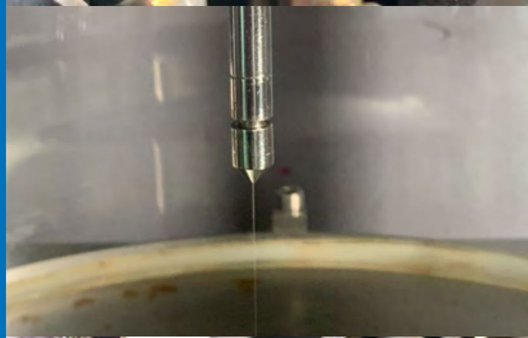
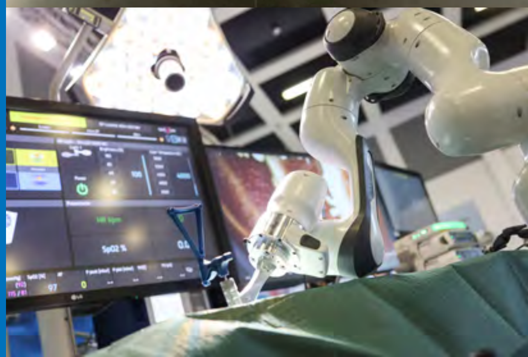
Chair of Medical Engineering
Faculty of Mechanical Engineering

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. Focus areas of our research are:

- Ultrasound & Shockwaves
- Biomechanical Modelling & Simulation
- Image & Model Guided Surgery
- Mechatronics & Robotics
- Integration, Usability & Risk Engineering

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. In addition to basic research grants, industrial cooperations, corresponding to about 50% of our annual turn-over, represent an important complementary application-oriented pillar of our work for the transfer of our research and developments into clinical applications.
After the years of pandemic, we were pleased to restart in 2023 to make greater use of scientific exchange in face-to-face meetings as part of bilateral contacts and international conferences. We are back to life! Based on networks with international partners from research, industry and clinics, existing collaborations were reenforced and a wide range of new projects were initiated or started.
This annual report summarizes some examples of current project work in 2023.

Selected Projects
DFG-Project MOFUMO – THA Biomechanics

Based on recent developments and demographic trends, an increase in the number of Total Hip Arthroplasty (THA) patients can be expected in the future. These patients tend to be younger, more active and have higher requirements on the prosthesis. Therefore, detailed preoperative planning becomes more important. With our clinical partners from Niigata Hip Joint Center (Niigata, Japan) and Charité Medical University Center (Berlin) we work on the integration of patient specific morpho-functional conditions and requirements for activities of daily living (ADL) into preoperative planning for THA. One aspect of this current research is the evaluation of range of motion (ROM) and hip joint forces for different ADLs.

Fig. 1: Hip joint force evaluation for the process of getting up from a chair and sitting down again

Patient Specific Optimization of TKA Implants

In the case of advanced knee osteoarthritis in combination with pain and functional impairment, total knee arthroplasty (TKA) is indicated. However, potential osteoarthritis-related deformities as well as genetic deformities should not be reconstructed in the design as they have been reported to have a detrimental effect on knee function. Therefore, they must be corrected prior to a patient specific evaluation of different OTS implant designs or a design of optimised patient-specific implants. For this purpose, we developed a fully automated workflow including a parameter-based deformity check and various methods for subsequent deformity correction, including a twin search, multiple linear regression and neural networks. After the deformity correction, adapted joint surfaces are created using previously published parameter models. The functional effects of the deformity correction on the knee kinematics are then evaluated using patient-specific biomechanic simulation.

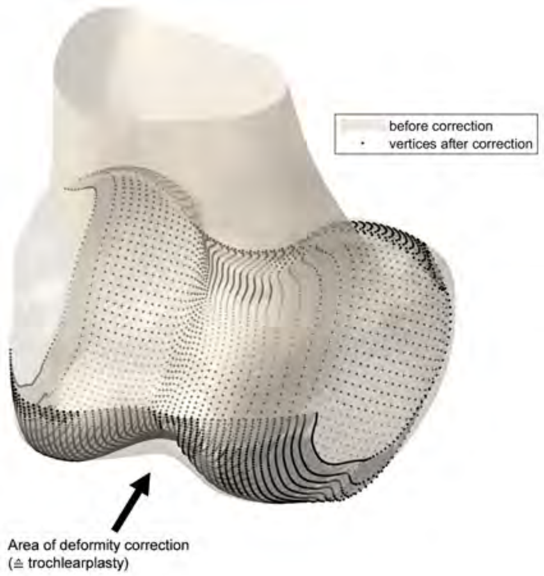

Fig. 2: Exemplary case with trochlear dysplasia before and after parameter-based deformity correction.

Biomechanics of the RNR

So-called “Redundant Nerve Roots” (RNR) are tangled, hypertrophied and accumulated nerve fibers in the area of stenoses of the spinal canal. Since the development of RNR is not entirely understood, a modular in vitro model being developed to investigate mechanical effects. The flexible model allows the variation of different pathological changes (e.g. osteophytes). Furthermore, a model of the spinal canal is integrated into an existing cerebro-spinal fluid (CSF) dynamics in vitro model in order to investigate hydrodynamic effects as part of our ongoing research on RNR and Normal Pressure Hydrocephalus (NPH).

Fig. 3: In vitro model of the lumbar section of the spinal canal with intervertebral discs and nerve fibers.

Cooperative Surgical Robotics

Although surgical robots have the potential to improve safety and surgical outcomes in neurosurgery and orthopedic surgery, their clinical adoption remains limited. One key reason for the limited adoption of current robotic systems is their restricted application scope. Further limitations arise from safety issues due to over-dimensioned kinematics, that contradict established safety standards for cooperative robotic systems. To address these challenges, we developed a modular dual robot system. The systems consists of an off-the-shelf lightweight carrier robot for pre-positioning and an in-house developed, highly dynamic, application-specific miniaturized tooling robot. The tooling robot compensates for patient breathing motion and robot elasticity. An admittance control allows the user to move the burr within pre-planned virtual fixtures. For the use case laminectomy, a formative usability study was conducted on a spine phantom, comparing the dual robot system with manual milling. Seven surgeons successfully performed a planar laminectomy with an accuracy better than 0.3 mm. Most surgeons rated the proposed dual robot system‘s safety, usability, and workload positively compared to manual milling.

Fig. 4: Cooperative robotic laminectomy on a spine phantom

Robotic Ultrasound System for TKA

For patient specific implants for TKA 3D bone models are required. These are typically generated by computer tomography (CT), causing significant additional costs and radiation exposure.
We investigate the use of ultrasound (US) imaging as a potential alternative for PSI design in TKA. But conventional US imaging results are highly user dependent and computer-aided recognition of bone is more challenging. Furthermore, the 3D reconstruction of bone requires 3D registration of the entire set of 2D US images. Using a robot equipped with an ultrasound probe, position information can directly be obtained for 3D reconstruction and an optimal path control with high reproducibility can be achieved.
In a fully autonomous process, initially the knee region to be scanned is recorded with a depth camera. This information is used as a basis for an autonomous path planning with an automatic model based optimization of the robotic scanning process with respect to the iteratively refined bone surface estimation. Subsequently, the robot follows the planned path and maintain a defined contact to the skin, while neural networks are used for an automatic bone surface segmentation and reconstruction.

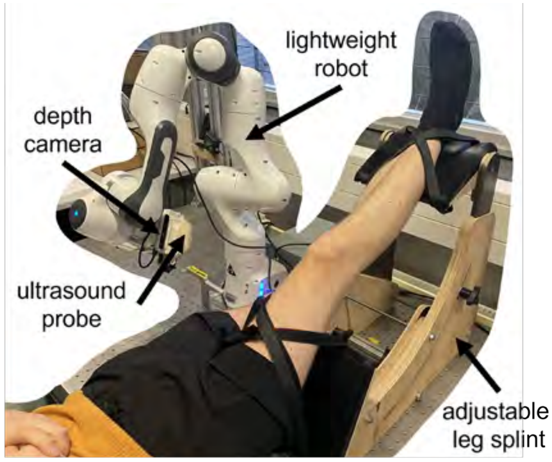

Fig. 5: Autonomous robotic ultrasound scanning of the knee

Ultrasound-based Fixation of Scaphoid Fractures

For the computer-assisted percutaneous fixation of scaphoid fractures, a patient-specific bone model is required for screw planning. This bone model is typically derived from pre-operative CT data, which exhibits the patient to radiation and moreover requires an intraoperative registration step. Conventionally repeated intraoperative fluoroscopic control induces significant radiation exposure for the patient as well as for the surgical staff. Alternatively, a 3D bone model for planning and intraoperative navigation of the screw may be derived from intraoperative ultrasound data directly. Since the scaphoid is only partially depicted in ultrasound images, statistical morphological knowledge is incorporated for the completion of partial bone surfaces. For this purpose, deep learning based approaches are employed.

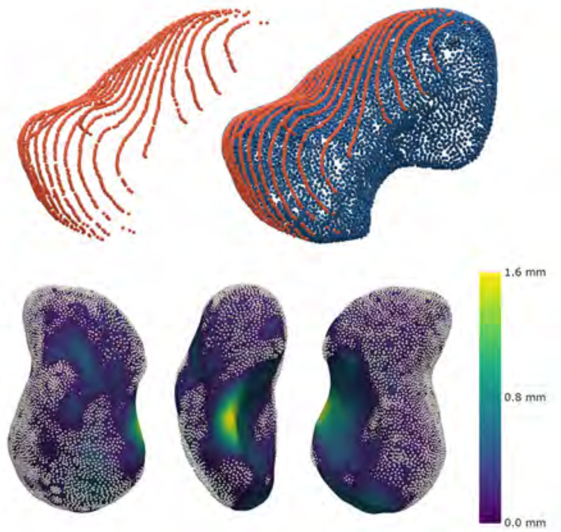

Fig. 6: Partial input and completed output point cloud (top), error between completed point cloud and ground truth mesh (bottom).

Modelling Piezoelectric Transducers for TUS

Piezoelectric Transducers are used in therapeutic ultrasound (TUS) for generating self-focusing shock waves. Designing transducers for this application is time-consuming as there are no readily available methods of simulating the transducer and its electrical and acoustical behaviour. Therefore, extensive iterative testing is required.
We developed a transducer model which can simulate the electrical and acoustical behavior of piezoelectric transducers dependent on time or frequency. The model can be combined to include control circuits and can be used to provide surface pressures for wave-field simulations as well.
By combining electrical and acoustical simulation, the model can simplify the design process of transducers and improve the understanding of related piezoelectric effects.

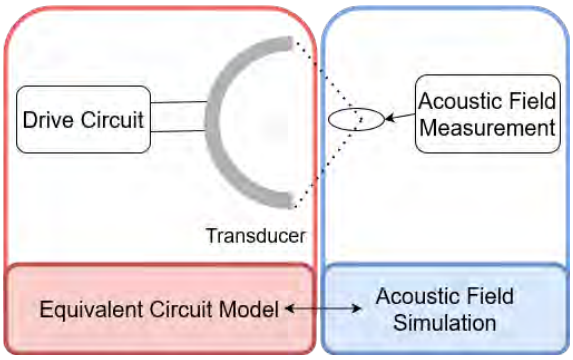

Fig. 7: Diagram of the shock wave generation simulation setup. The new equivalent circuit model can simulate both drive circuit and transducer, a second program can then simulate the acoustic field.

Benchmarking of Reprocessing Facilities

Previous field studies have revealed significant differences in the Performance Shaping Factors (PSFs) of German reprocessing facilities despite the uniform necessity to supply the operation theatres with clean and sterile medical devices. We developed the first German reprocessing benchmark in cooperation with the "Deutsche Gesellschaft für Sterilgutversorgung e.V." (DGSV) to facilitate the exchange and shared learning of the reprocessing facilities. 50 reprocessing facilities participated in the first benchmarking initiative. Our ongoing work focuses on statistical analysis of the retrieved data to identify PSFs with an especially strong influence on the reprocessing key performance indicators (KPI) and, therefore, patient safety.

Fig. 8: Visualisation of the first statistical analysis with brighter colours indicating stronger correlations

Automation in Surgical Instrument Reprocessing

Reprocessing of surgical instruments after use is essential for a continuous supply of the operation theatres and includes the manual opening of hinged standard instruments for cleaning. This manual interaction poses a severe risk to cleaning personnel, as reaching into contaminated instrument sets and respective handling of the different instruments is necessary. In the context of our broader R&D activities related to automated surgical instrument reprocessing, we investigated the feasibility of automating this handling task. We analysed a caesarean section set to consider various forms and sizes of hinged instruments. We developed and evaluated an automated device able to handle and open all instruments with or without locking mechanism.
Moreover, we conducted an interaction-centered user study with 13 participants performing typical reprocessing tasks using different assistance approaches. Digital assistant systems (DAS) and cyber-physical assistance systems (CPAS), including cooperative robots, have the potential to enhance usability and safety in complex tasks such as surgical instrument reprocessing. Various metrics were measured and documented, including time required, user errors, the criticality of errors and perceived workload.
In first trials the CPAS improved usability the most, improving effectiveness (number of errors) while maintaining the same efficiency (total duration). This ongoing study will provide comparative data on usability across different levels of assistance and automation for complex and workpiece-specific tasks in surgical instrument reprocessing.

Wireless Tracking Systems for the Integrated OR

Navigated and robotics have been established in recent years. However, the use of additional medical devices and especially tracking systems is necessary. Consequently, each navigation or robot system comes along with its wired (in most cases optical) localizer system. As operating rooms are crowded already, there is often a noticeable decrease in ergonomics and safety when more devices are added, especially ones that need both wired power and network connectivity. Our wireless tracking system (Fig. 1) is a novel battery-powered development which can operate for up to 24 hours on a single charge without any cable connections necessary. The device is easily manoeuvrable and creates less constrictions around the operating table. The data is transferred via WiFi or local 5G to the operating room network, where it can be harnessed by applications such as the surgical navigation software or robotic system. The communication of the wireless tracking system conforms to the open ISO/IEEE 11073 Service-oriented Device Connectivity (SDC) standard family. This means that the tracking is no longer a static component that comes bundled with only one software. Instead, the tracking data may be used by multiple applications even from different vendors, as long as the standard is safely implemented. This makes the tracking camera a modular component and decreases the cost while providing more benefits and flexibility to the surgical team.

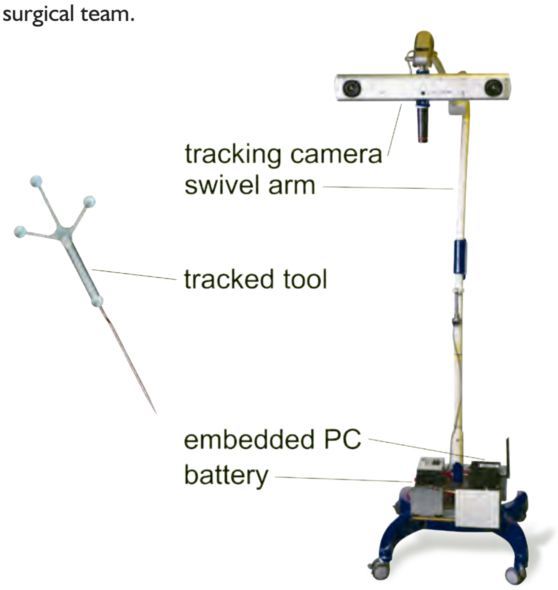

Fig. 9: Wireless tracking system with labelled components (right) and example of tracked pointer tool (left).

UI Profiles for the Open Networked OR

Safe and user-friendly interfaces are crucial in open networked operating rooms, where various medical devices communicate via the ISO/IEEE 11073 SDC protocol. The transmitted data currently contains technical device values and their descriptions but misses standardized human-machine interface (HMI) information, which is crucial for developing user interfaces. Categories such as grouping, visibility level, control speed or criticality could help designers build more useable and safer interfaces. Without that information, creating safe user interfaces is a challenging task. We developed a UI description language containing rules and design requirements for UI intended to increase usability for healthcare professionals and patient safety.

Scalable Cloud Architecture for 5G/6G RAN

In the framework of the CLOUD56 project, we are contributing virtualized clinical assistance functions for the operating room and the entire hospital to demonstrate the benefits of 5G campus networks and vRAN (virtualized Radio Access Network) implementations. In this context, we leverage SDC as a vendor-independent network protocol for medical devices. Clinical assistance functions are provided as containerized services within hybrid cloud-edge infrastructures and utilize intelligent interaction and data exchange of different medical devices (medical device ensembles). This approach enables the availability of vast computational performance for intensive and multimodal tasks, such as image or audio processing, from all connected areas in and around a clinic. New services can be dynamically integrated, and computing capacities can easily be adapted to the current and future demands. In addition, we investigate the specific requirements for forming ensembles of wireless medical devices and ensuring their seamless and secure transmission. To ensure security in device-to-device communications that require the formation of ensembles based on location or patient information before and after network changes, we develop and analyze specific processes and strategies. This includes linking ensembles based on the tracked locations of users and medical devices. At the same time, we optimize traditional manual processes for wireless workflows. The use of 5G offers the potential to ensure proper authentication and identification of users and devices, which is crucial for maintaining IT security, especially when dealing with wireless medical devices and mobile patient beds.

Fig.10: DMEA 2023 – SDC OR Demonstrator.

Awards

We also congratulate Sonja Ehreiser for the Best Technical Podium Presentation (1st place), Lovis Phlippen for the Best Technical Podium Presentation (3rd place) and Luisa Berger for the Best Clinical Poster Presentation (2nd place) – all funded by the ISTELAR foundation - , 22nd Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery - CAOS 2023, Pattaya, Thailand

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*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 and awards, please visit our website www.meditec.rwth-aachen.de or contact us directly.

Selected Publications

[1] A. Benninghaus, F. Huber, A. Müller & K. Radermacher: Experimental investigation of the influence of pathological blood dynamics on the CSF system with regard to normal pressure hydrocephalus. Hydrocephalus 2022: the 14th Meeting of the Hydrocephalus Society, Fluids and Barriers of the CNS, 19(104), 2023

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Medical Engineering