subsequently, we use statistical, correlation, and cluster analysis to investigate the knee morphology for patient specific implant design.

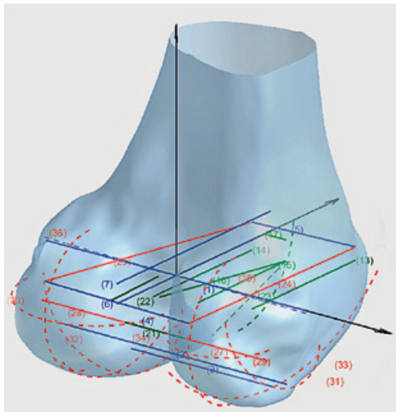

Fig. 6: Morphological analysis of the native knee.

Reconstruction of knee joint bones from multiple ultrasound images

A crucial factor for success in total knee arthroplasty (TKA) is the exact fit of the prosthesis on the involved bones. Under- or overhang may cause irritation of the surrounding ligaments or tendons as well as expose the spongy bone to abrasion particles. Further consequences include postoperative pain, osteophytes growth and inflammation. To ensure a tight fit, patient-specific implants may be planned and manufactured on the basis of CT- or MRI-based images. However these imaging modalities suffer from ionizing radiation or high costs. Therefore 3D ultrasound is investigated as an alternative. It is widely available, cheap and non-invasive. Yet it suffers from restrictions such as a limited field-of-view, acoustic shadowing and a low signal-to-noise ratio. This induces the need for a simultaneous segmentation of the bone surface in the image as well as a registration of the partial views. We developed an algorithm capable of both, the Interleaved Partitioned Active Shape Model Search (IPASM). Whereas our initial approach was based on 3D-US-Volumes, the actual algorithm is using conventional 2D B-Mode images while maintaining the precision of the reconstruction.

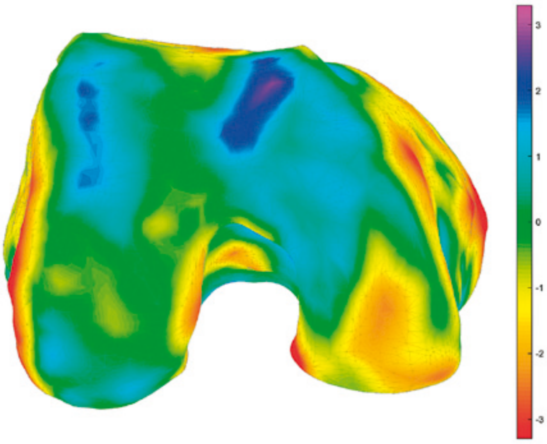

***Fig. 7:** Surface error compared to a CT-based ground truth of a distal femur reconstruction with the IPASM.*

Simulative evaluation of stone fragmentation during shockwave lithotripsy

The commonly used treatment for patients suffering from kidney stones is the extracorporeal shockwave lithotripsy (ESWL), where shockwaves are used in order to destroy the stones non-invasively. When the wave hits the stone, reflection and refraction arise due to impedance changes. Therefore, the pressure and the stresses inside the stone increase and cause fine cracks. Under the load of multiple shockwaves, these cracks lead to fractures. Since the fracture mechanisms of the stones are not completely understood we investigate the effects of various acoustic fields on artificial kidney stones in silico and evaluate their fracture efficiency.

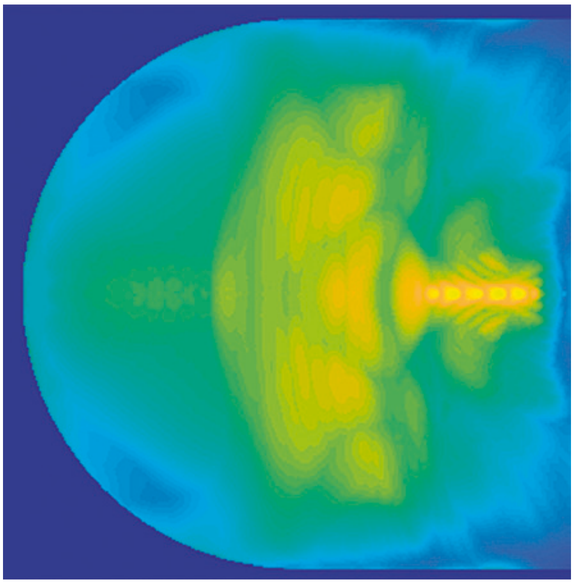

***Fig. 8:** Stress distribution inside an artificial kidney stone during shockwave lithotripsy.*

The simulation comprises wave propagation in water and gypsum as well as calculations of stresses and strains inside the stone. By application of e.g. the Tuler Butcher fracture criterion on the calculated stresses the approximate location and extent of fracture is determined. Moreover, our experimental shockwave test system for in-vitro analysis is used for verification.

ALLEGRO: Artificially intelligent robotic device for improved orthopaedic surgical care

ALLEGRO aims to bring to the market the first device of a new generation of intelligent and cost-efficient medical systems that will help surgeons significantly improve the usability (effectiveness, efficiency, learnability and user satisfaction) of surgical robot systems for orthopaedic surgery. The product suite combines a computer-assisted navigation system incorporating a real-time tracking device and a robotic surgical cutting tool associated with a smart stabilization support unit.

***Fig. 9:** Manipulator with milling tool for active path control in UKA and optional holding arm.*

Interoperability, risk management, usability engineering and approval of medical devices based on open communication standard

Based on the achievements of the OR.NET project (a flagship project of the Federal Ministry for Education and Research (BMBF) coordinated by our chair (2012-2016); 18,5 M €; more than 90 partners from industry, research, clinics and associations), the new standard IEEE 11073-10207 for "Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication" has been approved by the international IEEE standards association. Initiated by Prof. Radermacher, partners of the consortium founded the non-profit organization OR.NET e.V. in order to ensure sustainability of the project work and continued active cooperation. Apart from joint presentations of the OR.NET demonstrator e.g. on the exhibitions and international conferences (Fig.10a), further research projects (such as the EFRE project ZiMT on certifiable and integrated medical devices on the basis of IEEE 11073 and BMBF project MoVE on a modular validation environment for medical device networks) issued from these concerted activities. These projects enabled us to continue our research regarding the open integration of medical technology and corresponding approval strategies, methods and tools for the risk management and usability engineering as well as innovative human-machine-interfaces. Our team developed a surgical workstation with a touch-based graphical user interface including numerous device panels (e.g. OR light, 3D X-ray C-arm, OR-table, high-frequency cutting devices, endoscopic devices and ultrasound-cutting device) and a process-specific function group view (Fig. 10b) as well as a possibility for gesture control for the surgeon and OR nurse and a universal footswitch in combination with a vertically (and automatically) adjustable footboard for the surgeon. Moreover, the integrated system enables access to clinical information and PACS systems. The alarm concept (technical and patient related) and the workflow-supporting strategy provide the OR team with valuable information during the intraoperative process.

Fig. 10 (a): OR.NET demonstrator on the conhIT exhibition 2017, Berlin; ***(b)*** *Process-specific function group view*

Field studies and development for improved patient transport aids

Patient transport is a demanding task for emergency rescue personnel worldwide. According to several studies paramedics have the highest work related injury rates compared to all other industries. This is mainly caused by high physical loads during patient transport in association with unphysiological postures, which leads to musculoskeletal problems, especially lower back pain.

One approach may be the use of improved technical transport aids. The development of such a rescue and transport aid is the objective of the SEBARES-project. However, detailed information about the status quo in patient transport is essential but not yet available in literature, especially regarding the quantitative occurrence of obstacles. Therefore an objective survey at a local emergency medical service provider was conducted and 400 deployments could be quantitatively analyzed showing severe bottlenecks and very high workloads for the paramedics.

Fig. 11: Local medical service provider.

These studies are one major basis for the development of the novel SEBARES transportation system to improve the situation for paramedics by reducing the physical load during patient transport, while maintaining high maneuverability throughout the transportation process including stairs. To evaluate the ergonomics of the system in an early state and to get a first notion of the situational improvement for paramedics, a primary user study was conducted with a labtype (Fig. 12). The system was evaluated regarding different body sizes, terrains and slopes, while the postures of the different subjects and their applied forces and torques were recorded.

Fig. 12: Evaluation of the first SEBARES laptype

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- the German Research Foundation (DFG)
- the START program of the Medical Faculty of the RWTH Aachen University
- the European Union, the European Regional Development Fund (EFRE), the Ministry of Innovation, Science, Research and Technology and the Ministry of Economic Affairs North-Rhine-Westphalia

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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