Individual Contour Adapted Functional Implant Structures in Titanium

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Abstract
Apart from applications in mechanical engineering, now even the domain of medicine may benefit from the option of using metallic materials for Direct Manufacturing. In the medical domain, the use of biocompatible materials, such as titanium or titanium alloys is essential to produce individual implants. As a result of this development, it is now possible to generate new patient-specific geometries fitted to the contour. This paper elucidates the process chain to derive individual design variants and to produce patient-specific bone replacement implants for the lower jaw-bone regions by using innovative reverse engineering and manufacturing methods. For this interdisciplinary project, technical scientists, medical scientists at the university hospital and engineers from a product development firm work together.

Keywords:
Rapid Product Development, Direct Manufacturing, Reverse Engineering

1 INTRODUCTION

Scientific studies of CAD/CAM applications in medicine and dental prosthetics, which have been ongoing for approximately 15 years, focus on models, tooth crowns and bridges [1-3]. The use of CAD/CAM technology with CNC-milling and rapid manufacturing in dental industry is now very common. The majority of scientific approaches to use rapid manufacturing since 2006 have been aimed at endoprostheses in CoCr and titanium alloys [4-8].

In cases when jaw implants are required due to disruption of continuity in the lower jaw bone, the relevant anatomical regions are commonly represented by means of imaging techniques, such as computer tomography (CT). Based on these data, which are specific to each patient, we analyse the range of available standard care programs, choose the appropriate reconstruction plates for the jaw region and implant them. As a rule, the reconstruction plates currently in use are characterised by great variations in stiffness between implant and bone (Figure 1).

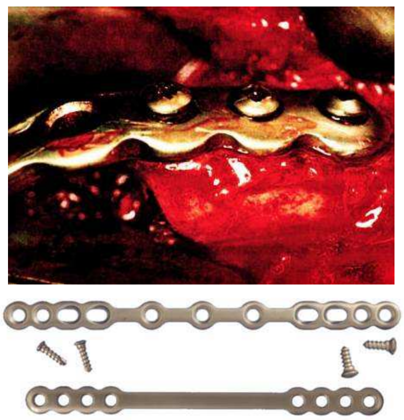

Figure 1: Standard reconstruction plate for jaw region

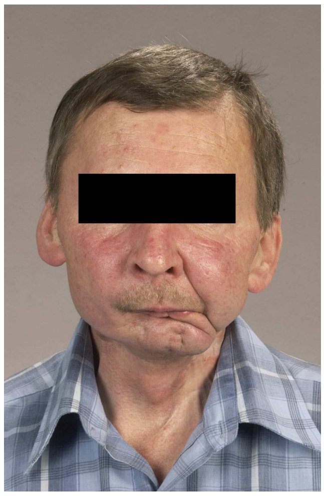

Figure 2: Patient after damage of standard reconstruction plate

In Figure 2 a patient is illustrated with aesthetic and clinical deficits as a result of the damage of a standard reconstruction plate after surgery and tumour resection on the left facial side.

Additionally, since the geometry is not significantly individualised, we also see obvious functional and structural-mechanical deficits, as well as aesthetic disadvantages. Consequently, an application that protects the tissue and is also highly stable, which is a necessity for optimal treatment, cannot be provided by any of the methods currently available [9-11].

As a result of ongoing globalisation, the greatly expanding market for medical implants made of biocompatible high-performance materials is under ever-increasing pressure from competitors. In this context, the reconstruction of bone defects, in particular in the oral, jaw and facial region, by means of osteosynthetic plates is regarded as a great challenge. Here, special advantages may accrue to a new implant design whose contour and stiffness are tailored to specific geometric and elastic conditions, since in this way it is possible to reduce complications during ingrowth.

The LaserCUSING® method [12-13] provides the first technological approach to manufacturing new filigree implants that are perfectly aligned with the contour and gradually modified in stiffness. LaserCUSING® is an innovative technique, following a generative approach, which is able to realise structures according to the direction of force action.

One objective of the planned research project is aimed at the development of a process chain that extends all the way from CT layer images of a diseased patient up to the manufacturing of individual bone substitute implants for the patient while taking into consideration a Rapid Manufacturing technique. Thus, the rapid manufacturing of individual implants that repair defects is primarily emphasized in order to keep the waiting periods for patients as short as possible.

2 APPROACH

The project consortium began with mandibular implants in 2006.

The work we are doing in Dresden is unique in that it features close interdisciplinary co-operation among radiologists and oral and maxillofacial surgeons, dentists and engineers. The study includes an ethics proposal for animal experiments and a patent.

The CT data required for diagnosis are also used to generate the virtual 3D model of the jaw bone. Individual design and modifications of the implant are performed based on the 3D model. The fundamental steps necessary to generate individual implants are listed below:

- Imaging of the diseased area and surrounding regions by means of CT
- Creation of a discrete surface model from the CT image stacks
- Alignment of the lower jaw model for design in a defined co-ordinate system
- Definition of cutting planes to isolate the defective regions
- Generation of a mathematical surface representation of the lower jaw contour in the affected area and the surrounding regions
- Definition of the positions of the holes that will later secure the implant in the residual bone
- Implant design with CAD system (Computer Aided Design)
- Design of the cutting templates, which are applied to the jaw before resecting the diseased bone
- Production planning for the LaserCUSING® system incl. placement in the working space
- Creation of the support structure taking into account the building layer configuration
- Manufacturing of the implant and the cutting templates with LaserCUSING®
- Removal of the implant from the building plate by means of erosion
- Manual removal of the support structure
- Corundum blast finishing of the implant surfaces.

2.1 From the CT image stack to the CAD solid Model

When generating the individual implant, the first step consists of mapping the defective bone regions and the surrounding soft part tissues by means of CT techniques. The result of this data acquisition procedure is made available in single images in the DICOM format. The next step is to read these images by means of VoXim® [14]. The following step is 3D soft tissue segmentation, wherein materials of different density, such as soft tissue and bone, are separated from each other. Afterwards, a faceted 3D model of the segmented bone regions is output in the STL format. This model is important for ongoing design.

Thus, discrete data is first made available. Now it is necessary to reverse these data into a solid model of mathematically correct representation for CAD modelling. To do this, the faceted data are processed with the Geomagic Studio [15]. The polygons are subject to various repair- and filtering measures. Here, the following steps are to be run in order:

- Diversify (deletes stand-alone object regions)
- Remove peaks
- Repair cuts
- Smooth
- Manually rework

At this point, we also define a uniform co-ordinate system and the cutting planes in co-operation with the surgeon. These cutting layers define the region that is to be removed in surgery and replaced with an implant. In this cutting region, the contour of the inner bone structure, the cancellous bone, is reversed as a Spline curve and simultaneously stored separate from the lower jaw model. This information is significant, among other things, for the definition of the positions of the holes that will later hold the implant in place. These positions should be in the region of maximal layer thickness of the corticalis (outer bone region).

In the strictest sense, Reverse Engineering describes the procedure of 3D digitising of workpieces with sculptured surfaces, conditioning the 3D point data and converting them to CAD models [16]. Positive results will only be obtained by 3D data recording in conjunction with qualified and problem-oriented data conditioning and application in the follow-up computer-aided strategy. Another equally important fact is that the CAD representation successfully withstands production planning, manufacturing and quality inspection [17].

Reverse engineering is performed then to generate a parametric solid model. The solid model is stored in the STEP format and is now available for design. The path from physical object to CAD solid model is represented in Figure 3.

2.2 Design of the individual implant

Current designs of implants that are identical in contour orient themselves to the organic bone structure configuration. They consist of an outer mounting shell design and an inner filigree tissue structure. The designed outer shell of the implant correspondingly follows the contour of the removed jaw region. Manufacturing technology allows this to be very thin in shape in order to reproduce the stiffness and strength of the bone. Thin-walled envelope geometry of about 0.3 mm thickness is realized; thickness in the areas attached to the residual bone is 0.4 mm.

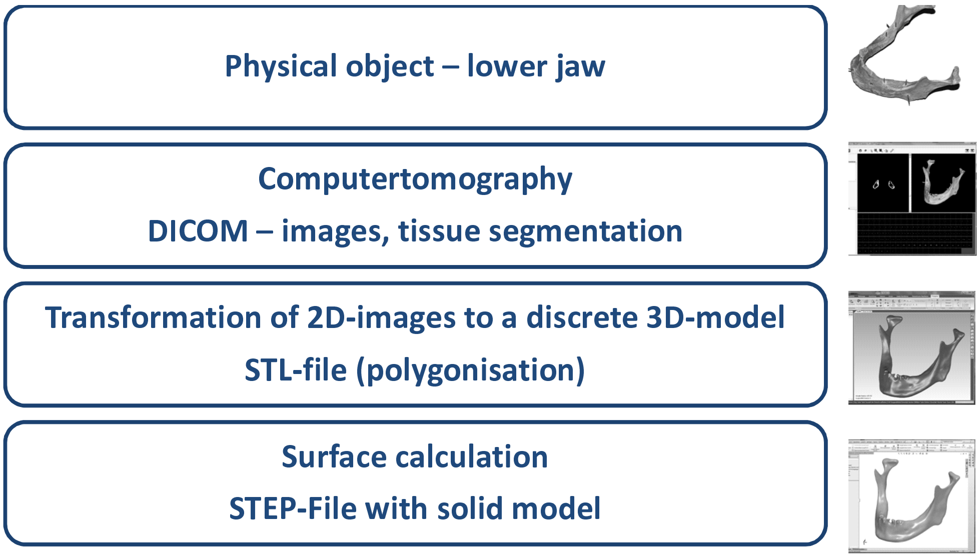

Figure 3: Sequence from physical object to CAD solid model [15]

In cases that the tumour destroyed the bone, there is no useful geometry. Therefor a database, containing characteristic curves, is planned (Figure 4).

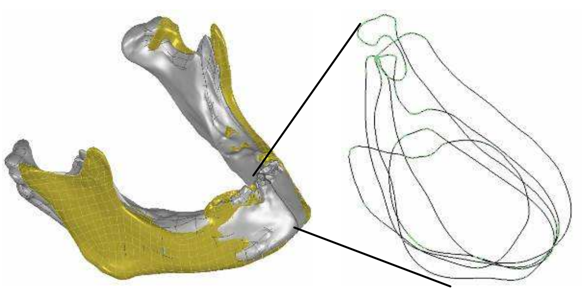

Figure 4: left: Registration of 5 different jaws, right: curves after virtual jaws cutting in position between tooth 31 and 41

It is also possible to intentionally include discontinuities in the enveloping geometry.

The shell design makes it possible to implement an inner filigree structure as well. These structures inside the implant are expected to offer greater reliability in the bone regeneration. In this approach, these structures may have a different geometric shape, as well as stochastic discontinuities and different dimensioning.

Design is carried out considering the positive contact with the residual jaw on both sides. In general, we are investigating two different ways to attach the implant to the residual jaw (Figure 5). The first connecting type (Figure 5, left) is based on a variant in which the implant is secured to the outer lower jaw contour. In the second variant (Figure 5, right), the implant is shifted into the bone and cemented with a suitable bone substitute material. The choice of variant must be based on the individual case.

The principal design procedure for an individual implant is described below using the variant in which the implant is attached to the residual bone:

- Insert section layers in lower jaw model
- Section the jaw model
- Prepare lower jaw stubs of residual bone (remove milling region)
- Transfer surface information of the milled overlapping regions
- Offset surfaces by wall thickness value
- Define length of the overlapping regions for the implant
- Fill in enveloping geometry according to the cut section of the jaw regions
- Insert inner filigree structure.

Before repairing the defect with an implant, it is necessary to remove the corresponding jaw region in a surgical operation. The section layers required have already been defined virtually in an earlier step. Since the operating team does not have access to these virtual layers during implantation, the position of the section layers is predefined in the form of cutting templates (Figure 6). These templates guarantee an unambiguously positive contact at the jaw. Figure 7 demonstrates one variant of the attached implant to the pig cadaver jaw.

The cutting templates are also designed with the CAD model of the lower jaws. Beginning with the parting planes where the resection will be performed, the adjacent surfaces are derived. From this, we create a two-piece body. One lateral surface of the body is used as the cutting surface along which the medical doctor moves the saw. Two-piece performance is necessary in order to secure the cutting templates to the jaw and to prevent undercuts.

Afterwards, the design results are also subject to finite element analysis to evaluate the implant's stability. We calculate using various extreme values due to the different strength values for the bone that are necessary for the computations. Finally, mechanical strength trends can be abstracted.

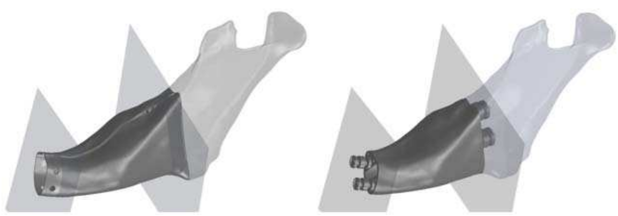

Figure 5: Different implant variants, left outer attachment to the residual bone, right inner attachment to spongious tissue

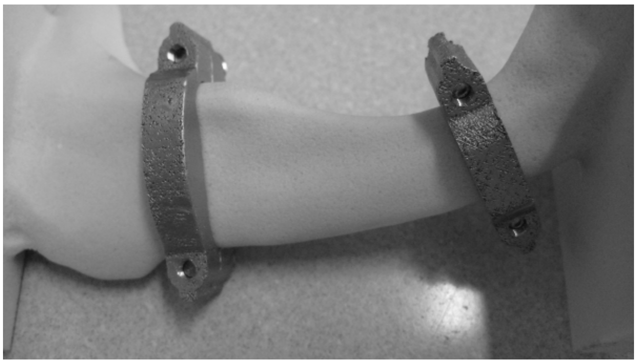

Figure 6: Cutting patterns, made by Direct Manufacturing, here in the model test carried out on a model of the lower jaw

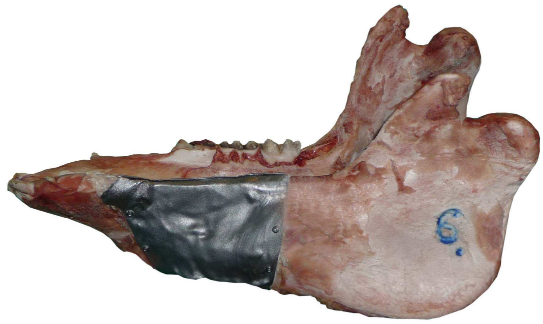

Figure 7: Implant was attached to jaw of pig cadaver, connecting type is based on a variant in which the implant is secured to the outer lower jaw contour.

2.3 Production planning and manufacturing of the implant

The implants are produced by means of LaserCUSING®, which is a generative technique based on amorphous material, such as powder. In this way, LaserCUSING® is able to produce functional models. The material characteristics obtained are commensurable with those of the series material and make it possible to use the parts thus produced even under the conditions of production. LaserCUSING® is a technology that works using a layer-by-layer technique, wherein layer thickness values vary from 30 µm to 50 µm.

Depending on the technology and the material, it is very difficult or simply impossible to produce surfaces lying under an angle of 45° to the building plate. For these surfaces, we need special supporting structures which have to be generated in the CAD system and later on by means of Magics®, which is a type of Rapid Prototyping software.

First, the implant is placed in the CAD system just as it is to be built in the LaserCUSING® system. Then it is shifted in Z direction by 0.5 mm so that is can be removed from the building platform by means of wire erosion later on. Thus it is possible to add the supporting structure to the overhung surfaces. After the building procedure, this supporting structure has to be removed again. For this reason, this additional structure should be kept as small as possible in order to reduce necessary rework. Afterwards, the implant model is exported as an STL file. Magics® is used to generate the remaining supporting geometry. The parameters for this supporting structure have to be dimensioned and modified as a function of the shape type and position. As a function of the focus diameter, the supporting structure is only fused in the building process as a line structure. Consequently, it may be easily removed afterwards. After this step, these generated data are virtually cut into layers. The LaserCUSING® system is filled with pure titanium powder and fitted with a titanium plate intended to be use as a building plate. Manufacturing of the mandibular implant using pure titanium, is a technological challenge since it requires inert gas. In contrast to other body regions, however, for the oral and maxillofacial zones, pure titanium is preferred due to allergic reactions.

Next, the layer data are entered into the software of the machine, and the implant is positioned on a virtual building plate. The implant and the support structure are assigned the corresponding manufacturing parameters. Thereby, laser power and rate are defined, among other parameters. The entire process, from setup to removal, is performed in an inert gas atmosphere to guarantee manufacturing free of oxidation.

In the first step, the building plate is lowered down by one layer element, and new powder is introduced. In the next step, the powder is surfaced with a lamination plate (coating). In the last step, the deposited powder coating, which has a constant thickness, is selectively fused by laser (exposing). This procedure is repeated until the component is complete.

After completion of the building procedure, the building plate is removed, and the implant erodes from the plate. After that, the support geometry is removed and the implant is cleaned.

Building of the cutting patterns is performed analogously, with the difference that stainless steel, processed in a nitrogen atmosphere, is used as material.

Figure 8 elucidates examples for an implant made of titanium and the corresponding drilling patterns made of stainless steel to be secured to the bone.

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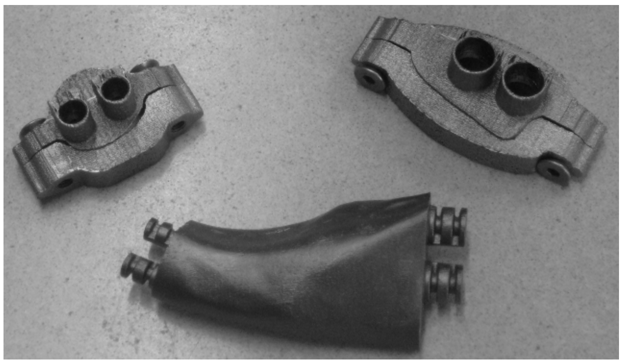

Figure 8: Direct Manufacturing - jaw implant created with laserCUSING® , made of titanium and drilling patterns (stainless steel) for attachment to the spongious tissue

3 SUMMARY AND OUTLOOK

The process chain introduced here shows the path from the CT image of a diseased patient via design of individual implants to the production of titanium implants by means of generative manufacturing techniques. This approach has been tested in eight lower jaws of pig cadavers, one human model lower jaw and two macerated human lower jaws up to now. Further operations were performed on the jaws of 10 living test animals (miniature pigs). So it was carried out, how the titanium implant is attached to the residual bone, the positions of the number of screws and the usability of the tools (Figure 9).

Figure 9: Titanium implant for outer attachment and cutting patterns to the residual bone of living animal

The results of these experiments show that we have succeeded in achieving a general fitting accuracy. At present, we are testing the process chain in animal experiments and are verifying the suitability of the implants in living beings.

It takes about 32 hours to carry out the entire process to produce individual implants. This span includes 7 working hours to prepare the CT data for the solid model of the jaw region. 13 hours are required to design the implant and the cutting patterns, while 12 hours are allotted for production planning and manufacturing.

In the future, the process may be optimised in the field of CT layered image processing. Process time should be positively influenced by segmentation and creation of the 3D model of the lower jaw. Adequate interpolation and filtering methods should contribute to higher data quality. Design of implants and cutting patterns should be improved by the generation of new software tools. To keep lead times to a minimum, we are currently optimising the support structures and their process parameters for production planning and manufacturing. The coating system is also subject to continuous improvement.

Other recent research topics focus on the computer-aided modelling of inner filigree support structures that stimulate growth. In the future it is expected that such structures will be efficiently created in an automated manner using a CAD system. A stable attachment to the residual bone is essential to the function of the individual implant. The presentation outlines possible design variants. In design, strength, biocompatibility and operating conditions are to be considered. Future tests will determine the stability of these connections. The authors are currently developing a test bench for investigations of the jaw model. The test bed is also used to validate the results obtained in the FE analyses.

4 ACKNOWLEDGMENTS

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