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Comparative Study of patient individual implants from β-tricalcium phosphate made by different techniques based on CT data

Vergleichende Untersuchung patientenindividueller Implantate aus β-Tricalciumphosphat hergestellt mit unterschiedlichen Techniken basierend auf CT-Daten

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Bone substitution or bone augmentation with synthetic materials (e. g. β-tricalcium phosphate materials, β-TCP) is usually done by standardized material shapes: block materials can be individually shaped by the surgeon for the specific defect situation. Granular materials are used for more complicated and hardly accessible defect situations. The granulate is mixed with blood. Also injectable putty materials are available.

The disadvantage is that none of these material modifications can guarantee a complete and strong press fit contact to the surrounding bone in complicated defect situations, which is essential for a complete and successful bone regeneration. The treatment of complicated defects where mechanical stability is necessary but not viable with a granular material (e. g. large mandibular defects) is therefore difficult.

Especially defects where surgeries have a longer planning horizon (e. g. bone tumours, cysts) can be treated with custom made patient individual implants. CT data can be converted to three dimensional CAD/CAM data for shaping or prototyping the implant.

For a manufacturer of bone augmentation materials also economical questions are necessary to solve for the decision, whether this technology can be an interesting possibility for the treatment of defect situations as described above.

Two different techniques for making patient individual implants from β-tricalcium phosphate with three-dimensional fabrication methods were experimentally realised and estimated.

Custom made porous scaffolds were produced by using conventional shaping techniques as well as rapid prototyping methods.

Keywords: Patient individual implants, Rapid Prototyping, Tricalcium Phosphate, Block Forms, 3D-Printing

Knochenersatz bzw. Knochenaufbau mit synthetischen Materialien (z. B. β-Tricalciumphosphat, β-TCP) wird normalerweise mit standardisierten Geometrien durchgeführt. Formteile können durch den Chirurgen individuell dem Defekt angepaßt werden. Granuläre Materialien werden für kompliziertere und schwerer zugängliche Defektsituationen verwendet. Weiterhin sind auch injizierbare, pastenartige Materialien erhältlich.

Nachteilig bei all diesen Materialmodifikationen wirkt sich aus, dass keine der Modifikationen einen vollständigen und starken Kontakt mit dem umgebenden Knochen in komplizierten Defektsituationen garantieren kann, was für eine komplette und erfolgreiche Knochenregeneration notwendig ist. Die Behandlung komplizierterer Defekte, bei denen eine gewisse mechanische Stabilität notwendig ist, die aber mit einem granulären Material nicht durchführbar ist, gestaltet sich daher schwierig.

Speziell Defekte, bei denen Operationen über längere Zeithorizonte geplant werden können (z. B. Knochentumore, Zysten), können mit patientenindividuell angefertigten Implantaten versorgt werden. CT-Daten können in dreidimensionalen CAD/CAM-Daten konvertiert werden, um ein Implantat zu formen oder zu drucken.

Für einen Hersteller von Knochenaufbaumaterialien sind wirtschaftliche Fragestellungen ebenso notwendig, um die Entscheidung zu fällen, ob und welche Technik eine interessante Möglichkeit zur Behandlung oben genannter Defektsituationen darstellt.

Zwei verschiedene Techniken zur Herstellung von patientenindividuellen Implantaten aus β-Tricalciumphosphat wurden vergleichend experimentell durchgeführt und bewertet.

Dreidimensionale Architekturen kundenspezifischer poröser Materialien wurden sowohl mit konventionellen Frästechniken, als auch mit der aufbauenden Methode des Rapid Prototyping hergestellt und verglichen.

Schlüsselworte: Patientenindividuelle Implantate, Rapid Prototyping, Tricalciumphosphat, Formkörper, 3D-Drucken

1 Introduction

Since the early 70ies biomaterials made from β-Tricalcium phosphate (β-TCP) are widely in use [1-2]. The knowledge about the manufacturing of β-TCP bone augmentation materials increased rapidly during this time. Resulting from the first experiments, the fundamental principles for making a risk-free biocompatible, osteoconductive, resorbable bone augmentation material from β-TCP are identified [3-4]. Today all this knowledge and experience was combined to form a resorbable β-TCP biomaterial named Cerasorb®. Different modifications of Cerasorb® are available: Round shaped Cerasorb® granulate with 35 % porosity, gravel-like Cerasorb® Perio/Paro for periodontal defects with a lower porosity (25 %), the highly porous (65 %) Cerasorb® M granulate with meso- (50-100 μm) and macropores (>100 μm) embedded in an interconnecting network of micropores (<50 μm) and Cerasorb® as well as Cerasorb® M block forms in standardized shapes all following the fundamental principles of a resorbable, biocompatible and risk free synthetic biomaterial[5].

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For irregular defects granular materials can be used. The biomaterials have to be mixed with fresh blood from the defect. Induced by air and calcium from the biomaterial the material is moldable, caused by blood coagulation and can be smoothed inside the defect.

For more standardized surgical treatments or more "regular" defects the block forms can be used and shaped individually by the surgeon to adapt the block on the special defect situation. Despite of these different material modifications there is a lack in terms of patient individual implants shaped or formed by a milling machine or rapid prototyping devices adapted on special complicated defect situations. Such custom made implants would have the advantage of a direct contact with the surrounding bone (press fit) which is essential for a successful bone regeneration. Furthermore, the handling would be much easier for the surgeon. Surgical treatments with a longer planning horizon can be planned individually, a custom made implant can be shaped as well as a template for the direction of the chirurgical cut.

Based on the principles of β-TCP biomaterials custom made implants were done with two different techniques: The conventional milling as a material removing method and Rapid Prototyping (Free Form Fabrication) as a material building method.

2 Materials and Methods

2.1 β-TCP material

For all kinds of custom made implants pure phase β-TCP powder was used. The material was manufactured in a solid state reaction out of calcium carbonate and calcium hydrogen phosphate as described in eq. 1:

$$CaHPO_4 + CaCO_3 \rightarrow Ca_3(PO_4)_2 + CO_2 + H_2O \qquad \text{(eq. 1)}$$

The raw material was isostatically pressed and heated to $>1000\,^{\circ}C$ for 8 hours. After sintering the fully reacted material was grinded, milled and sieved to a particle size of < 63 μm. By using Xray diffractometry the phase purity of the β-TCP was proved [6].

For the milled block forms the powder was cold isostatically pressed for making blank rods; this step is not necessary for the Rapid Prototyping process were implants are made by stepwise building of powder layers.

2.2 CT data and CAD/CAM planning

The process chains normally begin with the recording of the patient defect using computed tomography (CT). Afterwards a 3D-defect model is generated by an image processing software based on the single CT-images. Finally, the defect can be selected out of this model and the implant can be modeled specifically to the patient (see figures 2 and 6).

The transformation for Rapid Prototyping (3D Printing) implants takes place on the basis of patient specific data in connection with the DICOM image processing software Voxim of the IVS-Solutions AG Chemnitz and the CAD-program Pro/Engineer.

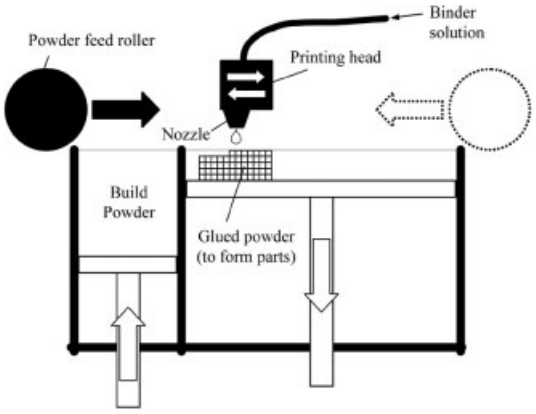

Figure 1. Principle of 3D printing
Abbildung 1. Prinzip des 3D-Druckens

2.3 Virtual planning of the surgical treatment

For the milled block forms the surgical treatment was planned using the program SimPlant® from Materialize: A piece of the lower jaw (mandible) was virtually cut (see figure 2), followed by CAD construction of the individual implant (see figure 3). For this, the teeth had to be removed first (see figure 3 step A to step B), before a porous network could be added in the growth direction of the bone (figure 3 step B to C). The block form for milling and the milling process was planned using the CAD/CAM software Mastercam 9.0.

2.4 Milling process

Outgoing from blank rods pressed cold isostatically from pure phase β-TCP powder as described before, the individual block form was milled using a KERN HSPC milling machine. After the milling process the block form was washed in an ultrasonic bath followed by an additional sintering process to stabilize the scaffold after the milling process which can cause microcracks in the β-TCP scaffold decreasing the mechanical stability [8].

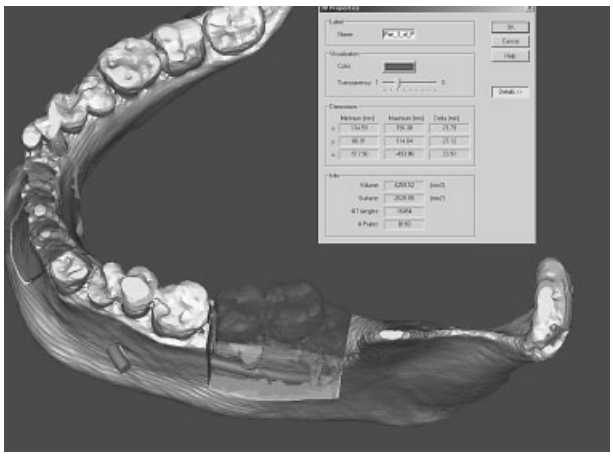

Figure 2. Virtual osteotomy at the 3D model of the lower jaw (Mandibula)
Abbildung 2. Virtuelle Osteotomie am 3D-Modell des Unterkiefers (Mandibula)

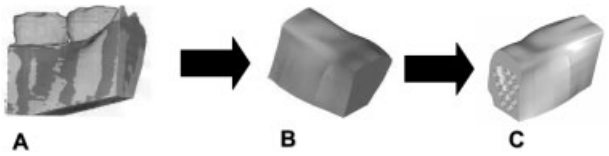

Figure 3. Virtual CAD processing steps on the osteotomied parts. A: as-cut mandible part, B: substracting the teeth, C: ready designed block form with unidirectional drilled pores in growing direction of the mandibular bone

Abbildung 3. Virtuelle CAD-Bearbeitungsschritte am osteotomierten Knochenstück. A: aus dem Kiefermodell geschnittenes Teil, B: nach Substraktion der Zähne, C: fertiges Formteil mit unidirektionalen Bohrungen in Wachstumsrichtung des Kiefernknochens

2.5 Rapid Prototyping (3D Printing)

For Rapid Prototyping patient individual implants a 3D printer Z 402 by ZCorporation was used. For binding the β-TCP particles a polymeric organic binder was used. The principle of the process is based on the stepwise addition of a new layer of β-TCP powder. The organic binder was squirt from the printing head on the areas, powder particles have to bind together forming the block form (see *figure 1*). Different process parameters were varied:

- Binder's core and shell saturation: A ratio of 1:1 to 2:1 led to mechanically most stable block forms with highest dimensional fit. A too high core-to-shell-ration led to wet block forms with incorrect dimensions caused by flowing effects of the binder across the powder bed.
- Location of parts in the construction area of the 3D-printer: The mechanical stability increases with increasing z-axis as described by the manufacturer.
- Oven-temperature and time for drying: 45 minutes drying time led to a compact block form mechanically stable to blow out the pores by pressurized air.

After the drying process a sintering process at $>1000\,^{\circ}\mathrm{C}$ was performed to burn out the binder and to sinter the particles together.

3 Results

3.1 Milled block forms

Using the surgical treatment planning software CT data of a the lower jaw (mandible) were used and a virtually osteotomy on two positions was carried out (see *figure 2*). The virtual cut bone part was CAD processed to substract the teeth and to design a block form for a high pressfit dimensional accuracy (see *figure 3*). Holes were virtually drilled in direction of the growing bone. After these steps the virtually modelled implant can be converted into STL data for manufacturing the individual block form by CNC machining.

The finished block form fits with high dimensional accuracy in the resected bone part. Simultaneously a positioning device (template) for surgery was manufactured. Therefore also a high dimensional accuracy by bone resection (osteotomy) and the dimensional fit of the finished block form can be ensured (see *figure 4*). The final sintering step after milling the block forms leads to a shrinkage of about 2 % in all dimensions. This shrinkage has to be taken in account before planning the manufacturing of the block forms.

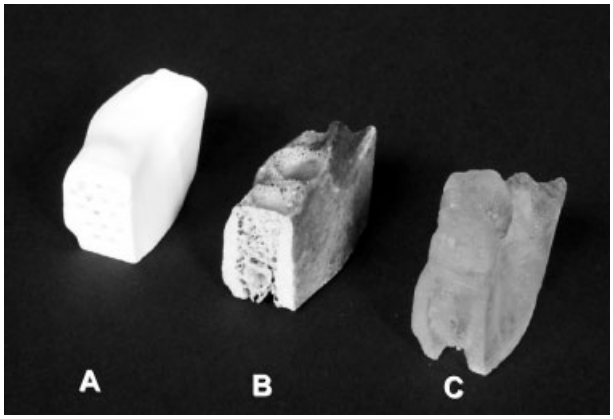

Figure 4. A. Finished milled custom made block form, B: Resected bone part, C: Template/positioning device for surgery

Abbildung 4. A. Fertig gefrästes individuell gefertigtes Formteil, B: Entfernter Knochen, C: Positionierungsschablone für Operation

3.2 3D Printed block forms

By using the software Voxim, complicated scull defects were virtually treated. Using a three dimensional CAD model implant an interconnecting network was substracted resulting in a macroporous scaffold (see *figure 5* and *6*). After conversion into STL data the file was transferred to the 3D printing machine.

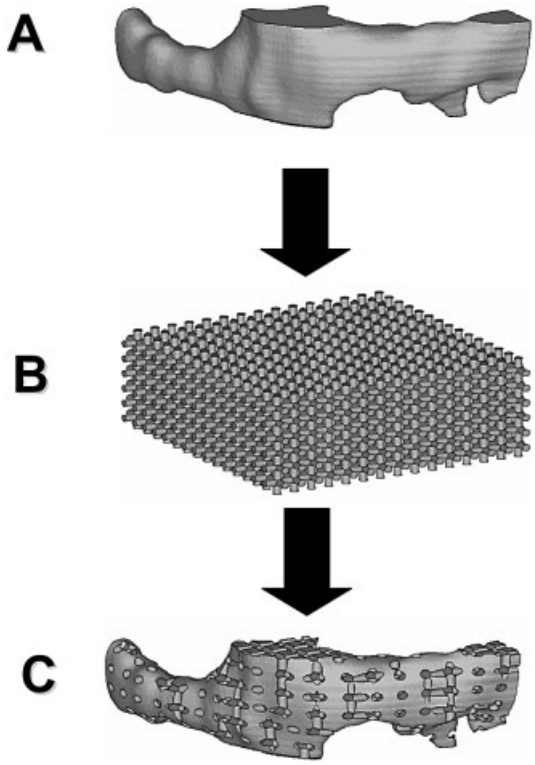

Figure 5. Virtual construction steps of 3D printed custom made implants: A: CAD designed bone part from CT data, B: Interconnecting network, C: Macroporous implant after subtraction network

Abbildung 5. Virtuelle Konstruktionsphasen der 3D gedruckten patientenindividuellen Implantate. A: mittels CAD konstruiertes Knochenstück, B: Interkonnektierendes Netzwerk, C: Makroporöses Implantat nach Subtraktion des interkonnektierenden Netzwerks

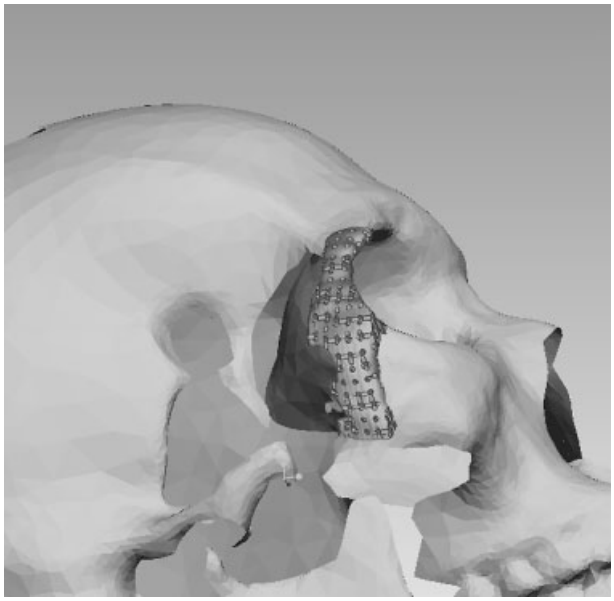

Figure 6. Virtual adjustment of the implant in CT scanned skull
Abbildung 6. Virtuelle Anpassung des Implantats im CT-gescannten Schädel

The 3D printing process is, unlike the milling process, a generative building process: out of a pile of powder, particles will be glued together. The non-glued remaining particles can be reused. Therefore, the production yield is with about 90 % (optimized) much higher than the milling process (about 20 % yield).

The building parameters can be varied within a wide range. The binder concentration was shown as an important factor of dimensional accuracy: too low binder concentration leads to irregular custom made block forms caused by irregular flow of the binder inside of the powder pile. Too high concentration leads also to irregular and brittle scaffolds caused by blocking the inkjet printer.

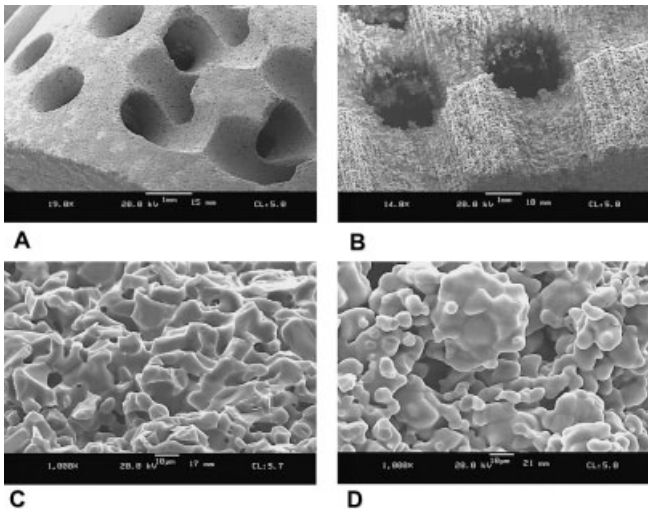

Figure 7. SEM comparison of milled (A, C) and 3D printed block forms (B, D). Magnification: A: 14 X, B: 19X, C, D: 1000X
Abbildung 7. REM-Vergleich von gefrästen und 3D-gedruckten Formteilen. Vergrößerung A: 14X, B: 19X, C, D: 1000X

Different powder particle sizes were used for printing block forms. A d_{50} value of 10 μm led to mechanically brittle block forms whereas powder samples with $d_{50} \geq 14$ μm led to a more homogeneous powder bed caused by its better flowing ability. As a consequence, printed block forms from this higher-sized powder were mechanically more stable.

After the 3D printing process the post processing or finishing (laying open implants, drying, blowing out pores by pressurized air) takes place. In this stage the implant is mechanically brittle. After drying in a final sintering step the already glued particles are sintered together forming a microporous scaffold with adaequate mechanical stability of 2-6 MPa (Cylinder) which complies with the values of human trabecular bone. Resulting from burning the organic binder in combination with sintering the particles the shrinkage was 5 % in all dimensions.

4 Discussion

The XRD spectra of both materials show pure phase β-TCP, fulfilling the specifications of a β-TCP for surgical implantation and the internal specification for a $\geq$ 99 % phase pure β-TCP [9-10]. Using milling methods as well as 3D-Printing leads to dimensional accurate block forms when the shrinkage by sintering is known and calculated. Main differences were found in the manufacturing time (see *table 1*), the waste and the mechanical stability (see table 2). Unlike the 3D printing technique, the CNC machine has to be additionally programmed: The machining conditions and particularly the order of processing steps have to be considered. The high stress on the material during the milling process can necessitate drilling the macropore holes as the final step to avoid breaking of the material. Depending on the machine size a higher amount of block forms can be made by 3D printing in one step whereas the CNC machine is only able to make one block

Table 1. Comparison of manufacturing time for milled and 3D printed custom made block forms from β-TCP
Tabelle 1. Vergleich der Herstellzeiten für gefräste und 3D-gedruckte patientenspezifische Formteile

Manufacturing time	**Milled block forms**	**3D printed block forms**
CT scan	Approximately 1 day	
Implant modelling		
STL file transfer		
Machining	Programming CNC machine: 1 day Milling: 1 day	Rapid Prototyping: 1 hour Finishing (post processing): 2 hours
Sintering	4 days	
Packing	1 hour	
Sterilization by γ-radiation	7 days	
TOTAL (approx.)	**14 days**	**12 days**

Table 2. Comparison of the characteristics of the milled block forms and the 3D printed block forms

Tabelle 2. Vergleich der Eigenschaften der gefrästen und der 3D-gedruckten Formteile

Milling	Rapid Prototyping
Fulfil the requirements of beta-TCP biomaterial (phase purity) [9], [10]	
Waste $\geq$ 80 %	Waste $\leq$ 10 %
Regular particle scaffold forming an interconnecting microporous system	Low particle coherence leads to areas with higher and lower porosity
Good mechanical stability (Cylinder $\sim$ 110 MPa)	Low mechanical stability (Cylinder $\sim$3-4 MPa)
High dimensional accuracy	Lower dimensional accuracy
Special forms, higher mechanical stability, more accurate	Applications in not high loaded sites and without the need of high accuracy

form in one step. Significant disadvantages of 3D printed block forms are the lower dimensional accuracy and the lower mechanical stability caused by the gluing process in contrary to the strong pressing and machining process used by making the milled block forms. Moreover, the accuracy and porosity of both manufactured block forms show remarkable differences. The milled block form is more accurate the surface appears smoother and more regular, caused by the cold isostatic pressing before milling (*figure 7* A in comparison with figure 7 B). Also the homogeneity of the primary particles which are sintered together forming the microporous β-TCP scaffold (figure 7 C and D) is higher by exploring the biomaterials at higher magnifications.

The porosity of the printed block forms were not dependend on the building parameters and was about 35-40 Vol.-% (milled block forms 25 Vol.-%) at a density of 1.3-1.4 g/cm^3 (milled block forms 1.2 g/cm^3).

Table 2 shows the comparison of advantages and disadvantages of both techniques. If a mechanical more stable block form with higher dimensional accuracy is needed and a higher manufacturing time can be accepted, the milling technique should be chosen. Higher porous material, shorter manufacturing time, a higher amount but mechanical more brittle β-TCP biomaterials can be produced by using Rapid Prototyping techniques.

5 Literature

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