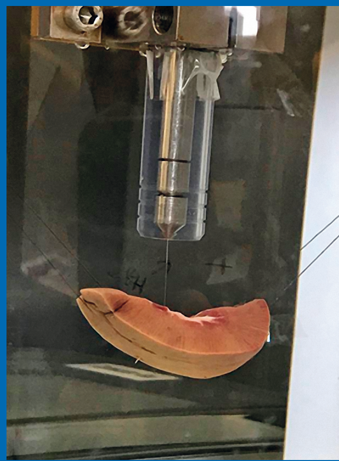
Chair of Medical Engineering at Helmholtz-Institute for Biomedical Engineering

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 represent an important complementary application-oriented pillar of our work for the transfer of our research and developments into clinical applications.
Based on the results of our research activities and technical developments of the last 10 years, we have been able to establish recognized expertise and a network of international partners from clinics, research and industry. Substantial industrial cooperation agreements have been contracted in each of our research focus areas. Furthermore, concerted actions such as the activities with our partners in the framework of the OR.NET initiative (www.ornet.org) resulted in a series of projects assuring the sustainability of our work on interoperability, usability and risk engineering of modular integrated medical work systems. New projects towards cooperative surgical robotics or on process automation for reprocessing of surgical instruments respectively as well as successful demonstrators of our approach towards cooperative emergency patient transport systems are further examples of our activities presented in this overview.

Selected Projects

In-vitro test bench for ESWL

A common practice to evaluate the efficiency of extracorporeal shock wave lithotripsy (ESWL) is to position a phantom stone in the focal area of the applied shock waves within a water tank. Thereby many factors are neglected, especially the impact of the surrounding tissue. Thus, we investigated the influence of different in-vitro setups on sound fields and stone comminution in order to evaluate transferability into clinical application. A kidney phantom, made of gel-wax and paraffin, with similar acoustic properties to kidney tissue was developed. It was analysed in a testing rig comprising a piezoelectric lithotripter and compared to a latex stone holder and porcine tissue. The influence on the sound field was investigated by pressure measurements, the amount and location of cavitation was determined and efficiency in stone comminution was analysed by fragmentation of gypsum stones.

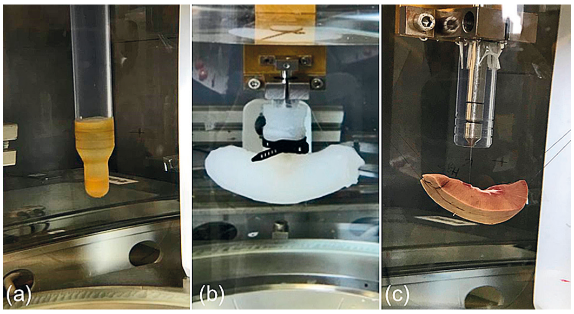

Fig. 1: Different in-vitro setups: latex holder (a), kidney phantom (b) and porcine kidney (c).

Sound field measurements behind phantom and tissue showed attenuation of the shock front as well as a reduced negative pressure in contrast to the latex holder. Cavitation amount and location differed for all setups. Stone fragmentation was less efficient in the kidney phantom than in the latex holder. Frequency-dependent material damping caused decreased peak pressures while negative pressure was absorbed by cavitation resulting in less efficient stone fragmentation behind tissue. Therefore, adapting in-vitro conditions closer to the in-vivo situation is necessary in order to analyse fracture mechanisms.

Image Processing for Diagnostic Ultrasound

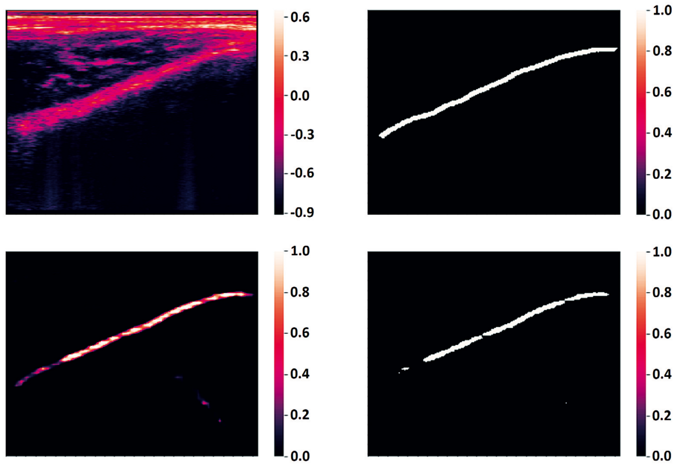

Fig. 2: Automatic segmentation of bone surface in an ultrasound image. Original image and ground truth on the left, and the raw confidence values as well as the thresholded prediction on the right.

Medical ultrasound is a widespread imaging modality utilized in a variety of different diagnostic tasks, ranging from echocardiography and mammography over prenatal screening to orthopedic applications like bone fracture detection. It offers real-time capabilities, which makes it especially useful for dynamic investigations. Yet, ultrasound requires skilled personal due to the low signal-to-noise ratio and other limitations. Therefore, we develop algorithms and tools based on image processing techniques that allow for an automatic processing of ultrasound images, easing the task of image interpretation for the sonographer. These tasks range from highlighting of relevant structures like bones to the full-automatic classification of injuries like a rupture of the anterior cruciate ligament. Furthermore, we develop a pipeline for full three-dimensional models of the knee and the wrist, reconstructed solely from ultrasound images, potentially replacing CT for preoperative planning in orthopedics. The reconstruction process is based on a-priori knowledge, statistical modelling as well as neural networks.

Preoperative Planning in Total Hip Arthroplasty

Preoperative planning is a mandatory step in total hip arthroplasty (THA). Usually, only the restauration of the osseous morphology derived from imaging data is considered in the planning process to determine the type, size and alignment of the implant components. However, other criteria such as the range of motion and implant loading are described in literature to reduce risk of implant failure due to edge-loading, accelerated wear, impingement and dislocation. We developed a preoperative planning tool incorporating multiple important criteria in a patient-specific target zone for both implant components. This includes individual postoperative functional parameters, such as the pelvic tilt, the range of motion or the resultant hip joint force. Our focus is on cost- and time-efficient methods that can be integrated into the common clinical routine.

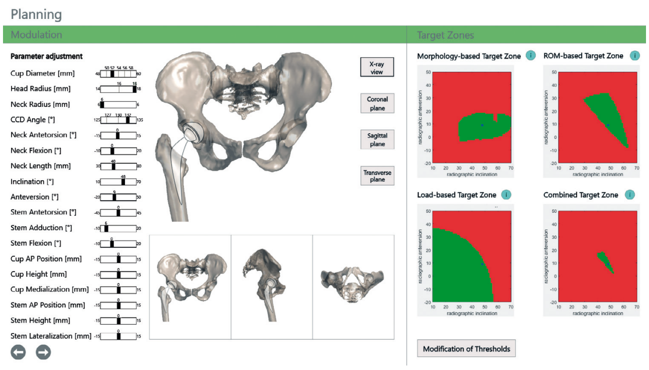

Fig. 3: Morpho-functional multiparameter optimization for preoperative planning of THA

Morpho-functional Analysis of the Knee

Total knee arthroplasty aims to restore function and to reduce pain. Despite decades of experience with this procedure, postoperative function is still limited and patient satisfaction is low in comparison to total hip arthroplasty. In order to address the described issues, implant design optimization is of major concern. Efforts are taken to better replicate the morphology of the native knee and thereby to better restore patient-specific kinematics and enable adequate functionality. In order to evaluate the population's knee morphology, we perform geometric parameter analysis on 3-dimensional surface data of the native knee's articulating surfaces. In addition, we perform statistical analysis to derive information on the main sources of shape variation. As an example, principal component analysis were conducted on the medial and lateral femoral J-Curve of 90 healthy knee joints (Figure 4). Furthermore, we compare the native knee's morphology and shape variation with those of modern implant designs. The results of the described analyses are relevant both for a better understanding of native knee morphology and kinematics as well as for implant design optimization.

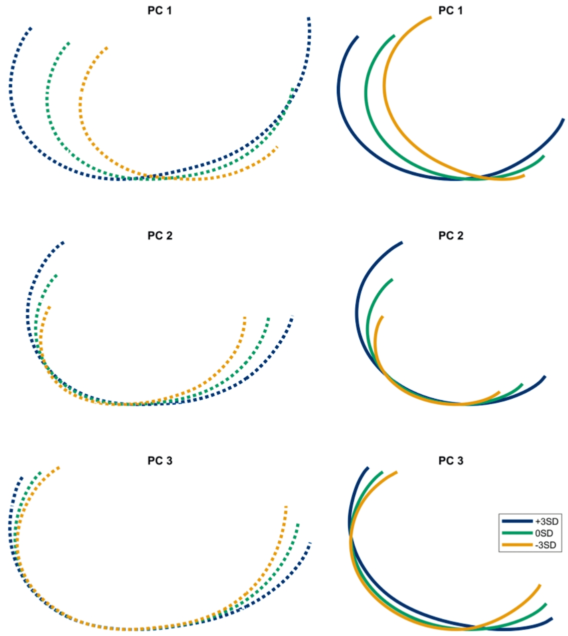

Fig. 4: Principal component analysis of the native femoral J-Curve based on surface geometry data of 90 healthy knees: Principal components 1-3 of (left) the lateral and (right) the medial femoral J-Curve.

Patient-Specific Wrist Implants

The wrist is one of the most complex joint systems of the musculoskeletal apparatus. It is prone to rheumatoid arthritis and is vulnerable to injuries due to its multi-layered ligament system. Due to the short lifetime, wrist implants are not a very common treatment option so far. Although wrist arthrodesis is substantially limiting the range of motion of the wrist, it is still the "gold standard" procedure to treat severe wrist joint degeneration. In this project, the current wrist implant designs are critically revisited and new patient-specific implant and spacer concepts are evaluated, taking the individual morphology and functional aspects into account. Furthermore, the use of additive manufacturing technologies for the production of the patient-specific implants is investigated.

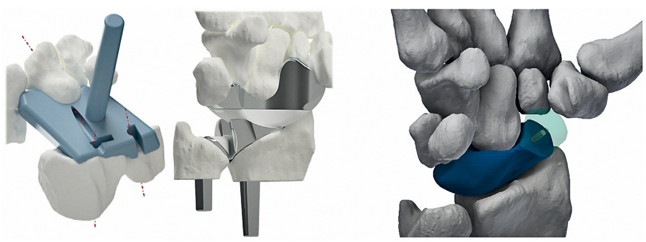

Fig. 5: A patient-specific instrumentation and wrist implant (left) and a patient-specific spacer (right)

Modular Design of Surgical Robots

There is a large variety of design approaches for surgical robotics. Robotic systems differ in e.g. functionality, size, kinematics and the degree of autonomy. An analysis of risks, requirements and context of use provides the basis for the definition of a generic reference structure of functions that can be modularized into universal and application-specific functions. Furthermore, systematic system design and risk management can be supported by a context specific catalogue of measures considering different design principles, rules or recommendations for further actions including usability evaluations and risk assessments. Module drivers, such as cost-efficiency, improved usability or simplified disassembly and reprocessing, are defined to optimize case-specific modularization.

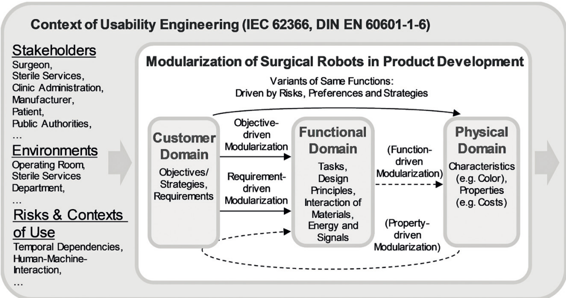

Fig. 6: Framework for integrated risk and usability engineering for modular surgical robotic system design

Cooperative Surgical Robotics

Cooperation is the natural human ability to work together in teams to reach a common goal, utilizing each team member's individual skills, knowledge, and judgement to generate synergistic effects. Cooperation, thereby, entails coordination and synchronization of individual actions and therefore requires communication and arbitration between team members. Especially within surgical teams, teamwork is of importance, as deficiencies are directly linked to adverse events.

While robots can improve surgical outcome with accurate execution of surgical plans, safe operation in highly unstructured environments is difficult due to limited perception and cognition. Cooperative surgical robotics combine the strengths of human and machine to collaborate successfully and improve the clinical outcome. In practice, different system implementations are developed which range from handheld robotic systems over collaborative hands-on robots to remote controlled master-slave systems. The latter, on one hand, offer the widest spectrum of cooperative functionalities, however, on the other hand, the surgeon is physically decoupled from the situs. To further investigate the impact of different modes of assistance, a cooperative surgical telemanipulator system is being developed. Thereby, planning-independent (PI) modulations such as scaling of movements or forces can be provided. Furthermore, the surgeon can be assisted by different patient-specific planning-based (PSPB) modulations, like haptic guidance on the master side. Additionally, forces on the surgical tool can be fed back to the surgeon. However, caution has to be taken when combining guidance and sensor feedback. The latter two can partly or fully cancel each other out resulting in the surgeon either not being able to differentiate the origins of the force information or not receiving any force information at all. The cooperative surgical telemanipulator will be used to evaluate different modes of interaction depending on particular surgical use scenarios to evaluate their effects on system usability.

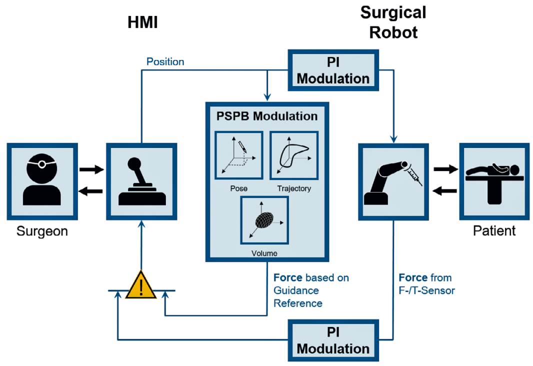

Fig. 7: Principle of Cooperative Bilateral Telemanipulation

Integrated Digital OR

Based on an initiative of the OR.NET association (www.or-net.org) founded in Aachen in 2016, the IEEE 11073-20701 SDC standard family has been approved at the beginning of 2019 by the international IEEE standards association. Thus, all three substandards of the SDC family (Service-Oriented Device Connectivity) are authorized by the IEEE and two substandards are already authorized by the international standardization organization (ISO).

Fig. 8: OR.NET demonstrator platform and integrated workstation on the DMEA exhibition 2019, Berlin

Under the direction of the OR.NET e.V. several research projects have been launched. The EFRE projects ZiMT (2016-2019) and PriMed (2019-2022) aim to develop, evaluate and synchronize basic concepts with safe and usable Human-Machine-Interfaces for surgical and anesthetic workstations as well as workstations for the OR management and the OR nursery. The projects ZiMT and PriMed have been represented at the DMEA 2019 and the Medica 2019 exhibitions at the NRW booth. Within the BMBF project MoVE different methods and testing procedures (conformity and interoperability tests), which support the approval and certification process (and therefore especially the risk management) of networked medical devices using

IEEE 11073 SDC, have been developed. For this, a simulation platform including test suite, test scenarios and device simulators has been developed, in order to provide future methods and tools for manufacturers, clinical operators and independent test institutions.
At mediTEC a central surgical workstation demonstrator with multimodal user interfaces has been developed. Numerous devices have been integrated (e.g. OR light, 3D X-ray C-arm, OR table, high-frequency cutting devices, endoscopic devices, ultrasound-cutting device, milling device, shaver, universal footswitch and hight-adjustable footboard).

Integrated Digital CSSD

Reprocessing of surgical instruments includes cleaning and sterilisation in the Central Sterile Services Department (CSSD) before they can be redeployed. Deficiencies in the process may be critical for the safety of the patient. OR personnel reports up to 30% of incorrectly assembled instrument-sets from the CSSD, leading to prolonged or postponed operations. In addition, more and more complex surgical systems, e.g. for robotic endoscopic surgery, demand high precision and focus from the CSSD staff. Reduction of associated workloads and infection risks are further motivations for the development of advanced concepts for process automation of integrated digital CSSDs.
Against this background, the integration of innovative concepts, based on multisensorfusion and cooperative robotics into the CSSD, are major objectives of the BMBF-project SteriROB. The goal is to standardize process steps and to decrease the workload of the employees. Multicenter field studies with in-depth work-flow and context analysis in the CSSD in cooperation with different clinics and major instrument manufacturers are conducted. On this basis use cases and concepts for integrated digital CSSDs will be developed and evaluated, including a cooperative robotic handling of surgical instruments and trays.

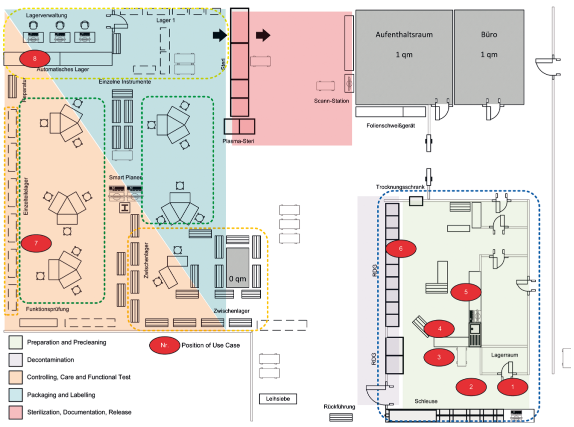

Fig. 9: Overview location of use cases in the CSSD Aachen.
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Patient Transport in Emergency Medical Services

Paramedics are not only responsible for execution of emergency medical services, but also for a safe and fast transport of the patient. Current active transport aids cannot offer universal assistance because of slow speeds and a big footprint, which leads to a limited range of use and a high rate of manual transports with critical loads on paramedics. A prototype for a novel transport aid was developed at mediTEC.
During patient transport paramedics need an intuitive control of the transport aid to be able to focus on the medical condition of the patient and the transport route. A specific self-balancing control strategy of the transport aid enables this, which allows for a synergistic cooperation with the paramedic without the need of user controls such as joysticks or buttons. However, the paramedic is not the only human in the loop and the patient has a significant influence on control, too. Therefore, the controller has to be optimized to be robust against uncooperative behavior of the patient, which occurs in 25 % of deployments as shown in our study. Based on these boundary conditions an advanced controller was designed and evaluated which simultaneously allows for a synergistic cooperation with the paramedic and robust characteristics against disturbances introduced by the patient. The evaluation with a control-prototype confirmed the good synergy and sufficient robustness for a stable and controlled behavior.
The combination with stair climbing kinematics provides a universal transport aid with the ability to efficiently overcome a wide range of obstacles. First results of initial usability studies show a reduced workload with healthy postures and acceptable loads in comparison to commercially available transport aids and emphasize the benefits of the new concept.

Fig. 10: Demonstration of the stair climbing prototype at the emergency medical services Düren district

To safely transport the patient in the ambulance vehicle, novel loading techniques as well as integration concepts are needed. Several concepts have been evaluated with respect to different vehicle categories used within the ambulance domain. Due to the integrated drives new compact loading solutions and innovative attachment options emerge. To evaluate the safety of the vehicle attachment a FEM analyses was conducted according to international standards.

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- 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: CureMED Research and Travel Fellowship Laboratory for Orthopaedic Implant Design, NYU Langone Orthopedic Hospital, New York, USA
- M. Vossel et al., 2nd Best Technical Podium Award, 19th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery - CAOS 2019, New York, USA7
- M. Asseln et.al.: 2nd Best Technical Poster Award, 19th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery - CAOS 2019, New York, USA
- M. Fischer: Travel Award German Academic Exchange Service (DAAD) 25th Congress of the European Society of Biomechanics (ESB) in Vienna, Austria

Selected Publications

[1] M. Asseln & K. Radermacher: Automatic analysis of morphological parameters of the patella based on three-dimensional (3D) surface data. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, pp. 31-35

[2] M. Asseln, M.C.M. Fischer, H.Y. Chan, P. Meere, P. Walker & K. Radermacher: Automatic standardized shape analysis of the sagittal profiles (J-Curves) of the femoral condyles based on three-dimensional (3D) surface data. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, pp. 21-25

[3] M. Asseln, P. Meere, P. Walker & K. Radermacher: Relationship of the tibial tuberosity (TT) position, tibial tuberositytrochlear groove (TT-TG) distance, and internal and external rotation of the knee under weight-bearing conditions. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, pp. 26-30

[4] A. Benninghaus, O. Balédent, A. Lokossou, C. Castelar, S. Leonhardt & K. Radermacher: Enhanced in vitro model of the CSF dynamics. Fluids and barriers of the CNS, 2019, 16(1), pp. 1-11

[5] L. Bohner, D. Habor, F. Gremse, P. Tortamano, S. Wolfart & J. Marotti: Accuracy of High-Frequency Ultrasound Scanner in Detecting Peri-implant Bone Defects. Ultrasound in Medicine & Biology, 2019, 45(3), pp. 650-659

[6] L. Bohner, D. Habor, P. Tortamano, K. Radermacher, S. Wolfart & J. Marotti: Assessment of Buccal Bone Surrounding Dental Implants Using a High-Frequency Ultrasound Scanner. Ultrasound in Medicine and Biology, 2019, 45(6), pp. 1427-1434

[7] C. Castelar, F. Fluerenbrock, L. Korn, A. Benninghaus, S. Shchukin, K. Radermacher & S. Leonhardt: FEM simulation of bioimpedance-based monitoring of ventricular dilation and intracranial pulsation. Int. J. Bioelectromagnetism, 2019, 21(1), pp. 7-20

[8] M.C.M. Fischer, F. Krooß, J. Habor & K. Radermacher: A robust method for automatic identification of landmarks on surface models of the pelvis. Scientific Reports, 2019, 9, pp. 1-10

[9] M.C.M. Fischer, K. Tokunaga, M. Okamoto & K. Radermacher: Proximal Femoral Asymmetry in Japanese Patients before Total Hip Arthroplasty. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, pp. 127-132

[10] J. Habor, M.C.M. Fischer, K. Tokunaga, M. Okamoto & K. Radermacher: Patient-specific ROM and load-based Target Zone for Total Hip Arthroplasty and its Application in a retrospective Analysis. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, pp. 161-165

[11] B. Hohlmann & K. Radermacher: The interleaved partial active shape model (IPASM) search algorithm - towards 3D ultrasound-based bone surface reconstruction. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, pp. 177-180

[12] J. Hsu, M. de la Fuente & K. Radermacher: Calculation of impingement-free combined cup and stem alignments based on the patient-specific pelvic tilt. Journal of Biomechanics, 2019, 82, pp. 193-203

[13] K. Lange, A. Janß, S. Farjoudi Manjili, M. Nowak, W. Lauer & K. Radermacher: Users' Awareness of Alarm Settings : Analyzing the User Interface of a Physiological Monitor. In: S. Bagnara, R. Tartaglia, S. Albolino, T. Alexander & Y. Fujita (ed.): Proceedings of the 20th Congress of the International Ergonomics Association (IEA 2018), 1: Healthcare Ergonomics, 2019, pp. 453-464

[14] J. Marotti, J. Broeckmann, F. Chuembou Pekam, L. Praça, K. Radermacher & S. Wolfart: Impression of Subgingival Dental Preparation Can Be Taken with Ultrasound. Ultrasound in Medicine & Biology, 2019, 45(2), pp. 558-567

[15] P. Schleer, S. Drobinsky & K. Radermacher: Evaluation of Different Modes of Haptic Guidance for Robotic Surgery. In: B. Mettler (ed.): IFAC-PapersOnLine, 51(34), 2019, pp. 97-103

[16] P. Schleer, S. Drobinsky, M. de la Fuente & K. Radermacher: Toward versatile cooperative surgical robotics: a review and future challenges. Int J CARS, 2019, 14, pp. 1673–1686

[17] P. Schleer, S. Drobinsky, T. Hmaid & K. Radermacher: Haptic Modes for Multiparameter Control in Robotic Surgery. Medical Image Computing and Computer Assisted Intervention – MICCAI 2019 22nd International Conference Shenzhen, China, October 13–17, 2019 Proceedings, Part V, 11768, 2019, pp. 173-181

[18] L. Theisgen, M. de la Fuente & K. Radermacher: Approach towards a design method to appropriately modularize surgical robots for sterile reprocessing. 20th Annual World Sterilization Congress - Book of Abstracts, 2019, pp. 165-166

[19] M. Verjans, P. Schleer, J. Griesbach, M. Kinzius, W. Alrawashdeh & K. Radermacher: Modelling patient dynamics and controller impact analysis for a novel self-stabilizing patient transport aid. In: B. Mettler (ed.): IFAC-PapersOnLine, 51(34), 2019, pp. 208-213

[20] M. Verjans, L. Phlippen, P. Schleer & K. Radermacher: SEBARES - Design and Evaluation of a Controller for a novel externally guided self-balancing patient rescue aid. European Control Conference (ECC), 2019, pp. 209-214

[21] M. Vossel, M. de la Fuente, D. Wieschebrock, O. Yilmaz, K. Radermacher & A. Janß: Integrating a Tracking Camera in the OR Using the IEEE 11073-SDC Communication Standard. In: P. Meere & F. Rodriguez Y Baena (ed.): CAOS 2019, 2019, pp. 409-414

mediTEC-Team