

DECISION-MAKING SUPPORT TECHNOLOGIES USING THE CAD/CAM/CAE SYSTEM DESIGN AND MANUFACTURE OF BONE SUBSTITUTES WITH FUNCTIONAL PROPERTIES

ANTON PANDA¹, KOSTIANTYN DYADYURA², IGOR
PROKOPOVICH³

¹Faculty of Manufacturing Technologies with a seat in Presov,
Technical University of Kosice, Presov, Slovak Republic

²Department of Biomedical Engineering, Odesa Polytechnic
National University, Odesa, Ukraine

³Department Of Design Information Technologies and Design,
Odesa Polytechnic National University, Odesa, Ukraine

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e-mail: anton.panda@tuke.sk

Currently, the use of additive technologies for the production of bone substitutes determines the effectiveness of the latest methods of treatment and prosthetics in traumatic surgery, oncology, crania-maxillofacial surgery, dentistry, etc. The introduction of additive technologies is the result of the integration of medical visualization, in particular, based on the technologies of computer imaging, and engineering CAD/CAM/CAE systems. In connection with the increase in the number and severity of various types of bone tissue injuries received as a result of wounds during military operations in Ukraine, an important issue in orthopaedics and traumatology is making informed decisions about the possibility of restoring the integrity and functions of bone tissue when using different types of composition, the strength of biopolymer composites. The scientific aim of research is the development of principles and methods for making scientifically based decisions in the design and additive manufacturing of bone substitutes based on biopolymer composites with functional properties depending on the nature of the localization of the cavity bone defect and its size. The new knowledge will become the necessary basis for making optimal decisions in practice for the introduction of the latest methods of treatment and prosthetics in trauma surgery, oncology, crania-maxillofacial surgery, dentistry, taking into account the risks of biocompatibility of biopolymer composites. The results of the research will be used to design bone substitutes with controlled composition, structure, porosity, and mechanical strength for the further selection of additive technology for its production from apatite-polymer composites, which will contribute to increasing the efficiency of treatment and prosthetics in orthopaedics and traumatology.

KEYWORDS

Tissue engineering, three-dimensional (3D), bone scaffold, computer-aided design (CAD), topology optimization (TO) additive manufacturing

1 INTRODUCTION

Today, in connection with the increase in the number and severity of various types of injuries, received, including, as a

result of various terrorist acts and during military operations, the introduction of the latest methods of treatment and prosthetics for bone tissue damage forms a demand for various in composition, porosity, and strength of biopolymer composites [Dyadyura 2017, Sukhodub 2018]. The production of bone substitutes with functional properties that take into account the patterns of new formation of bone tissue became possible thanks to the application of the CAD/CAM/CAE design system and the use of additive technologies [Zaborowski 2007, Panda 2011a & 2012, Jurko 2011-2013, Mrkvica 2012, Bahraminasab 2013 & 2020, Monkova 2013, Michalik 2014, Svetlik 2014, Rimar 2016, Olejarova 2017, Balara 2018, Duplakova 2018, Flegner 2019 & 2020, Murcinkova 2017, Baron 2016, Chaus 2018, Vagaska 2017 & 2021, Straka 2018a,b, Modrak 2019, Valicek 2016, Sedlackova 2019, Kurdel 2014 & 2022, Labun 2017 & 2019, Pollak 2019 & 2020, Zaloga 2020].

Making informed decisions in the design of bone substitutes for their additive manufacturing, taking into account all risks, is possible only on the basis of the results of image analysis, which are highly effective according to the criteria of accuracy and speed, obtained using modern methods of radiography, computer, and magnetic resonance imaging, etc. [Pavan Kalyan 2022] Despite the existence of a significant variety of biopolymer composites that differ in composition, porosity, and, accordingly, strength, until now there is no differentiated approach to the selection of a bone substitute depending on the nature and localization of the cavity bone defect, its size, and loading conditions. The conducted analysis showed that in recent years a number of methods [Zhongboyu 2022] and algorithms [Marwa 2022, Chen 2022, Yasaka 2020] were presented, which are used to solve these problems. The relevance of further research is due to the fact that the development of an intelligent decision support system [Zaloga 2019, Zaloga 2020, Panda 2013] based on the modelling of neural networks [], the development of methods for their training, and multi-criteria optimization of design processes [Panda 2011b, Jurko 2012 & 2013, Valicek 2016] will allow the creation of three-dimensional solid models of defects taking into account their spatial structure and bone substitutes for the synthesis of biomaterials with controlled composition, porosity and mechanical strength, which are optimal for a specific area of bone replacement, which will increase the effectiveness of treatment and prosthetics in orthopaedics and traumatology. The purpose of this study is to develop an information model for choosing the optimal spatial shape of a bone substitute based on polymer composites with controlled composition, structure, porosity, and mechanical strength depending on the nature and localization of the cavity bone defect, its size, and load conditions.

2 MATERIALS AND METHODS

Tera Harz TC-80DP material is used to restore bone tissue. The material has CE, and FDA material certificates. The properties of the material after 3D printing were investigated at the Center for Collective Use of Scientific Equipment "Laboratory of Materials Science of Helioenergy, Sensor and Nanoelectronic Systems" (Sumy State University, Sumy, Ukraine) using a scanning electron microscope SEO-SEM Inspect S50-B equipped with an Aztec One energy dispersive spectrometer with X-MaxN20 detector. The mechanical properties were investigated according to the methods given in ISO 6872 [ISO 6872:2015] and ISO 10477 [ISO 10477:2020] standards. The assessment of possible biological safety was made in accordance with the methods specified in the ISO 10993-1 [ISO 10993-1:2018] and ISO 7405 [ISO 7405:2018] standards. The research is based on a systematic analysis of the

results of modern theoretical and applied developments of 3D printing, including standards [ISO/ASTM TR 52916:2022]. The 3D printing process at work according to ISO/IEC 3532-1 [ISO/IEC 3532-1:2023] is divided into seven steps, as shown in Fig. 1.

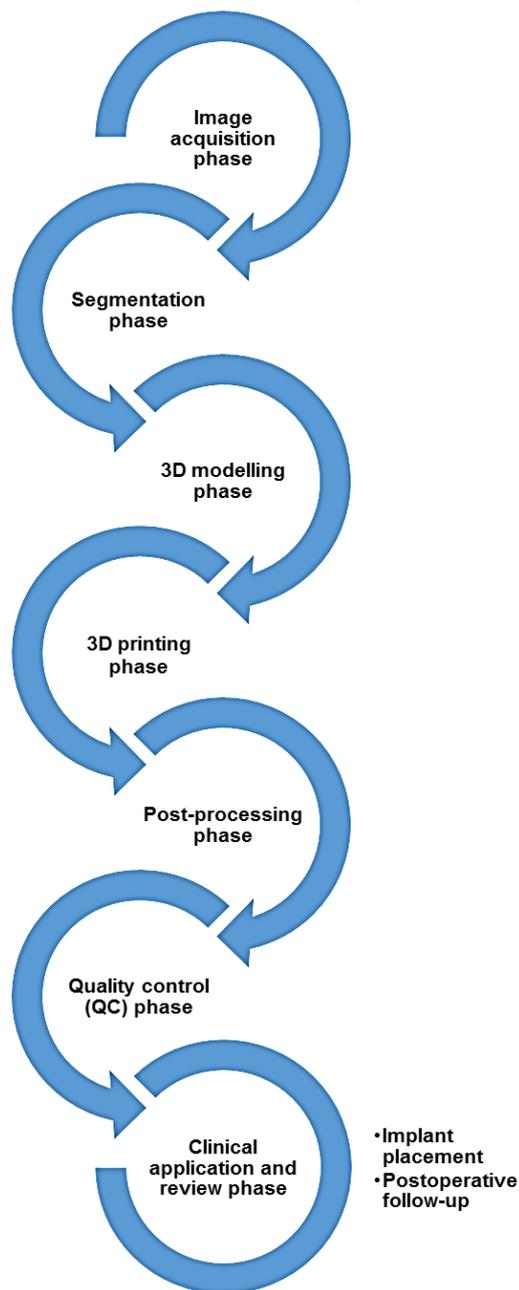


Figure 1. Algorithm of the 3D printing process for medical applications

- 1) Image acquisition phase
In the imaging phase, medical images are obtained using medical imaging devices such as CT scans.
- 2) Segmentation phase
In the segmentation step, the resulting medical images are segmented according to the design objective and processed for separation (segmentation) to extract a subset that will represent the part(s) of anatomy under consideration.
- 3) 3D modeling phase
At the 3D modeling phase, segmented data representing human tissue is transformed (reconstructed) into a 3D model optimized for 3D printing.
- 4) 3D printing phase
In the 3D printing phase, the 3D printing is done using the developed 3D model. For this step, the 3D model is processed for 3D printing by slicing, assigning build parameters, orienting,

and placing it in the build space, and may have support structures created.

5) Post-processing phase
In the post-processing step, the 3D printed part undergoes post-processing to become suitable for real medical use.

6) Quality control (QC) phase.
At the quality control stage, the 3D printed part is finally checked for compliance with all requirements (user/design/quality/risk).

7) Clinical application and verification phase
In the stage of clinical application and verification, the medical professional checks the 3D printed part as suitable for clinical use, installation of the implant with suture material and fixation elements, and control examination after surgery.

DICOM images were used for 3D image reconstruction through segmentation and 3D modeling. The 3D image model is transformed and exported to the design software as a stereolithography (STL) file. Post-processing such as heat treatment, machining, cleaning, and grinding is performed. Extrusion and photopolymer printing (Fortus 450mc™ 3D printer from Stratasys®) were used to create bone substitutes based on 3D models.

3 RESULTS

The 3D model of the skull (Fig. 2 a,b) was created from the computer tomography data of the patient's face (diagnosis: left orbital floor fracture) who visited the rehabilitation and reconstruction surgery department (10 clinical hospitals, Odessa).

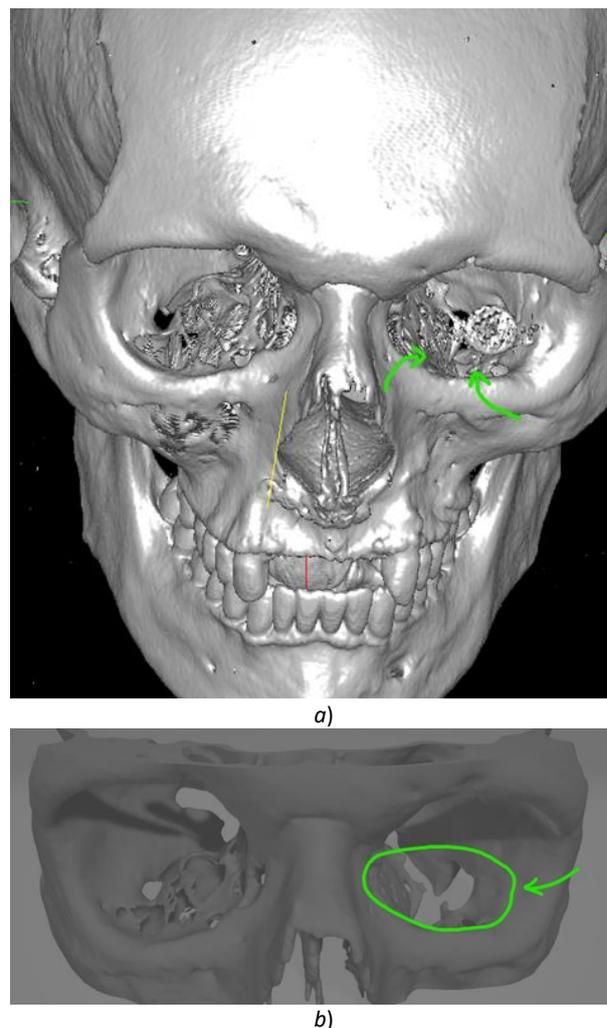


Figure 2. Model of the skull (a) with a unilateral defect (b) (fracture of the orbital floor on the left)

The assessment of the patient's condition, as well as the assessment of the results of implantation of the bone tissue defect, is carried out based on the results of subjective and clinical research methods. Additional medical imaging software (3-matic®, Materialize NV, Leuven, Belgium) was used to generate the specular plane, including mirroring and surface-based registration functions (Figure 3 a, b).

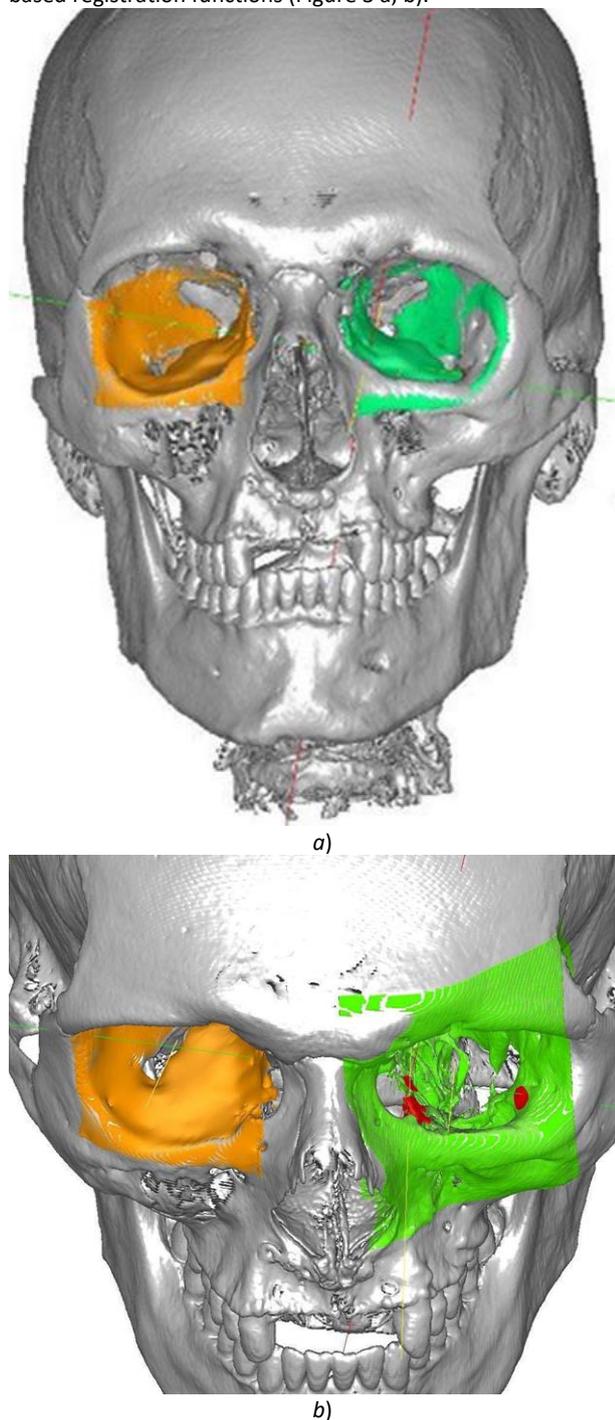


Figure 3. The initial mirror plane (orange) was created from three reference points. (a). The mirror image of the original defect model (b).

An initial mirror plane was created as a temporary middle plane for the start of the mirror reflection process (Fig. 3a). The reflection of the original model of the defect by the initial middle plane created a mirror mode of the defect (Fig. 3b). A surface-based registration was performed, and a displaced specular plane (green) was obtained. Dividing the original mid-plane and the displaced specular plane in half allowed us to obtain a final specular plane that was adjusted and optimized for the original defect model (Fig. 4). The final specular plane (in red)

was created by splitting the two planes in half: initial and moving mirror planes.

After registration, complete reconstruction of the defective areas of the model was achieved. The obtained results will be a new theoretical and practical informative material that will contribute to more effective treatment and prosthetics of bone tissue in case of military and civilian injuries, thanks to the design and manufacture of bone substitutes with controlled composition, structure, porosity, and mechanical strength depending on the nature and localization of the cavity bone defect, its dimensions and load conditions.

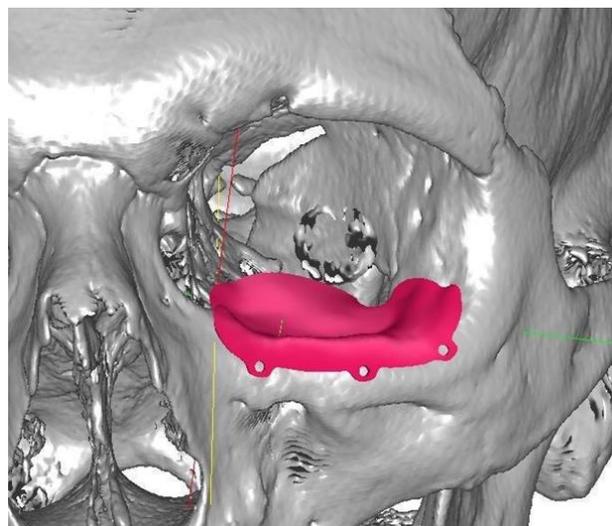


Figure 4. Final mirror plane (red)



Figure 5. 3D printed part

Printed bone substitute for preoperative preparation is shown in Fig. 5. The results of the study of the structure and microrelief of the surfaces (scanning electron microscopy) of composite materials are shown in Fig. 6.

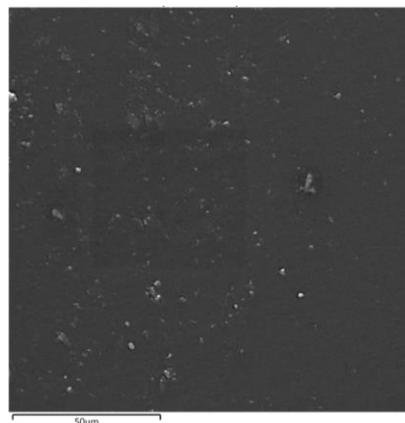


Figure 6. Image of the resulting 3D sample using the SEO-SEM Inspect S50-B Scanning Electron Microscope

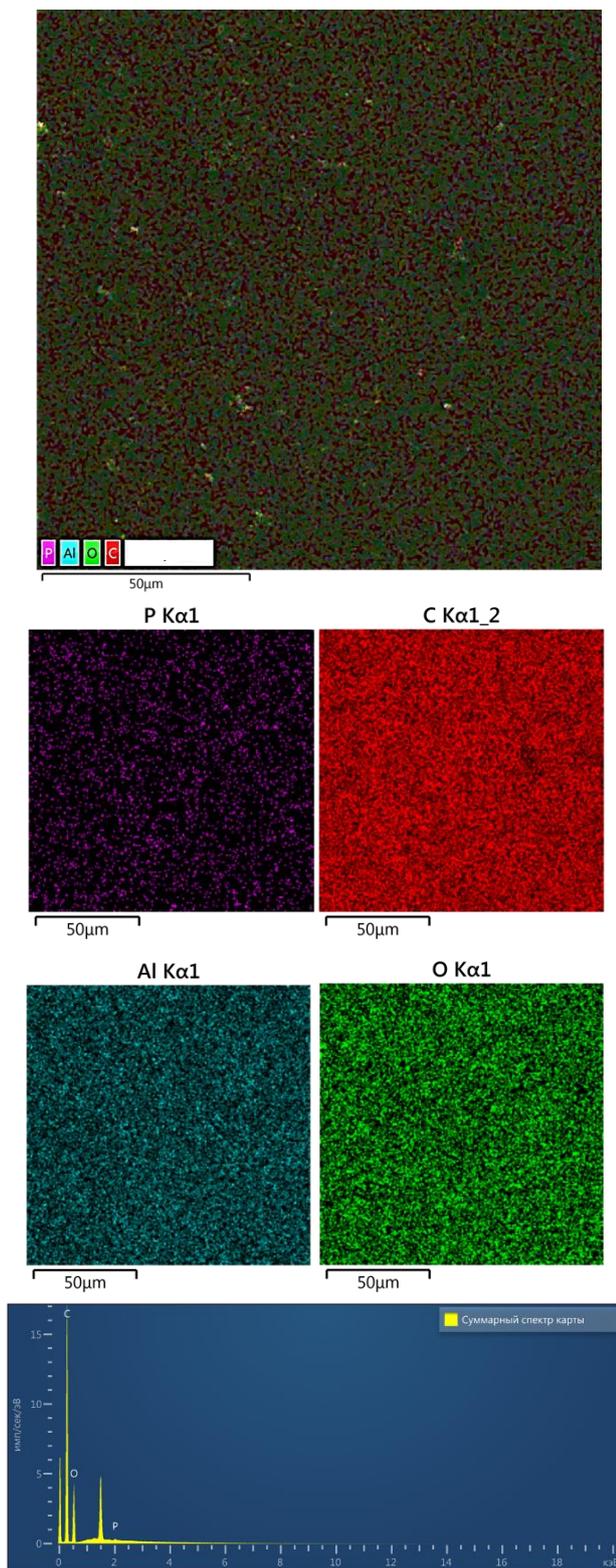


Figure 7. Results of analysis of energy dispersive X-ray spectroscopy

Analysis of the structure allows us to assert the homogeneity of the polymer material of the obtained bone substitute. The image in Fig. 6 shows that the resulting material is dense with a closed porous structure, not rough. This, in turn, prevents the development of microorganisms. In addition, it was found that there are no clearly defined directional chip lines for the studied materials, which indicates insignificant residual stresses in the composite. This fact additionally confirms the high physical and mechanical properties of the composite material: shore hardness (≥ 90); bi-axial flexural strength ($\geq 350\text{MPa}$); flexural strength ($\geq 220\text{MPa}$); flexural modulus ($\geq 4500\text{MPa}$).

Energy dispersive X-ray spectroscopy (EDS) spectra and elemental mapping of C, P, O, Al are shown in Figure 7. Well-defined areas of carbon (C) (Weight 64.9%), detected by X-ray energy dispersive spectroscopy, are one of the components of the polymer material of the oligomer Poly(methyl methacrylate) (PMMA). As for oxygen (O) (Weight 34.95%), it can be attributed to both Methyl methacrylate (MMA) and Phosphorus pentoxide. The presence of a metal component (Al) was also observed on the surface of the samples. It was assumed that Al can be attributed to pigment impurities.

Meanwhile, phosphorus (P) (Weight 0.15%) is one of the components of phosphorus oxide [Kim 2022]. Taking into account all of the above, we analyzed samples for in vitro toxicity using laboratory and analytical studies generally accepted in microbiology on model systems with typical intestinal microflora (probiotic strains of *Lactobacillus acidophilus*, *Bifidobacterium Bifida* and *Escherichia coli* isolated from an aqueous environment). The obtained data may indicate that after long-term contact with the test culture with the studied material, the microflora changes its adhesive properties, reducing the adhesive potential. These results indicate the suppression of the initial stage of biofilm development, namely the attachment of bacteria to a biotic or abiotic surface, which prevents the transition to a biofilm lifestyle. Thus, the surface of the implant meets the requirements of a multifunctional system that responds to microbiological signals by releasing antimicrobial substances and other emollient compounds.

4 CONCLUSIONS

Approaches to the treatment of bone injuries are ambiguous, therefore, efforts are being made to improve and optimize them. Searching for opportunities to manage reparative processes, studying the features of the newly formed bone tissue under the conditions of plasticity of defects with various materials, and shortening the terms of reconstruction of the latter by modifying the physical and chemical properties are important tasks.

A complex of bone tissue image analysis methods is proposed, taking into account its spatial structure. A new methodology for researching the structure of newly formed bone tissue under the conditions of plasticity of defects with biomaterials with different physicochemical properties and analysis of possible risks has been developed, taking into account the requirements of international standards.

The results make it possible to determine the composition of bone substitutes, taking into account biological variation, which reflects the body's reaction to various environmental factors and is subject to statistical patterns. All stages and elements of the information model in the process of optimizing the shape of the bone substitute are considered in detail.

System-wide evolutionary models are used, which take into account the organization of the structure of the processes of additive manufacturing of bone substitutes. The new knowledge obtained as a result of the research will become the necessary basis for making optimal decisions in practice for the introduction of the latest methods of treatment and prosthetics in traumatic surgery, oncology, craniomaxillofacial surgery, stomatology, by identifying the risks of biocompatibility of biopolymer composites.

Further research is aimed at creating an intelligent decision support system for the analysis of bone tissue images, taking into account its spatial structure obtained by sensors of neural network models, the development of methods for their design, optimization, and training, as well as multi-criteria optimization of processes designing.

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CONTACTS:

Prof. Eng. Anton Panda, PhD.
Faculty of Manufacturing Technologies with a seat in Presov
Technical University of Kosice
Sturova 31, 080 01 Presov, Slovakia
e-mail: anton.panda@tuke.sk