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RAPID MANUFACTURING IN MEDICINE

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Kulcsszavak: Személyre szabott biomodellek, gyors gyártás, fémpor, szelektív lézeres olvasztás, 3D nyomtatás
Keywords: Customised biomodels, Rapid Manufacturing, metal powder, SLM, 3D-printing

ÖSSZEFOGLALÁS

Napjainkban az orvosi modellekre, az implantátumokra és a protézisekre a nagyfokú egyénre szabottság jellemző, különösen a koponya- és arcsebészeti eseteknél, a fogászatban és a ortopédiában és az ezekhez hasonló beavatkozásoknál. Az elmúlt évtizedben számos eltérő eljárást és implantátumgyártási technikát vezettek be, ezek nagy része a Gyors Prototípus technológiát képviselik. A Gyors Prototípus technológia jól reprodukálható és a személyre szabott implantátumok számítógéppel irányított tervezését és gyártását jelenti. Az az elvárás, hogy kissorozatú vagy egyedi gyártás bevezetésé az iparba, kiegészítve a Gyors Prototípus technológia alkalmazásával, az egyes paciensekre kidolgozott biomodellekkel ígéretes az orvosi végtermékek terén.

ABSTRACT

Nowadays there is a tendency for medical models, implants and prostheses to be highly individual and customised, especially when considering implementation in cranio-maxillo-facial surgery, dentistry, orthopaedic surgery or similar areas of medicine. During the last decade a number of different processing techniques have been developed and fabricate customised implants for medical applications, the majority of them representing Rapid Prototyping technologies. RP are highly reproducible and computer-controlled methods for designing and fabricating customised implants. It is expected that besides small batch or one-off production for the industry, additive metal RP technologies may be applied to provide customised biomodels for individual patients, and – what is most promising – end-use medical products.

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1. INTRODUCTION

The extraordinary fast developments in tissue engineering (TE), especially in scaffold fabrication and in hard tissue reconstructions bring new solutions for better, faster and safer ways to help people. The interdisciplinary field of TE combines engineering and life science in order to develop techniques enabling restoration, maintenance or enhancement of living tissues and organs [3]. It becomes natural to fabricate customised phantoms, implants or scaffolds. It is also essential to fabricate 3D scaffolds that can provide the required mechanical strength and access to nutrients for the new tissue with bonelike internal and external structure. A scaffold provides the necessary support for cells to proliferate and maintain their differentiated function; its architecture defines the ultimate shape of the new bone [7].

A few years ago, generative technologies (GT) have been introduced into the medicine application field. This introduction was successful and interesting since new possibilities and chances were created for nowadays surgery. When looking at the historic evolution, it is both surprising and impressive to see that it was possible for such an advanced (and at that time immature) technology to be appreciated and used in such an overregulated and conservative science area like medicine. Research areas working on the manufacturing of customised implants show that the recent developments and usage of generative technologies open ways for faster, more accurate and better planned implant surgeries. Things that would not have been possible in such a big degree if conventional, uncustomised implant fabrication methods would have been used.

The reason GT could be introduced in such an early stage of its development was because of a combination of the following factors, listed based on their validity:

i) the required extremely complex models could impossibly be manufactured via conventional methods;
ii) the close technological link between GT and medical imagine methods (like CT or MRI) enables to exchange input/output data in STL format; and biomodels;

iii) enable high independence in making decisions for young doctors;

iv) enable doctors to make decision regarding the technologies to use, before the risky operations have to be performed;

v) showing reduced costs of the advanced, new and customised models compared to the conventional, traditional and already better know techniques.

Already for some years, but especially nowadays, the use of Rx in the various stages of bone surgery has increased. This is mainly due to the fact that three dimensional biomodels are excellent enhancements compared to traditional 2D X-ray pictures. They help in diagnostic objectivities, and in the following stage of preoperative planning [9].

The major next step is the use of fabricated biomodels during surgery, i.e., using it in intraoperative planning conditions [5]. This implies that GT has to be used in a heavily regulated medical environment, where surgery success and patients safety is extremely important. As a result, design choices during Rx are narrowed down. Till not so long ago patients did not come into direct contact with Rx models. Nowadays however models are used more and more during surgery. The biocompatibility and sterility of the models, together with the assurance that the model has the required accuracy, is a strict demand.

The rapid prototyping techniques are widely used in the industry. Their main advantage is the ability to build highly complex design models in extremely short time, compared to other technologies. The possibility of manufacturing free-form physical objects is given by additive, layerwise building method. Concept models, prototypes, visual models, functional models, sand-casting moulds, etc. may be created in this way. These techniques found an application also in medicine. For years rapid prototyping has been used for preparing precise anatomic models for operation planning, e.g. in cranio-maxillo-facial surgery, dentistry and orthopaedics. These anatomic models significantly improve safety and quality of operations and reduce their times.

2. Rapid Manufacturing Technology In Medicine

In the last years the medical environment have shown more interest in generative technologies, which was caused by the introduction of new RM machines for producing fully dense metal parts, e.g. in biocompatible titanium TiAl6V4. One of those machines is “Realizer” from MCP Group, which uses the “selective laser melting” method for producing parts. Because of nearly no limits to the degree of complication of models, good accuracy, short building time and good material properties, the SLM method is perfectly suited for producing customised medical implants.

These studies are presented to illustrate the complete process of custom implant design, manufacturing and verification (Fig. 1).

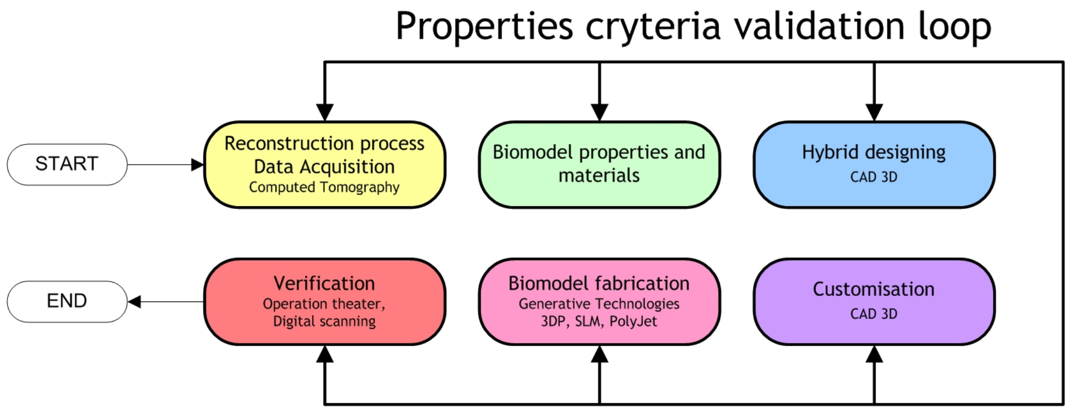

Fig. 1 Steps for designing the structure, functions and the development of manufacturing method of customised implants

2.1. Technology Overview

The SLM method was developed in 2002. It is based on local melting of a thin layer of metal powder by a focused beam of a Nd:YAG laser with the maximum power of 100W [1], [11]. The layers are created by depositing 50 μm (±2 μm) of powder, which is then levelled by a wiper and then selectively melted by a laser. Metal powder is dosed from the build powder container, where it is supplied by a system of valves from the main powder container. Built models achieve up to 100 % density. Accuracy of model building is 0.1mm and more, depending on many factors, e.g. laser spot size. Model were build on platform dimensions of 248x248 mm (X-Y) the laser spot size is 60-250 µm. Parts are built in a controlled atmosphere with the argon gas, which prevents oxidization. The building speed is 5-7 cm3/h [1]. After the last layer is completed and the model, joined by a support structure to the removable build platform, is taken out of the machine, the supports have to be cut off. This is a hand work with traditional tools. The part can be also post-machined for better surface quality.

2.2. Material

Titanium in medical applications. 'Fit and forget', is an essential requirement for equipment in critical applications [21]. Once installed it cannot readily be maintained or replaced. In this respect, there is no greater challenge than implants in the human body. The effectiveness and reliability of implants, medical instruments and surgical devices is an essential factor in saving lives and in the relief of suffering and pain. However, implantation represents a potential assault on the chemical, physiological and mechanical structure of the human body.

There is nothing comparable to a metallic implant in living tissue. Most metals in body fluids and tissue are found in stable organic complexes. Corrosion of implanted metal by body fluids, results in the release of unwanted metallic ions, with likely interference in the processes of life. Titanium is judged to be almost completely inert and immune to corrosion by all body fluids and tissue, and is thus wholly biocompatible.

One of the main physical properties of titanium is its high strength-to-weight ratio. It is a light, strong metal with a low density that, when pure, is quite ductile (especially in an oxygen-free environment) [1]. The relatively high melting point (over 1,649°C) makes it useful as a refractory metal.

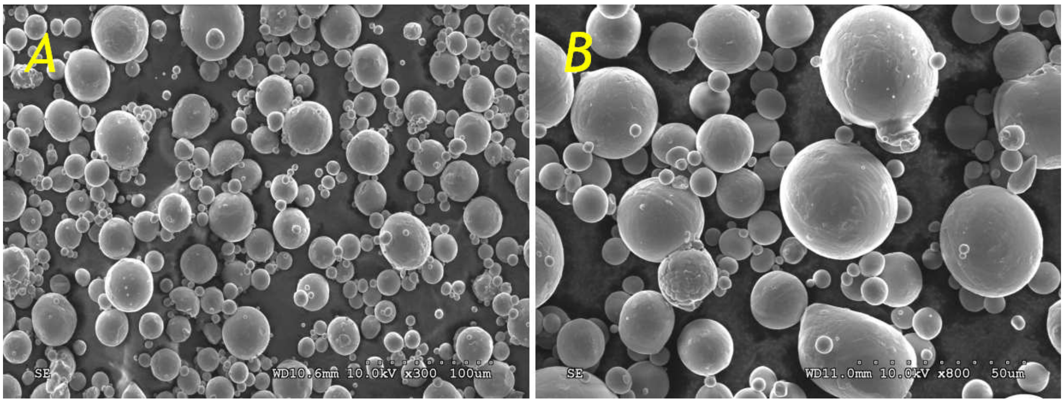

Fig. 2 *SEM pictures of Titanium (made for report „Ocena wielkości cząstek proszków metalicznych") (pure Ti and Ti6Al4V)*

Commercial (99.2% pure) grades of titanium have ultimate tensile strengths of about 434 MPa, equal to that of some steel alloys. However, they are 45% lighter. Titanium is 60% heavier than aluminium, but more than twice as strong as the most commonly used 6061-T6 aluminium alloy. Certain titanium alloys achieve tensile strengths of over 1380 MPa. However, titanium loses its strength when heated above 430°C.

Not only for these physical properties, but also because of the biocompatibility (non-toxic and is not rejected by the body), is titanium used in a gamut of medical applications. These applications include surgical implements and implants, such as hip balls and sockets (joint replacement) that can stay in place for up to 20 years. Titanium has the inherent property to osseointegrate, enabling use in dental implants that can remain in place for over 30 years. This property is also useful for orthopedic implant applications (Fig. 2).

This reasons inspired the authors of this article a methodology for fabricating customised implants from titanium for real patients.

3. Customised prototypes of implants

The first case study concerning customised implants was performed in the Centre of Advanced Manufacture Technologies at Wrocław University of Technology. This study is about the design and manufacturing process of exemplary mandible implant. The second case study is about a maxilla reconstruction. The described biomodels was manufactured with an LBMM. The overall (worldwide) first reported case on an implanted maxilla biomodel, made with LBMM, was documented at the turn of 2006 and 2007. This case study was carried out by Dr. Jules Poukens at the Academisch Hospital Maastricht, the Netherlands [6], [9].

A process of medical model(implant) preparation involves the following steps [15], [16], [17]:

i) **Reconstruction process - data acquisition:** the building of customized, hard tissue biomodels will be possible thanks to the availability of output data from medical imaging systems (CT, MRI). The reconstruction of hard tissues will be based on processing the data received during the scanning of 2D cross-sectional images of the human body. The 2D data (in format DICOM) will be processed using medical visualization applications like e.g., Mimics.

ii) **Implants properties and materials**: the selection of materials and build process parameters is subject to the chosen manufacturing method.

iii) **Hybrid designing of the structure and functions of implant (Fig. 3)**: this is possible thanks to applications (like CAD system) or medical imaging systems (like CT or MRI). Transferring data: creating data compatible to manufacturing technologies (required data format STL).

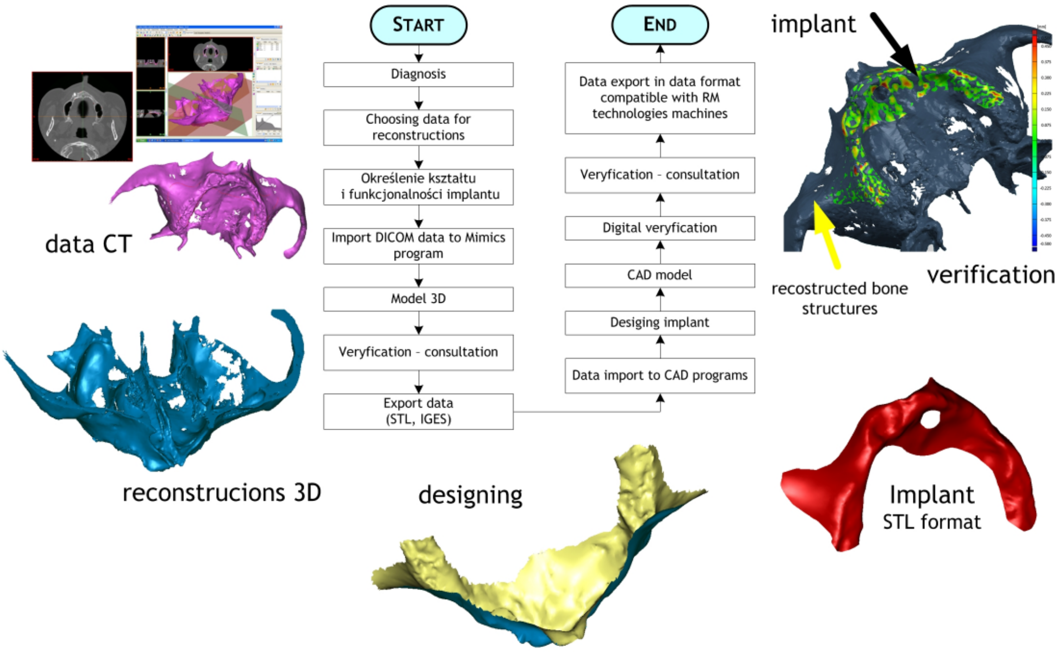

Fig. 3 Base process of designing biomodels, describing main steps of work with examples of designed prototype of implant

iv) **Customisation** of implant is a result of data chosen for reconstruction (CT, MRI data of specified patient)

v) **Implant fabrication**: RP/RM technologies enable the building of 3D models based on computed data, in the Institute of Machine Technology and Automation (at Wroclaw University of Technology).

vi) **Verification of the received results:** determine the mechanical strength, porosity, and accuracy of the manufactured implants / scaffolds (accuracy of input data and output model). Under this topic also the falls, consultations of achieved results with medical doctors is discussed.

3.1. Mandible Case Implant

Described clinical case in this paper is highly complicated and not usually consider in non-traditional way of clinical treatment. High number of accidents connected with described bone makes this case interested for research. Accidents of the cranio-facial skeleton in the biggest number of cases concern the mandible [19]. The largest percentage of mandible fractures is a result of injury from the side or the front of the head. One of the places where the fracture appears most often is at the condyle.

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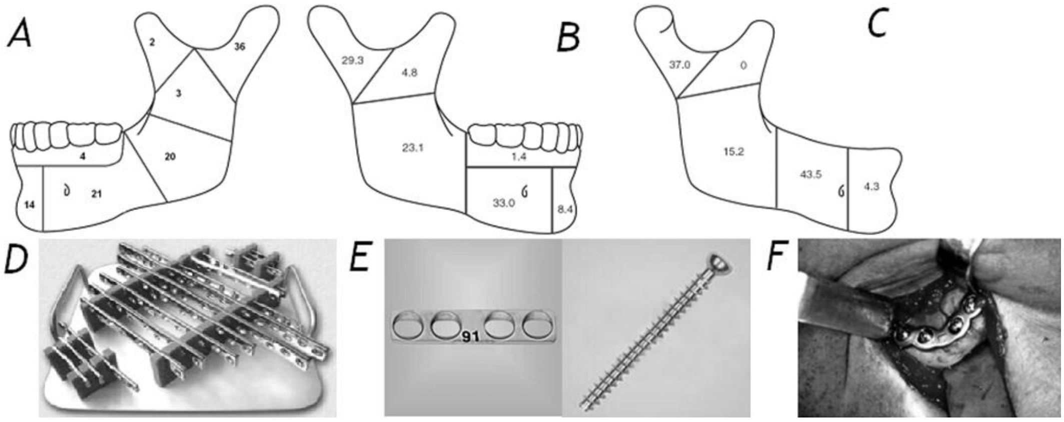

Fig. 4 *Percentage of fractures sites in different areas of the human mandible A/ According to [20], B/ Adopted by Lyuk N.H. [4], C/ In edentulous patients, D/ Commercially available set for stabilizing osteosyntesis. E/ Commercial four hole plate (22x5x1 mm) and corresponding screw Ø1,5 x 6 mm. F/ Plate as shown in E/ screwed to the mandible bone [4]*

The diagnosis, identification and medical treatment of temple-mandible joint fractures can cause a lot of complications and difficulties. Operation can be difficult because of the complex structure of this joint. Also, the surgery location is complicated because this bone is covered with a thick layer of tissue.

The essence of the medical treatment in this case is to revive the morphology and functionality of the mandible [19]. The choice on the kind of medical treatment depends on the level of complexity of the fracture. The best results however are always obtained with the open reposition of bone and an internal merging of the bones. To get to this area condyle head there are only a few traditional surgical cutting procedures [10]. An optimal condition for the healing process is to have a stiff connection between the bone fragments, as this makes relative movements of the bones impossible.

One of the traditional method is called stable osteosyntesis. For this conventional method usually traditional, commercially available, osteosintesis stabilization sets are used. Pressure screws and metal plates are used to stabilize the fracture (see Fig. 4 E and F). The metal plates are usually made from titan or cobalt-chromium [10]. The standard surgery procedure is to drill several holes and jigs. It is required to have at least two screws on each side of the fracture, as shown in Fig. 4. The operation has to be carried out after the earlier reposition of bone fragments.

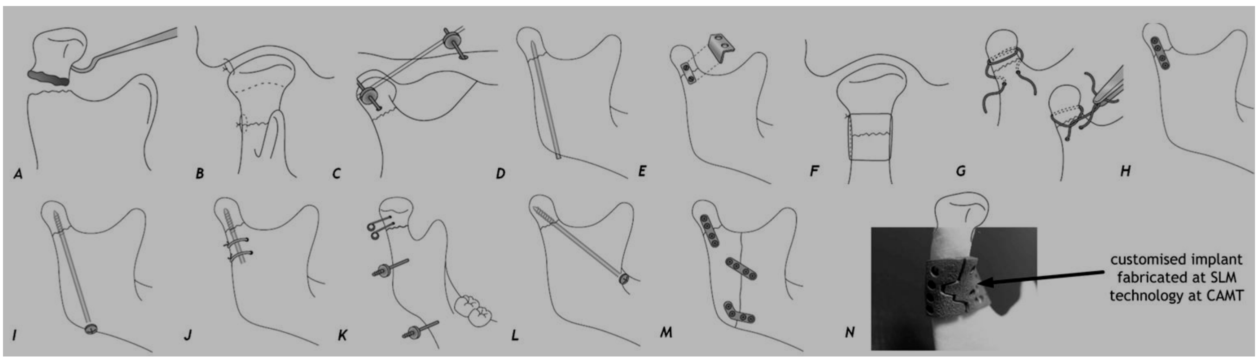

Fig. 5 *Traditional methods for direct stabilisation of a condyle fracture. Reported by: A/ Silverman (1925), B/ and C/, Thoma (1945),D/ Stephenson (1952), E/ Robinson (1960), F/ Robinson (1962), G/ Messer (1972), H/ Kobert (1978), I/ Petzel (1982), J/ Brown (1984), K/ Fernandez (1978), L/ Kitayama (1989), M/ Elllis (1989), N/ example of customised stabilization implant of condyle fabricated in CAMT Wrocław University of Technology (2007) [12]*

Hitherto existing surgery methods were based on the fracture case and the bone condition before and after injury, in which the plate has to be screwed. In case of a multi-fragment fracture, metal plates can no longer fulfil their role. Due to this, the open reposition of condyle with stable osteosynthesis is difficult. In this case many surgeons prefer to use only rehabilitation [19] even though there a multiple traditional way to operate this kind of case (Fig. 5).

The idea of customised designed implant is that it should be possible to solve the above mentioned problems, and also to assure sufficient stabilisation even in the case of multi-fragment fractures (example of prototype implant versus traditional methods of surgery treatment for this common fracture - Fig. 5).

3.1.1. *Data Acquisition and 3D Reconstruction*

The clinical case described here gives an overview of the process of implant design and manufacturing. The first step in this process is taken by radiologists. The next step is to design the model. This is usually performed by a technically skilled person. In many cases it would be better if the model design was made by the surgeons. However, because of lack of required skills this is not always possible. During the last step, the actual surgery is performed. Till now the biggest problem and weakest point of the custom implant process chain is the lack of validation during the first two steps. Mistakes usually only show up during surgery.

In bone surgery, CT is by far the most commonly used scanning technology nowadays. In some cases also MRI scans are used, in order to provide soft tissue information and to help with solving some of the more complicated problems. The present status in the medical world is that very little is know about the accuracy of CT scans. This is mainly due to lack of sufficient ways to establish the accuracy. Nevertheless, in the last 15 years some research has been carried out concerning this matter. The goal of this research was to determine the accuracy of the scans and of the resulting model surface. The research approach of this investigation was to first take a phantom model (with known and pre-determined design dimensions), subsequently scan it, and then to convert the data into STL. During the analysis, the exact dimensions of the surface model were determined and the obtained results were compared to nominal values.

The biggest disadvantage of the adopted method is that it is not possible to determine in which part of the process the inaccuracies occur. It is also not possible to learn from mistake. In most of the documented cases the obtained accuracy was approximately in the range from 2 to 4,7 mm [9]. This accuracy was considered acceptable. The measuring accuracy established for this work shows that distortion was from 0.033 to 1,2 mm, i.e., substantially better.

3.1.2. *Hybrid Design of Implant*

CT-imagines and surface models of defects are not longer exclusively used for diagnostic purposes. Since the last few years, the role of medical customised phantoms is not perceived as strange any more.

CT scans give every surgeon a clear picture of the geometric aspects of the problem. Especially in complicated cases where the bone structure is so diversified like in the case of the skull. In those cases CT scans and 3D surface models are replaced or supplemented by physical customised phantoms. The models give enough information to make a detailed planning for the complete surgery procedure.

Traditional, commercial available implants are usually made of relatively flexible material so that they can be reshaped into their final form during the operation. However, since medical doctors now have access to 3D computer models, and since the implants can be designed accurately, it has become possible to produce pre- and intraoperation biomodels, according to the defect. Customised operation guidelines can be planned entirely before the operation.

In the case study as described in papre, the time between the scanning and designing of the model, and the operation, is not important. However, in many cases this time can play a crucial role and should therefore not be neglected. The design should receive the scanning data in an uncomplicated way. Since models of sculls are extremely complex and organic in shape, it is very difficult to design the implant using conventional CAD – systems.

3.1.3. *Fabrication & Verification*

The first concept of a customised snap fastener for the condyle neck was fabricated using the PolyJet technology. A transparent material was used in order to verify the functionality of the fastener (material: FullCure, built time: approximately 45 minutes, Fig. 6). To verify the functionality of the prototype a lower jaw was constructed from plaster, using the 3DP technology (ZPrinter 406). After a few tries to close the customised snap fastener, the device was already broken (Fig. 6, A). During the design of the next prototype this experience was taken into account. The closing mechanism design was changes. Also introduced was a new concept to lower the weight and strength of the implant: designing orifices in the prototype structure (Fig. 6, B). The functionality verification of the second prototype was successful. The actual (final) implant was built using SLM technology from Ti6Al4V (built time 8h).

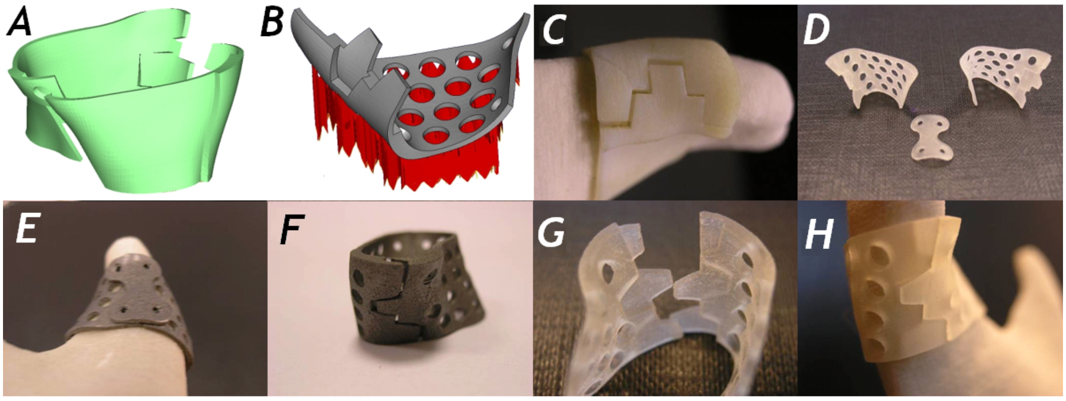

Fig. 6 *Three 3D models design for condyle neck, A/ CAD models of condyle implant, C/first exemplary phantom (PolyJet), D, G and H/ second phantom to validate the solution for self-closing implant (PolyJet), E and F/ titan implant Ti6Al4V (SLM), placed on 3D model of lower jaw built on 3DPrinter*

3.2. Maxilla Case Implant

Most of the more complicated cases are connected with native alveolar bone response to the functional effects (or lack thereof) caused by edentulism. This is especially common for older people. Increased resorption, due to traditional methods of oral rehabilitation with complete and partial dentures, often results in an overall acceleration of the resorptive process. The mandible is affected to a greater degree than the maxilla owing to muscle attachments and functional surface area. As a result, there is a qualitative and quantitative loss of tissue, resulting in adverse skeletal relationships in essentially all spatial dimensions (Fig. 7).

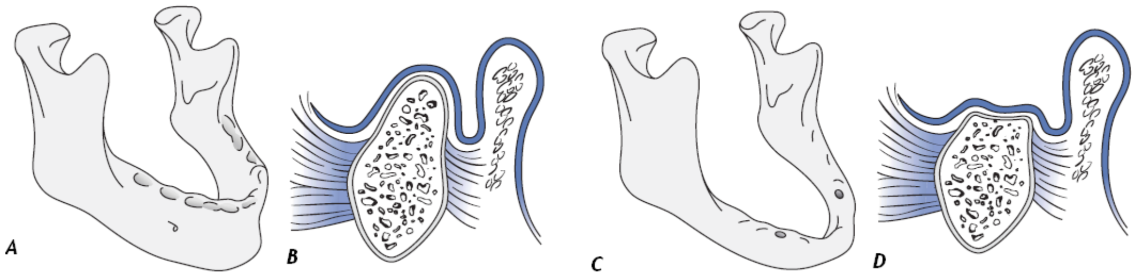

Fig. 7 *The diagrams show patterns and varying severity degrees of mandibular atrophy.* ***A/*** *Mandible shows minimal alveolar bone resorption****;*** ***B/*** *cross-section of large alveolar ridge including mucosal and muscular attachments;* ***C/*** *mandible shows severe loss of alveolar bone which has resulted in residual basal bone only;* ***D/*** *cross-section shows resorbed alveolar ridge, with muscular attachments (Adapted from Tucker MR. Ambulatory preprosthetic reconstructive surgery [14])*

General systemic factors in case of mandible and maxilla, such as osteoporosis, endocrine abnormalities, renal dysfunction, and nutritional deficiencies, play a role in the overall rate of alveolar atrophy. Local factors, including jaw function, vascular changes, adverse prosthetic loading, mucosal inflammation, vascular changes, and the number and extent of previous surgeries involving mucoperiosteal elevation, also contribute to progressive alveolar bone loss.

Although the factors contributing to bone loss and the resulting patterns are well understood, the rate of bone loss varies significantly from individual to individual. The consistent factor is the overall duration of the patient's edentulous state.

In the complicated surgery cases like describe in this experiment it is crucial that all the implants: 1) are positioned in strong bone, 2) are able to work with loadings that will occur during eating, chewing etc., 3) provide the initial stabilization and,

4) help in osseointegration. Important is also to see the quality of the bones, sinuses and nerves. This possibility is provided by CT imaging.

3.2.1. *Data Acquisition & 3D Reconstruction*

The parameters of CT scanning were the standard ones (model was create form 75 slices, where slice a increment value was 0.5 mm, more details about scanning in Table 1).

Table 1. Example of scanning and reconstructing data of patient used for fabricating dental maxilla phantom

Patient Information	Age	53
	Sex	Female
Doctor & hospital information		n/a
		NZOZ Wrocław Medical Centre
CT Information		GE Medical Systems/CT/e Dual
Scanning information & parameters	Date of scanning	07/12/06
	Wight [pxl]	512
	Height [pxl]	512
	Pixel size [mm]	0,268
	Algorithm	EDGE
	Reduction	1
	Orientation	RTP
	Field view [cm]	13,70
	Gantry tilt [°]	0
	Number of slices	75
	Slices increment [mm]	0.500
	Contras	No
Model Information		Model Construction and Technology Materialise
	Threshold 1 [HU]	187
	Threshold 2 [HU]	3071

Reconstruction process was performed in Mimics and the bone structure was created. After consultations with a medical doctor, the external shape of the implant was established (Fig. 8).

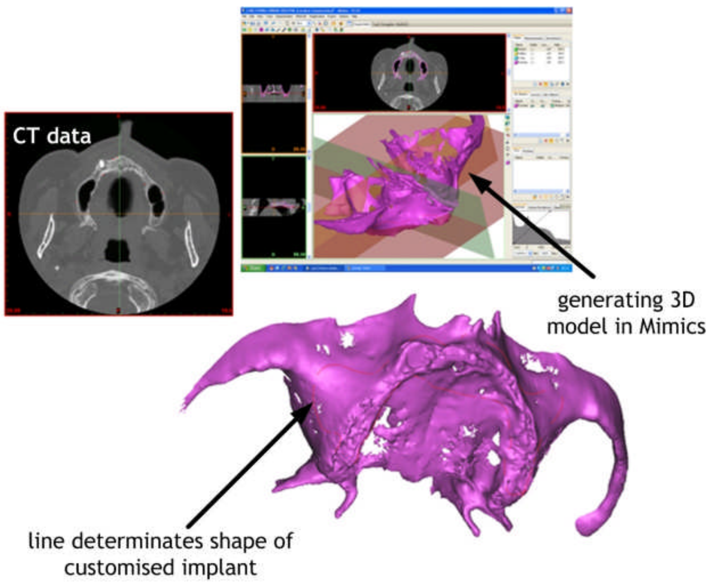

Fig. 8 *Designing process of customised implant – data acquisition*

3.2.2 Designing, Introductory Verification & Fabrication

The structure of the implant was based on CT data and the shape of the implant determine by line (Fig. 8). The design focussed on exporting the data form Mimics (STL file), into Magics. In this program the structure of the bone required for further design was chosen. The cut data were imported in the same format to GeoMagics. In this program the following design steps were followed (Fig. 9):

i) selecting the structure upon which data implant has to be designed,

ii) filling holes, closing discontinuity in structure,

iii) creating an STL surface model (putting nodes, patches, etc.)

iv) making shell –creating shell surface in a distance 0.6 – as was demand by surgeon.

The model was fabricated using SLM technology. The built time was approximately 14h. The used material was Ti6Al4V (Fig. 10).

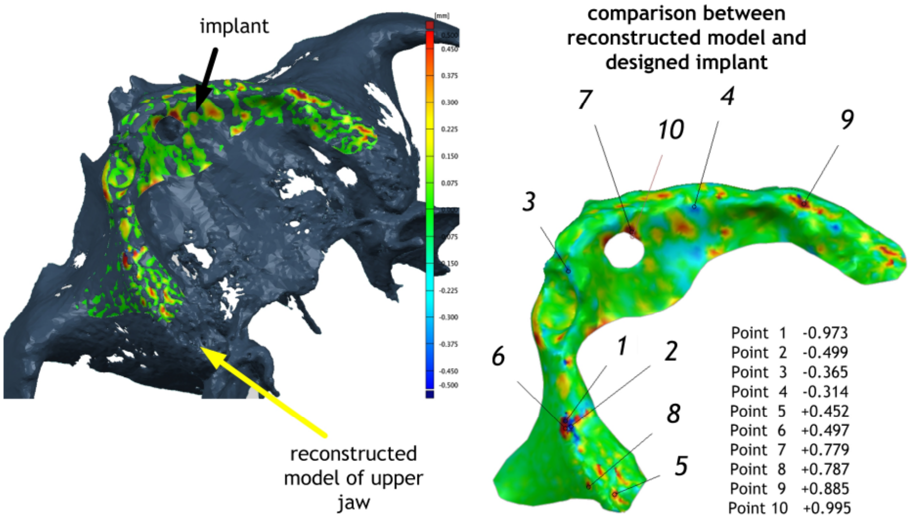

Fig. 9 *Introductory verification of results with specified characteristic points on implant structure with measured differences between patient's bone structure and implant design structure*

3.2.3 Conclusions

The process of designing an implant was developed and tested. After completion of the process some changes were suggested to increase the functionality and versatility of the designed model. The implant prototype was fabricated form titanium alloy (Ti6Al4V). This material provides biocompatibility, an essential for implantation. The problems related to implantation and restriction and regulation are not discussed in this article. The process of implantation of one of fabricated models can be solved after additional experiments.

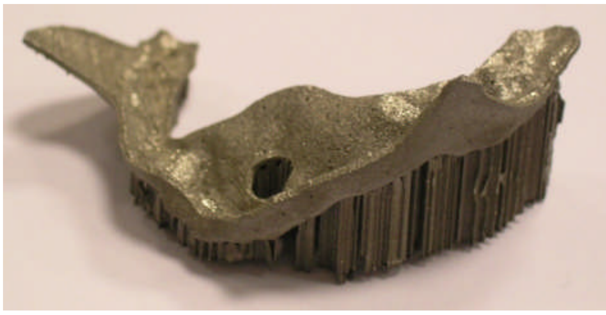

Fig. 10 *Customised titanium implant with support structures fabricated using SLM technology*

4. Discussion and Conclusions

Through the designing and fabrication process and because of the possibility to verify the received results it has been possible to fabricated newly invented and fully customised implants for the condyle neck. The obtained satisfactory results suggest that there can be a large amount of possibilities for the use of generative technologies in the fabrication of customised implants. The results can also be used to prepare the medical sector for the use and implantation of this kind of models. In order to produce parts directly from metal powder the Selective Laser Melting process has been developed. Physical biomodels manufactured in the process may be used in diagnostics, pre-, intra-, and post-operational planning for difficult cases, implantation and surgical template production and as educational aids.

It was shown that RM technologies may be applied to provide customised biomodels for individual patient, and – what is most promising – end-use medical products.

Biomodels produced by RM technologies can help a patient to understand better the aim of an operation. They help to understand a surgical problem, facilitate the communication between doctors and patients and contribute to decision making among doctors. They are designed to conduct a simulation of an operation which helps shorten the time of the real procedure. They guarantee very good modality of the shape and geometry of anatomical structures which are often manufacturable only with the use of one of RP technologies. 3D anatomical models are usually used for teaching anatomy, in training courses and to demonstrate difficult medical cases [13]. In case where the building model is from titanium, regarded biocompatible, it could be implanted to a patient's body.

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