Title:
Onsite Medical Implants Creation by Combination of Enhanced Design Methods and 3D Printing

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Introduction:

Patients who have experienced functional limitations in the course of their lives – for example due to diseases, age-related problems or accidents – can be given back a piece of their quality of life with the help of certain medical technologies. This medical-technical knowledge includes, among other things, medical implants that can serve as a kind of bone replacement after severe trauma or pathological issues such as tumors, infections or necrosis. For these implants to be used as bone replacements, an exact replica of the previously undamaged bone must be achieved [9], [13], [15]. In addition to achieving functional regeneration of the damaged bone area, consideration must also be given to a satisfactory cosmetic result.

This extended abstract introduces an enhanced process enabling onsite provision of medical implants by integration of medical experts, advanced data processing, computational design and 3D printing techniques. As an added value in comparison to time-consuming traditional manufacturing of implants, the new approach provides higher geometrical quality and at the same time significantly reduced time for delivery. This can extensively support healing progressing, reduce the number of surgical complications, decrease surgery time and lower the duration of hospitalization and consequently decrease medical costs. The new process is based on data extraction from computational tomography as basis for the computational design process. The involvement of knowledge from automotive industry enabled the creation of an effective procedure that delivers highly accurate 3D models of the affected bones and the surrounding areas that are incorporated in the CAD-based creation of implants. Geometrical modelling and shape optimization are performed onsite according to the instructions of the surgeon team. The implants are produced also onsite by use of 3D printing technology within a short time, so that implementation can be performed within a few hours after arrival of the patients in the hospital.

In this way, a comprehensive procedure is provided, which utilizes knowledge-based CAD methods (e.g. [7], [8]) to improve the implant's geometrical quality and involves 3D printing technology to accelerate the manufacturing process significantly enabling short term delivery of medical implants.

Problem Statement & State-of-the-Art:

An important prerequisite for healing of patients' bones are precisely fitting implants. To be able to effectively redesign damaged bones, very detailed computational tomography (CT) data must be obtained. In the current process chain for generation of medical implants (c.f. Figure 1) CT data are produced in an initial surgery step and made available to external companies that produce the implants (external manufacturing).

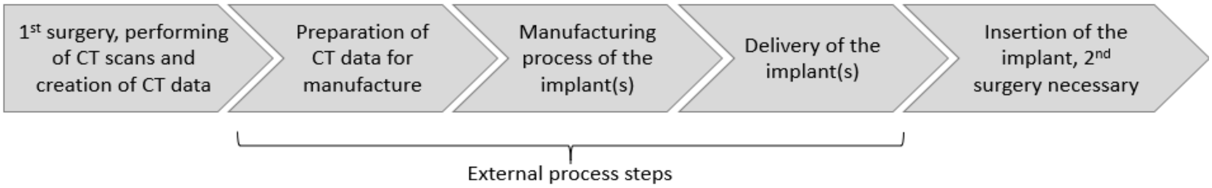

Fig. 1: State-of-the-art process chain for the generation of medical implants.

After an elaborate phase of manufacturing with a duration of typically about 2 to 3 weeks, the patient-specific implants are sent back to the clinical facility and inserted to the patients in a second surgery step. This outsourcing of the manufacturing process brings some significant disadvantages to the regret of patients and health care system:

- Complex and time-consuming provision: Patients have to wait up to several weeks for the implants.
- Cost-intensive manufacturing process: The costs of such an implant can reach thousands of Euros, leading to considerable expenditures for the health care system.
- A second surgical intervention is necessary for patients as external fabrication involves a period of time (no immediate implants available). The second surgery places an increased psychological and physical burden on the patients and increases the resources and efforts of the health care system.
- Furthermore, due to the long period of time required to manufacture the implants, the bones can change their shapes, which can lead to an inaccurate fit of the implants and associated limitations for the patients.

Due to these limitations, a new procedure has been introduced that uses onsite technologies, which enable design and manufacturing of medical implants within a few hours instead of weeks. The procedure involves enhanced methods for data transfer, computational design and manufacturing that have been developed in the automotive industry during the past decades and that are now adapted to support the generation of medical implants.

<u>The Onsite Implants Creation Process:</u>
The aim is to realize both development and manufacturing of the implants in-house and if possible, during surgery to avoid the highly complex and time-consuming provision of medical implants by outsourcing to external manufacturing. In order to achieve this goal, an optimization of the required core technologies such as patient data acquisition, analysis and conversion of these data, selection of the optimal materials as well as the preparation of geometrical models and their combination and clinical integration is crucial. This leads to an internally applicable process chain (c.f. Figure 2) that uses enhanced data preparation for the development (integrated into commercial CAD software, e.g. [3], [11]) and 3D printing methods as manufacturing technique.

Fig. 2: Optimized process chain for the generation of medical implants.

The introduced new approach of optimized generation of implants for medical cases with short-time delivery and, at the same time, high quality consists of four steps. Data obtained from CT scans are processed, collected in a database structure and made available for data processing, e.g. by use of deep learning technologies [8], to support the development of geometry models. Data preparation and processing involves enhanced technologies for evaluation, comparison and clustering of information to support the creation of geometry models (c.f. [1]), provided by parametric-associative technologies. The high demands on the geometrical quality of the implant surfaces and the complex geometrical boundary conditions requires an involvement of specifically tailored computer-aided design methods, which have been derived from enhanced geometry modelling processes as they are used e.g. in automotive development, [4], [5]. As software tools, standard CAD environments can be used, e.g. [3], [11]. The created geometry models of both bones and implants are evaluated in 3D by medical experts and optimized according to the specific surgery case. Finally, 3D data are exported to onsite 3D printing to produce the implants. Here, selected materials are used according to the specific demands of the actual medical case and the connected requirements, [10], [14]. In this way, a faster, more cost-effective and – especially for the patients less stressful – development- and production process is introduced. It is targeted, that the creation of the implants can be conducted during the first surgery within tight duration, so that the second surgery (c.f. Figure 1) is not required anymore. The introduced optimized process chain requires additional infrastructure and experts onsite, including infrastructure and experts for data processing and implants modeling as well as certified medical 3D printers.

One important aspect of the optimized implants creation process includes the provision of enhanced data supporting effective and quick implants geometry modelling. This requires the involvement of medical experts and the provision of a knowledge-database consisting of a large number of concerned bones from different humans, covering aspects of gender, age, human's size and anthropology, as well as different types of damage of the corresponding bones, e.g. torsional-, bending- or impact-caused fracture. Based on this information, a database can be set up that enables fast and effective modelling of implants according to the actual case. The CAD-based implants design process includes following steps:

- The CT procedure delivers large data volumes, which requires a reduction of the scan data to enable practical processing within CAD-applications. This can be done by use of standardized neutral geometry data formats, e.g. Standard Triangle Language (STL, c.f. [2]). The size of the STL models can be reduced by lowering the model resolution, but in this case different quality-related aspects (e.g. point cloud data noise, reduction of accuracy, geometrical influences) have to be considered. In addition, the model size can be reduced by limitation and cutting to the specific concerned geometrical areas of the model.
- CAD-model surface preparation is performed by preparation of erroneous geometrical elements, filling of holes and removal of disturbing bone structures so that the model can be converted from a CAD surface model to a CAD volume model.
- The implant design process is conducted under consideration of geometrical boundaries, bone structure, aesthetics aspects, implant placement-related requirements during the surgery as well as 3D printing-related specifications. The definition of geometrical shape and characteristics is accomplished under consideration of medical aspects by involvement of the corresponding surgeons and medical experts.
- Finally, the CAD-volume model is converted to a STL-file format to deliver data in a suitable format for the subsequently performed 3D printing processes [4], [5], [7].

The introduced implants design process provides a sequence of steps to effectively develop the suitable geometrical model for 3D printing. One important issue represents a time-effective implementation of the process, so that a quick delivery of the geometrical model is enabled. To achieve this, knowledge-based design methods come to use, which are based on industrial, automotive CAD-processes involving parametric models and automotive surface design techniques to support effective geometry creation [4], [5], [7], [8], [12]. In addition, knowledge databases can be implemented to enable automated creation and combination of sectional geometrical models and serve as basis for the development of techniques based on artificial intelligence. By use of deep learning techniques, the process of geometrical implants modelling can be supported in a way, that solutions are automated proposed under consideration of a broad range of boundary conditions concerning patient data (age, size, gender, etc.), reasons and circumstances of injury, as well as different medical factors. This requires large data acquisition considering different bone shapes as well as different injury cases. In this way, an involvement of comprehensive international medical data bases is planned in the course of future activities.

Application of the Onsite Implants Creation Process:
In the following, an application of the introduced method is presented by two examples. Figure 3, left, shows a CAD-model of a humerus CT-scan, that was developed out of data delivered in STL file format. In today's status of surgery and depending on bone size and type of fraction, standard metal implants (SMI, c.f. [6]) in different dimensions are used for supporting the broken bone coalescence after a fracture. If necessary, the plates are bent during the surgical intervention to optimize bone fitting, which is time-consuming and requires a lot of experience by the surgeon. Furthermore, the plate may break during or after the surgery due to material overloading. As suggestion for improvement of this situation, a 3D printed implant concept designed for a specific humerus bone is shown in Figure 3, middle and right. The implant consists of two separate parts for easier attachment onto the bone during the surgery. After attachment, the plates are firmly joined together and fixed with screws. The plates enclose the bone surface, provide a precise fit and fasten the broken bones. The implant prevents high misalignment of the broken humerus during healing and the material strength remains intact because it is not reduced by deformations due to bending.

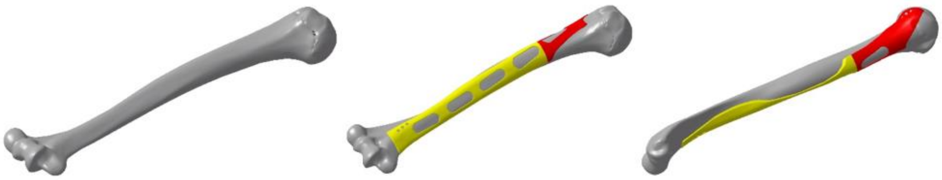

Fig. 3: Left: CAD-model of the humerus CT-scan. Middle and right: Different CAD-model views of the humerus with a customized implant for 3D printing.

Figure 4, left, shows the CAD-model of a skull bone CT-scan. In this medical case, certain surgical interventions require a skull bone part removal and the subsequent insertion of an implant. Especially for such complex geometry, handmade implants are time-consuming and costly. To avoid several surgery interventions, brain injuries and for supporting the patient healing process, it is important to provide an implant with high geometrical quality as soon as possible.

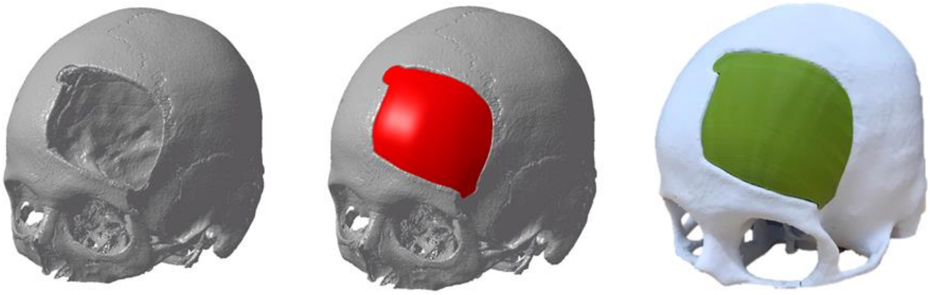

Fig. 4: Right: CAD-model of the skull bone CT-scan with open skullcap after a surgical intervention. Middle: Skullcap implant modelled with CAD. Right: 3D printed skull model with implant.

State-of-the-art 3D printer techniques and human body tolerable 3D printing materials open new possibilities for implants - complex bone structures can be re-produced by fast manufacturing techniques, [10], [14]. Figure 4, middle, shows the skull implant CAD-model, which was custom designed by CAD surface-based techniques. Due to the high complexity of the design task, the geometry creation process was accomplished in a combination of automated geometry extraction- and extrusion procedures in combination with manually performed geometry integration and optimization. The resulting 3D printed skull bone and implant model is represented in Figure 4, right.

Conclusion:

A new approach for smart integration of enhanced computer-aided design methodologies, data processing and 3D printing enables an effective processing of medical scan data, inclusion of medical and geometrical specifications conditions and consequently supports the generation of implants with a high geometrical quality within a timeframe of a few hours. This opens great possibilities for just-in-time delivery of medical implants for bone structures to enable significantly shorter clinical treatment durations with great benefit for both patients and health care system.

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