Fraunhofer IWU

FRAUNHOFER INSTITUTE FOR MACHINE TOOLS AND FORMING TECHNOLOGY IWU

MEDICAL ENGINEERING

INNOVATIONS FOR THE PATIENT

Physicians, therapists, engineers – there is hardly a second field of research as interdisciplinary as medical engineering, offering such potential for innovations. The increasing life expectancy in Germany is not least based on the continuous improvement and development of diagnostic methods, therapies and the associated technologies.

Endo- and exo-prostheses, injections or band-aids, high-tech or mass products – clinical every day life cannot be imagined without medical products. Due to demographic change and the increasing average age of the population, high expectations are placed on medical engineering of the future. Mobility and independent actions of the patient have to be maintained up to old age. The research tasks in medical engineering lie in the development of new methods and products for the reduction of risks of surgeries and the increase of implant lifetime.

The integration and application of new materials and technologies is indispensable. Adaptive materials, such as nickel-titanium-alloys have shown how much potential novel materials offer. Today's vascular surgery cannot be imagined without super-elastic stents (vessel supports). And there is still more potential in these adaptive materials. Future implants will hold novel functionalities and will contribute to tackling the diverse challenges of surgery. Modern processes of diagnostics for navigation during surgery or preoperative planning will support the surgeon in complex surgeries and in choosing suitable implants and will contribute to a better treatment quality.

However, in addition to an effective treatment, in healthcare the cost also plays an important role. Innovative concepts will only prevail in clinical practice if they are affordable and at the same time offer a distinct advantage compared to the state-of-the-art. In order to achieve this goal, it is necessary to implement innovations of production technology.

The innovative production processes include additive manufacturing processes like laser beam melting, which enable patient-specific solutions. However, the conventional processes also offer further development. The integration of adaptive components or the further precision and miniaturization allow innovative approaches to be technically realized.

The Fraunhofer IWU is involved in a multitude of projects in the area of medical engineering. The portfolio covers the development and conception of active materials to the development and improvement of novel production processes and tools up to the implementation of unconventional materials or composites. In addition to the equipment of measuring and machine technology at the locations of Chemnitz and Dresden, three new laboratories of medical engineering have been available since 2011 in the Dresden branch of the institute. Various testing machines and a micro computer tomograph (µCT) for material or component tests improved the preconditions for future research and development plans in the area of medical engineering.

Hip stem implant produced by laser beam melting, with porous surface and functional elements.

MEDICAL ENGINEERING AT THE FRAUNHOFER IWU

At the Fraunhofer IWU, a multitude of projects is performed in various areas of expertise. These are divided into four subject areas and represent important elements of the integrated process chain in technology development and prototype production of medical product components.

Subject area
Determination of characteristic values

Biomechanical characterization and coverage of technical parameters often form the basis for further developments. Computer and parameter models can be verified by means of experimental investigations.

Exact knowledge of the mechanical structure environment is required for the indication of implant-specific deficits and provides a significant assistance in the conception and the selection of suitable components.

Subject area
Testing and integration

The implementation of the developed component into the clinical environment first of all requires proof of effectiveness. This can take place in a first step of a demonstrator testing. The testing is closely linked to the determination of biomechanical characteristic values and represents a cycle of optimization.

Experimental and numerical investigations may perform fine tuning of target parameters for integration into the clinical environment. In this context, the applicability for the surgeon has to be taken into account. With increasing complexity of existing medical technologies, surgery planning and navigation, for example, are helpful tools for the surgeon.

Hip bone excited by electrodynamic shaker for modal analysis of the biomechanical characterization.

Subject area
Conception, design and simulation

Conception is a decisive step in the development process and should consider integrated and interdisciplinary influencing factors.

The design represents the pre-stage to production. In contrast to conception, it is completely dependent on the later feasibility and the technologies available. The integration of active materials enables the development of new complex systems with new functionalities.

Simulation is significant for implementation of the developed concepts to optimize goals and efforts.

Subject area
Implementation in production technology

Technical implementation of the developed innovative concepts often poses high requirements on production. It is often a limiting factor in design possibilities of new medical technologies and products as well as in technical realization. However, further development of conventional production processes and the use of new technologies open up new opportunities:

- By means of additive manufacturing processes like laser beam melting, implants can be optimized in terms of topology but also patient-specific implants are realized.
- Technology development for cutting, removing and forming processes in precision and micro production enables the implant production to a range of micrometers.
- Bone-like structures are manufactured by means of cellular structures, for example out of metal foam or by using additive manufacturing processes like laser beam melting.
- Bulk metal forming can help improving material properties and reducing material inventory.

LIFE SCIENCE – CORE COMPETENCIES AND TECHNOLOGIES

Biomechanical modeling

Detailed knowledge of the biological model is the basis for demand-oriented conception in the area of implant development. Various testing machines and processes can be used for determining biomechanical characteristic values at the Fraunhofer IWU. In addition to conventional tensile, compression and torsion testing machines, optical testing processes are also available. A 3D laser vibrometer measures the dynamic properties of the object of investigation, which allows the verification of numerical models.

A human hip bone has so far served as object of investigation. By means of a motion analysis system, the relative displacement of several components in relation to one another can be investigated. This provides significant indications for the regeneration of the original range of motion or for establishing motion models.

1 *Patient-specific skull implant with porous boundary structure, manufactured by laser beam melting.*
2 *Board with forty micro-milled prosthesis geometries made of Titanium, as components of novel middle ear prostheses.*

Design and numerical simulation

The Finite Element Method (FEM), which is widely used in engineering for simulating object properties and processes, has also proved successful for the illustration of biomechanical processes. The utilization of numerical models is considered helpful for constructive optimization in medical research as well as in clinical practice (such as in surgery planning).
In this area of research, Fraunhofer IWU is competent in the field of numerical modeling and in the relevant experimental verification. Established experience can be found in the area of numerical investigation of active materials, such as shape memory alloys and their integration in implants or textiles.

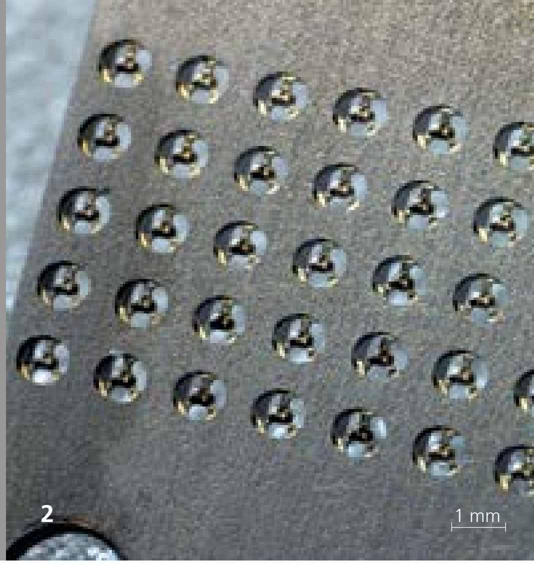
Active materials

Active materials, such as shape memory materials or piezo ceramics, offer diverse applications to medical equipment technology and prosthetics. They can be applied as alternative drive elements, but they also allow the development of new, complex systems with new functionalities. Depending on the application, they can act as sensor or function actively to influence, for example, the force contact at the bone-implant interface, thus preventing loosening of implants in the long run.

Additive manufacturing of implants

Fraunhofer IWU uses the additive manufacturing process of laser beam melting to manufacture implants of biocompatible metallic materials (titanium, cobalt-chromium, stainless steel) with almost any complex geometry. The implants can be equipped with a complex or, if necessary, variable geometric structure either in their complete volume or only at the surface, in order to optimally adapt their properties of strength and stiffness to the surrounding bone and to improve the incorporation behavior.

1



2

It is also possible to integrate functional channels and cavities into the implant which can ensure, for example, the postoperative supply of medication at the implant-bone interface. Furthermore, the geometry of implants can be adapted to the individual patient. Here, computer tomographic data of the patient often form the basis for individual, patient-specific implant design.

Precision and micro production

Fraunhofer IWU develops technologies and plants for the production of miniaturized and micro structured components for applications in many areas – also in medical technology – and implements them in different application steps. Main research takes place in:

– production of miniature prosthesis by using cutting and forming processes
– production technology for medical components and devices
– plastic micro fluid sensors
– economic glass sensors

Bulk metal forming

The high requirements for, above all, strength and safety in dynamically stressed parts are reliably fulfilled in the medical technology field of application by workpieces forged in die. As in almost all forming processes, a structured, long end shape cannot be produced in one forming step in die forming. The initial shape often consists of a section with constant cross section. In order to reduce the amount of waste it is reasonable to distribute the volume of the initial shape along its axis according to the end shape. The production process cross wedge rolling creates the precondition for the application of low-burr die forging by economically producing precisely dosed intermediate shapes of mass distribution. In addition to the process of hot bulk forming, load-bearing implants are also manufactured by cold extrusion at the Fraunhofer IWU. This process is specifically appropriate for small implants.

Hot embossing

In the field of medical diagnostics, micro fluid lab-on-chip-sensors are used to detect various blood or urine data. Complex micro fluid systems often require functionalized surfaces to control the fluids in the micro channels. The goal of optimization by production technology is the reproducible, reliable structure transfer in one embossing step with sub-structured tools as well as the reduction of the process time of the fluidics component production.

Metal foam

The utilization of metal foams as starting material for implants offers numerous advantages. For example, the rough surface provides optimal conditions for incorporation of bone cells. Also the modulus of elasticity as well as the weight can be adapted to the bone by variation of the foam density. The reduction of the stiffness compared to solid implants and the associated adaption of the modulus of elasticity to that of the bone actively counteract loosening of the implant due to atrophy of the bone (osteoporosis).

Target groups

Fraunhofer IWU offers research and development services for manufacturers of medical products as well as for hospitals and physicians in private practices. The service spectrum covers the investigation of individual components up to complex complete systems. This also includes the development of prototypes.

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