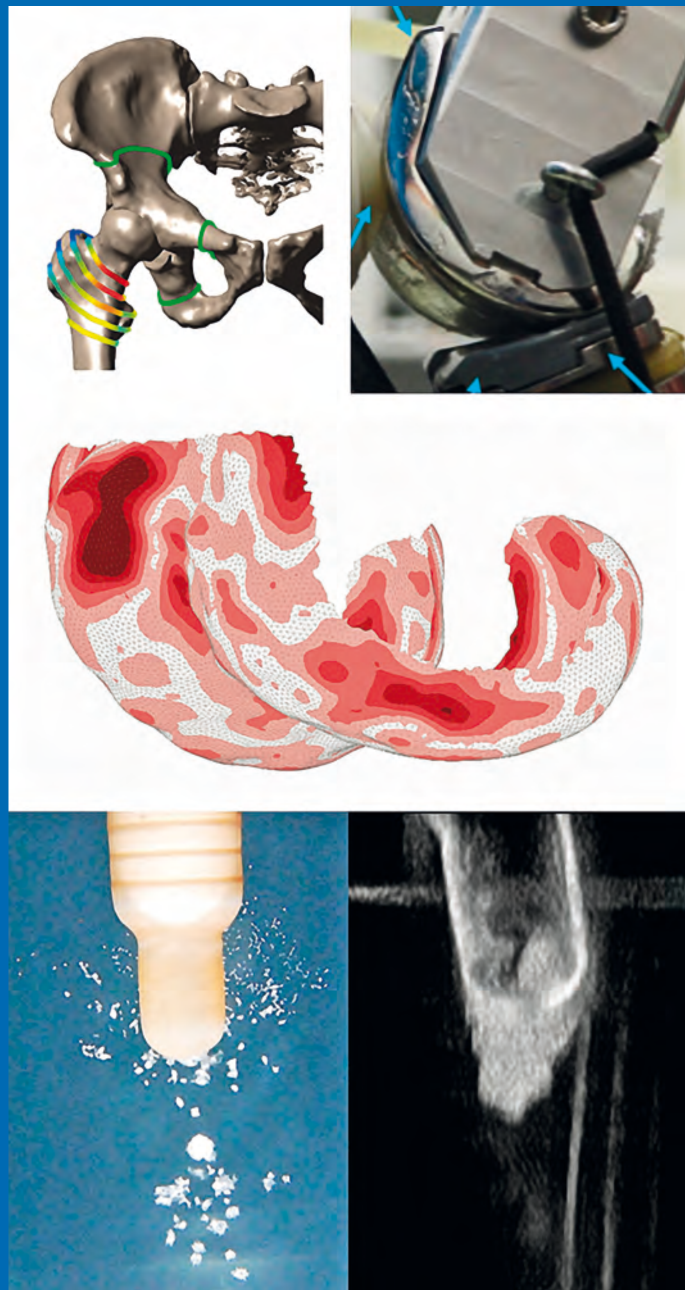
Chair of Medical Engineering at Helmholtz-Institute for Biomedical Engineering
RWTH AACHEN UNIVERSITY

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 (e.g. DFG), 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.
Some activities are presented in this overview.

Selected Projects

Biomechanics of the CSF System

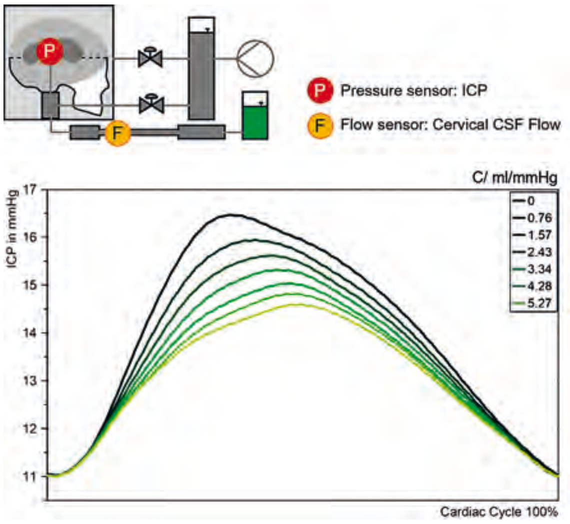

Fig 1: (Top) In-vitro setup and (bottom) impact of spinal compliance (C) on intracranial pressure (ICP) in the course of a cardiac cycle.

The etiology of Normal Pressure Hydrocephalus (NPH) is still not clear. However, it is known that a reduced compliance of the craniospinal system could be one key factor explaining typical NPH symptoms such as high intracranial pressure (ICP) amplitudes and a decreased cerebrospinal fluid (CSF) flow in the spinal canal. Nonetheless, so far the impact of the cranial or spinal compliance on the fluid dynamics is still unclear. An *in-vitro* model of the craniospinal system, including ventricles in a parenchyma, a cranial subarachnoid space connected to a first compliance chamber and a spinal canal including a second compliance was developed to investigate the impact of cranial or spinal compliance respectively. The ICP and the spinal CSF flow were measured (Fig. 1) and compared with in-vivo PC-MRI flow data. NPH patients with a reduced spinal CSF flow are likely to have a reduced spinal compliance. Whereas increased ICP amplitudes result from a decreased overall compliance.

Patient-specific Wrist Arthroplasty

The wrist is one of the most complex joint systems of the musculoskeletal apparatus. The wrist is prone to rheumatoid arthritis and is vulnerable to injuries due to its multilayered ligament system. In contrast to knee and hip, wrist arthroplasty is much less established due to the short lifetime of the wrist implants.
Based on the review of current wrist implant designs and *in-silico* as well as *in-vitro* analysis of wrist biomechanics, new patient-specific concepts are evaluated taking the individual morphology and functional aspects into account (Fig 2). Furthermore, the use of additive manufacturing technologies for the production of patient-specific implants is investigated.

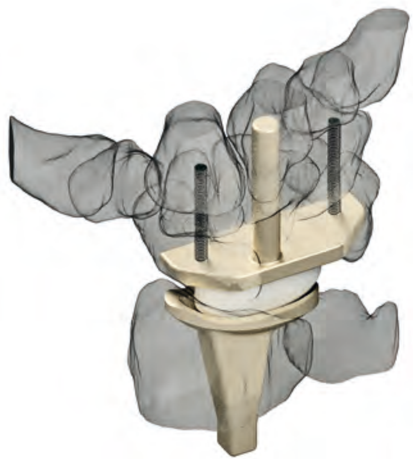

Fig. 2: Concept study on a parameterized, patient-specific adaptable wrist implant.

Morpho-functional Planning in THA

Edge loading is considered a major risk factor for a reduced lifetime of total hip endoprosthesis. Magnitude and orientation of the resulting hip joint force are inter-individually different and change during activities of daily living. Therefore, the prediction of the postoperative hip joint force has to consider the individual morphological and functional characteristics of the patient. Comparative studies with sophisticated inverse-dynamics models as well as less complex analytical models have been conducted in order to evaluate the validity of the models and their usability and scalability in clinical practice (Fig 3). Apart from edge loading, the outcome of total hip arthroplasty depends on several other parameters related to the alignment and design of the implant components. Unsuitable combinations of them could lead to impingement, dislocation, increased wear, and loosening. The prosthesis has to fulfil certain constraints that might be contradictory to each other. The components have to be properly fitted to the

Fig. 3 Comparative parameter studies using inverse-dynamic simulations and analytical models.

bony structures, the range of motion of both the prosthesis and the bones should be sufficient and the resulting hip force should not be too high in amplitude and not at the edge of the cup causing edge loading. A method for calculating a patient-specific target zone incorporating all the above mentioned criteria was developed (Fig. 4).

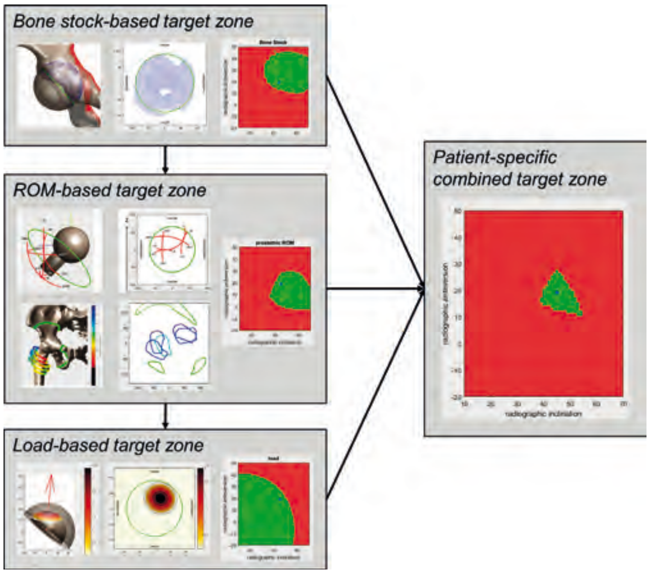

Fig. 4: Concept of a patient-specific combined target zone.

Morpho-functional Analysis of the Knee

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. In order to ensure a smooth transition between the implant and the bone, the design of the implant should be based on the morphology of the femur and tibia. A crucial investigation is whether there are several "morphotypes" of the involved bones, i.e. distinct shapes into which every bone can be classified (e.g. gender, age or ethnicity). In this case implant manufacturers could produce prosthesis that not only differ in size, but also match the different types or classes respectively.

Based on several hundred knee geometries obtained from CT-Scans, a set of shape features have been extracted and subjected to a cluster analysis. The distinctiveness of these clusters has been evaluated. Fig. 5 shows two cluster representatives found for the femur. The similarity of the two shapes as well as low cluster validity indices computed imply a high overlap of the clusters and therefore that no morphotypes exist.

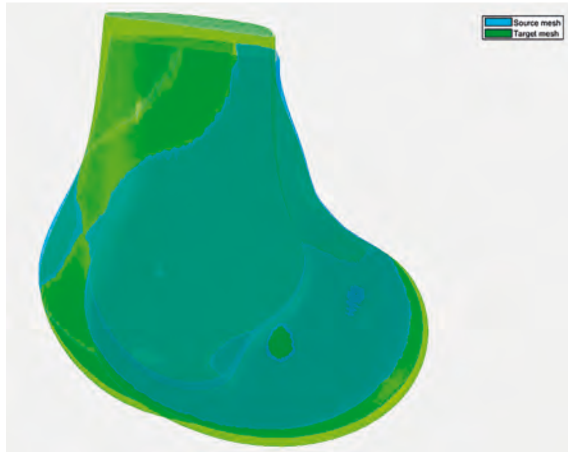

Fig. 5: Representative shapes of the cluster analysis of the distal femur.

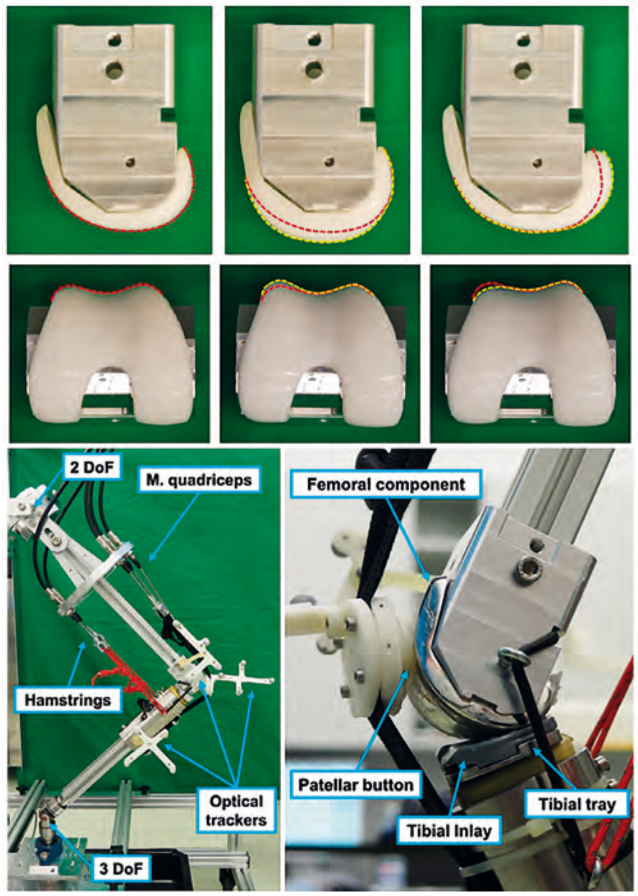

Fig. 6: Parameter variation of replica implants and experimental setup.

Apart from these morphological analyses, further implant design parameter studies regarding the relationship between morphology and (passive/semi-active/active) knee kinematics in *in-silico* multi-body simulations as well as in experimental testing rigs (Fig. 6) have been conducted.

Today, CT (and MR) are commonly used for the acquisition of 3D bone morphology. In order to reduce imaging cost and circumvent exposition of the patient to radiation, we are developing a demonstrator system for ultrasound based 3D-reconstruction of the knee (Fig. 7).

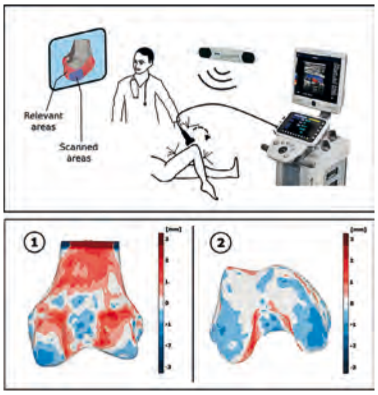

Fig. 7: Concept and first in-vivo results of US based 3D reconstruction of knee morphology.

Experimental Evaluation of Cavitation in ESWL

Cavitation is a major fracture mechanism in extracorporeal shock wave lithotripsy (ESWL). However, it can cause tissue trauma and its effects on kidney stones and surrounding tissue are not fully understood. Therefore, experimental setups enabling systematic parameter studies are crucial. We developed and evaluated a testing rig comprising three measuring methods in order to examine this mechanism. Cavitation was visualized by high-speed photography and B-mode ultrasound imaging (Fig. 8). Furthermore, stone comminution at different pulse repetition rates was investigated by fixed-dose fragmentation.

Fig. 8: Primary cavitation (left) and B-mode image of secondary cavitation (right).

The experimental setup provides reproducible results regarding the development of primary and secondary cavitation on the one hand and the fragmentation of phantom stones on the other hand. Therefore, it can be utilized to further investigate the effect of different boundary conditions and shock wave parameters on cavitation and stone comminution.

Modular Design of Cooperative Surgical Robots

Surgical robots have been introduced in the field of Computer Assisted Surgery to assist the surgeon by providing an accurate link between the computer-based plan and the exact (a) positioning or (b) dynamic path control of an instrument on the operating site respectively. Whereas initial systems mostly have been based on an active supervisory control scheme of industrial robots with large universal workspaces, later on specialized miniaturized kinematics have been proposed, with restricted workspaces adapted to specific applications in order to ease handling and provide inherent safety properties. However, this specialization resulted in even narrower fields of application, low quantities and higher costs. Modularization seems to be a key factor to combine the benefits of both approaches. Based on several proprietary developments and an in-depth literature review, concepts for a systematic modularisation scheme based on module indication matrices (Fig. 9) have been developed and evaluated.

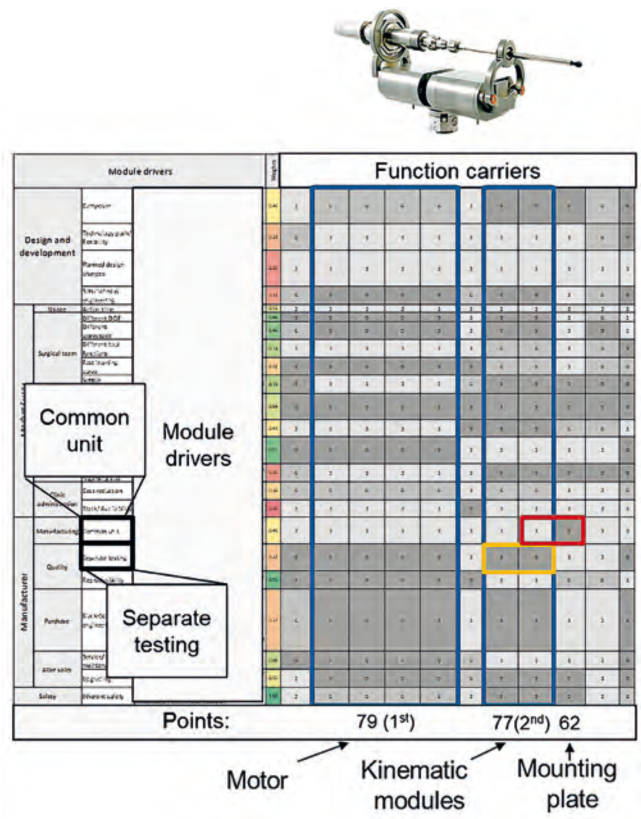

Fig. 9 Exemplary Module Indication Matrix for the MINARO modular minirobot system.

Modularity is also related to a flexible provision of cooperative robotics covering the entire spectrum from master-slave telemanipulator systems for endoscopic keyhole surgery to active autonomous robotic machining of structures for minimal invasive spine surgery. Haptic assistance seems to be a very promising option to reduce the complexity of a surgical control task while keeping the surgeon in-the-loop and allowing intervention at any time during surgery.
Based on experimental set-ups enabling the interactive simulation of different modes of feedback and levels of arbitration (Fig. 10) we perform user studies regarding different assistance functions to evaluate their effect on system usability. The aim is to identify appropriate configurations depending on the requirements of specific intraoperative scenarios as a basis for a comprehensive framework and modular user interfaces providing a flexible integration of cooperative robotic functionalities suited to the needs of a particular surgical scenario.

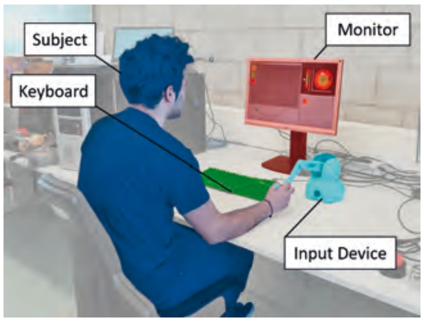

Fig. 10: Haptic Assistance Test Stand.

Interoperability in Open Medical Devices Networks

Based on the achievements of the BMBF flagship project OR.NET (2012-2016) our team continued its activities in the cooperative network of the OR.NET initiative (www.ornet.org). Initiated by OR.NET, the IEEE11073-20701 was approved as a new standard by the IEEE-SA Standards Board on September 27th 2018. The binding standard defines the interoperation of the participant and communication model defined in IEEE11073-10207 to the profile for transport over Web services defined in IEEE11073-20702. Thus, all substandards of the SDC standard family are approved by the IEEE and can be implemented by device and software vendors.

Fig. 11 (a): ZiMT surgical Workstation on the conhIT exhibition 2018, Berlin; (b) Tablet user interface with process-specific function group view.

In 2018, OR.NET related work was continued in the framework of the ZiMT project aiming to develop, evaluate and synchronize basic concepts with safe and usable human-machine-interfaces for the safe dynamic networking of components in operating theatres. ZiMT project results have been presented at the conhIT 2018, Berlin and the Medica 2018, Düsseldorf (Fig. 11a). The goal of the MoVE project is to research methods and testing procedures (conformity and interoperability tests) that support the approval and certification process and therefore especially the risk management of networked medical devices using IEEE 11073 SDC. For this, a simulation platform including test suite, test scenarios and device simulators is currently being developed, in order to provide future methods and tools for manufacturers, clinical operators and test institutions. Our team further develops inter alia a central surgical workstation for an open integrated operation room in the framework of the ZiMT project. This can either be controlled via a central touch display, which provides all relevant OR information and device panels, or by flexible remote controls (Fig. 11b). Numerous devices of different vendors have been integrated (e.g. OR light, 3D X-ray C-arm, OR table, RF devices, endoscopic devices, US-cutting device, different power tools such as high speed milling and shavers, an universal footswitch and an height-adjustable footboard).

Self-Balancing Mechatronic Rescue Aid (SEBARES)

Paramedics transport and monitor patients during 12 million deployments in Germany each year. Thereby, paramedics regularly lift and carry patients as currently available transport aids either do not offer any load reduction or have major other usability deficiencies. Therefore, paramedics frequently are overburdened due to high workloads far above ergonomic limits associated with unphysiological working postures. Therefore, the main objective of the SEBARES project is the development of an enhanced transport aid for paramedics with a self-stabilizing control. The goal is to simultaneously offer a universally applicable rescue aid with high mobility and a small footprint taking into account common constraints in patient transport. To be able to overcome stairs the transport aid shall incorporate a stair climbing mechanism which is currently developed based on a comprehensive market and literature analysis. Fig. 12 shows an exemplary scaled down functional model. These models are used to conduct first experiments on different staircase models and to identify issues and shortcomings early during the development process.

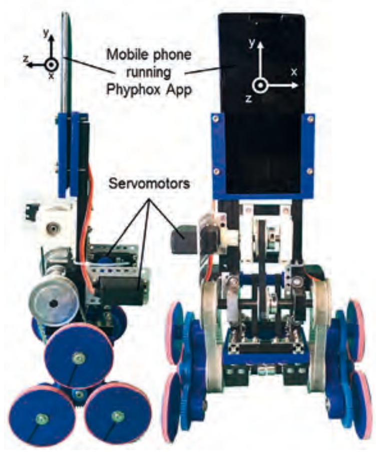

Fig. 12 Scaled Down Stair Climbing Mechanism.

Although self-balancing systems are in general well-analysed and described, the application as a patient transport system entails several specific requirements. For instance, about 25 % of the patients are not cooperative during transport and therefore might influence the stability of the control loop. To analyse this influence a parametric multi-body model was developed and validated experimentally (Fig. 13).

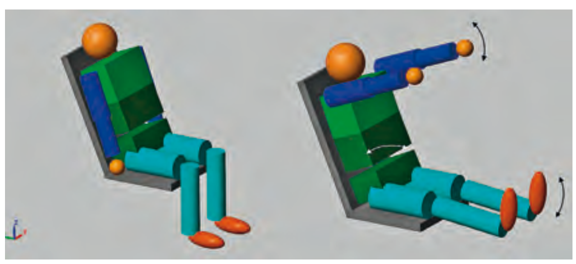

Fig. 13: Patient model, left: resting, right: seizure.

Simulation of different patient behaviors showed that the patient can critically influence the control loop especially by movements of his torso and introducing external forces such as holding onto a rail. Apart from system design modifications (e.g. for fixation of the patient), advanced control strategies which take possible movements of the patient into account are currently under development and evaluation.

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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.

Awards

- Philipp Schleer, M.Sc.: DAAD Travel Grant and IFAC CPHS 2018 Young Author Prize, 2nd Conference of International Federation of Automation Control on Cyber Physical & Human Systems 2018" in Miami, USA
- Anne Benninghaus, M.Sc.: DAAD Travel Grant and 3rd Prize - Young Investigator Award, Hydrocephalus 2018, Bologna, Italy
- Lukas Theisgen, M.Sc.: 3rd Prize – VDE Student Competition, Annual Meeting of the German Society for Biomedial Engineering – BMT2018, Aachen, Germany
- Dipl.-Ing. Malte Asseln: Travel Award of the German Society for Biomechanics - DGfB

Selected Publications

[1] M. Asseln, L. Berger, M. Verjans & K. Radermacher: Effects of the medial and lateral tibial slope on knee joint kinematics in total knee arthroplasty. Current Directions in Biomedical Engineering, 2018, 4(1), pp. 207-211

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[7] J. Hsu, M.C.M. Fischer, K. Tokunaga, G. Esnault & K. Radermacher: Analyzing Bony Constraints as a Key Stone of an Integrated Approach Towards Functional THA Planning. In: W. Tian & F. Rodriguez Y Baena (ed.): CAOS 2018. EPiC Series in Health Sciences, 2, 2018, pp. 74-78

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[10] S. Jeromin, M. Vossel, C. Rauchholz, S. Billet, C.-A. Mueller, S. Lavallée, K. Radermacher & M. de la Fuente: A new approach for safe planning transfer using semi-automatically adjustable instrument guides. Int. Journal of Medical Robotics and Computer Assisted Surgery, 2018, 14(4), pp. e1907

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[16] P. Schleer, M. Kinzius, M. Verjans, F. Kähler & K. Radermacher: Development of a Stair Climbing Mechanism for a Novel Mechatronic Transport Aid: Preliminary Results. Current Directions in Biomedical Engineering, 4(1), 2018, pp. 283-286

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[19] K. Tokunaga, J. Hsu, M.C.M. Fischer, M. Okamoto & K. Radermacher: Why did Anterior Dislocation Occur During Dandling her Baby in front of her in Standing Position after THA?. In: W. Tian & F. Rodriguez Y Baena (ed.): CAOS 2018. EPiC Series in Health Sciences, 2, 2018, pp. 219-222

[20] M. Verjans, A. Schütt, P. Schleer, D. Struck & K. Radermacher: Postural workloads on paramedics during patient transport. Current Directions in Biomedical Engineering, 4(1), 2018, pp. 161-164

mediTEC-Team