Chair of Medical Engineering at Helmholtz-Institute for Biomedical Engineering | RWTH AACHEN UNIVERSITY

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.
In 2020 the pandemic situation forced our team to put a lot of efforts in the reorganisation of our teaching as well as of our research and development activities. However, based on established networks and in many cases long lasting cooperation with partners from research, industry and clinics, we have been able to continue major research projects as well as to successfully initiate new activities.
This annual report summarizes some examples of our project work.

Selected Projects

Ultrasound and AI

Medical ultrasound is a widespread imaging modality utilized in a variety of different diagnostic tasks, ranging from echocardiography and mammography over prenatal screening to orthopaedic applications like bone fracture detection. It offers real-time capabilities, which makes it especially useful for dynamic investigations. In contrast, other imaging alternatives like computed tomography (CT) or magnetic resonance imaging (MRI) are expensive and potentially dangerous for the patient as well as the clinical personal. Yet, ultrasound requires skilled personal due to the low signal-to-noise ratio and several other limitations.

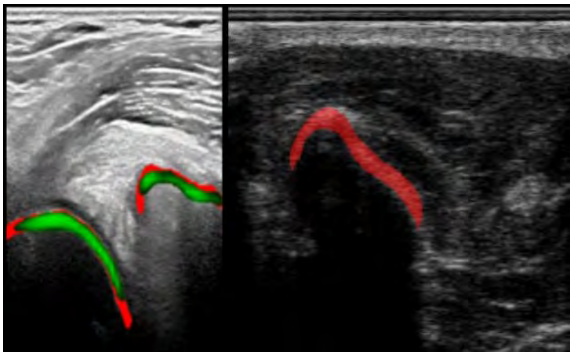


Fig. 1: Automatic segmentation of bone surface

Therefore, we develop image processing algorithms that allow for an automatic processing of ultrasound images, easing the task of image interpretation e.g. for a fully automatic classification of injuries like a tear of the anterior cruciate ligament. Furthermore, we develop a pipeline for full three-dimensional models for knee and wrist joint surgery, reconstructed solely from ultrasound images, potentially replacing CT for preoperative planning in orthopedics. The reconstruction process is based on a-priori knowledge incorporated with a statistical model as well as various neural networks specialized on image and sequence processing.

Extracorporeal Shock Wave Therapy

Extracorporeal Shockwave Therapy (ESWT) is used for treatment of Achilles tendinopathy. Line-focused ESWT is a novel technique treating a larger tendon area than point-focused ESWT. Monitoring capacities of clinical symptoms with ultrasound under ESWT treatment are unknown. We hypothesized that point-focused and line-focused ESWT have a superior outcome compared to placebo ESWT and that ESWT leads to tendon changes, which are detectable with ultrasound.
The present study is a single-blinded placebo controlled RCT. Three cohorts were compared: ESWT point, ESWT line and ESWT placebo. VISA-A score was measured before intervention (T0), after 6 (T1) and 24 weeks (T2). All cohorts performed daily physiotherapy for 24 weeks and received 4 sessions of point-focused, line-focused and placebo ESWT in the first 6 weeks. Ultrasound was performed with B-Mode, Power Doppler, Shear Wave Elastography (SWE) at T0 and T2 and with Ultrasound Tissue Characterization at T0, T1 and T2.

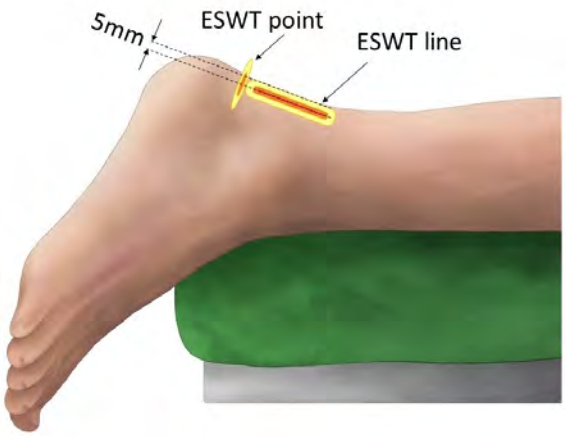


Fig. 2: The tendon volume treated with line-focused ESWT is larger than in point-focused ESWT. However, the maximum energy density is higher in point-focused ESWT than in line-focused ESWT.

There was a significant VISA-A improvement over time for all groups ($p<0.001$). ESWT point had the strongest VISA-A score improvement +23 (ESWT line: +18; ESWT placebo: +15), but there was no significant interaction between time and group. Ultrasound Tissue Characterization, Power Doppler and B-Mode could not show significant alterations over time. SWE revealed a significant increase of elastic properties for ESWT point in the insertion and midportion over time.

Morpho-functional analysis of the knee joint

Morphological parameters are considered in clinical practice for various reasons. For example, in the case of patellar instability and/or (recurrent) patellar subluxation, morphological parameters of the knee may support the decision for an adequate treatment option. The parameters considered include e.g. the femoral sulcus angle and the tuberositas tibiae to trochlear groove (TT-TG) distance. We investigate the relationship between such parameters used in clinical practice and knee kinematics e.g. by in silico analyses, both in the native knee and after knee arthroplasty. As an example, we evaluated the relationship between the TT-TG distance and patellar kinematics. The TT-TG distance is affected by various morphological parameters of the knee, including the mediolateral position of the tuberositas tibiae and the trochlear groove, as well as the relative rotation of femur to tibia. We considered various changes in the model setup, in order to represent changes in TT-TG distance. The described analyses are relevant both for a better understanding of the reasons for patellar instability as well as for implant design optimization.

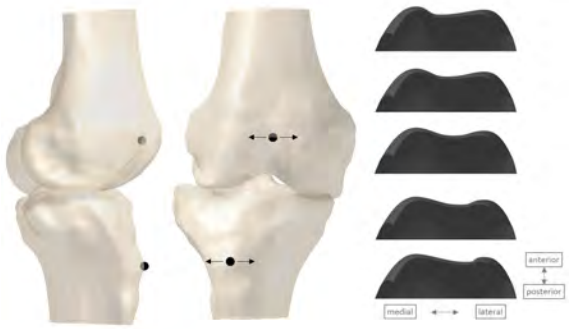


Fig. 3: (A) Native knee morphology with landmarks (tuberositas tibiae & trochlear groove point). (B) Parametrized surface models with changes in trochlea geometry.

CSF dynamics in NPH

As Normal Pressure Hydrocephalus (NPH) is associated with higher age, there might be a correlation with age-associated changes of vascular and craniospinal fluid (CSF) dynamics. To investigate this correlation of blood and CSF dynamics a computational model was developed, which can simulate the vascular pressure propagation inside the vessels with spatial and temporal resolution and its interaction with the CSF space and dynamics.

It consists of 11 compliant segments, from the bigger artery, to the capillaries and finally to the vein, which are all connected to the intracranial pressure (ICP). Input parameters are the venous pressure in the bridging veins and the pulsatile flow in the big arteries. The results show, that elevated capillary pulsations can damage the brain parenchyma and lead to higher aqueduct stroke volume as seen in NPH.
Further parameter studies of age associated geometric alterations, craniospinal compliance and blood pressure are part of our ongoing research.

MINARO HD – handheld mini-robotic bone milling

Current surgical robotic systems consist either of a large serial arm, resulting in higher risks due to their high inertia and no inherent limitations of the working space, or they are bone-mounted, adding substantial additional task steps to the surgical workflow.
To overcome these disadvantages, a robot was developed that has a handy and lightweight design and can be easily held by the surgeon. No rigid fixation to the bone or cart is necessary. A high-speed tracking camera together with a fast control system ensures the accurate positioning of the milling tool, while automatically compensating for movements of the surgeon or the patient's bone.

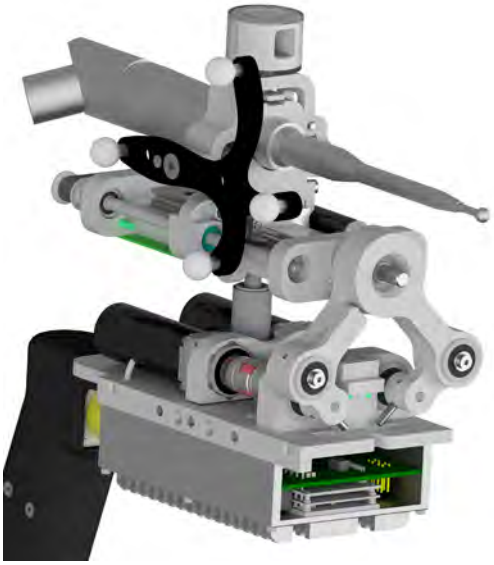


Fig. 5: Handheld robot Minaro HD

After the manipulator has been pre-positioned and activated by the surgeon, the milling tool is automatically moved by the robotic system along a previously planned trajectory with a latency of 24 msec and an offset of 0,044 mm. In case of any unforeseen event, the handheld manipulator can be stopped and reactivated at any time providing the benefits if robotic milling while avoiding the drawbacks of bulky robot arms.

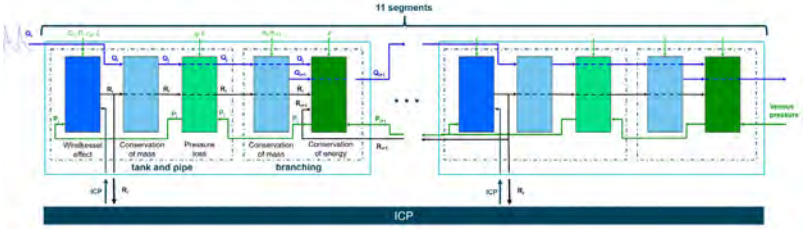
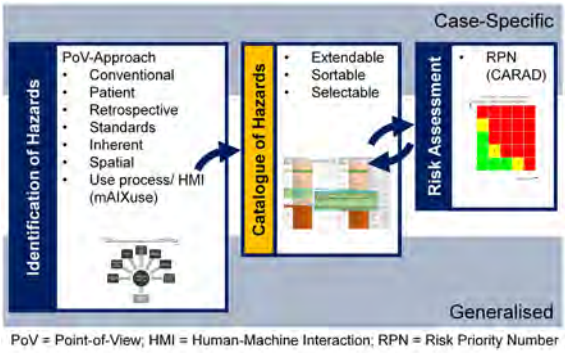


Fig. 4: MATLAB Simulink Model of cerebral vessels in connection with the intracranial pressure (ICP)

Catalogue of Hazards for Surgical Robot Design

Intrinsic safety is a major objective in surgical robot design. Inherently safe mechanisms can be based on modularity. Due to promising benefits of modularization approaches regarding safety, usability and costs, a design framework is being developed that streamlines the modular design of surgical robots wherein intraoperative safety is only one of many module drivers.
Furthermore, a multi-perspective method for hazard identification was established to make risk analysis as comprehensive as possible and easy to apply. Our Point-of-View (PoV) approach aims to capture relevant hazards by taking multiple overlapping perspectives. The perspectives are applied chronologically according to the degree of system determination. PoV1 and PoV2 relate to an early stage of development in which the functioning of the system is not need to be known. The subsequent PoVs require the stepwise development of scenarios and ease decision making during design. Each identified hazard is archived in a catalogue of hazards which can be accessed in subsequent developments.



PoV = Point-of-View; HMI = Human-Machine Interaction; RPN = Risk Priority Number

Fig. 6: Three stages approach for risk analysis

Cooperative Surgical Telemanipulation

Various cooperative strategies have been proposed to combine the individual strength of humans and machines to improve the surgical outcome. Based on the analysis of target applications in orthopedics and neurosurgery a cooperative surgical telemanipulator concept has been developed. The approach offers a variety of haptic assistances as well as haptic feedback, which are available based on the requirements of the underlying surgical application. The surgeon is then able to choose between applicable assistances based on his preferences and expertise.
Three experiments were designed with respect to different bone milling tasks. The implemented interaction modes avoid overlapping and masking of forces from haptic assistance and haptic feedback to avoid misinterpretation and confusion about the origin of the force information. The cooperative surgical telemanipulator was compared with the direct manual execution as well as automated milling. Results show that the cooperative surgical manipulator improves effectiveness, measured by the mean absolute depth and contour error, and efficiency close to an automated execution. In addition, the user satisfaction is increased compared to the direct manual process. Nevertheless, the surgeon is part of the control loop at all times and remains able to adjust the surgical plan according to the intraoperative situation and his/her expertise.

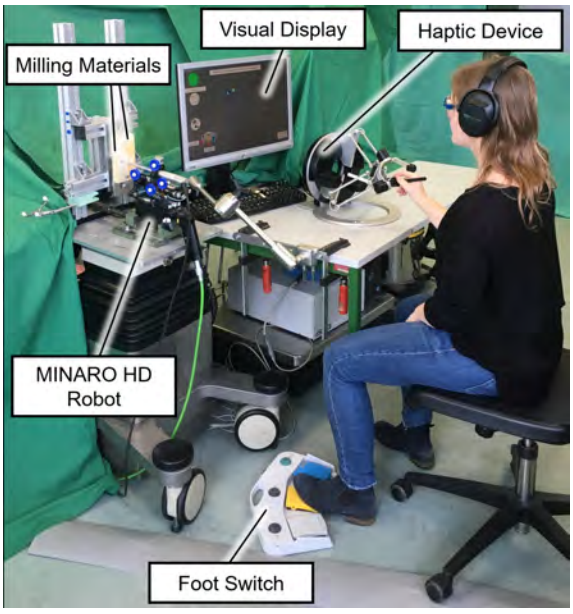


Fig. 7: Lab set-up of a cooperative surgical telemanipulator for bone milling tasks

SEBARES patient transportation aid

Patient transport in emergency medical services is a highly challenging task. The currently used transportation aids support the paramedics on flat surfaces but are not ergonomically applicable if obstacles, like stairs, occur. In these cases paramedics have to carry the patient, which leads to extreme physical stresses and short and long-term musculoskeletal injuries and diseases. A novel patient transportation aid, which can be used both on flat surfaces and a wide range of stairs was developed within the SEBARES project. To determine the actual loads for the paramedics and to compare the results to current transportation aids an ergonomic evaluation study was conducted. Twelve test participants performed a transport with the prototype and a simulated patient with a total transported mass of 137 kg, while force and posture data were recorded. The results show that over 90% of the time the loads were long-term acceptable according to ergonomic guidelines and a healthy upright posture of the back could be maintained at all times. In comparison to the currently most ergonomic tool, a caterpillar stair chair (according to a study of the Institute for Occupational Safety and Health of the German Social Accident Insurance), the forces could be reduced by 53%. Therefore, the study confirms the benefits of the novel approach and promotes further developments with our industrial partners to develop a sustainably effective solution for patient transportation in emergency medical services.

Fig. 8: Ergonomic evaluation of the SEBARES stair climbing patient transport aid

Risk Management in the Reprocessing Unit for Medical Devices (RUMED)

The quality of medical device reprocessing affects patient care in the operating theatre and, if deficient, can lead to nosocomial infections, as well as the prolongation or postponement of surgeries. Surgeons frequently complain about inadequately prepared or incomplete instrument sets. The processes in RUMED are partially standardized and automated, however, safety-critical work steps must be performed manually, which reduces the reproducibility and documentability of the results. For complex, high-risk applications, considering performance shaping factors (PSF) in the context of human reliability analysis (HRA) has proven effective in designing processes to support human performance and avoid errors. While human reliability analysis is already used in the field of nursing, no approaches have thus far been developed for RUMED.
A Germany-wide survey with RUMED executives identified PSFs suitable for reprocessing medical devices. In parallel, a Process-FMEA was performed to identify areas of particularly high risk due to potential for human error in RUMED. The next step is to apply the identified PSFs to the located risk areas to identify root causes of failures and develop potential solutions. The current approach in RUMED is related to the symptoms of process errors; knowledge of the underlying causes can enable process improvements and standardization that ultimately benefit the patient in the operating room.

Fig. 9: Exemplary performance shaping factors

Integrated Operating Room

Based on the OR.NET initiative (www.ornet.org), which has been significantly driven and supported by mediTEC, the ISO IEEE 11073-20701 SDC standard family (data model, protocol and architecture) for the open communication of medical devices has been approved in 2020.
The objective of the EFRE project PriMed in the pre-competitive area of medical technology research and development is to develop concepts and conduct feasibility studies for the optimization of perioperative workflows on the basis of SDC application.
Within PriMed devices like video-switch, OR-table, OR-light and patient monitor have been adapted and integrated into a surgical and anaesthetic SDC Workstation and can be controlled by using a tablet, a smartphone and a centralized cockpit including a universal foot switch. The OR personnel is supported by workflow specific dialogues and the OR management e.g. becomes more efficient due to the detailed information and overview, which is provided.

Fig. 10: Integrated surgical and anaesthetic workstation

Within the PriMed project user interface profiles (for standardized Human-Machine-Interaction in the open connected OR), which complement the technical profile of medical devices, are further developed and introduced into the supplementary standards (Base Key Purposes P11073-1070x) of the SDC series.
In cooperation with the nonprofit organization OR.NET e.V., mediTEC established a working group with the IG-NB (German Community of Notified Bodies) to develop guidelines for the approval of medical SDC devices.

Acknowledgements

We would like to thank all our clinical, technical and industrial partners for the fruitful cooperation*.
Apart from basic funds and industrial cooperation, in 2020 our research has been substantially funded by:
- the German Federal Ministry of Education and Research (BMBF)
- the German Federal Ministry of Economic Affairs and Energy (BMWi)
- the German Ministry of Health (BMG)
- the German Research Foundation (DFG)

- German Academic Exchange Service (DAAD)
- 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.

Awards

M. Asseln: Klee-Award 2020 of the German Society for Biomedical Engineering (VDE|DGBMT) and the Klee Family Foundation for his PhD-Thesis „Morphological and Functional Analysis of the Knee Joint for Implant Design Optimization“

Selected Publications

[1] M. Asseln, J. Eschweiler, A. Trepczynski, P. Damm & K. Radermacher: Evaluation and validation of 2D biomechanical models of the knee for radiograph-based preoperative planning in total knee arthroplasty. PLOS ONE, 2020, 15(1), pp. 1-16
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[3] M.C.M. Fischer, S.A.G.A. Grothues, J. Habor, M. de la Fuente & K. Radermacher: A robust method for automatic identification of femoral landmarks, axes, planes and bone coordinate systems using surface models. Scientific Reports, 2020, 10(20859), pp. 1-11
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[10] P. Schad, M. Wollenweber, J. Thüring, J. Schock, J. Eschweiler, G. Palm, K. Radermacher, F. Eckstein, A. Prescher, C. Kuhl, D. Truhn & S. Nebelung: Magnetic resonance imaging of human knee joint functionality under variable compressive in-situ loading and axis alignment. Journal of the Mechanical Behavior of Biomedical Materials, 2020, 110(103890)
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[12] P. Schleer, D. Körner, M. Vossel, S. Drobinsky & K. Radermacher: Conceptual design of force reflection control for teleoperated bone surgery. Current Directions in Biomedical Engineering, 6(1), 2020, pp. 1-5
[13] P. Schleer, M. Vossel, L. Heckmann, S. Drobinsky, L. Theisgen, M. de la Fuente & K. Radermacher: Usability of cooperative surgical telemanipulation for bone milling tasks. International Journal of Computer Assisted Radiology and Surgery (IJCARS), 2020, Onlinefirst
[14] R.M. Sellei, U. Warkotsch, P. Kobbe, C.D. Weber, N. Reinhardt, M. de la Fuente, K. Radermacher & F. Hildebrand: Non-invasive and reliable assessment of compartment elasticity by pressure related ultrasound: An in-vitro study. Injury, 2020, Onlinefirst
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[16] L. Theisgen, F. Strauch, M. de la Fuente & K. Radermacher: Catalogue of Hazards: A fundamental part for the safe design of surgical robots. Current Directions in Biomedical Engineering, 2020, 6(1), pp. 1-5
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[18] M. Vossel, K. Radermacher & M. de la Fuente: Evaluation of Motion Compensation Dynamics of the Handheld Robot MINARO HD. In: F. Rodriguez Y Baena & F. Tatti (ed.): CAOS 2020. The 20th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery, 4, 2020, pp. 278-282
[19] O. Yilmaz, D. Wieschebrock, J. Heibeyn, K. Radermacher & A. Janß: Development and Evaluation of a Platform-Independent Surgical Workstation for an Open Networked Operating Theatre Using the IEEE 11073 SDC Communication Standard. Digital Human Modeling and Applications in Health, Safety, Ergonomics and Risk Management. Posture, Motion and Health, 2020, pp. 79-92

The mediTEC team