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

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Abstract. In the field of medical surgeries, many optimization measures can be carried out based on the ongoing technology progress of the last decades and future considerations. In this context, 3D printing offers an interesting and auspicious approach, especially in the field of bone replacement through inserted implants. These implants are subject to strict medical regulations as well as technical limitations, constraints and requirements. Particularly regarding design and accuracy of the implants technical improvements can be applied to accelerate the creation process and increase the accuracy of fit at the same time. One approach to support this includes the use of well-established surface modeling techniques from the automotive industry combined with novel artificial intelligence methods. In this context, the paper provides insights into the initial process from the development, over the creation to the insertion of implants and introduces an improved process to accelerate surgical steps while saving resources and costs for the healthcare system. Furthermore, the impact and benefits of automotive-based design paired with artificial intelligence methods in surgical processes are discussed. In addition to technical requirements and medical boundary conditions, the presented approach also considers ethical aspects in order not to limit the application of the approach to restricted patient groups as well as sustainability aspects enabling a general resource management in the newly developed procedure.

Keywords: Medical Implants Design, Medical 3D Printing, Knowledge-Based Design, Process Optimization, Surface Modelling
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1 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 bone replacements 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 [19], [25], [30]. In addition to achieving functional regeneration of the damaged bone area, consideration must also be given to a satisfactory cosmetic result.

This paper introduces an enhanced process enabling onsite provision of medical implants by integration of medical expertise and know-how, advanced data processing, computational design and 3D printing techniques, [10], [14], [15], [17], [29]. As an additional value in comparison to time-consuming traditional manufacturing of implants, the new approach provides better 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 chain is based on data extraction from computational tomography (CT) as a 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 computer-aided design (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], [10], [14], [16]) 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. Besides merging automotive development methodologies with medical surgical methods, the new approach also considers ethical issues related to the application of artificial intelligence (AI) methods to patients, as well as ecological aspects of sustainability enhancement for the entire process chain.

2 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 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. Therefore, external manufacturing steps, which have significant disadvantages in terms of sustainability and time factor, are part of the process chain. 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.

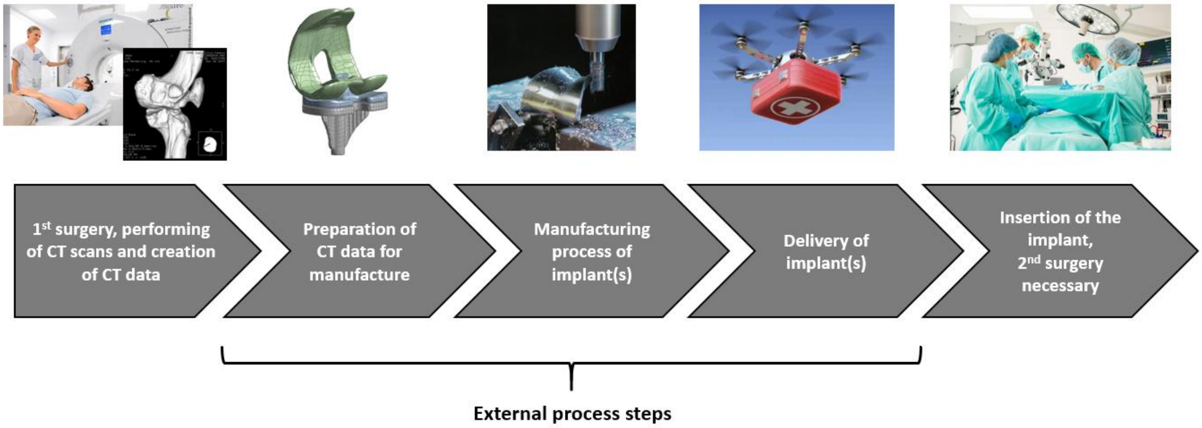

Figure 1: State-of-the-art process chain for generation of medical implants including external process steps, referring to [1], [6], [8], [11], [20], [27].

3 APPROACH OF AN ONSITE IMPLANTS CREATION PROCESS

Due to the limitations mentioned in chapter 2, 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.

The aim of the optimized procedure is to realize both styling, design and manufacturing of the implants in-house and, if possible, in the course of one comprehensive surgery to avoid the highly complex and time-consuming provision of medical implants by outsourcing to external manufacturing.

3.1 Optimization Steps for the Onsite Implants Creation Process

In order to achieve this goal, an optimization and smart integration of the required core technologies such as patient data acquisition, analysis and data conversion, 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 development integrated in commercial CAD software and 3D printing methods as manufacturing technique. 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 main steps:

- Step I: 1st surgery, performing of CT-scans and creation of CT data
- Step II: Internal preparation of CT data
- Step III: Internal implant(s) manufacturing process
- Step IV: Insertion of the implant(s) in one and the same surgery

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 (DL) technologies [16], to support the development of 3D 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. [2]), provided by parametric-associative technologies. The high demands on the geometrical quality of the implant surfaces and the complex geometrical boundary conditions require 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, [7],

[10]. As software tools, standard CAD environments can be used, e.g., [4], [21], [23]. 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, [22], [28]. 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 for data processing and implants modeling as well as certified medical 3D printers.

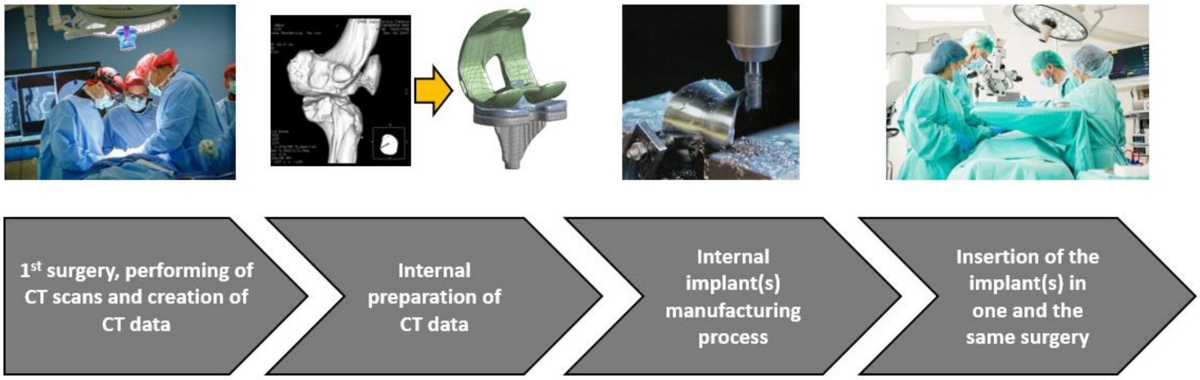

Figure 2: Optimized process chain for generation of medical implants without any external process steps, referring to [6], [8], [11], [20], [26].

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 bone models 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. [3]), Virtual Reality Modeling Language (VRML, c.f. [12]). The size of e.g., 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 treatment 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 [7], [10], [14].

3.2 Implementation of Automotive CAD Methods Combined with AI-Approaches

The introduced implants design process provides a sequence of steps to effectively develop the suitable geometry-models for 3D printing. One important issue represents a time-effective implementation of the process in a way that a quick delivery of the geometrical model is enabled. To achieve this, knowledge-based engineering (KBE) methods come to use, which stem from industrial, automotive CAD processes involving parametric-associative design models and automotive surface design techniques to support effective geometry creation [7], [10], [14], [16], [24].

In addition, knowledge databases can be implemented to support automated creation and combination of sectional geometrical models and serve as basis for the implementation of techniques based on artificial intelligence. By use of DL methods, 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 (c.f. sub-chapter 3.3.). This requires large data acquisition considering different bone shapes as well as different injury cases. In context, an involvement of comprehensive international medical data bases is planned in the course of future activities [18].

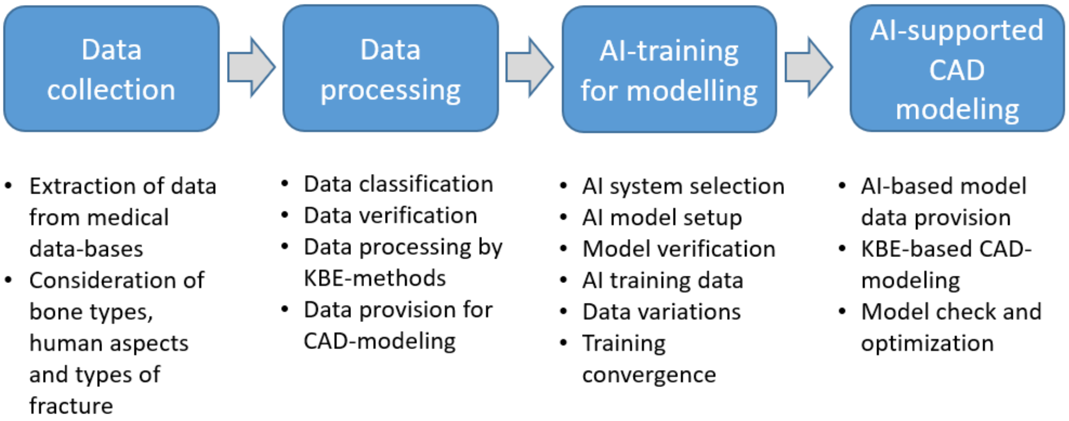

Figure 3: Process of AI-supported creation of implant geometry models, referring to [16].

The provision of training data for AI-techniques for the implants creation is based on knowledge-based design (KBD) and optimization to achieve a quality-related improvement of the model proposals. By learning and imitating the optimization process procedures and methods, AI-algorithms can be continuously expanded and improved with the target of fully autonomous implants creation. In this way, the training data are extracted from large medical databases by use of clustering and classification methods under consideration of quality criteria. Figure 3 introduces the sequences of an AI-supported modeling process for medical implants.

- In the first step, data are collected and extracted from medical databases. This can include large information sources and web-based data gathering. The data are collected under consideration of pre-defined requirements and boundary conditions that address the corresponding bone type, different types of potential fractures and additional information, e.g., in view of human's age, size, gender and genetic characteristics.

- In step 2, the collected data are classified and verified under consideration of pre-defined quality criteria. In this way, clustering of the large data is accomplished by use of KBE methods as they are common in industrial development processes. Finally, the data are structured and prepared for subsequent steps.
- Step 3 targets to a preparation of the AI including selection of a proper AI-software and setting up the corresponding AI-models. There are several standard AI-solutions available today that can be taken from the shelf, but they have to be adapted to the specific problem of medical geometry creation. The chosen AI-models are verified and can then be trained by use of the previously generated data structures. This includes different case-related variations and the consideration of convergence criteria of the training. Because the success of AI-application is significantly influenced by the quality of training, the provision of comprehensive and correct data represents an important aspect. Here, CAD automation should be applied to generate a broad variety of geometry models for training purposes, [16].
- In the final section, the prepared AI-solution is applied to support effective creation of the CAD models by provision of geometrical data according to the actual surgery case. The data are automated created in the CAD environment and then verified under consideration of pre-defined boundary conditions and geometrical constraints, e.g., scan data of the broken bones. For time-efficient conduction, the automated created geometry models can be verified automated by involvement of pre-defined quality criteria in combination with KBE-CAD methods and tools. Finally, the automated created AI-based geometry models of the implants are manually finalized and adopted according to the inputs of medical experts and then released for 3D printing.

It has to be stated, that AI has potential to solve CAD-oriented problems with good approximation. But as today's state-of-the-art, the technology is limited in view of a consideration of geometrical details. Exemplary, AI can be used to develop suggestions for the general shape of a geometrical object on a basis of pre-defined boundary conditions, but the detailed structure of the geometry cannot be developed sufficiently yet, [16]. In this way, the technology is applied to develop suggestions of solutions, which are evaluated and optimized by the surgeries and engineers involved. Based on intensive research in this field and increasing computation capacities of the systems, an increasing share of application is expected in the near future. This topic is content of intensive research activities with the target to reduce the share of required manual interaction in the entire process.

3.3 Ethical and Sustainable Aspects in the Process

The approach of an onsite implant creation process considers ethical and sustainability issues to ensure the applicability of the process to all patient groups and to achieve sustainability benefits over the current process. Starting with the ethical aspects, AI-based approaches offer a much less restricted field of vision, both in the development of new innovative approaches and in view of automatic creation of implants that is supported by knowledge-based design methods. A large database, which serves as the basis for the accelerated implants creation, provides the input while taking into account the most important ethical principles in the context of AI-applications. According to [5], these are respect for private data and information, human autonomy, harm prevention, fairness and transparency/traceability of applications. These principles are rooted in the fundamental rights of the European Union and other regions worldwide and must also be adhered to in order to ensure the implementation and use of AI-systems in a trustworthy manner [9]. Among other things, adherence to these principles prevents the AI-based optimized approach from negatively impacting the physical and mental well-being of people, both decision makers (e.g., doctors, medical personal) as well as patients and their relatives. The focus is on the reduction of psychological suffering of patients, for example by reduced expenses for surgeries, as well as the attention to diversity. The latter should be reflected in the optimized process chain in such a way that the quality of the implants, as well as all decisions from the preparation of the surgery of the patients, over the generation of CT data, up to the 3D printing of the implants, are supplied with optimized predictions and results, independently from the age, gender, degree of injury, etc. of the patients.

In addition to the integration of ethical principles, the onsite implant creation process also specifically addresses the issue of sustainability. The entire process, starting with the creation and processing of CT data and ending with the production of the implants, is optimized in a resource-saving manner. Due to the in-house production of the implants, i.e., the omission of external manufacturing steps, costs, resources and emissions for transport can be saved from an ecological point of view. Furthermore, the in-house production can massively reduce surgery time, which supports cost reduction of the health system, reduction of psychological burden of patients and their relatives and also reflects positively on the ecological side by reduction of total resources (e.g., reduction of used material and tool quantity, reduction of energy expenditure) during surgeries. The quality of the implants can also be massively increased by the AI-supported optimization process, so that the post-treatment (e.g., manual final shaping of implants) can be reduced to a minimum to reduce surgery time.

4 APPLICATION OF THE ONSITE IMPLANTS CREATION PROCESS

In the following, an application of the introduced method is presented by two examples. Figure 4, 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. [13]) 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 surgeons. However, even after multiple deformations of the plates, coupled with a high level of expertise of the surgeons, it cannot be assumed that the plates will be perfectly adapted to the fracture, respectively the bone. Furthermore, the procedure of deformation increases the risk of plate breaking during or after surgery, e.g., due to material overload.

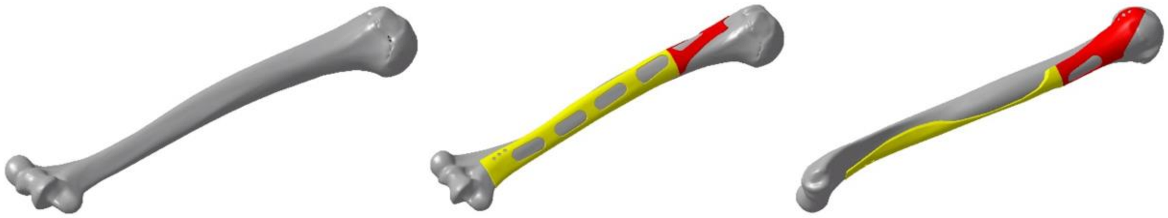

Figure 4: Left: CAD model of the humerus CT-scan. Middle and right: Different CAD model views of the humerus with a customized two-parted implant for 3D printing.

As suggestion for improvement of this situation, a 3D printed implant concept designed for a specific humerus bone is shown in Figure 4, middle and right. The implant consists of two separate parts (one part is displayed in yellow and one part is displayed in red color) for easier attachment onto the bone during the surgery. After attachment, the plates are firmly joined together and fixed with screws to ensure the accuracy of fit. 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. Figure 5, left, shows the CAD model of a skull bone CT-scan. In this medical case, certain surgical interventions required 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, potential brain injuries and for supporting the patient healing process, it is important to provide an implant with high geometrical quality as soon as possible. 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, [22], [28]. Figure 5, middle, shows the skull implant CAD model, which was custom designed by use of 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 as well as extrusion procedures in combination with manually performed geometry integration and optimization. The resulting 3D printed skull bone (displayed in white) and implant model (displayed in green) are represented in Figure 5, right.

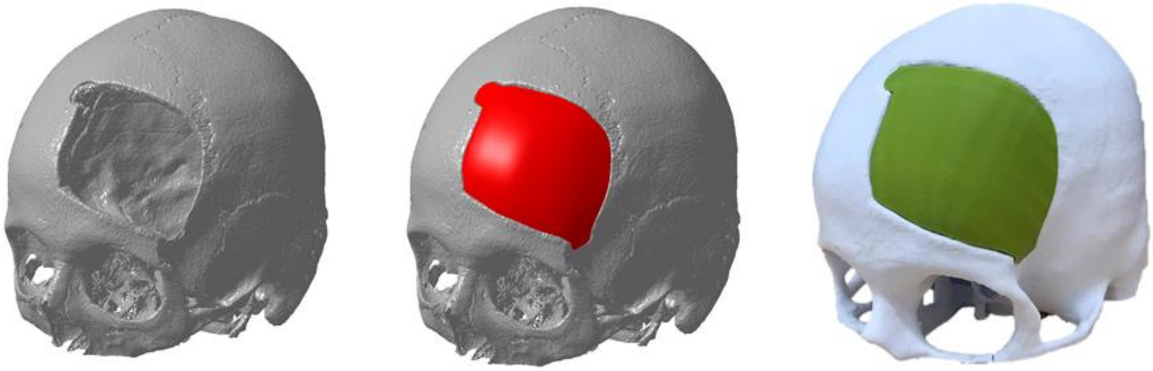

Figure 5: Right: CAD model of the skull bone CT-scan with open skullcap after a surgical intervention. Middle: Skullcap implant modelled with CAD. Right: 3D printed skull model with implant.

Both examples, the implants of humerus (c.f. Figure 4) and skull bone (c.f. Figure 5) are based on the process presented in Figure 3 and use KBE methods in combination with AI-approaches. After the first phase "Data collection", which is described in detail in sub-chapter 3.2., the phase "Data processing" follows that includes the application of the corresponding KBE methods, [10], [16], [24]. The input data, which are available as STL file format at this point, are processed and utilized with the help of automotive-based KBE methods (e.g., use of enhanced CAD programs, [4], [23], and application of surface design methodology). The process of preparation and further processing of STL data is done by using automation applications (e.g., macros, interactive CAD applications, programming applications), which are supported by AI-approaches (c.f. sub-chapter 3.2.). The AI-approaches draw on an available database, which enables statements about meaningful predictions and evaluation of potential solutions.

5 CONCLUSION

The novel 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 and consequently supports the generation of implants with a high geometrical quality within a timeframe of a few hours, instead of weeks. 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 the patients as well as the medical personal and the health care system. To apply the new approach in industrial and medical applications, a close interaction of medical experts and know-how, automotive knowledge in CAD method development and novel approaches in AI was provided. Furthermore, the approach considers both ethical (e.g. gender issues in AI development and the derived predictions, implementation of diversity aspects in the creation process of implants, reduction of patients' psychological and physical burden, etc.) as well as economical and sustainability aspects (e.g. in-house production and thus emission savings, reduction of surgery time, relieving the burden on medical staff and conserving resources in the healthcare system, etc.), which in turn contributes to the optimization of the entire process chain. In this way, a smart combination of computational scan data gathering and processing, the implementation of knowledge-based design methods and artificial intelligence for geometry creation and the in-house-provision of implants within short timeframes provides great potential to improve the surgery processes significantly for all involved stakeholders, but of course mostly for the patients.

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