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Modeling and Manufacturing of Individual Implants for Traumatology and Orthopedics

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Orthopaedic surgery is becoming increasingly common due to recent significant improvements in medical imaging, biomechanical modelling, and additive manufacturing. For the pelvis, surgical reconstruction using metal implants remains challenging due to the involvement of complex anatomical structures. In Kazakhstan, these operations are performed using typical implants. The purpose of the present work is to develop a spersonalised implant and its real application to work out the procedure and master the technology. This article describes all the relevant stages, from medical imaging to an accurate three-dimensional anatomical model of the implant. This described procedure can also be fundamental for virtual preoperative planning and the development of patient-specific incision guides.

1. Introduction

The development and implementation of modern digital high-tech systems and tools in surgery increase diagnostic accuracy and contribute to the successful treatment of bone injuries. The most promising method of treatment method in traumatology and orthopaedics is the modelling and manufacturing of scustomised implants using additive technologies. An implant is a pre-prepared element for the patient that is installed during surgical treatment of injuries.

The use of 3D printing is growing and has become more prevalent in medicine over the past decade as surgeons and researchers increasingly use the flexibility of the technology to produce objects. 3D printing is a type of manufacturing process in which materials such as plastic or metal are applied in layers to create a 3D object based on a digital model. The advantage of this additive manufacturing method is the production of objects with complex free-form geometry, which is not possible with traditional subtractive manufacturing methods. Particularly in surgical applications, 3D printing techniques can not only create models that provide a better understanding of complex patient anatomy and pathology and help in surgical education and training but can also produce patient-specific surgical guides or even scustomised implants that meet surgical requirements.

Custom-made - products created using additive technologies and used in traumatology and orthopaedics are "convenient" high-tech implants. Their distinctive feature is the scustomised form factor, and in most cases, they are the last "optimistic option" when the possibilities of known treatment methods have already been exhausted (Tihilov et al., 2018).

The use of additive manufacturing provides a flexible solution for rapid and cost-effective production of implants as well as surgical instruments with high quality for the specific patient. Additive manufacturing technologies offer many advantages over traditional implant manufacturing methods. Based on 3D CAD data, patient-specific parts are manufactured without the use of any tools, from the necessary medically compatible materials, with a high quality of precision and accuracy. This facilitates the surgeon's work, and soptimises patient treatment with minimal unpleasant side effects. Additive manufacturing techniques allow the production of individual

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instruments and the easy fabrication of various medical devices. This technology is finding new applications in orthopaedics, which allows the rapid fabrication of implantable devices using bioactive materials and polymers. In addition to anatomically conforming to the surgical requirements of the patient, 3D-printed implants can be made with scaffold grids that can facilitate osseointegration and reduce implant rigidity. Early results in revision hip arthroplasty and bone tumour surgery have been promising. However, limitations, including high implant cost, manufacturing time, and lack of intraoperative flexibility, need to be addressed. Materials such as PEEK, which are biocompatible and have excellent strength and heat resistance, have been investigated for use in 3D printing. In addition, 3D printing has been incorporated into drug delivery systems that can restore bone anatomy and deliver the therapeutic compound to the target tissue. For wider use of 3D printing technology in orthopaedics, a universal computing platform for easy planning and seamless communication between different medical professionals needs to be developed.

Further research on the clinical effectiveness of the technology is needed before it can be introduced into routine clinical practice in orthopaedics. Full-dimensional volumetric models of the spine for deformities of various etiologies allow us to more fully assess the nature of the deformity and perform preoperative planning. Three-dimensional volumetric models and computer modelling make it possible to manufacture individual metal structures for spinal fixation, which is especially relevant for severe spinal deformities (Kuleshov et al., 2018).

Four additive manufacturing technologies are used in medicine: stereolithography (SLA), selective laser sintering (SLS), deposition modelling (FDM), and electron beam melting (EBM) (Javaid et al., 2019). Full-dimensional 3D bone models allow for a complete assessment of the nature of the deformity and preoperative planning. Volumetric 3D models and computer modelling allow the fabrication of scustomised metal structures, which is especially relevant for severe injuries. 3D printing technology involves creating a three-dimensional object layer by layer using various computer software (Vaz et al., 2021). 3D printed models for orthopaedic cases such as: scoliosis, hip dysplasia, osteosarcoma of the hip, pelvic trauma, and others are made from several types of new materials using modelling technology (Ulici et al., 2019). The increased availability of this technology has prompted hospitals to implement their own 3D printing programs designed to internally build knowledge and reduce the delivery time and cost of 3D printed products (Calvo-Haro et al., 2021). Creating professional teams with the necessary resources contributes to a qualitative breakthrough in spersonalised medicine. Sahnan et al. (2018) studied three-dimensional (3D) imaging and reconstruction platforms. They performed magnetic resonance imaging (MRI) image transfer with spectral inversion reconstruction and imported it into validated open-source segmentation software. The segmented files were exported as stereolithography files. Cura (Ultimaker Cura 3.0.4) was used to prepare the files for printing on the Ultimaker 3 Extended 3D printer. The animations were created in collaboration with Touch Surgery.

Haleem (2018) uses scanning technology to produce medical as well as orthopaedic implants using additive manufacturing (AM). The obtained images are exported to various programs such as OsiriX Imaging Software, 3D Slicer, Mimics, Magics, 3D Doctor, and InVesalius to create a digital 3D model. The various criteria achieved using CT and MRI to design and develop orthopaedic implants using additive manufacturing are also briefly discussed. The AM model created by this process shows the exact shape, size, dimensions, texture, colour and features.

According to world statistics, per one thousand people in any country, one needs prosthetics, and 97% of all replaced joints in the world are knee and hip joints. The population of Kazakhstan is about 19 M; consequently, 19 k people need these operations annually. To date, in our country, approximately seven to eight thousand such operations are performed annually. Application of methods of mathematical modelling in technological processes with the subsequent computer modelling and svisualisation allows forming forming essentially new decisions of actual problems of the medical branch on the basis of artificial intelligence. The idea of the present work is to create a new integrated software environment that will provide improved spersonalised healthcare for the patient.

2. Materials and methods

The methodology for creating a 3D model using additive manufacturing using computed tomography (CT) and magnetic resonance imaging (MRI) results is shown in Figure 1.

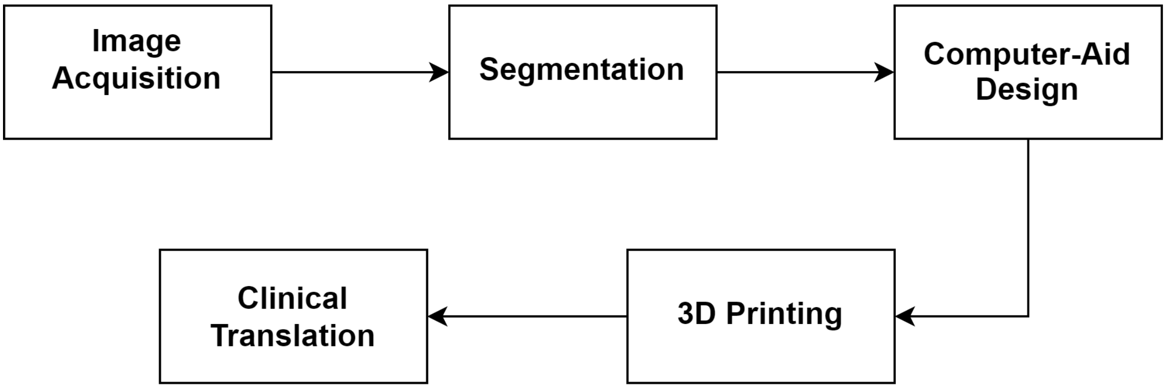

Figure 1: A method of creating a 3D model using additive manufacturing using computed tomography (CT) and magnetic resonance imaging (MRI) results

A brief description of each stage of the simulation follows.

- Image acquisition - CT and MRI scans are used to obtain images, which allow us to examine the parts of the body hidden under the skin, such as bones, tissues, organs, etc. In the design process - this is an important step, as it allows to obtain accurate data about the patient;
- Segmentation - to create a 3D model (Rengier et al., 2014) from CT and MRI data, there are different software used for virtual modelling in surgery, which allows separating different tissues and areas for further elaboration and revealing the anatomical features of the structure, volume, shape and size of the patient tissue;
- Computer-aided design systems - the digital 3D model developed from patient data as a result of segmentation is exported to STL format for printing using additive manufacturing techniques. The thickness of the printing layer is increased or decreased in the slicing software to increase the accuracy of the implants (Martelli et al., 2016);
- Additive manufacturing - Additive manufacturing is used to create 3D physical implants from a 3D model obtained using a computer-aided design (CAD) system;
- Clinical applications - 3D physical implants produced using additive manufacturing provide the surgeon with the most appropriate implants tailored to the individual patient.

The combined use of CT and MRI scans with additive technologies allows sindividualised medical devices to be designed with high accuracy, and additive technologies allow them to be manufactured. A model can be well designed using scanning/assistive software technologies and printed using additive manufacturing technologies. Modelling facilitates the fabrication of complex shapes that match the patient's anatomy and internal structure with greater flexibility, without any additional tools or equipment.

CT images were obtained at N.D. Batpenov National Scientific Center for Traumatology and Orthopedics, Nur-Sultan. Computed tomography (CT) is an imaging technique based on the use of X-ray photons to produce an image using digital reconstruction. CT scan data from a patient who suffered a pelvic bone fracture were obtained by the Serikbayev VCTU in Digital Imaging and Communications in Medicine (DICOM) format and were imported into 3D Slicer software to build a triangle-based model of the pelvic surface. 3D Slicer is distributed free and open-source (BSD license) and provides a flexible, modular platform for image analysis and s visualisation. 3D Slicer can be easily extended to develop interactive and batch processing tools for a variety of applications. 3D Slicer provides image registration, DTI (diffusion tractography) processing, an interface for external devices, and GPU volume support, among other capabilities. 3D Slicer has a modular sorganisation that makes it easy to add new functionality and provides a number of common features not available in competing tools.

3. Results and discussion

In traditional orthopaedic procedures, surgeons have to mentally integrate all preoperative two-dimensional (2D) images and create a three-dimensional surgical plan. Such preoperative planning is particularly difficult in areas with complex anatomy and severe deformity or in cases of bone tumour surgery. With the advent of volumetric medical imaging and computer technology, 2D axial images can be processed into other reformatted views (sagittal and coronal), and 3D virtual models can be created with the anatomy of a particular patient. With improved s visualisation, surgeons can sanalyse this processed information for the more detailed patient-

specific diagnosis, planning, and surgical intervention. Figure 2 shows a schematic representation and creation of a 3D model of an implant for orthopaedics.
The analysis of specific patients in the orthopaedic practice requires accurate medical imaging data representing the individual patient. Modern multi-row detector computed tomography (MDCT), and magnetic resonance imaging machines provide fast and accurate high-resolution 3D imaging data. Using image post-processing tools, multi-planar reformatted 2D images and 3D views of the patient's anatomy are obtained. The technique for converting digital medical images into a three-dimensional physical object involves the steps of: 1) image acquisition, 2) image post-processing, and 3) 3D printing.
Based on a detailed study of the result of magnetic resonance imaging of the patient's acetabulum using sspecialised software, a 3D model of the pelvic bone area with the defect was obtained (Figure 3).

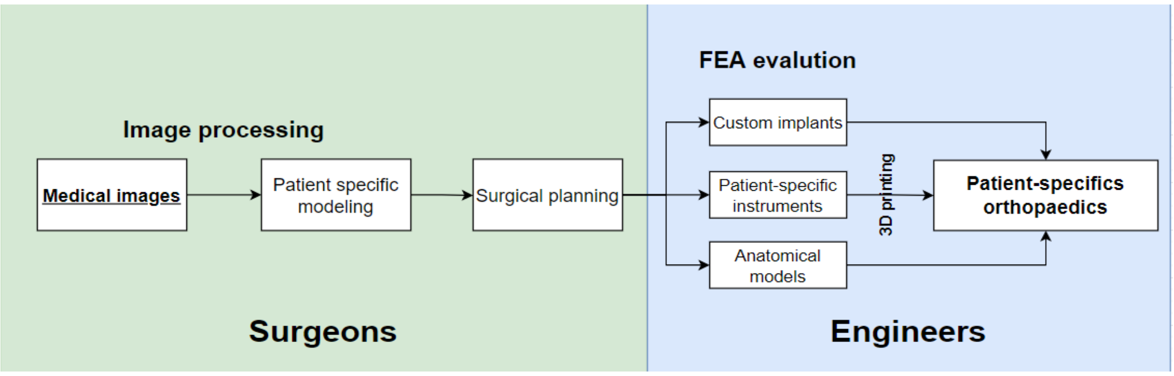

Figure 2: Workflow for obtaining a 3D model of an implant for orthopaedics

Figure 3: sVisualisation of a model of a pelvic bone with a defect

A prototype implant was developed according to the task of treating injuries and consequences of acetabular trauma. After fitting, the implant was fabricated from medical steel using CNC machines (Figure 4).

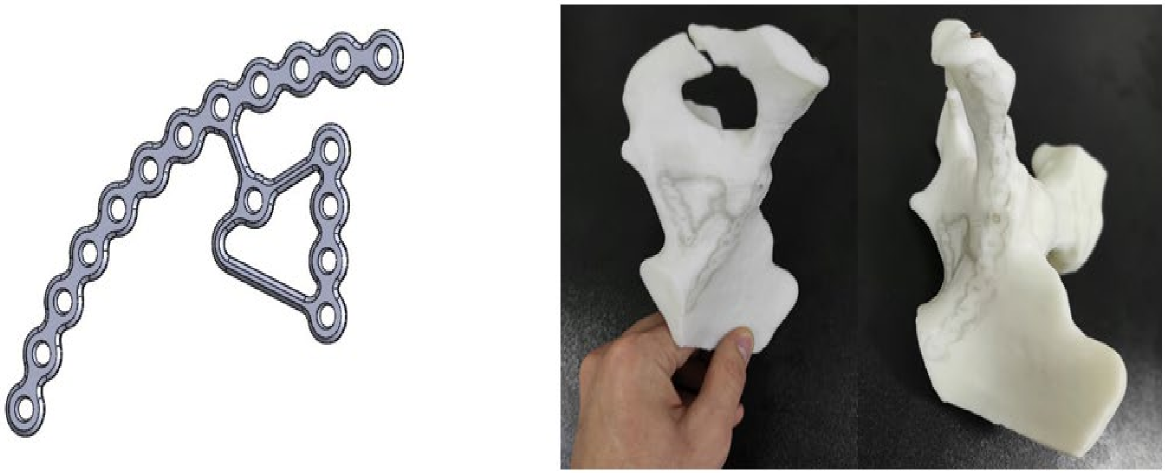

Figure 4: Developed prototype medical steel implant

The quality of the product was checked by X-ray fluorescence spectrometry and profilometry. The geometry was checked for consistency with the dimensions obtained from the MRI data. In pelvic surgery, low-traumatic osteosynthesis of the acetabulum is the most sought-after technique. The resulting 3D model of the pelvis was printed from PLA plastic using FDM technology on a Picasso Designer X PRO 3D printer and examined by the doctor, who decided that a scustomised medical device was needed. The pelvic bone plate was designed using SolidWorks CAD. SolidWorks is a CAD software package for automation of industrial enterprise operations at the stages of design and technological preparation of production. It provides the development of products of any degree of complexity and purpose. It can be seen that the plate consists of two parts, located at an angle of about 90 degrees to each other and are connected by two crosspieces. The main part of the plate is located on the terminal line. The second part fixes a square space and is triangular in shape. The plate must bear the load of the damaged area of the bone.

The development of minimally traumatic surgery is related to the scientific and technical progress of recent years. Minotraumatic osteosynthesis requires special tools and implants (the plate). The proposed plate is designed for the fixation of acetabular fractures from low-traumatic anterior intracavitary access. During the surgical intervention, a skin incision was made 2 cm above the symphysis, and its length is 8 cm. The resulting implant was placed in the patient (Figure 5) and is undergoing clinical testing. The rigidity of the plate allows the broken bone to heal in the correct position because movement in this area is and minimised. This stiff plate must be contoured to match the anatomical shape of the bone surface. The surgical method of plate implantation includes preliminary adaptation (contouring) of the plate to the anatomical shape of the bone, implantation of the plate itself by fixing it to the bone.

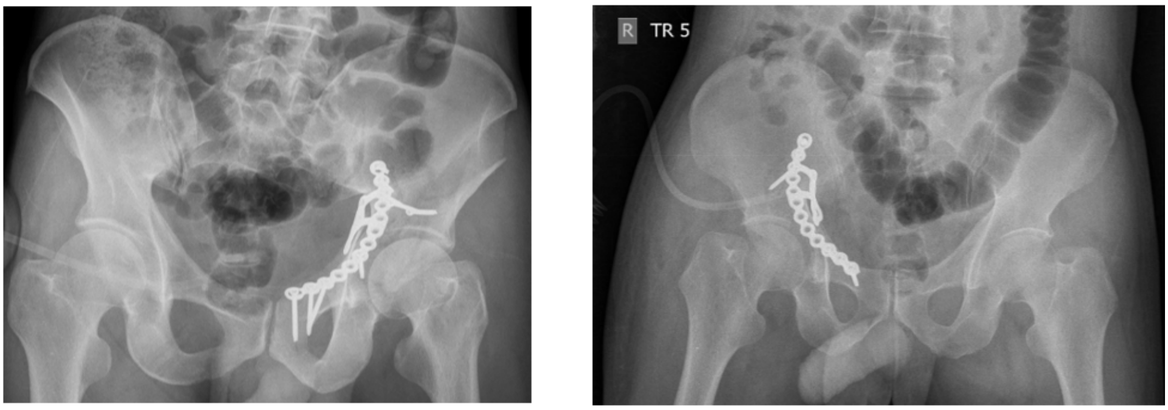

Figure 5: X-ray of a patient with an implant in place

4. Conclusion

This study presents the result of creating a patient-specific hip implant made of medical steel, describing a step-by-step algorithm from model building with discussion of process parameter estimation, model validation and evaluation, to manufacturing the target product. The work is based on a combination of knowledge of chemical engineering, basic mathematics, statistics, and programming. Vera et al. (2021) share in their work that biomedical research has immediate clinical relevance, whether the results are obtained through mathematical modeling or experimentation. Basic research has unpredictable long-term potential to improve clinical practice. In most of the disciplines of science and engineering, mathematical and computational modeling are basic methods whose utility is not in doubt. These disciplines would not have reached their current level of sophistication without the intensive use of mathematical and computational models along with quantitative data. The idea behind this work is to create a new integrated software environment that will complement existing expertise in the development of personalised medical engineering. The methodology for creating a custom hip implant based on detailed magnetic resonance imaging of the patient's acetabulum using specialised software is shown. At the first stage, a 3D model of the pelvic bone area with the defect was obtained. Then, the model was printed on a plastic 3D printer using FDM technology. In the next stage, a prototype implant was developed for the treatment of injuries and consequences of acetabular trauma according to the set task. After fitting, the implant was manufactured from medical steel on numerically controlled machines. The quality of the product was evaluated by X-ray fluorescence spectrometry and profilometry, and the geometry was verified to match the dimensions obtained from the MRI data. The implant is currently undergoing clinical testing.

Acknowledgements

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