

3D Printing of Titanium Implants at the University of Debrecen

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Abstract: Additive manufacturing technologies are becoming increasingly popular in the field of medicine. Advances in laser-based techniques, which can also be used to print metals, have made it possible to produce fully customized, biocompatible implants, which are a major breakthrough in the treatment of bone defects. The University of Debrecen is involved in the production of such implants. On the basis of the available literature and preliminary experience, the individualization of implants, the implantability and material requirements, and the novelties offered by the technology are summarized in this paper.

Keywords: Additive manufacturing; Bone grafting; Direct Metal Laser Sintering; Implant; Reverse engineering; Titanium

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1. Introduction

The advancement of technology has opened more and more avenues for innovation in all areas of life, including medicine. The emergence of various metal printing techniques has allowed the production of biocompatible implants that can be fully customized.

However, this is not possible with traditional material forming processes although customization benefits both patients and doctors. Therefore, the University of Debrecen started a research project on the design and 3D printing of unique titanium implants, in which the first phases involved the collection and evaluation of existing knowledge, the development and preparation of the project, and the study and deployment of the technologies to be used.

The additive manufacturing of medical implants is a complex subject that requires practical application of engineering skills. However, it is essential to carry out thorough research, to systematize and summarize previous experience and to draw conclusions, and if possible, to propose further alternatives before starting the project. The aim of this research is to make the knowledge base as comprehensive as possible, with emphasis on the engineering aspects.

2. Basic information

The basic principle of additive manufacturing technologies is that the workpiece is built directly from a pre-designed three-dimensional computer model by depositing material bottom up, layer by layer. The model can be based on the digitization of an existing object (laser scanning, CT, MRI) or created directly through a three-dimensional design software, which is quick and cost-effective. These benefits are also being exploited in many areas of medicine.

- (i) Manufacturing custom hearing aid housings and designing of specialized medical devices;
- (ii) The production of anatomical models for surgical planning
- (iii) Printing tissue for research purposes
- (iv) Creating dental crowns, bridges, custom-made braces, and prostheses
- (v) Cost-effective production of prostheses for limb replacement
- (vi) Printing orthopedic implants ^[1]

3. About orthopedic implants in general

Implants are devices that can be implanted in the body to maintain, or in some cases improve or restore the functions of the human body, or for aesthetic purposes. The primary function of orthopedic implants is to correct defects in the musculoskeletal system, such as damaged or deficient bones or damaged joints.

The most commonly used prostheses are for replacing hip and knee joints. Usually, these prostheses are made in units of a certain size range. The components that best fit the patient's physical characteristics are selected from a range of mass-produced products and then implanted. The advantage of this method is that the components can be produced relatively quickly in large numbers according to a certain pattern, and they usually meet the implantability requirements. However, there are special cases where, for example, the patient's bone structure or geometry does not allow the placement of conventionally manufactured implants. In such cases, individual solutions are required, with particular attention to individual specificity and special needs, without neglecting the basic implantology requirements.

4. Implantability requirements

The two main requirements for implants are biocompatibility and biofunctionality. In the case of the latter, the emphasis is on ensuring performance, i.e., the implanted device must be able to perform a predefined function with a given set of properties, or in simple terms, the expected lifetime of the implants. This functionality is influenced by the prosthetic loads, the resulting stress distribution, the main mechanical properties of the materials, the degree of friction, and the resistance to wear and corrosion ^[2,3].

Biocompatibility is the ability of a device to maintain its expected properties while performing a predefined function, and to affect the tissues of the body only to a certain extent. The degree of compatibility may be influenced by, the chemical and physical properties of the material used, the geometry, the size and mechanical properties of the device, the types of tissue present at the implantation site and their relationship to the tissues, and the way the surgery is performed ^[2,3]. Another important factor is the compatibility of different materials, as the formation of an upper electrode element must be avoided.

From an engineering point of view, the selection of the right materials and the correct design and manufacture of the implant play the most important role in ensuring biocompatibility and thus performance.

5. Material requirements

In the case of devices implanted in the body, the compatibility of the materials used with the original functionality of the device is particularly important. Biocompatible materials that are biologically, chemically, and physically best suited to the task would be preferable. In all cases, it is important that the devices do not release particles that cause toxic reactions or interact with the body's tissues in undesirable ways. Examples of biocompatible materials are gold, titanium, Co-Cr-Mo and Ti-6Al-4V alloys, porcelain, or acrylate ^[2].

The position of the implants varies from place to place and individual to individual, and the material properties should not be determined based on the location of the implant alone. In the case of bone replacements, the first priority apart from biocompatibility is to ensure load transfer, so adequate mechanical strength is important. In addition, the material should be wear-resistant and have a similar

weight to the bone structure and a modulus of elasticity as close as possible to that of natural bones [4-6].

The importance of similar mechanical properties lies in avoiding the so-called “stress shielding” phenomenon, whereby implants with a higher strength than natural bone increasingly transfers the load to the surrounding bone over time. Bone tissues have a special structure that can change under the influence of stress, so in this case they gradually lose their function, as they have to bear the mechanical stresses that they are subjected to. As a result, bone resorption occurs, the implant starts to loosen out of place, and in the worst case, the bone itself can break [7,8].

6. Titanium implants

One of the most commonly used materials for implantation today is titanium and its alloys. Pure titanium is a bioinert non-ferrous metal, i.e., it does not react or reacts only slightly with the body’s tissues. The effects caused have not been associated with negative consequences, so titanium is considered to be biocompatible [4-6].

Titanium, which has a solid hexagonal crystal lattice structure in the α -phase, undergoes an allotropic transformation at about 882.5 °C, i.e., its lattice structure is modified without any change of state: above this temperature, the metal is characterized by a central cubic lattice structure in the space, which is now in the β -phase [4,5,7] (Figure 1).

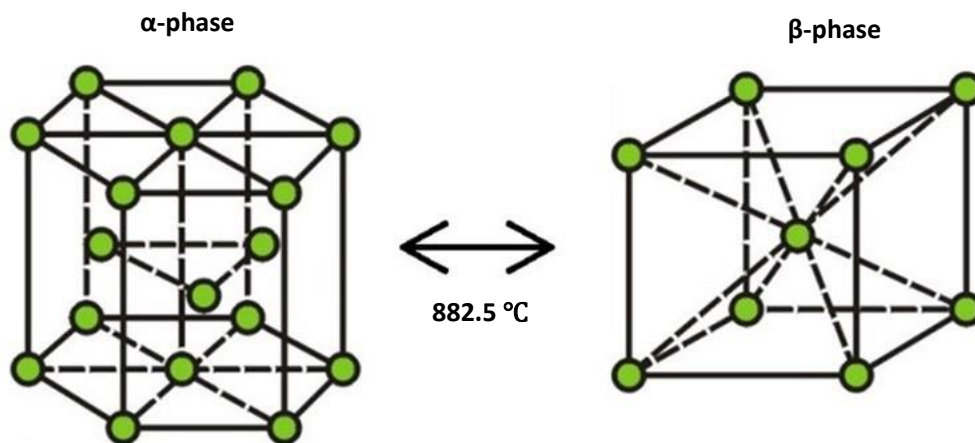


Figure 1. Phase transformation of titanium allotrope [9]

Metals are alloyed so that certain physical, chemical, and mechanical properties can be achieved according to the desired application. Depending on the alloying materials, titanium alloys can be α -, $(\alpha+\beta)$ - or β -phase. The main materials used for orthopedic implants are titanium alloys of the $(\alpha+\beta)$ -type, such as Ti-6Al-4V alloyed with aluminum and vanadium or Ti-6Al-4VELI (extra low interstitials). When using these alloys, however, it is important to ensure the correct proportions, as they reduce the biocompatibility of titanium above a certain percentage by weight [8].

In short, titanium is widely used because of its high mechanical strength, good corrosion resistance, relatively low material density, and lower elastic modulus compared to other stainless steels. It also has lower thermal and electrical conductivity compared to other metals and does not exhibit ferromagnetic properties, which is important for certain tests (MRI, NMRI). Furthermore, the oxide layer that forms on its surface, in addition to its corrosion resistance, plays a role in the so-called bone integration phenomenon, which allows a direct, fixed contact between the implant surface and the surrounding tissue [4-6].

This is because if the bone tissues were to penetrate sufficiently into the properly formed porous surface of the implant, the prostheses could be fixed naturally. The advantage of this is that, if no other defects occur, no further revision surgery is needed to correct any implant loosening, and the prosthesis,

once in place, can last a lifetime. An additional advantage is that titanium has a low density, which reduces implant mass, and the flexibility of additive manufacturing allows the implant to be adapted to the bone.

7. Surface design

However, in order for the bone implant to assemble properly, it is necessary to create surfaces that enhance integration and stimulate biological activity. The desired surface shaping is achieved primarily by using biochemical and physical methods. In the chemical approach, coatings are applied to the implant surface to promote the desired biological interactions, such as hydroxyapatite (HA), which is also found in bones [4]. These coatings create a concrete connection between the surfaces of the implanted structure and the bone tissue. The advantages of chemical coatings are cost-effectiveness, ease of control, and the fact that they do not require significant alteration of the surface morphology to achieve the correct adhesion [4,6].

Physically, the implant is mechanically shaped to create a porous surface into which bone tissue can grow to the desired extent. Numerous experiments have been carried out to find the optimum geometry, from which it can be concluded that the degree of bone integration depends on a few factors (**Figure 2**).

- (i) The size of the pores
- (ii) The gaps between the bone and the implant
- (iii) The porosity of the implanted device
- (iv) The shapes and spatial arrangement of the pores
- (v) The presence of holes exposed to the surface
- (vi) The presence of pores connected to the channels [10-13]

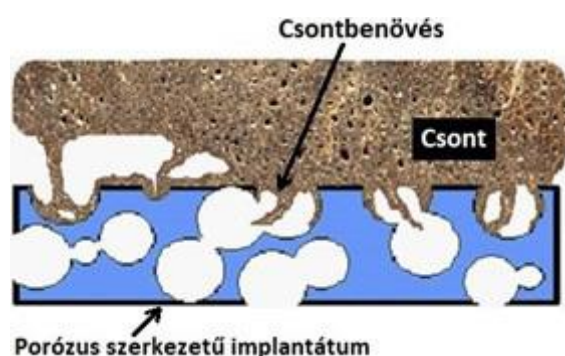


Figure 2. Bone integration phenomenon [4]

In conclusion, the primary requirements for the replacement of bone defects are implants with high mechanical strength that is similar to that of natural bone and a porous structure that promotes the formation of vascular networks and bone integration. However, these two characteristics have opposing effects, and it is therefore very important to find a balance between biological and mechanical needs.

One of the solutions could be to develop devices with a solid “core” inside, responsible for the load-bearing capacity, and pores in the outer layers to reduce the stiffness differences that are responsible for ossification and stress shielding. In addition, it is advisable to use metals with a high strength as a basic material in order to achieve the required structural properties, as their porosity can be modified accordingly [4].

8. Customized titanium implants

Based on the points mentioned previously, it is clear that in order to produce ideal implants, it is necessary to map the bone gap in detail, to create a suitable structural model and develop a material shaping method that allows the creation of arbitrary geometric structures, essentially without any formal constraints. The

additive manufacturing technologies mentioned above are the most suited for this purpose, since they do not achieve the desired structural shapes by material selection like traditional methods but use only as much material as the predefined structure requires, and the workpiece is built layer by layer directly from a pre-modelled three-dimensional CAD (Computer Aided Design) construction ^[14].

9. Computer modelling

To design a suitable implant structure, accurate data on the geometry of the area to be replaced and the patient's bone structure and its condition should be taken into consideration. The most appropriate method is known as "reverse engineering," ^[15] whereby a 3D CAD model is derived from an existing physical object and the resulting realistic shape is used to estimate the shape and the mechanical properties of the bone structures to be replaced.

One of the commonly used methods is to first obtain CT images of the problem area at an appropriate resolution. At this stage, the scanned shapes are represented as spatial point clouds, from which a triangular approximation is generated using a software to generate a Standard Tessellation Language (STL) file of the selected bones or bone fragments. This file essentially stores the mesh structure of the model in binary or ASCII format, where the given parameters are the coordinates of the vertices of the triangles in the x , y , z directions. The smaller the descriptive triangles, the more accurate the approximation of the measured surface, but the larger the data set required ^[15-17].

Once the out-of-body normal vectors of the descriptive triangles are defined, the 3D mesh model can be effectively constructed using CAD software. The bone model generated from the CT images is then used to model the implant to be produced according to the measured data and to shape the desired features ^[15-17] (**Figure 3**).

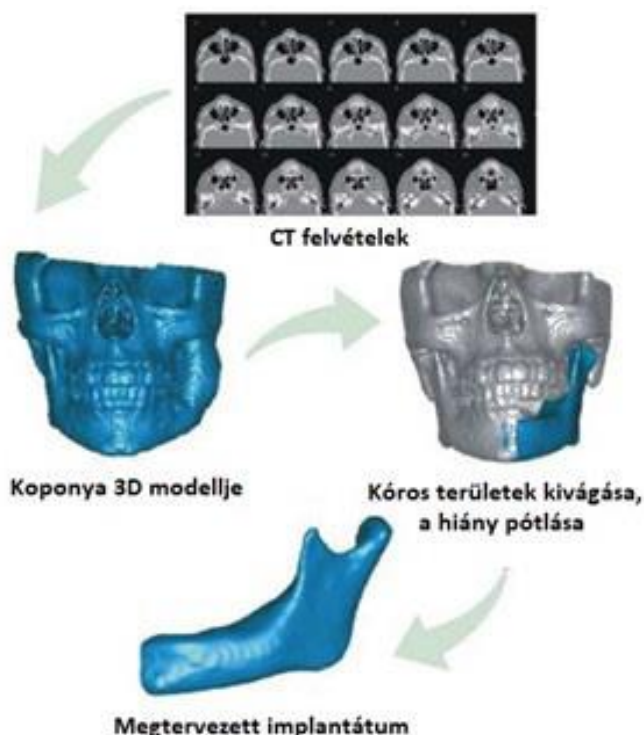


Figure 3. Mandibular implant modelling based on CT images ^[16]

After the modelling, the modified STL file is transferred to the computer of the production equipment, where the workpiece is segmented after the appropriate settings have been made, and the layer-by-layer production is started (**Figure 4**).

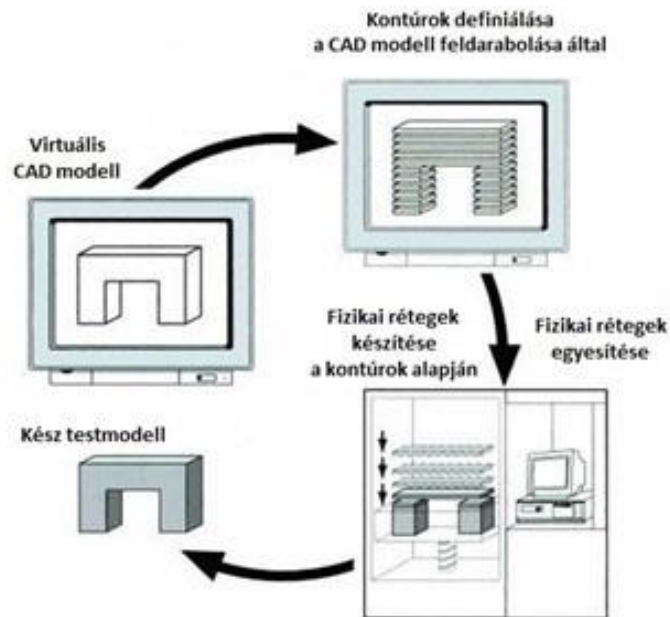


Figure 4. Principle of additive manufacturing ^[18]

10. Technologies used in additive manufacturing

Among the additive manufacturing technologies, the most suitable ones for metal implant manufacturing are powder-based systems, namely DMLS (Direct Metal Laser Sintering), SLM (Selective Laser Melting) and EBM (Electron Beam Melting) ^[20]. In this paper, the DMLS technology will be explained in detail.

11. Direct Metal Laser Sintering

The first step of the DMLS method is where a smoothing bar is used to spread the granules obtained from the powder feeder on the work surface in a layer thickness according to the preset settings, while the excess metal powder is collected in a collection chamber, which can be reused after filtration. The first layer of the model to be produced is then sintered in the x-y plane by focusing a high-energy laser beam at specific locations, and the workpiece is fixed to the worktable during the building process. The laser first scans the contour of the shape predefined in the STL file, then continuously passes over the entire cross-section, several times per line. The metallic powder, which is kept below the melting point temperature, is then heated to the melting point at the points hit by the laser beam, and the energy from the beam causes the powder particles to solidify ^[16,20].

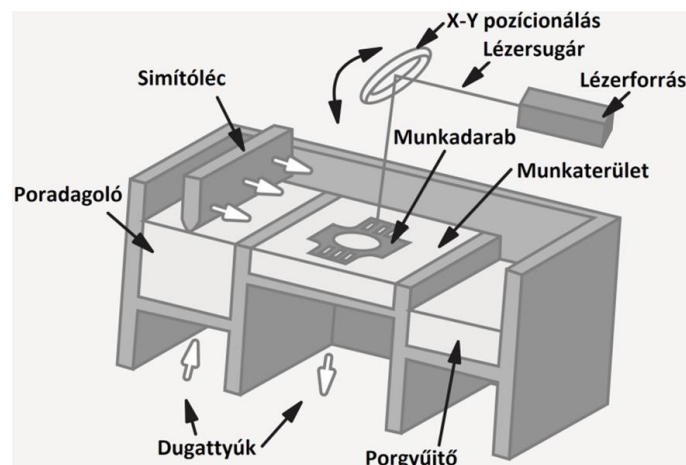


Figure 5. General structure of DMLS equipment

After the first layer is completed, the worktable is lowered to the predefined thickness, and a powder dispenser is used to spread the required amount of powder. The laser beam then focused on a optics mirror system, and the beam will be reflected into the required positions to combine the next layer of material, which will then also bond to the underlying surface. The lower layer is then lowered, and the new layer is sintered. This process is repeated until the model is completed. Before the completed model is removed from the powder bed, the system must be allowed to cool and any support material(s) must be removed [16,20] (**Figure 5**).

12. Key parameter settings

Setting the right layer thickness is very important, because if it is too thick, the desired degree of fusion between layers cannot be achieved; if the layers are too thin, the dust cover may touch the surfaces, which causes the layer to move out of place. During the build-up of the workpiece, it is also important to avoid oxidation during the sintering of metals, so the process is carried out in an argon gas-filled medium for titanium powders [13,20,21].

It is also important to reduce the internal stresses that develop, which can be achieved by applying heat treatments to the finished object or by modifications prior to sintering. Previous experiences has shown that reducing the scanning depth of the laser, increasing the distance between the laser scans, and increasing the thickness of the layers results in lower internal stresses. Stress reduction can also be achieved by continuously changing the scanning directions of the laser and reducing its length. In addition, the workpiece should be placed in the workspace in such a way that minimal support is needed during the building process and that these supports can be easily removed after the model is completed without damaging the surface of the workpiece [13,20,21].

By modifying the parameters of the process, it is also possible to control the porosity of the layers and the size, the shape, and the distribution of these pores. This allows us to control the overall structure of the model, which is in this case the production of a fully biocompatible implant. However, in the meantime, it is important that the shaped workpieces meet predefined standards, both in terms of their chemical composition and mechanical and physical properties.

13. Marketability of custom orthopedic implants

From what has been described so far, it is clear that this technology is suitable from a manufacturing point of view, but in order for the manufactured implants to be marketable and usable in practice, conformity approvals and certifications are required. The basis for this is Directive 93/42/EEC. On the basis of this Directive, medical devices are classified into risk classes, which determine the approval and authorization procedures that the devices must undergo.

Individual-specific implants can be categorized as “ready-to-use” devices, so the procedure defined in Annex 8 of the Directive should be taken into account. This means that the information listed here should be provided, in order to attest to the safe use of these devices for their intended purpose. These documents must include, inter alia, the name and address of the manufacturer, the name of the ordering practitioner, and a statement that the device is intended exclusively for a specific patient [22].

14. Prospects

The medical history of the use of additive manufacturing technologies, such as the implant development methods discussed in this paper, offers a wealth of opportunities. These technologies will allow the production of customized implants with much higher biocompatibility and biofunctionality than the devices available currently, while making them more cost-effective, faster, and simpler to manufacture. However, the development of the system also requires the optimization of pre-production processes, including the

development and optimization of radiological image processing and modelling methods to ensure better image quality, research of the most favorable grid structures for bone integration, and analyses of the performance of finite elements. The ultimate goal is to develop bone defect treatment services to the maximum level, both in Hungary and internationally.

15. Summary

This paper was written to summarize as much knowledge as possible about the production of titanium custom implants using additive technology. To achieve that, the available literature was analyzed in order to provide an overview of the requirements for implementation, especially in terms of material knowledge, model design, and manufacturing with DMLS technology, and to investigate the basic legalities for marketability. This information is essential for the successful implementation of the desired service.

Disclosure statement

The author declares no conflict of interest.

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