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### **Data-driven leaflet modeling for personalized aortic valve prostheses development**

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While the aortic valve geometry is highly patient-specific, state-of-the-art prostheses are not capable of reproducing the individual geometry. Valve prostheses are only tested on their dynamical performance while the leaflet geometry is barely taken into account. One challenge is the mapping from the curved 3D shape extracted from imaging modalities to the planar 2D leaflet shape.

To address this problem, we set up a database to evaluate valve leaflet shape models. First, we acquired 3D ultrasound images of an ex-vivo porcine valve under physiologically realistic pressure. We extracted geometric key parameters describing the individual geometry from these volumetric images. In a second step, we cut out the valves leaflets, spread them on an illuminated plate and took a photograph of them. From these images, we extracted the leaflet shape using edge detection. We did this for 10 porcine aortic valves.

For all valves in the database, we modeled the leaflet shape using a state-of-the-art leaflet model based on the geometric key features and compared the result to the reference. Additionally, the database allows the derivation of a data-driven leaflet model. We estimated this model utilizing nonlinear Support Vector Regression (SVR) and evaluated it using a leave-one-out-method.

To the best of our knowledge, we created the first possibility to evaluate aortic valve leaflet shape models. The mean contour distance between the modeled leaflet shape and the reference was 2.92 mm for the state-of-the-art model and 1.46 mm for the data-driven model. These results indicate that state-of-the-art aortic valve prostheses are far from optimal with regard to the reproduction of a realistic leaflet shape and valve geometry. Utilizing machine learning, more realistic leaflet shapes can be estimated. This presents an important step towards personalized aortic valve prostheses.

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### **Long-term study of sound localization in cochlear implantees: measured with a modified clinical diagnostic setup using virtual sound sources (ERKI-method)**

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Directional hearing is a fundamental characteristic of binaural hearing, because the perception of acoustic space is based on processing sounds with two ears. A person with normal hearing can pinpoint and discriminate different sound sources very accurately. But, how do Cochlear Implantees (CI) perform in localization tests? In clinical audiology, there is no standardized measuring method to evaluate the binaural localization ability in the free-field. So far it was impossible to determine the advantage of the CI implantation regarding localization ability.

The aim of our project was to upgrade a common diagnostic setup for audiology in Germany. Our ERKI-setup consists of the “Mainzer Kindertisch” with five loudspeakers in a semicircular position (angular resolution =  $45^\circ$  between speakers). To achieve a higher angular resolution in the horizontal plane the setup was modified. In our study we generated virtual sound sources by loud speaker level differences (LSLD) between two adjacent loudspeakers obtaining 37 discriminable reference angles (five real and 32 virtual sound sources) in  $5^\circ$ -steps in a total frontal range of  $\pm 90^\circ$ . The responses were recorded by a control dial and a LED-light strip to give visual feedback. We used different stimuli with a length of 300ms. This developed ERKI-method is an automated diagnostic tool for measuring sound localization in the free-field.

We measured localization patterns in three different groups: SSD, bimodal and bilateral CI implantees. The results revealed that it is possible to measure the directional hearing by using a mixture of real and virtual sound sources. Our modified setup can help to track the development of directional hearing in CI implantees. However, the improvement of localization ability over a period of several months is different for each patient. The localization patterns show a broad variety of different localization accuracy.

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### Online particle measurements during the simulated use of drug coated balloons

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The evaluation of particulate matter of vascular implants, especially of drug coated balloons (DCB), is required by international standards (ISO, ASTM) as well as FDA guidance documents. Particles released during acute application of such devices may bear the risk to occlude small vessels causing micro embolization. The aim of this study was to investigate the number of particles during a simulated use procedure of DCB via online particle measurements.

Test samples were commercial PTCA-catheters (3.0x22 mm, n = 10) coated by homogenous pipetting 100 µl of a coating suspension (Paclitaxel-substitute fluorescein diacetate and ionic liquid cetylpyridinium salicylate 50/50 % (w/w) on the folded balloon surface. The simulated use procedure was conducted within a specifically developed flow loop, containing a guiding catheter, a tortuous path according to ASTM F 2394-07(2013) and an online particle counter (CHEMTRAC LaserTrac PC3400). Additionally, particle solutions were collected for further measurements (after 5 and 120 minutes) with an offline particle counter (Hach Lange HIAC ROYCO 9703).

Validation of both particle counting systems with particle count standards (Thermo Fischer CountCal) showed very equivalent results. Measured particle release from DCB was highest during the online measurements (56700 ± 28300, particles ≥ 10 µm) and reduced by 43 % after 5 min or 59 % after 120 min, respectively. Time dependent decrease was even higher when separately considering particles ≥ 25 µm and ≥ 50 µm (76 % after 5 min and 85 % after 120 min).

It is assumed that the massive particle reduction was caused by the dissolution of the water-soluble ionic liquid. The measurements show that online particle measurement is necessary to obtain information about the acute generated particulate matter, although it remains unclear, if water soluble particles have a negative effect on the human body regarding vessel occlusion or embolization.

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### Development of a measuring system to prevent extravasations

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During intensive care highly effective medications are delivered into the venous system. Thereby the infusion fluid may be not administered correctly into the vein. If the vein catheter is located outside the vessel and the infusion fluid is delivered into the tissue, the growing fluid accumulation is named extravasation. Extravasations occur as a result of lack punctures or catheter dislocations due to patient movements.

Extravasations can be found in up to 6% of all infusion therapies. Owing to special vein properties and uncontrolled movements, preterm infants suffer from extravasations in up to 78% of all treatments. As a result of extravasations nervous dysfunctions, necrosis or sepsis can arise. Thereby extravasations of chemotherapeutics and liquids for parenteral nutrition are most critical.

Technical detection of the beginning extravasation is currently not available. Therefore, the research project reaches to develop a tool capable of detecting the beginning extravasation and protecting the patient.

In this context, a measuring system in dependence on the impulse-oscillometry is developed and tested. To identify the beginning extravasation, a pressure pulse is applied to the infusion line liquid column and the resulting pressure and flow trends are recorded at the vein catheter. Using the impulse response, the mechanical properties of the vein and the tissue are calculated respectively to differentiate the correct and the extravasational position of the vein catheter. The developed measuring system was tested in software simulations (LTSpice) and authentic pig tissue.

Both, simulations and tests in real tissue, showed differences in the impulse response for correct and extravasational placement of the vein catheter. These differences increase with rising infusion fluid flow and can be measured instantly after applying the catheter. Thereby the beginning of extravasations can be detected and their development inhibited.

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### **Adaption of ankle joint prostheses from CT data and determination of data on ankle joint strength**

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The ankle joint endoprosthesis has reached a standard of development, which allows calling it a routine treatment option of ankle joint arthrosis. However, there are still shortcomings with ensuring a long-lasting fixation of the prosthesis as well as with adaption to the individually different dimensions of the tibia. Therefore, investigations for the adaption of the ankle prostheses were carried out with a higher number of 500 patients. CT data were used which are usually obtained for medical report and surgery planning.

A method is presented that allows the adaption of ankle joint prostheses from CT data. The transversal sections were manually digitized and classified using geometrical parameters. The classification allows the dimensioning of the tibia component of ankle joint prostheses and a simplified estimation of the fixation of the prosthesis according to the linear beam theory.

Results of the dimensions of the tibia plateau and the derived magnitudes like principal area moment of inertia and the direction of the principal axes of inertia are presented for the patients and conclusions on the optimal design for a tibia component are derived.

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### **Gait biomechanics of patients with forefoot amputation using a customized carbon fiber prosthesis**

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Forefoot amputation are mainly caused by diabetes and cardiovascular diseases, while only a minority is linked to traumatic events. In 2013, the German federal bureau of statistics registered 46 cases of trauma caused amputation affecting the foot or ankle. Therefore, prosthesis manufacturers are less interested in the development of an adequate device supporting physiological gait. Existing prosthesis and orthosis do mainly cover cosmetic aspects, but do not take the foot's biomechanics into proper account. This reduces the patient's quality of life and does, in most cases, not allow sportive activities at all. Due to the lack of economical interest, the level of scientific knowledge in gait biomechanics of forefoot amputees is moderate.

The Ulm University of Applied Sciences developed in cooperation with Häussler (medical supply store) a novel highly dynamic patient customized forefoot prosthesis made of carbon fiber composite. The device restores the lost forefoot lever arm and enhances sportive activities such as walking, running and biking. Initially, the status and desired activity of five patients with forefoot amputation (Lisfranc and Chopart) treated with silicone prosthesis (standard treatment) was identified by an anamneses protocol. After patients were supported with a customized forefoot prosthesis, biomechanical gait parameters (kinetic and kinematic) were collected using 3D motion capturing (SIMI Reality Motion System) in combination with an instrumented treadmill (zebris medical). Initial tests with the novel device showed significantly improved specific gait parameters. Overall, all patients were walking at a higher velocity. The shift of the center of pressure (CoP) was reduced towards the body's core. The data on angle balance in the knee and ankle as well as plantar pressure distribution indicate an enhancement in direction of standard values.

## P 310

### **Requirement specifications for the development of a minimal-invasive venous valve prosthesis based on electrospun cusp structures.**

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**Introduction:** Chronic venous insufficiency defines the manifestation of venous diseases resulting from persistent venous hypertension as consequence of muscle pump failure and valvular incompetence leading to various pathologies. Goal of this study is to identify requirement specifications for the development of a minimal-invasive venous valve prosthesis to compensate insufficient valves for venous pressure reduction as a permanent device-based alternative to conservative treatments.

**Methods:** In cooperation with clinical experts and by analyzing existing literature, physiological and technical requirements are specified. For characterization of native venous structures, post-mortem macro-/microscopic analysis of donor material was performed using different microscopical techniques (e.g. immunohistochemistry; REM/TEM; xray micro computed tomography) and sonographical detection of inner vein diameter in standing (Valsalva maneuver) and supine position. Uniaxial tensile testing and hydrostatic compliance testing by laser scanning are used for mechanical characterization.

**Results:** The Vena femoralis communis below the inguinal ligament was identified as relevant/potential (anatomical) site for implant application. For restoring insufficient valve function in this deep vein segment, clinical experts confirm an expected reduction of venous disease symptoms due to pressure reduction. Post-mortem mapping showed unsymmetrical valve deviation in corresponding veins (left/right) and that the segment has up to two valves (mostly bicuspid). The mean inner diameter post mortem is  $11.6 \pm 2.3$  mm. Sonography shows a diameter increase by 20% performing Valsalva maneuver while standing compared to supine position. Uniaxial tensile testing revealed anisotropic mechanical behavior of venous wall. For cusps higher breaking strain and tensile strength were measured (36%, 3.9MPa) compared to the wall (longitudinally: 19%, 0.7MPa; circumferentially: 15%, 1.9MPa).

**Conclusion:** The elaborated specifications will be used for structural design and dimensioning of a venous valve prosthesis, and to identify potential electrospinnable materials meeting the mechanical properties of venous tissue structures.

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### **Cardiac support systems with embedded ultrasonic flow measurement**

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Medical devices for liquid based therapeutic applications typically require adequate flow control and management to fulfil risk and safety related requirements. Cardiac support systems with an impeller pump often calculate liquid flow indirectly, based on the hydraulic load resulting in a force on the impeller which can be measured electrically. Yet, such an indirect flow measurement does not satisfy all needs regarding patient safety and pump management and additionally requires a running pump. Therefore, independent non-invasive flow measurement, such as the ultrasonic based transit-time flow measurement technique is highly advantageous since it doesn't affect the flow path of the hemodynamically optimized systems.

This flow measurement technology was already successfully integrated about 15 years ago at em-tec in the centrifugal "RotaFlow" (Maquet, Getinge Group) pump which also presents a high challenge with respect to the complex flow profile due to strong flow disturbances and pulsatile flow. The technology ever since proved a high level of reliability and therefore is considered state-of-the-art.

Based on the previous experience, the design of the pump of the cardiac support system is analysed in detail to identify the optimal flow sensor position for a reliable flow measurement, especially taking into account material, electrical, hemodynamic and ultrasound aspects.

Additionally, general regulatory conditions for medical device development and relevant technical standards for circulatory support devices have to be considered in the early design phase to ensure compliance with approval requirements.

Technical signal processing solutions face on challenges with respect to specific hydrodynamic and electrical distortions in ultrasonic signals, which is a well-known limitation in many available cardiac assist device systems. Therefore, a special signal correlation analysis of the entire signal with a high sample rate is used to measure flow even under these compromised conditions. In-vivo trials have demonstrated long-term reliability of the flow measurement in implanted systems.

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### **Conduct a study on the research and exemplary development of context-sensitive support systems for dementia patients with subsequent evaluation**

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**Situation:** Although the field of assistance system research has made great progress in the last few years, there is almost no medical technology solution for intelligent support of dementia patients available. The aim of the study was to develop and evaluate an infotainment system (video/audio) for dementia patients.

**Method:** On the basis of patient observations and family surveys, requirements for user-centered product development for dementia patients were collected. Based on the findings of the requirements analysis, an exemplary infotainment system was realized. In the next step, the developed system was implemented in the living environment of dementia patients and evaluated for ergonomics and improved quality of life (clinical benefit). The evaluation was carried out in a combination of usability studies and physiological measurements. It was investigated whether the infotainment system has a positive effect on the well-being of dementia patients.

**Results:** By analyzing the requirements and system implementing in the living environment of the patients, important insights and experiences for the development of assistance systems and further research activities are gained. A further gain in knowledge results from the analysis of the transferability of the methods is used for requirement analysis and for usability engineering for the target group of dementia patients.

**Discussion / Conclusion:** There is still a high need for research to analyze the user requirements for dementia patients, the design and development of appropriate assistance systems, and the evaluation of these systems taking into account the user group.