Design and 3D-printing of titanium bone implants: brief review of approach and clinical cases

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Abstract

Additive manufacturing (AM) is an alternative metal fabrication technology. The outstanding advantage of AM (3D-printing, direct manufacturing), is the ability to form shapes that cannot be formed with any other traditional technology. 3D-printing began as a new method of prototyping in plastics. Nowadays, AM in metals allows to realize not only net-shape geometry, but also high fatigue strength and corrosion resistant parts. This success of AM in metals enables new applications of the technology in important fields, such as production of medical implants. The 3D-printing of medical implants is an extremely rapidly developing application. The success of this development lies in the fact that patient-specific implants can promote patient recovery, as often it is the only alternative to amputation. The production of AM implants provides a relatively fast and effective solution for complex surgical cases. However, there are still numerous challenging open issues in medical 3D-printing. The goal of the current research review is to explain the whole technological and design chain of bio-medical bone implant production from the computed tomography that is performed by the surgeon, to conversion to a computer aided drawing file, to production of implants, including the necessary post-processing procedures and certification. The current work presents examples that were produced by joint work of Polygon Medical Engineering, Russia and by TechMed, the AM Center of Israel Institute of Metals. Polygon provided 3D-planning and 3D-modelling specifically for the implants production. TechMed were in charge of the optimization of models and they manufactured the implants by Electron-Beam Melting (EBM[®]), using an Arcam EBM[®] A2X machine.

Keywords Additive manufacturing · Bio-medical implants · Electron beam melting · 3D-printing · Ti–6Al–4V · CAD design · Computed tomography

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1 Introduction

The main goal of the authors is to create new designs in order to accelerate osseointegration, shorten the operation and rehabilitation time, and prevent the development of infections and pathology.

Nowadays, there are two main technique families for metal powder bed additive manufacturing (PB-AM) using laser or electron beam for melting. Typical representatives of these techniques are selective laser melting (SLM) and electron-beam melting (EBM[®]). Each one has its advantages and disadvantages. For example, laser-printed parts have lower surface roughness and can form thinner and “sharper” elements in comparison to parts produced by EBM[®]. However, EBM[®] allows producing parts with smaller residual stresses and lower contamination by gases in the final product. This difference yields benefits in various applications: laser PB-AM with better surface resolution is widely used for dental implants, and EBM[®], due to its improved mechanical properties, is commonly used for patient-specific bone implants.

The conventional material for PB-AM of bone medical implants is Ti–6Al–4V powder. Its fraction size is different for different AM methods. For example, for Arcam EBM[®] the common particle size distribution is 45–100 μm [1], for laser machines 25–50 μm [2]. Figure 1 presents a photo of Arcam A2X machine (Fig. 1a), by Arcam EBM[®] (Molndal, Sweden).

The chemical composition of the powder supplied by Arcam EBM[®] [1] is shown in Table 1, and SEM image of the powder particles is shown in Fig. 1b. Figure 1c illustrates the typical two-phase microstructure of the Ti–6Al–4V alloy produced by Arcam EBM[®].

Fig. 1 a Photo of the Arcam EBM[®] A2X machine used by TechMed. b SEM-image of the Ti–6Al–4V powder provided by Arcam EBM[®] (Molndal, Sweden). c SEM-image of the typical microstructure of Ti–6Al–4V alloy

To illustrate the current possibilities in direct manufacturing of titanium implants, this paper presents a description of the typical manufacturing cycle, as well as the hardware and software used for AM, and presents several cases of TechMed—Polygon of design and manufacturing of personalized biomedical implants.

2 Computed tomography (CT) as the first step in the production chain

The advantage of PB-AM technology lies in its rapid response ability for surgery and production of the necessary complex net-shape structures. The evolution of medical imaging technology allows easy access to 3D-visualization of the patient bones, on which a surgeon can plan the implant, which is then printed.

CT is a standard and well-known instrument used by clinicians to diagnose the problem and find the optimal solution. For 3D-Printing of implants, CT is the first step of the production pathway (see Fig. 2). From this step, a surgeon starts to work together with the AM-engineer. Figure 3 shows an example of such a cooperation. From the CT, the AM-engineer has to only consider the bone part in order to assess the damage. The personalized implant is designed in accordance with the surgeon’s instructions, depending on the nature of the damage. Usually, the undamaged part is printed from ABS plastic, and the implant is printed from Ti–6Al–4V alloy. The ABS plastic is close in its physical properties to the bone material [4, 5]. Such a model allows a surgeon the possibility to simulate the future operation and plan how many connecting points to the bone should there be in the implant. The titanium printed implant has to be perfectly fit for the individual patient. The planning process of the surgery allows the surgeon to clearly visualize the operating steps, thus dramatically decrease its duration.

3 Software for bio-medical 3D-printing

The AM engineer may use different software in the design of implants. Some of the most popular software packages for bio-medical 3D-modelling are presented in Fig. 4. The work flow for creating a 3D model consists of the following steps:

- A CT/MRI scan of the patient is performed;
- The images are imported into specific AM-software package (Mimics, 3-Matic, etc.);
- 3-dimensional models of the bones/ligaments/muscles are created in the program, muscle attachment points are determined [6];

Table 1 Ti–6Al–4V powder chemical specification [1, 3]

Composition	Arcam Ti–6Al–4V (%)	Ti–6Al–4V, required ^a (%)	Ti–6Al–4V, required ^b (%)
Aluminum (Al)	6	5.5–6.75	5.5–6.75
Vanadium (V)	4	3.5–4.5	3.5–4.5
Carbon (C)	0.03	< 0.1	< 0.08
Iron (Fe)	0.1	< 0.3	< 0.3
Oxygen (O)	0.15	< 0.2	< 0.2
Nitrogen (N)	0.01	< 0.05	< 0.05
Hydrogen (H)	0.003	< 0.015	< 0.015
Titanium (Ti)	Balance	Balance	Balance

^aASTM F1108 (cast material), ^bASTM F1472 (wrought material)**Fig. 2** The process stages of titanium EBM[®] implant production **Fig. 3** Example of conversion of CT into a final mandibular implant for a cancer patient case **Fig. 4** Different software packages for bio-medical 3D-modelling and 3D-printing

- The attachment positions of the titanium implant are adjusted to the specific anatomical model.

The specific medical software by Materialise is the most popular one used by industrial designers working in the bio-medical field. This software is designed and developed

specifically for processing of medical images obtained by any of the existing methods like X-ray, CT, MRI, micro-CT, and 3D-ultrasound. Then these data are imported into Mimics[®]/3-Matic[®]/Magics[®], and then a 3D-model is generated. The capabilities of these medical programs to create a highly accurate anatomical patient-fit 3D-model are presented in Table 2.

4 3D-printing machines for bio-medical application

Nowadays, there are already multiple manufactures of 3D-printers [2], that can be used for biomedical implant manufacturing. However, the Powder-bed EBM[®] technology is still exclusive to Arcam EBM[®], that offers a line of A2X (see Fig. 1a) and more novel Q10/Q20 machines (see Fig. 5a, b) [1, 2].

The Q-10 model (very similar to A2X machine) is classified as a machine for bio-medical implant production, while Q-20 is primarily targeting the aerospace application (see Fig. 5). This definition is rather arbitrary, as the most significant difference is the internal size of the chamber, and the maximum size of the build. The novel Q-machines offer additional options such as Q-Cam, which allows analysis of each layer during the build process, to ensure the required quality of printed parts.

Laser 3D-printing is also widely used for titanium implant manufacturing. The specific features of the process include handling of powders in dangerous conditions (fine powders in the air are explosive) and a required heat-treatment to reduce the high residual stresses. As it was already mentioned above, laser manufactured implants have a smoother as-built surface, and the process enables manufacturing of thin, accurate parts with complex internal channels. However, the laser printed parts usually require full post-processing, including heat treatment, removal of supports, and machining after the removal of supports.

German producers EOS and SLM are among the market leaders in laser 3D-printer production. Examples of their machines are presented in Fig. 5c, d. These companies lead in the number of machines sold. Moreover, they offer the best characteristics of the process (in terms of speed, accuracy and repeatability) and the best quality of the manufactured components, after treatment [2].

5 Specific software for 3D-printing machines

The 3D-machines of the main producers are supplied with original software. For Arcam EBM[®], it is ABF—Assembler, for EOS there are several software packages: EOS Estate, Exposure Editor and MeltPool Monitor. The main function that is provided by the specific software is slicing of the 3D-CAD file (.stl) into 2D cross-section files, one “frame” for each layer, optimizing the task for proper application of the energy source—laser or EB.

6 Post-processing/etching/sterilization/HIP

The printed parts, produced by EBM[®] or by laser printing, must be cleaned of the powder using specialised powder recycling system (PRS), ultra-sonic or etching technique [7].

For EBM[®] printed implants, an additional heat treatment is needed only for parts that are used under fatigue cyclic loading. Arcam EBM[®] advises to conduct hot isostatic pressure (HIP) treatment to decrease the porosity level. HIP is a well-known recommended post-processing procedure for EBM[®] parts, that improves the fatigue resistance of the printed parts [8]. It is more relevant for aerospace parts than for medical implants. However, for some kinds of implants, especially for mandible repairs and others that are subjected to repetitive loading, HIP is highly

Table 2 Mimics[®]/3-Matic[®]/Magics[®] medical software for implant design [6]

Mimics [®]	3-Matic [®]	Magics [®]
Create an accurate 3D-model based on imaging data	Perform 3D measurements and engineering analyses	
Take accurate measurements in 2D cross-section and 3D-model	Design patient-fit implants and surgical guides	A simple process of importing and exporting files
Export the 3D-model into STL-format for analysis and production	Prepare anatomical data and/or implants for finite element analysis and simulations	Smoothing, marking and many other useful functions
One of the typical tasks, which is solved by means of Mimics[®] Innovation Suite , is the design of knee implants and guides	An engineering instrument enabling thorough 3D measurement and analyses, to design an implant or surgical guide, or prepare a mesh for finite element modeling	STL editor software for Additive Manufacturing that allows one to convert files to STL, repair errors, edit your design and prepare your build platform

Fig. 5 **a** Arcam EBM® Q-10. **b** Arcam EBM® Q-20. **c** EOS DMLS® M290. **d** SLM-500

needed, though there is no universal consensus on this matter.

In some cases, the outerskin surface has to be polished. A rougher surface is beneficial for better bone ingrowth/connection. For the implants that should be removed later, the contact surface with the bone is polished. In case of surfaces that come in contact with soft tissues—surgeons often prefer them to be polished. In general, it can be said that the final decision whether the surface has to be polished or remain rough is made by the surgeon.

For laser printed implants, heat treatment is a part of the standard production routine. The typical heat treatment is performed in a vacuum furnace, by heating to 800 °C for 2 h to reduce the residual stresses in the manufactured titanium parts.

The mechanical properties of as-built EBM parts are sufficient for bio-medical application because of the residual stress free microstructure, as a result of the high build temperature of 730 °C [8, 9].

The EBM® part (or laser manufactured part, after heat treatment) is sent to the surgeon, who sterilizes the implant and implants it in the patient. An implant could be additionally coated to decrease inflammation and tissue rejection. The scientific field of specific organic and non-organic coatings for titanium medical implants is still in development. The most widely used coatings for implants are hydroxiapatite and calcium phosphate, making it more biocompatible and accelerate the recovery process [10].

7 Experience of TechMed AMC IIM, Technion

TechMed is a newly established Department of the Additive Manufacturing Center at Technion, focused on developing 3D-Printing of titanium medical implants made with the of EBM® technology.

TechMed was the first Israeli institution, to successfully pass the ISO 14385:2003 certification [11] of the Israel Institute of Standards (IIS) for manufacturing of bio-medical devices by electron beam melting.

TechMed works in collaboration with Polygon Medical Engineering, (Russia), a company focusing on biomedical

design, and developing a specific software for effective on-line communication between a surgeon and 3D-engineer.

The main attention in the development and manufacturing of individual medical products in the framework of our work is devoted to research and ensuring optimal porosity and topography of the surface to ensure proper osseointegration. The creation of new structures, and in particular, the formation of channels of an arbitrary shape in the implant, ensuring the supply of blood vessels and osteoblast proliferation; search for optimal profile options, diameter and thread pitch; the use of new powder materials that provide a special biomechanically compatible structure and strength, to exclude degenerative processes in the bone tissue that comes in contact with the implant and provide optimal conditions for regenerative osteo-synthesis [12].

7.1 Case study 1: clavicular implant

From the CT image of a broken clavicular it was decided to eliminate some of the small bone pieces, leaving a gap between the two long pieces to be connected. According to the final decision of the surgeon and 3D-engineer, the two main broken parts were combined by means of a complex geometry titanium implant, following the approach of [13]. The specific feature of the implant (see Fig. 6) is the middle lattice structure part that should help the bone to regenerate, attached to the long fixation piece holding the two sides together.

Fig. 6 **a** Anatomic design, **b** manufactured clavicle implant with a lattice structured insert by TechMed Technion: 1—titanium implant polished from the upper side for better interaction with muscles; 2—3D-printed polymer model of the broken clavicular bone; 3—lattice structure part of a titanium implant. Image processing was done using medical R&D software package Mimics by Materialise [6] Courtesy of J. Ramon and G. Muller, TechMed Technion

This solution is based on the fact that the inner part of a human bone consists of a network of struts enclosing large voids with up to 55–70% interconnected porosity (see Fig. 7a). 3D-printing of porous structures is beneficial for medical orthopedic application because of their potential to stimulate the tissue ingrowth [14, 15]. The size of the pores/voids may vary due to the balance that facilitates better interconnection between the tissue and implant; and to prevent an excessive amount of air in the lattice structured implant (see Fig. 6b), to prevent airborne infection.

In [15], it was concluded that the diamond lattice structure (see Fig. 7b) exhibits mechanical properties comparable to trabecular bone. The structure properties lie in between those of trabecular and cortical bone [15]. There are many other factors influencing the bone mechanical properties, such as the age of the bone tissue, the loading direction and the location where the sample was taken from [15].

7.2 Case study 2: mandibular implant

The goal was to design an implant for a patient with extensive mandibular damage by carcinoma. Since a large part of the mandibular bone was lost due to the disease, the implant connection had to be strong, yet minimal, thus the resulting saddle-like chin part of it. The task of minimal connection was solved by use of only 4 screws for the chin-part, and natural-like click-connection of the upper part (see Fig. 8).

In order to enhance the bone ingrowth and recovery process, and simultaneously decrease the risk of air bacterizes infection, the dense-cellular structure was chosen (see Fig. 8a).

Mandibular implants undergo high cycle fatigue loading. In order to improve the fatigue resistance, HIP-treatment was performed for the implant.

For better joining with the rest of the bone parts, a plastic bone model was printed (see Fig. 8b). The combination of a plastic printed “bone” with a titanium printed

Fig. 7 **a** Healthy human hip bone structure. **b** Proposed by PB-AM lattice structure replacements

Fig. 8 Overview of the anatomic design of the mandibular implant with a lattice structure by TechMed: 1—ABS-model; 2—EBM-manufactured titanium implant with 4 connecting points; 3—the upper click-connection. Courtesy of G. Dzhenzhera and E. Strokin

implant allows a surgeon to simulate the surgery process and choose optimal fixation solutions.

7.3 Case study 3: foot osteotomy

Figure 9 presents 3D-modelling of an implant for a foot osteotomy case. Such patient-specific implants usually are not produced by 3D-printing, but by traditional machining techniques. However, their production is relatively expensive. The pair of implants was manufactured by EBM[®] as an alternative technology for complex cases.

Figure 9 presents the production chain from the 3D-modelling, implant manufacturing up to surgery replacement. The surface of the EBM[®]-manufactured implant contacting the soft tissues was polished. Figure 9c presents the replacement of the upper “loop”-implant at four connecting points, by screws.

7.4 Case study 4: flanged acetabular cup with augment

Significant acetabular defects, especially together with pelvis discontinuity, are a serious problem and make each revision hip replacement rather unique [17]. The fixing of such acetabular components is an additional challenge. However, there are already multiple surgeries showing positive results using 3D-printed acetabular flanged cup implants [17–19].

The surgery primary endoprosthetics, was conducted in 2004. The case was not applicable for standard cup-implants because of the progressed dysplastic bone arthrosis.

Using 3D-planning, the acetabulum was investigated: the condition of the walls and the possible position of the connecting points between implant and a bone were thoroughly checked. The individual patient-specific cup made of titanium was manufactured by PB-AM, followed by polishing and sterilization by the surgeon. Figure 10a

Fig. 9 Left to right: **a** Anatomic design 3D-planning image. **b** Titanium bone implants made from Ti-6Al-4V using EBM[®] technology. **c** Implant surgery. Image processing was done using the medical R&D software package by Polygon Medical Engineering [16]

illustrates the 3D-planning process determining the contour of the future implant, and the connecting points with the bone and holes for the screws. The final titanium implant (see Fig. 10b) was polished and sterilized before surgery. The surgery/implant replacement is shown in Fig. 10c—the cup was installed with screws (see Fig. 10c), and then hip replacement was performed (see Fig. 10d).

8 Conclusion

The purpose of the current review is to provide an overview for operators of metals 3D-printing machines, namely, instruct them how to start/develop their work in biomedical applications.

The use of 3D-printing for biomedical applications has huge advantages, which opens new opportunities for surgeons. The extraordinary pre-surgical planning advantages and relatively low cost of implant prototyping are the most prominent ones. The costs of additive manufactured

implants is already quite competitive, providing good value for money [7]. Additionally, it enables multiple surgery procedure rehearsals. The EBM[®] 3D-Printing has a potential of significantly reducing the operation times, and at the same time accelerate patients' recovery and improve the anatomical alignment. These are the reasons why numerous research groups and industrial companies are already working in the field [7, 10, 12–16, 20].

However, because of the novelty of the 3D-printing technique for titanium medical implant manufacturing, there is a lack of basic scientific knowledge about the process (phase formation, new alloying elements, etc.), and lack of post-processing procedures (sterilization, polishing, filling the lattice structures in implants) [7]. Therefore, the contribution of research centers to the understanding and development of additive manufacturing is strongly needed.

Moreover, the current approach in industrial medical implant production and certification focuses on standardization of the manufacturing process, and of the shapes/sizes of implants [7, 13–15]. It may be explained by the

Fig. 10 Left to right: **a** 3D-model of anatomic design. **b** Titanium implant with a plastic model. **c**, **d** Surgery of titanium hip replacement implant made from Ti-6Al-4V using EBM[®] technology. Image

processing was done using the medical R&D Software package by Polygon Medical Engineering [16]

fact that personalized patient specific implant production is a novel and quite independent industrial application. This means that joint development of the biomedical 3D-printing process by surgeons, engineers and manufacturers is also expected to promote the new requirements and standards for medical additive manufacturing.

This article aims to present the experience gained from the collaboration of TechMed (Israel) and Polygon (Russia) in biomedical patient-specific titanium implant production by means of EBM® 3D-Printing. The present review and examples are aimed at supporting the development of biomedical additive manufacturing in Israel and worldwide.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Ethical approval was obtained in Russia according to the local guidelines.

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