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Faculty of Mechanical Engineering

Engineering Science and Innovation for better Health Care

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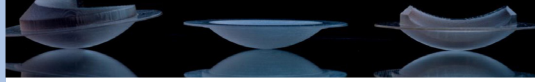


Introduction

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 2022 the pandemic situation continued to challenge our team regarding teaching as well as research and resumed international conference activities. Especially our novice students and younger colleagues, even not knowing "normal" live and cooperative work, suffered from the ongoing demanding boundary conditions. However, based on established networks and our long-lasting cooperation with international partners from research, industry and clinics, we have been able to succeed in creating fertile ground for diverse ongoing as well as new projects.
This annual report summarizes some examples of our project work.

Selected Projects
Biomechanics of HTO

Open-wedge high tibial osteotomy (OWHTO) is used for the treatment of unicompartmental (medial) osteoarthritis in varus knees, especially in young to middle-aged, active patients. The procedure represents a relevant alternative to unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA). Advantages of OWHTO include joint preservation (delay of TKA) and a higher functionality e.g., a higher range of motion postoperatively. However, HTO is more challenging and requires extensive planning. Due to limited resources and methods, the biomechanical effects of the different HTO variants are not comprehensively considered in the planning process. Therefore, a workflow for easy and fast simulation of (OW)HTO biomechanical outcome could substantially support the planning process, and may help to find individualized targets for (OW)HTO cutting parameters. Together with our clinical partners (MUM-LMU, Munich), we perform simulation analyses of knee kinematics and loading after different OWHTO variants. With the simulation of the biomechanical outcome, the surgeon can be supported in decision-making during the planning of the deformity correction.

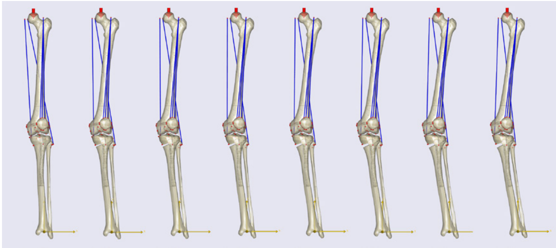


Fig. 1: Individualized simulation models for one cadaveric knee for different OWHTO variants

3D robotic ultrasound of the Knee

Surgical interventions on the knee joint such as for example personalized implants for the hip (THA) and knee (TKA) or deformity correction surgery can benefit from 3D imaging and 3D reconstruction of surface models of bone structure. In order to plan the correct shape and position of implants or cuts, a 3D model is required. Gold standard for its acquisition is computed tomography (CT), which exposes the patient to radiation. Ultrasound (US) is investigated as an alternative imaging modality that provides fast, inexpensive and widely available imaging. A pipeline for fully automatic and robust bone modelling was developed and evaluated in a small-scale in-vivo study with 10 probands together with our clinical partner (Luisenhospital, Aachen).

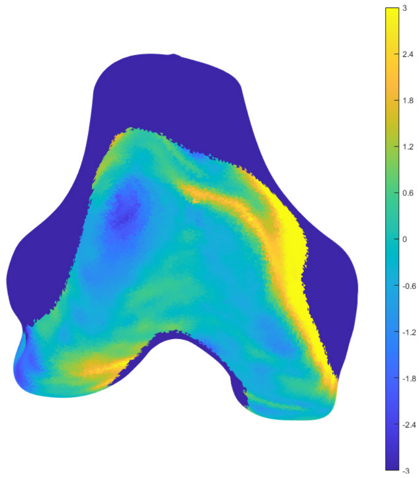
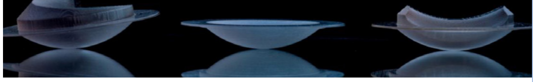


Fig. 2: Distal femur reconstruction based on free hand ultrasound imaging compared to the MRI reference.

However, free hand ultrasound imaging results are highly user dependent and continuous image-based probe pose optimization with respect to the scanned bone surface is very demanding. In contrast, a near real time image processing and automatic robotic probe guidance based on machine learning algorithms can address these bottlenecks. Position information can directly be obtained for referencing of the images and a high reproducibility is feasible.
Initially, for a fully autonomous process, the region to be scanned has to be recognized and autonomous robot path planning must be performed. Subsequently, the robot must follow the path and maintain a defined contact to the skin, while optimizing its orientation for optimal ultrasound-based acquisition of bone surface.



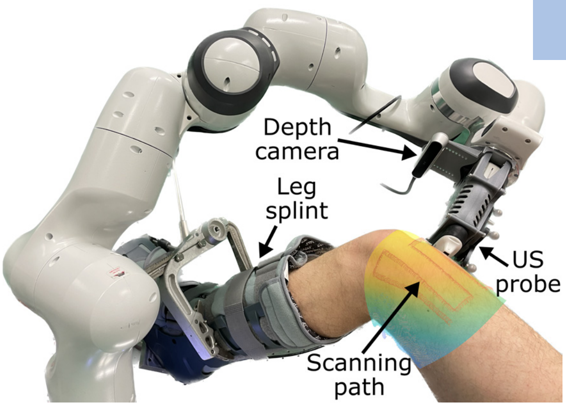


Fig. 3: Setup for autonomous robotic ultrasound scan of the knee

Ultrasound-assisted Scaphoid Fixation

Scaphoid fractures are predominant in young males and are often caused by a fall on the outstretched hand. For the percutaneous fixation of scaphoid fractures with an osteosynthesis screw, fluoroscopy is conventionally used to guide screw placement. However, screw placement based on projective imaging is challenging and furthermore exposes patient and medical staff to harmful radiation. To address these drawbacks, we proposed a fast and fully automated, navigated approach based on intraoperative ultrasound imaging. Recently, this approach was evaluated in an in-vitro study on carpal phantoms together with our clinical partners (UKB, Bonn), which demonstrated the successful and seamless integration to a surgical workflow. Pre-clinical ex-vivo and in-vivo studies are subject of ongoing work.

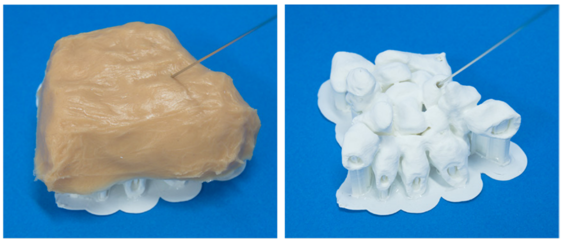


Fig. 4: Carpal phantom with (left) and without (right) silicon soft tissue model overlay as used in the in-vitro study.

Morpho-functional analysis for THA

Morpho-functional preoperative analysis for total hip arthroplasty (THA) is an important aspect to enable an optimal planning and implantation of the hip prosthesis. In order to investigate the impact of patient specific preoperative pain and movement restrictions subjectively assessed by the patient, score values from questionnaires, such as the Harris Hip Score can be used. In retrospective clinical studies, the relationship between these parameters and the postoperative functional parameter pelvic tilt have been investigated. The analysis of the impact related to further activities of daily living (ADLs) is subject to ongoing studies with our clinical partners (Nigata Hip Joint Center, Niigata, Japan and Charité Medical University Center, Berlin).

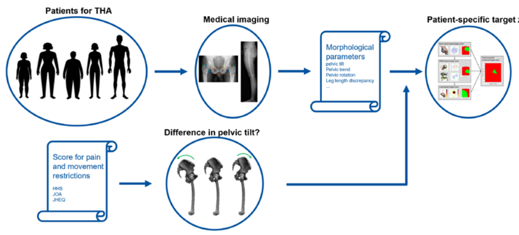


Fig. 5: Workflow for integration of pain and movement restrictions in the preoperative planning process for THA

Robotic Gripper for Surgical Instrument Handling

Robotic handling of contaminated surgical instruments during cleaning and sterilization could protect staff from infection risk and compensate for staff shortage. The robotic gripper handling the instruments are contaminated, leading to potential risks of cross-contamination between instruments. Therefore, the gripper must be cleaned regularly. Ideally, the cleaning can be automated and can take place after one shift of 8-9 hours. The duration of usage contradicts the requirement to clean surgical instruments 5 hours after use, after which dried contamination might make cleaning impossible. Therefore, we investigated if we could design a robotic gripper enabling a secure gripping and handling of contaminated instruments while being optimized for cleanability. We developed a gripper design for toolless disassembly and cleanability. Afterward, we tested the design according to DIN EN IST 15883-1 by applying sheep blood, cleaning the gripper using a standard cleaning cycle in a cleaning and disinfection machine, and taking samples by applying sodium dodecyl sulfate to the surfaces of the gripper.

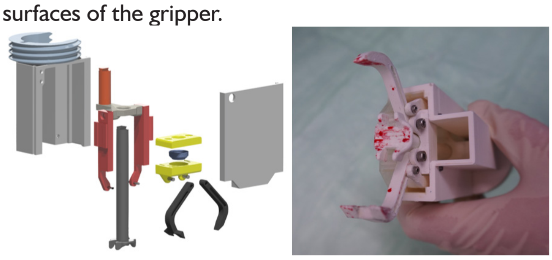
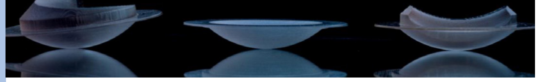


Fig. 6: Gripper designed for toolless disassembly (left), test contamination with sheep blood (right)

The samples were evaluated using a fluorescence measurement. The results showed a protein level below the required threshold of 100 μg, even after a drying time of 10 hours. The gripper is an integral part of the ongoing development of a robotic workstation for pre-processing contaminated instruments.

MINARO DRS: A Dual Robot System with Haptic Control

Combining the high dynamics of a miniature application-specific parallel robot for machining of bone, with the large workspace of a serial robot arm for prepositioning, the Minaro DRS enables flexible use in the OR. The demonstrator system incorporates an off-the-shelf lightweight serial cobot arm and the custom developed



distal parallel mini-robot for a burring task in case of laminectomies for spinal decompression.

Fig. 7: Hands-on Minaro DRS for spinal decompression.

In order to preserve the sensitive structures right underneath the bone (dura mater and spinal cord) while removing the thin laminae efficiently, highest accuracy of the robotic system together with efficient surgical control is essential. Cooperative control was implemented to transcend the accuracy boundaries of computer-assisted surgery from image acquisition, planning, and registration. The robotic system's precision, which is much higher than its accuracy due to the abovementioned issues, is combined with the intra-operative visual control of the surgeon during hands-on or optionally telemanipulated synergistic control.

Model Based Risk and Usability Engineering for Cooperative Surgical Robotics

In bone surgery specialties like orthopaedic-, maxillo-facial-, and neurosurgery cooperative robotic assistance can support surgeons by reducing task workloads and support surgical plan implementation. Internal and external performance shaping factors (PSFs) need to be considered when designing cooperative robotic assistance systems. Design decisions during early development phases have a large impact on final device usability and cost. Modelling the of the underlying processes and systems potentials can support the identification of risks and support evidence-based design decisions in early development stages. Analyses are performed based on a common process description, which allows to identify application requirements and analyse system integration. Standardized ranking scales were derived by engineers and surgeons that allows to assess the characteristic workload of surgical tasks with respect to human resources and performance shaping factors to find root causes of excessive workloads and latent error conditions. Modelling the clinical work system and workflows in Matlab Simulink and System Composer, the modular approach allows to separately parametrize surgical process requirements and system properties and analyse system behaviour with respect to defined hazards. Standardized process macros on the one side and variant system components for different technical assistance systems on the other allow iterative system adaptations and tests in early design stages. Model validation is possible in later-design phases when data from unit tests is available. The modular approach allows to flexibly extend the model quality with respect to prediction scope and accuracy.

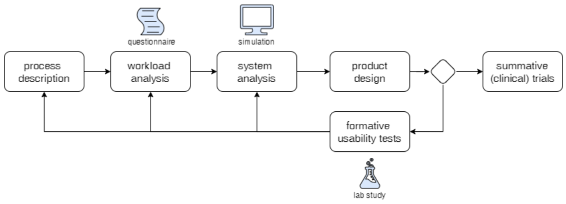
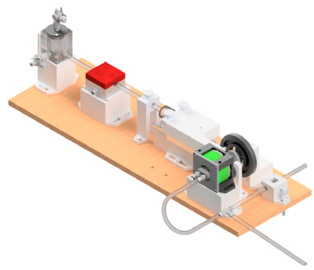


Figure 8: Workflow for process-based risk and usability analysis during early stages of cooperative robotic assistant development

MR compatible pump for PC-MRI flow validation

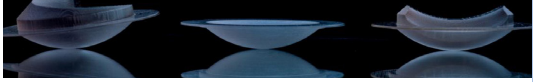
Phase-contrast MRI (PC-MRI) enables non-contact flow measurement of blood or cerebrospinal fluid. Conclusions about pathological changes can help to diagnose diseases (e.g. normal pressure hydrocephalus). Although measurements have been performed on both healthy subjects and patients for many years and significant changes have been seen, the accuracy of PC-MRI was questioned. In order to be able to quantify the accuracy of the measurement method, an MR-compatible pump was developed together with our clinical partners (CHU, Amiens, France). The drive was realized by a pneumatically driven pump using rapid prototyping. The entire setup is composed of 3D printed MRI compatible components. In addition, the speed can be adjusted by the air pressure and the flow profile can be modified by the cam geometry.

Fig. 9: Pump-setup PC-MRI flow validation.



Design method for acoustic lenses for piezoelectric shock wave transducers

The increasing number of indications for extracorporeal shock wave therapy (ESWT) makes it necessary to adapt the generated sound field to the specific requirements of the treatment. In wound treatment, for example, a more extensive area is treated, whereas in tissue ablation a defined treatment area can be advantageous. We developed and evaluated an acoustic lens design method to arbitrarily adapt the sound field used for ESWT. An iterative method for lens design using the principle of phase shift was adapted and validated for spherical piezoelectric ESWT transducers. It offers the possibility to create both symmetrical and asymmetrical target sound fields. Additionally, the acoustic properties of various lens materials were determined. Sound field simulations with MATLAB k-wave and in-vitro measurements in water were performed to evaluate three different lenses.



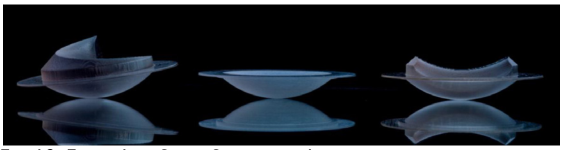


Fig. 10: Examples of specific acoustic lenses.

The validation of the new method using a complex target image showed comparable results to an iterative method for planar sources reported in the literature. Three lenses were designed to shift the focal position and to enlarge the treatment area and were fabricated using rapid prototyping. The simulated and measured sound fields were in good accordance. With the lenses, 80-90% of the energy of the original sound field was obtained in the target plane. However, the lenses distributed the energy of the originally highly focused sound field more widely. Nevertheless, clinically relevant peak pressures were reached. The new method is well suited for spherical sources and arbitrary target images, with asymmetric solutions leading to improved results. The designed lenses show good results for transient input signals such as those generated by ESWT devices and thus provide a cost-effective and easily interchangeable option for sound field adaptation.

Safe and ergonomic control of surgical devices through recommendation software

This increases complexity and number of technical devices in the OR can lead to confusing or dangerous situa-tions. For example, many devices come with their own foot switch unit, which occupies floor space and creates tripping hazards. Surgeons have to observe the situs and therefore may confuse foot pedals, leading to erroneous triggering of functions. Timely access to a function like bipolar coagulation is paramount to patient safety. The ISO IEEE 11073 SDC standard for interoperable medical device communication is key standard to address the related issues. Human-Machine interfaces can now address multiple manufacturer‘s devices and interact with them reliably. However, the enormous potential of this technology raises new questions. In an OR setup where various device functions can be controlled through multiple user interfaces, defined restrictions must be applied so that control is safe, usable and complies with existing regulations. Therefore, an automated recommendation system for surgical control interfaces is one objective of our research. It builds on specifying user interface profiles. With this new software tool, surgeons and other clinical staff can configure their control inputs prior to surgery, associate mappings with different workflow steps and save everything to their own user profile which can be deployed to any operating room. Changes during surgery are possible unless any safety-critical function would be made unavailable through that change. The system‘s knowledge of the ongoing procedure, involved medical devices, critical steps and even patient state can be incorporated to optimize controls and risk management.

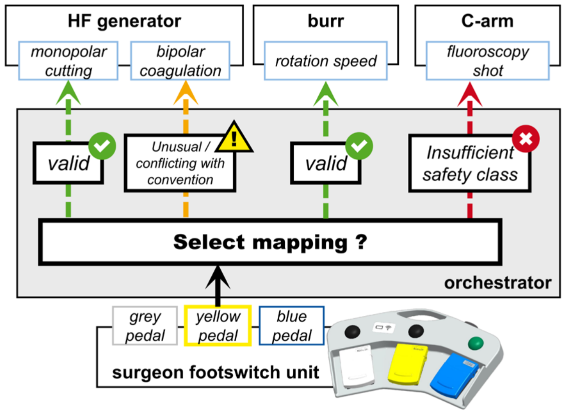


Fig. 11: Mapping options for a control element.

To assure that a certain mode of operation has been considered during risk management and usability engineering, the manufacturer may provide a machine-readable „rule book“ for their device. It lists the requirements for each controllable parameter or human interface element. The rule book may include hard limits as well as dissuasive notifications for mappings which are not strictly forbidden but may lead to subpar usability. The tool may also serve the purpose of checking the compatibility of a newly compiled ensemble prior to surgery. The objective is, to decrease the time needed to configure medical devices and human interfaces for surgery, while maintaining inherent usability and risk engineering standards. The evaluation of this approach is subject to ongoing studies together with our industrial and clinical partners (University Clinic Aachen) as well as in close contact with notified bodies and FDA.

Process Optimization through Integrated medical devices in the operating room and clinic

Several studies identified the Operating Room (OR) as costly to maintain, but on the other hand the OR is also the most profit generating department. In the PriMed research project concepts to increase the overall efficiency and patient safety have been developed and evaluated. Medical device manufacturer can now be interoperable by following the 2019 approved ISO IEEE 11073 SDC communication standard. SDC defines the syntax and semantic, the technical description of medical devices as well as responsibilities and requirements network participants have to fulfil, to be an interoperable network participant. Workflow analysis have been performed with the OR-management and surgeons (University Clinic Aachen). Functional models of user interfaces have been developed and evaluated as part of a central surgical SDC workstation. Presently, using proprietary systems does not allow to collect relevant data and therefore i.a. hinders the preparation of protocols during an operation. Automatic documentation through interoperability helps to save important time, and potentially improves clinical processes by increasing the efficiency and safety. A concept for workflow step specific device settings has been developed and evaluated with clinical users. Further optimization and implementation into OR.NET demonstrator OR in our institute is subject to ongoing work.

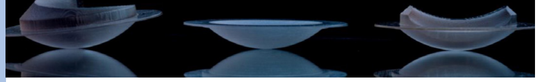


Fig. 12: Evaluation setup in our OR.NET demonstrator

Awards

We congratulate Sergey Drobinsky for the award for patient safety in medical engineering of the Action Alliance Patient Safety. We also congratulate Sonja Grothues for the Emerging Researchers Award of the ISTELAR Foundation.

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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] M.C.M. Fischer, P. Damm, J. Habor & K. Radermacher: Effect of the underlying cadaver data and patient-specific adaptation of the femur and pelvis on the prediction of the hip joint force estimated using static models. Journal of Biomechanics, 2022, 139, pp. 110526

[2] M.C.M. Fischer, K. Tokunaga, M. Okamoto, J. Habor & K. Radermacher: Implications of the uncertainty of postoperative functional parameters for the preoperative planning of total hip arthroplasty. Journal of Orthopaedic Research, 2022, pp. 1-7

[3] S. Grothues, B. Hohlmann, S.M. Zingde & K. Radermacher: Potential for femoral size optimization for off-the-shelf implants: A CT derived implant database analysis. Journal of Orthopaedic Research, 2022, Onlinefirst

[4] S. Grothues, L. Berger & K. Radermacher: Automated analysis of morpho-functional interbone parameters of the knee based on three dimensional (3D) surface data. In: F. Rodriguez Y Baena, J.W. Giles & E. Stindel (eds.): Proc. CAOS2022, pp. 81-88

[5] S. Grothues & K. Radermacher: Criteria for Implant Fit Assessment in Total Knee Arthroplasty – A Review. Current Directions in Biomedical Engineering, 8(2), 2022, pp. 165-168

[6] J. Heibeyn, O. Jansen, K. Wiese, F. Deinet, M. Roitsch, R. Stens, A. Janß & K. Radermacher: Ableitung von Anforderungen an eine AEMP-Benchmark. Zentralsterilisation, 2022, 30(5), pp. 228–234

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[9] A. Janß, S. Schlichting & K. Radermacher: Operating Room and Clinic 4.0: The OR.NET Approach. In: W. Frenz (ed.): Handbook Industry 4.0: Law, Technology, Society, Springer Berlin Heidelberg, 2022, pp. 857-878

[10] P. Pandey, B. Hohlmann, P. Brößner, I. Hacihaliloglu, K. Barr, T. Ungi, O. Zettinig, R. Prevost, G. Dardenne, Z. Fanti, W. Wein, E. Stindel, F. Arambula Cosio, P. Guy, G. Fichtinger, K. Radermacher & A. Hodgson: Standardized Evaluation of Current Ultrasound Bone Segmentation Algorithms on Multiple Datasets. In: F. Rodriguez Y Baena, J.W. Giles & E. Stindel (ed.): Proceedings of the 20th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery, 5, 2022, pp. 148-153

[11] N. Reinhardt, J. Wegenaer & M. de la Fuente: Influence of the pulse repetition rate on the acoustic output of ballistic pressure wave devices. Scientific Reports, 2022, 12(18060), pp. 1-7

[12] L. Theisgen, F. Strauch, M. de la Fuente Klein & K. Radermacher: Safe design of surgical robots – a systematic approach to comprehensive hazard identification. Biomedical Engineering / Biomedizinische Technik, 2022, Onlinefirst

[13] M. Vossel, L. Theisgen, K. Radermacher & M. de la Fuente: Accuracy Evaluation of Image-Based Virtual Fixtures in Robotic Laminectomy. In: F. Rodriguez Y Baena, J.W. Giles & E. Stindel (ed.): Proceedings of the 20th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery, 5, 2022, pp. 180-184

[14] C. Castelar Wembers, F. Flürenbrock, B. Maurer, A. Benninghaus, K. Radermacher & S. Leonhardt: A mechatronic test-bench to investigate the impact of ventricular pulsation in hydrocephalus. Biomedical Signal Processing and Control, 2022, 75, pp. 103579

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The mediTEC team