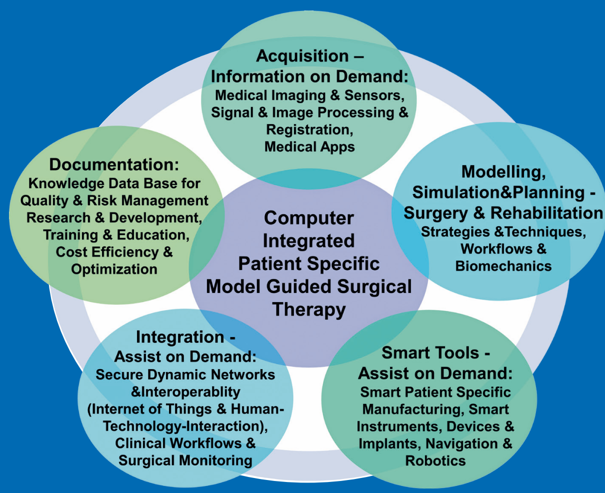
Chair of Medical Engineering
Faculty of Mechanical Engineering

Engineering Science and Innovation for better Health Care



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Introduction

The main objective of our research activities is the development of new approaches for efficient and smart health care. In cooperative projects with national and international partners from clinics, research and industry, the topics range from basic research to application oriented developments with the aim to find, validate and transfer new solutions for clinical applications. However, in many cases technical solutions remain worthless in a clinical context without an in-depth understanding of related boundary conditions, requirements, clinical processes and workflows. Therefore, one major focus is the optimization of clinical usability of complex human-technology systems by efficient integrated risk management and usability engineering methods.

Actual trends towards personalized medicine (including e.g. biomechanical modelling and patient specific implants) are based on modern technologies such as 3D-imaging or sensor technologies, image processing and statistical morphological and functional modelling as well as additive manufacturing technologies ("3D-printing"). The numbers and complexity of technical components, e.g. in the operating room, are rapidly increasing, which requires the integration of smart communication concepts and technologies as well as open medical networks ("internet of things").

In this context, our activities cover a wide range of topics from feasibility studies to usability testing and clinical trials e.g. in orthopedics, traumatology, neurosurgery, general surgery, interventional radiology and cardiology in close cooperation with academic, clinical and industrial partners. Current projects range from the acquisition, segmentation and reconstruction of relevant information, its registration and integration for patient specific modelling and simulation, to adequate technical (software or mechatronic) means for model guided therapy.
In 2016, the OR.NET project on secure dynamic integration of modular OR-systems, a flagship project of the German Ministry for Education and Research (BMBF) has been officially concluded successfully with a symposium and demonstrator presentation at the conhIT 2016 trade fair and conference in Berlin. At the same time, continuity and sustainability of the OR.NET project has been assured by the successful acquisition of follow-up project grants as well as by the foundation of charitable OR.NET association by partners of the OR.NET project from industry, clinics and research.

Based on the results of our initial BMBF project IDA (Medical Technology Innovation Award 2008 of the BMBF), members of the mediTEC team founded the Whitesonics GmbH (www.whitesonic.com) and received substantial funding of the Federal Ministry of Economic Affairs and Energy (BMWi) and the High-Tech Gründerfonds (HTGF) for the transfer of our basic research and development of a dental ultrasound microscanner to its clinical application.
Additionally, various projects related to basic research issues (e.g. funded by the German Research Foundation (DFG)) as well as industrial co-operations in different focus areas have been continued or started by our team. International cooperations, publications of our research, the market applications of products originally developed in our lab as well as international patent applications continuously confirm our general concept of combining basic as well as problem oriented medical engineering research and application development. Last but not least, this also provides a sound basis for the education of our students.

Fig. 1: mediTEC-team members engaged in workshops, field trips and public hands-on demonstrations.

We contribute to bachelor and master programs of different faculties of the RWTH Aachen University, including the coordination of the master program for general mechanical engineering of the Faculty of Mechanical Engineering. Apart from these educational programs and internships we offer field trips and hands-on workshops to get young pupils, students and future researchers hooked on the fascinating field of medical engineering (Figure 1).
The tight connection between actual research topics and the theoretical as well as practical education of our students from different disciplines and specialities is an essential basis for the success of our alumni in their international industrial as well as academic careers.

Selected Projects

Modelling and Analysis of Shoulder Biomechanics

Understanding biomechanics of the shoulder is essential to cope with current shoulder problems. To investigate shoulder biomechanics we developed an ex-vivo shoulder-simulator. Our shoulder simulator comes with an innovative "teach-in" function which allows us to investigate the behaviour of the shoulder in any assigned free spatial movement without the need of EMG data or external input. Moreover, the simulator allows us to conduct parameter studies and evaluation of various shoulder implant designs which shows very promising results. The experimental results are also useful in the multi-body in-silico simulations for shoulder model verification or analysis. This could lead to a better understanding of the shoulder behaviour and related innovative implant concepts.

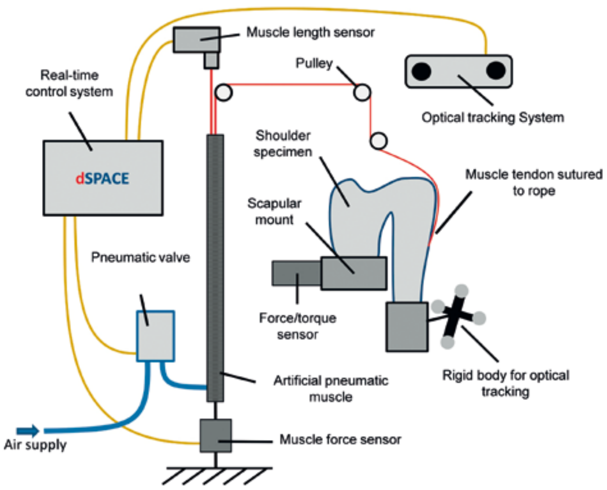

Fig.2: Simplified schematic of the shoulder simulator.

Patient-specific Safe Zone in THA

In total hip arthroplasty procedures, standard values are often used for component positioning and orientation alignment. Despite high success rates, complications such as dislocations, wear and loosening still occur. They could be reduced by considering patient-specific parameters. In this project, a planning procedure based on the definition of a so-called patient-specific safe zone will be developed. This includes the consideration of anatomical as well as functional parameters such as the required range of motion and resulting hip forces. Furthermore, concepts for integrating this process into the clinical workflow will be developed and analysed.

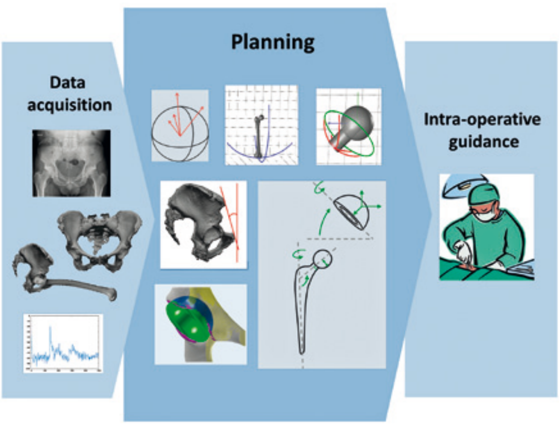

Fig. 3: Clinical work-flow of optimized patient-specific planning of THA.

Simulation of the Craniospinal Fluid Mechanics

The craniospinal fluid (CSF) system is a very complex part of the nervous system and until today its dynamics is not fully understood. Since flow and pressure measurements in the brain ventricles or the subarachnoid space are highly invasive, it is inevitable to simulate the biomechanics of the fluid system in the context of parameter studies and developments of innovative implant solutions. Using simulation tools, such as MATLAB Simulink or COMSOL Multiphysics®, enables us to reproduce the CSF dynamics including the significant mechanisms: compliance, vascular pulsation, CSF production and absorption. The gained knowledge about the CSF system can be used to find alternative therapies for treating e.g. normal pressure Hydrocephalus.

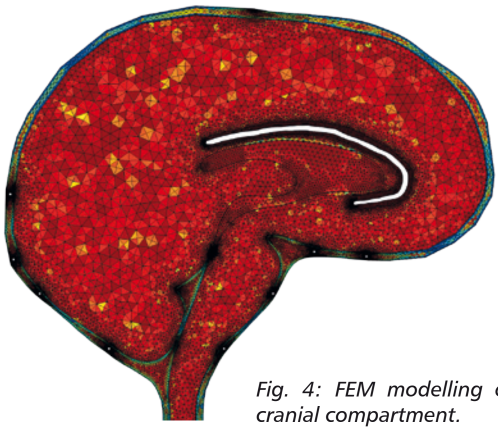

Fig. 4: FEM modelling of the cranial compartment.

Parametrization of the Pelvis for Morpho-functional Analysis

Total hip arthroplasty is the most frequently performed artificial joint replacement in the human body. During the planning phase it is necessary to identify anatomical parameters and landmarks to take the individual anatomy and biomechanics of the patient into account. A manual identification requires medical knowledge, is time-consuming and error-prone. Therefore, a robust, automatic detection process is preferable and was developed to determine patient specific parameters and landmarks of the pelvic bone. This is the basis for sensitivity analysis regarding the correlation of morphologic and functional parameters.

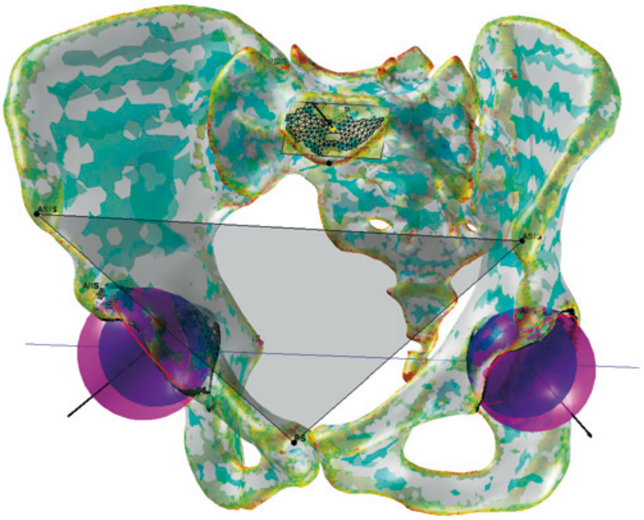

Fig. 5: Automatic alignment, landmark detection and acetabular analysis of a patient specific surface model of the pelvis.

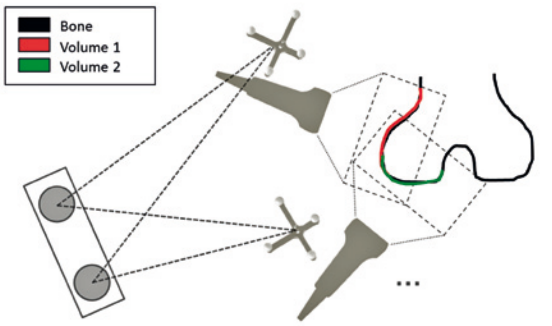

Fig. 7: Various parts of the bone are recorded with a 3D ultrasound probe from different perspectives. The probe is tracked as well as the bone.

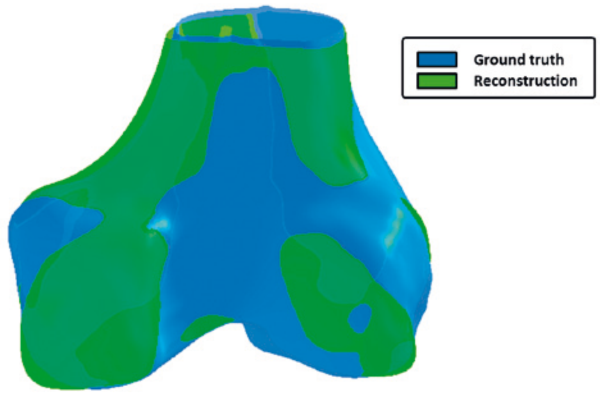

Fig. 8: The reconstruction of the femoral bone surface.

3D-US imaging of the Knee

There are numerous applications like biomechanical simulations or implant design and planning that need patient specific bone surface information. This information is mostly extracted from CT data associated with ionizing radiation. Alternatives such as MRI are expensive or suffer from distortions. Therefore, ultrasound is investigated as an alternative imaging modality. It has a high resolution, is cheap, and it is widely available. Its drawbacks, however, are a small field of view, acoustic shadowing, and a low signal-to-noise ratio. Thus, established segmentation algorithms do not work and new algorithms must be developed.

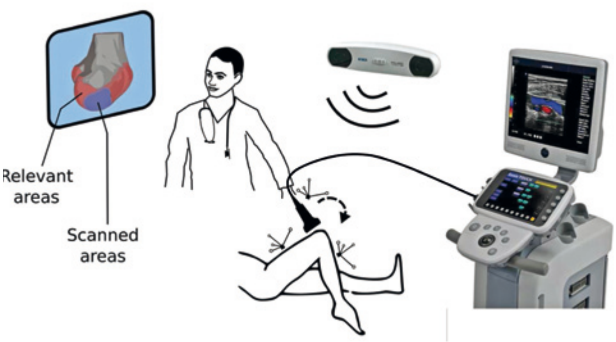

Fig. 6: A clinician records 3D ultrasound data from the knee. The probe, as well as the upper and lower leg are tracked.

We develop methods that allow clinicians to scan the knee from various sides using a 3D ultrasound probe. The probe is tracked as well as the upper and lower leg. A statistical shape model trained from semi-automatically segmented CT data is used to adapt to all ultrasound images. The entire information is combined to reconstruct the bone surfaces. Current in-silico and in-vitro investigations are very promising and yield reconstructions that deviate only in the sub-millimetre range from the real geometry.

Enhanced Skin Regeneration by Shockwaves

Shockwaves are high intensity focused acoustic waves with a high bandwidth from about 100 kHz to 100 MHz. They are used in medicine for the treatment of several indications like the disintegration of kidney stones, bone growth stimulation for non-unions and skin regeneration, especially for diabetic ulcers. As the effective mechanisms are yet not well understood, and shockwave treatment effectiveness for some indications is not proven, most indications are still under investigation.

Together with the Department of Dermatology and Allergology (RWTH Aachen University Hospital) we investigate skin regeneration in-vitro. We use a 3D model which consists of dermis and epidermis as well as the main dermal cell types. Thereby, it represents a functional model of the skin with a realistic geometry and wound healing process. The 3D model is wounded, then treated with shockwaves and afterwards the histology and gene expression are investigated.

For undisturbed and reproducible sound propagation towards the cells, we developed an experimental setup. It consists of the 3D skin model which is submerged in cell culture fluid. A silicone insert was build, which fits on the cell model and ensures the constant positioning of the focal point on the cells. Thereby, we achieve a reproducible sound field reaching the cells, which gives us the possibility to correlate our sound field measurements with the biological results.

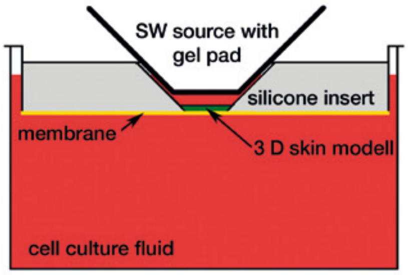

Fig. 9: Experimental setup.

SICOSI – Smart Impedance Controlled Osteotomy Instrumentation

Cutting of bone tissue (osteotomy) is a frequently performed surgical procedure which often carries the risk of damaging sensitive soft tissue underneath the bone. Especially the craniotomy and re-sternotomy, which are standard surgical procedures to enable access to intra-cranial or intra-thoracic structures respectively, carry a high risk of causing serious damage on the vessels and meninges which leads to worse surgical outcomes. Within the SICOSI project (funded by the German Research Association (DFG)) the feasibility of a novel hand guided, sensor integrated instrument for craniotomies is investigated. To achieve better cutting results the concept is based on a thin ceramic sawing blade equipped with electric conductors to perform a live bioimpedance spectroscopy of the treated bone during the operation to determine the minimum required sawing depth. Results of simulations and first laboratory trials suggest that the use of bioimpedance measurements is practicable to build a system which automatically adjusts to the minimum sawing depth during the operation without the need for any additional imaging or external sensor information

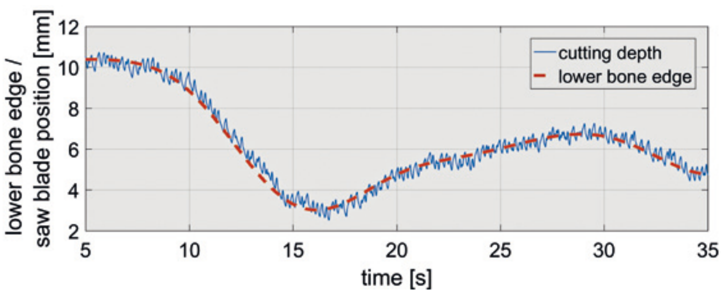

Fig. 10: HiL simulation for cutting with bipolar saw blade.

Open Medical Devices and IT-System Networks in OR and Clinic

The coordination and conduction of the OR.NET project on the open integration of OR-systems, a flagship project of the Federal Ministry for Education and Research (BMBF) with an overall budget of 18,5 M EUR (2012-2016) and finally more than 100 project partners from industry, research, clinics and associations has been a major challenge in the last 4 years. The overall concepts for integrated OR-systems is based on the open communication standard IEEE 11073 and further established standards. The extended medical device and service profile developed in OR.NET complement the standardization activities in the OR.NET project especially regarding the ISO 11073 extensions for the data model and especially for safety aspects of medical device communications. Medical Device User Interface Profiles (MDUIP) have been developed in order to extend the technical device profile, enabling an automatic optimized selection and composition of various user interfaces and an integrated human risk analysis in terms of quality assurance in human-machine interaction.

On this basis we developed a surgical workstation with an integrated graphical user interface including numerous device panels (e.g. 3D X-ray C-arm, OR-table, high-frequency cutting devices, endoscopic devices and ultrasound-cutting device). In conventional operating rooms, e.g. in neurosurgery, up to 10 foot switches are used to operate different devices. Unintentional displacement or confusion of footswitches may cause serious adverse events. In contrast, the OR.NET demonstrator system includes a universal footswitch optionally integrated onto a motorized positioning platform for the surgeon. Usability evaluations in cooperation with industrial and clinical partners showed very promising results.

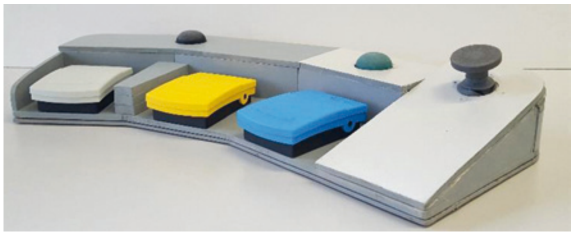

Fig. 11: Prototype of the Universal Footswitch.

Moreover, the integrated system enables direct access to clinical KIS and PACS systems. The alarm concept and surgical workflow navigation provide the OR team with valuable information, surgical checklists and surgical monitoring features.

Fig. 12: Graphical user interface of surgical workstation.

The final OR.NET demonstrator system has been successfully presented on the conhIT (Connecting Health Care IT) conference and exhibition in April 2016 in Berlin. Together with OR.NET partners, sustainability of the project work and continuing research and development will be assured by the OR.NET association founded in March 2016 (for more information: www.ornet.org) and the follow-up project ZiMT funded by the European Regional Development Fund (EFRE) and the State of North-Rhine-Westphalia (NRW)

Fig. 13: OR.NET demonstrator on the conhIT exhibition 2016, Berlin.

SEBARES – Self balancing rescue aid

Annually in Germany 10 Million patients are transported by emergency services. In a great number of cases the patients have to be transported over stairs, which is associated with enormous physical effort for the paramedics and longer mission times. Currently available rescue aids are often unsuitable because of structural circumstances, lack of dynamism or insufficient compactness. Because of this in most of the cases the paramedics have to carry the patients' weight resulting in an increasing rate of work-related injuries and premature incapacity to work. In combination with an increasing rate of obese patients the transport is a rising problem for emergency services.

In the context of the project SEBARES a novel mechatronic rescue and transport aid is under development. An innovative self-balancing concept enables high mobility, compactness and speed for the transport of patients via staircases. Together with a compact patient chair and a docking interface in the ambulance a universal rescue and transport aid may help to speed up the transport and to re-duce the physical effort of paramedics, and there-fore improve the working conditions in emergency services.

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 2016 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 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
- ERS@RWTH Aachen

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.

Selected Publications

[1] J. Dell'Anna, A. Janß, H. Clusmann & K. Radermacher: A Configurable Footswitch Unit for the Open Networked Neurosurgical OR – Development, Evaluation and Future Perspectives. i-com, 2016, 15(3), pp. 227-247

[2] K. Dietz-Laursonn, R. Beckmann, S. Ginter, K. Radermacher & M. de la Fuente: In-vitro cell treatment with focused shockwaves—influence of the experimental setup on the sound field and biological reaction. Journal of Therapeutic Ultrasound, 2016, 4(10)

[3] J. Eschweiler, J.-P. Stromps, M.C.M. Fischer, F. Schick, B. Rath, N. Pallua & K. Radermacher: A biomechanical model of the wrist joint for patient-specific model guided surgical therapy: Part 2. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 2016, 230(4), pp. 326-334

[4] J. Eschweiler, J.-P. Stromps, M.C.M. Fischer, F. Schick, B. Rath, N. Pallua & K. Radermacher: Development of a biomechanical model of the wrist joint for patient-specific model guided surgical therapy planning: Part 1. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 2016, 230(4), pp. 310-325

[5] J. Hsu, M. de la Fuente & K. Radermacher: Determination of the mechanical axis of the femur using 3D-2D model to X-Ray registration. Bone Joint J, 2016, 98(SUPP 5), pp. 35-35

[6] A. Janß, S. Plogmann, K. Radermacher: Human Centered Risk Management for Medical Devices - New Methods and Tools. Journal of Biomedical Engineering / Biomedizinische Technik, 2016, 61(2), pp. 165–181

[7] D. Teichmann, L. Rohe, A. Niesche, M. Müller, K. Radermacher & S. Leonhardt: Estimation of penetrated bone layers during craniotomy via bioimpedance measurement. IEEE Trans Biomed Eng, 2016, epub,ahead of print

[8] E.-M. Zeißig, A. Janß, J. Dell'Anna-Pudlik, M. Ziefle, K. Radermacher: Development and experimental evaluation of an alarm concept for an integrated surgical workstation. Journal of Biomedical Engineering / Biomedizinische Technik, 2016, 61(2), pp. 199–209

[9] M. Verjans, M. Asseln & K. Radermacher: Rapid Prototyping of replica knee implants for in vitro testing. Current Directions in Biomedical Engineering, Band 2, Heft 1 (Sep 2016), 2016, pp. 553-556

[10] M. Verjans, N. Siroros, J. Eschweiler & K. Radermacher: Technical concept and evaluation of a novel shoulder simulator with adaptive muscle force generation and free motion. Current Directions in Biomedical Engineering, Band 2, Heft 1 (Sep 2016), 2016, pp. 61-67

Team