Orlando Abstract

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Today's challenges in 3D printing process chain of custom-made implants

Personalization in joint replacement surgery has become an area of high interest and large potential. Custom-made implants can replace lost bone or rebuild the joint function specific to the patient's situation, such as bone augments or partial bone replacements, limb diaphysis components or full anatomical replicas. While advancements in digitalization and processing of patient data have greatly facilitated this development over the past decade, one key enabler was progress in the production technology of 3D printing.

3D printing, or in industry generally termed as Additive Manufacturing, is regarded as disruptive technology that will shift the production paradigm. One category that allows for production of medical implants are so-called powder bed fusion processes. Here, thin layers of powder in the range of typically 30 µm to 100 µm are selectively exposed to an electro-magnetic energy source, such as a laser or an electron beam, hence known as Selective Laser Melting (SLM) or Electron Beam Melting (EBM). At the position of exposure the powder melts locally and the cyclical process restarts by adding a new powder layer. Additive Manufacturing allows for a layer by layer production of implants with complex surface shapes from biocompatible and load-bearing metal alloys such as Ti-6Al-4V. Complex in itself with a multitude of parameters, it is focus of numerous research and development initiatives in science community.

The process of Additive Manufacturing, however, is only one component embedded in a process chain that is yet evolving and facing a multitude of challenges today. The elements of this process chain, as well as the connecting interfaces, are not necessarily available as off-the-shelf blocks and may require extensive research and development to achieve the desired goal: To translate the patient's needs into a quality assured product that meets the customer's expectation and addresses the requirements of the regulatory framework.

These challenges were identified along the complete process chain and addressed appropriately. They typically required novel approaches for each specific problem, since Additive Manufacturing is not yet an established process in industry in general. Some of these challenges will be presented in the following.

The design phase defines the digital input data for the Additive Manufacturing process. First, the patient's situation has to be translated into a three dimensional virtual model. A designer uses the patient's CT or MRI images as basis for the patient specific geometry. Segmentation of the images yields a surface model of the bone and allows for planning and subsequent modeling of the implant. Due to the nature of the product, each clinical case represents a novel task. Shortcomings in conventional computer-aided design (CAD) software tools limits the designer's creative potential in applying the optimal solution. A set of software tools has thus to be procured or developed that allow for complex surface modeling or design of osseointegrative porous structures. Such features can uniquely be produced with Additive Manufacturing cost-efficiently.

For large defects the custom-made component has to be used in combination with standard or modular implant systems. It was derived that such interfaces can already be incorporated in the design of the custom-made component. Instead of conventional post processes such as milling or turning, interfaces can be additively manufactured and reduce overall production effort. Templates for interfaces of sockets, screw threads or bayonet joints were established and validated for use.

However, not only medical boundary conditions have to be considered during design, also the Additive Manufacturing process itself and subsequent finishing operations have to be taken into account. Best results were achieved by training designers in Additive Manufacturing and establishing a continuous process of knowledge transfer. By implementing this process knowledge into the design, custom-made implants can be manufactured without need for prototyping or testing.

Quality management poses another significant challenge in the regulated medical environment. Additive Manufacturing as relatively young technology, however, has not been defined appropriately in standards and regulations. In cooperation with several research institutions and a university, good manufacturing practices were applied to develop a production process that is validated and verified in all aspects.

All in all, the process chain of Additive Manufacturing possesses challenges for industrial application in general and cannot necessarily be procured off-the-shelf. Each component of the process chain requires research and development. Overcoming these challenges, custom-made implants of great patient benefit can be provided.