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Modular systems and lightweight construction concepts - new possibilities for the defect-specific treatment of hip joint diseases

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In tumor endoprosthesis, implants are applied to reconstruct the proximal femur. The main problems of these implants are often the high weight and the biomechanically not optimal attachment of soft tissue. The aim of this work is the development of a long-term stable biomechanically correct implant of a proximal femoral replacement.

Based on lightweight construction concepts from vehicle construction, a topology optimization was performed with an existing modular implant basic body. The additive manufacturing process laser beam melting was applied to produce the implant with the material TiAl6V4. The individual modules were coupled by a specially designed polygon interface. To disconnect the interface, a joining instrument was used which applies a force at two defined points and thus elastically deforms the internal contour of the interface. This allows the reversible joining of the modular components. In order to fix the muscles anatomically correctly, textile attachment points made of multifilament polyester were produced by embroidery.

A functional model of a modular implant was produced. On the basis of a topology optimization, the new implant has a mass reduction of 400 g compared to a proximal femoral set, which was assembled from the MML system. The greatest savings potential was found in the trochanter module (weight reduction by 55%). The load-bearing structures consisted of TiAl6V4, whereas the shell of the neck module was made of polyethylene.

The reversible coupling was implemented by a polygonal interface. The force closure took place by switching off the external force effect and thus the deformation of the round bore hole into an elliptical geometry, which resulted in a "jamming" of the spigot.

According to ISO 7206 the fatigue strength of the implant was determined. The test implantation at a body donor showed that the implant can be placed under realistic conditions.

NW 14

Development of a measuring system for the investigation of the force and the damping situation during the making of conical clamping between THA-shaft and -head

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Nearly all of today's hip implants have a modular hip stem system in which the artificial joint head is connected to the femoral stem of the prosthesis during the operation. The junction of the two components is realized by the frictional connection of a conical clamping, which is produced by means of a hammer stroke. Decisive for the connection strength of the clamping is the maximum force applied once in the direction of the axis of the cone, which depends both on the initiated pulse and the damping of the human body. In order to investigate the applied forces of different operators and the influence of the damping soft tissue situation, a measuring system was developed which can be used in situ.

Because of its small size and the high upper frequency limit, a piezoelectric force sensor is used. This sensor is applied between the cone and the stem of a special measuring prosthesis. The measurement prosthesis is symmetrical from the lateral side, so that it can be implanted both left and right. As a result, the sample size is doubled in the case of planned in-situ tests. The attenuation is calculated by the impulse response of an acceleration sensor, which is applied to the top of the cone. The processing of the measurement data is done by a PC-software developed for this purpose.

Both sensors were validated by means of various pendulum tests. The pendulum initiated a defined pulse whose properties were measured with the sensors and compared with the theoretically available values. The force sensor showed a deviation of less than 1% and the acceleration sensor of approx. 2%.

The laboratory tests are followed by extensive in-situ experiments with the aim of examining the variance of different operators and the damping properties.

NW 15

Applied research in the field of medical engineering in interdisciplinary networks of physicians and engineers - challenges and results

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The development of new medical products and technical systems is a major challenge for all participants. In addition to clinical-medical and technical questions, questions of examination, approval and remuneration must also be considered. However, these challenges can only be addressed by a pooling of all stakeholders along the value chain in the development of new components and systems. At the same time, the creation of appropriate communication interfaces between all partners is essential.

The starting point of the development should be the determination of needs of physicians or therapists point of view. Based on this, the analysis and the transfer of the identified challenges into the engineering environment are carried out by means of appropriate intermediate stages. In the subsequent concept and development stages up to prototyping, the collaboration of physicians and engineers should always take place.

One way of working together along the entire value chain is to establish common networks or platforms. For example partners along the entire value chain are working together in the networks “Kinetek” (focus: locomotor system) and “Kunstgelenk” (focus: artificial joints), which were founded by Fraunhofer Institute for Machine Tools and Forming Technology IWU and the University Hospital of Leipzig.

Establishing a process chain for new medical devices and systems first requires taking a look at potential development paths that have various underlying motives. For example these approaches can be divided into technology-driven and findings-driven implant design. Creating a joint development platform for topology-optimized implants for example is viewed as an innovative approach. It requires suitable software interfaces that facilitate efficient communication and transfer of results between engineers and medical professionals since the approaches of the two disciplines differ as much as do the languages of the two disciplines.

NW 16

Non-invasive measurement of electroencephalographic and electromyographic signals for the development of a brain controlled muscle stimulation system

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Brain-computer interfaces are an innovation and great progress has already been made in this field of biomedical engineering. The basic principle of these systems is the conversion of neuronal activity of the central nervous system into motor actions as an example of direct communication between man and machine. Our group is developing a non-invasive system for the stimulation of muscles by surface electrodes. The initialization and control of the stimulation is triggered by the neuronal activity of the subjects. During the planned training phase, the activity in a specific frequency range of the electroencephalogram (EEG) will be displayed on a screen. The subjects will be required to deliberately influence this and specifically stimulate their leg musculature with specially developed electronics. From these measurements, a suitable frequency band in the EEG signal was determined and the chronological course of the muscle activity was examined by electromyography (EMG). For this purpose, the activities of the brain and muscles of a subject were recorded and analyzed during the movement of the lower limbs. Measurements in which the subject just imagines the movement were also made. An electronic system displays the beginning of an action by acoustic and visual signals and sends a trigger signal to the measuring devices to synchronize the signals in time. The EEG analysis showed that the activity in the range of the μ -band changes during the requested muscle actions. Software was developed which acquires and process the data online and displays the results as a feedback to a subject. The temporal course of the activity of the measured muscles could be determined from the EMG data. In order to study the shape of stimulation signals which are required for a determined muscle activity, the measured characteristic shapes of the EMG signal are reproduced with MATLAB and a microcontroller-based circuit.

NW 17

Accuracy study of a 3D printed patient specific brain biopsy system for veterinary medicine

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The sampling of brain tissue in veterinary medicine usually underlies a freehand performance without exact localization. The aim of the project was the accuracy evaluation of a 3D-printed subject specific system for brain biopsy in dogs.

At the beginning of the procedure, three small bone screws were fixed (bilateral and occipital/frontal) to the dog skull. Subsequently, three MR-markers filled with contrast agent were adapted and MRI scans performed (layer-thickness 1.0 mm). Within the MR images the coordinates of the target and entry point are determined by the surgeon. For evaluation an additional pre-CT (layer-thickness 0.7 mm) was realized. After image recording the MR-markers were removed. Due to a self-made algorithm a patient individual template was constructed. The final biopsy device made of ABS M30 was produced by a 3D printer (FDM).

To perform the biopsy the device was connected with the already embedded bone screws. Through a guidance track the skull was minimally invasive accessed at the intended location. Controlled by a depth stop the biopsy needle could be exactly moved in a desired direction up to the target point.

A further post-CT (thickness 0.7 mm) with inserted needle was performed to determine the final position of the biopsy needle tip. For receiving information about the difference between preoperative planned and achieved tip position the pre-CT was matched with the post-CT. Therefor 10 dog cadavers (n=20 target points) were applied.

The results showed an accuracy of $0.58 \text{ mm} \pm 0.34 \text{ mm}$ (ranging from 0.09 mm to 1.17 mm) between the preoperative planned and the achieved needle position.

A patient specific 3D-printed biopsy system based on MR images was developed which enables a high precise brain biopsy. Moreover, the system matches up to current costly diagnosis techniques of image-guided neurosurgery and robot systems. Prospectively, it shall be transferred to human medicine.