

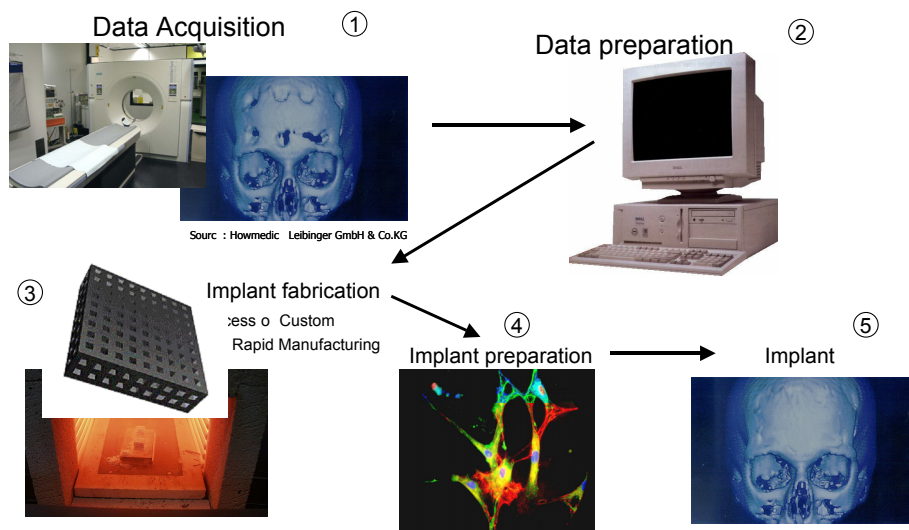
## FABRICATION OF SCAFFOLD STRUCTURES BY RAPID PROTOTYPING METHODS

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### 1. Introduction

This study aims at the creation of a porous artificial extracellular matrix or scaffold to accommodate cells and guide their growth and tissue regeneration in three-dimensions (3D). These scaffolds should be created individually for each patient, with interconnected porosity, controlled porosity and pore distribution. Furthermore the mechanical strength depends on the 3D structure of these scaffolds.



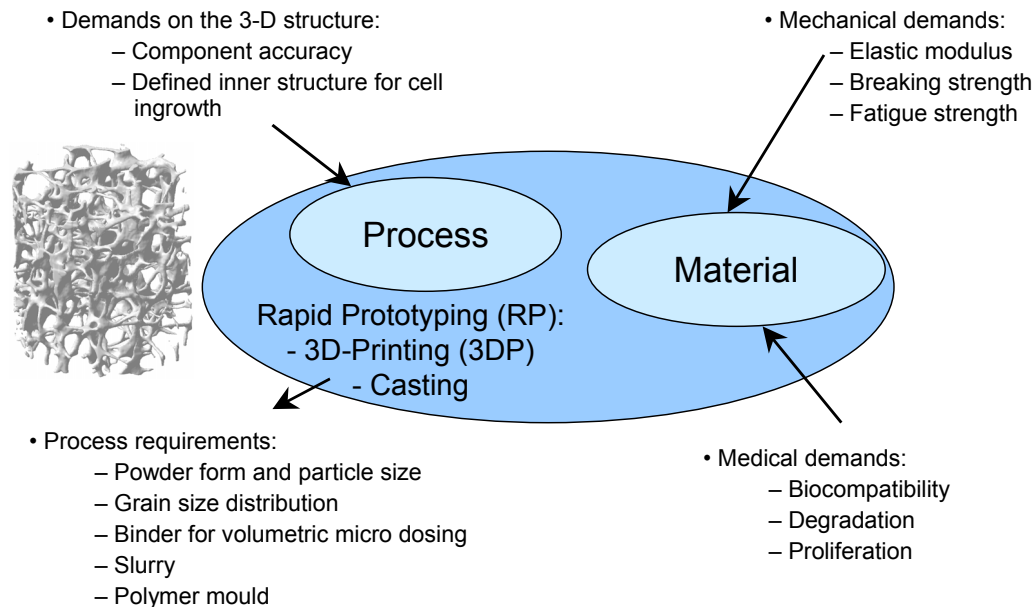
**Figure 1. Principle process sequence**

The research group Fortepro is developing processes for fabricating these scaffolds. These implants will replace bone defects at the head and musculoskeletal system. They are made by hydroxyapatite (HA) and should be replaced by endogenous bone material after implantation by building new tissue. A key requirement in this field is the development of scaffold structures on which cells can adhere. The aim of the institute "Feingerätebau und Mikrotechnik" is to fabricate these scaffolds with controlled internal porosity.

Therefore the Rapid Prototyping (RP) technique is used. Figure 1 shows the principle of the process sequence. In a first step data from the defect is collected with computer tomography (CT). Then the three-dimensional geometry of the implant is designed with a special software and converted in a standard triangulated language (STL) file [Sun 2002]. With the two different RP processes 3D-printing or casting, the implant geometry is produced and prepared with cells [Taboas 2003]. Now the prepared scaffold can be implanted in the patient.

## 2. Demands on the implants

The demands on the 3-D structures are very important for the later implantation (Figure 2). Part accuracy is the basic requirement for implantation at the bone defect. Another intention is a defined inner structure for cell growth and flow transport of nutrients and metabolic waste [Hollister 2002]. Mechanical demands are also important, desired is an elastic modulus, breaking strength and fatigue strength with values similar to those of natural bones [Koch 2000]. But for the first step it's sufficient if the doctor is able to handle and implant it.



**Figure 2. Demands on the implant**

Medical demands are also important. For example, biocompatibility and proliferation are some critical, but manageable factors. The degradation of the implant depends on the used material and is only particularly achievable at the moment.

## 3. Processes

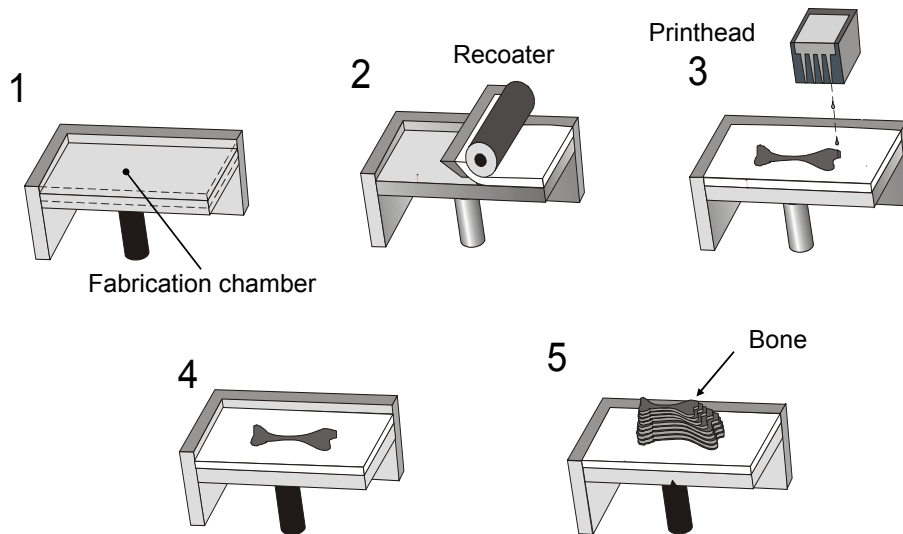
To reach these aims Rapid Prototyping technology has to be used. Therefore it was decided to modify the 3D-printing technique and the casting process with moulds, produced by stereolithography and 3D-printing processes.

### 3.1 3D-printing

This process creates parts by a layered printing process with adhesive bonding, using powder as a base material. After loading the STL-file, which defines the geometry and the interconnecting pores, the software of the Rapid Prototyping machine slices the three-dimensional data into two-dimensional pictures according to the cross-sectional area of the object.

Each layer of powder is selectively joined where the scaffold is to be formed by ink-jet printing of a binder material. This process is repeated layer by layer until the scaffold is complete (Figure 3). This printing process requires a special powder form and particle size with a grain size distribution, which depends on the required resolution. The major problem is to choose an appropriate binder for micro dosing. The used hydroxyapatite powder is spray dried with particle sizes between 100–200µm diameter for this process. The binder, which interconnects the powder particles, was also specially developed for this process. Each powder layer is about 200µm thick and finished with a counter rotating roll, which sleeks the HA. The micro dosing of the binder is realized with a piezoelectric drop on demand system, derived from an institute internal-development. Therewith it became possible to

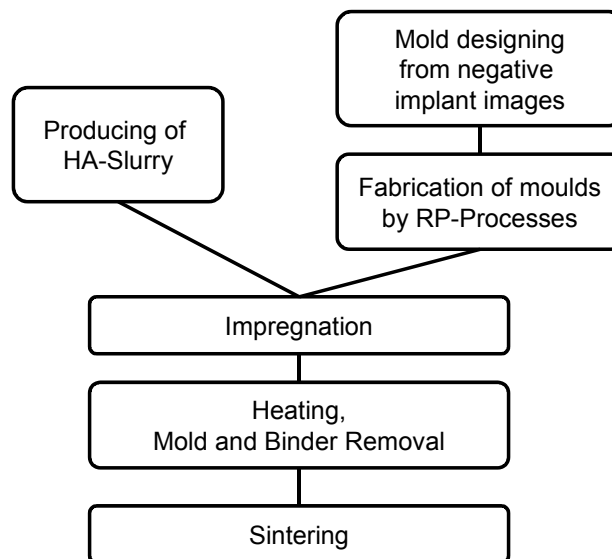
insert drops with a diameter of 60-80µm into the powder bed. Afterwards the printed 3D structures are sintered to HA ceramic and are proliferated with cells before implantation [Pelzer 2003].



**Figure 3. 3D-printing principle**

### 3.2 Casting

Figure 4 shows the flow chart of the implant manufacturing process by casting. On the left side the process of the hydroxyapatite suspension preparation can be seen. This is done by the Friedrich Bauer Institute, which is highly experienced in ceramic materials.



**Figure 4. Flow chart of the manufacturing process**

On the right side you see the investigation of the department of Feingerätebau und Mikrotechnik. The designing of moulds from negative images of implants and the fabrication of the moulds by RP processes. We are focused on the stereolithography as we expect the highest accuracy for getting the desired internal structure of the moulds. But there are also alternative RP methods like the 3D Wax printing process.

In the next step the prepared slurry is filled into the mould. Followed by a thermal process to remove the binder components of the suspension and to combust the mould. By rising the temperature up to 1250° Celsius the HA ceramic is sintered. After that the sintered ceramic is used as the implant.

## 4. Technical requirements

### 4.1 Casting

Despite of preparing a suitable slurry there are two main challenges. The designing of the mould and the filling process.

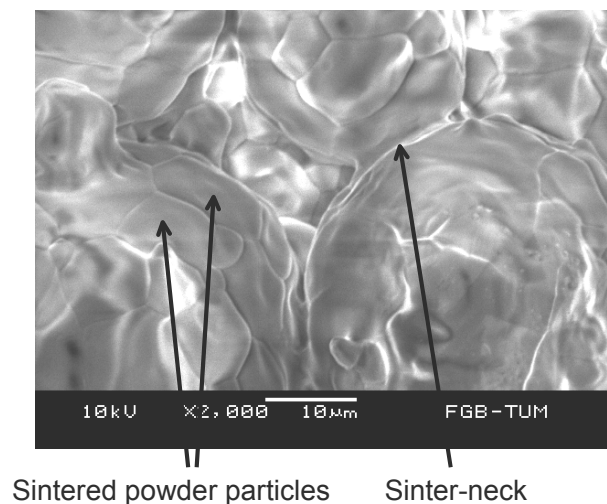
The design of the mould is strongly dependent on the design of the implant, where interconnecting pores for cell proliferation are demanded and channel size and wall thickness have influences on the strength of the implant. But due to the different thermal expansion coefficients between the ceramic slurry and the mould material, the design of the moulds also has a big influence during the heating process. The first results with described geometry in [Chu 2002] of sintered ceramics failed because of the thermal expansion. Furthermore the design must guarantee that the moulds can be impregnated without air bubbles.

For the filling process the vacuum-, the centrifuge- and the pressure/vacuum method have been investigated. This was necessary after the impregnation of the mould could not be sufficient improved by adding tensides to the slurry. One major question for the whole process is the influence of the toxic vapor on the ceramic parts during combustion the mould material. This can be done by chemical analyses or by analyzing the cell proliferation on the material. Therefore most types of available materials for the stereolithography had to be tested.

## 5. Results

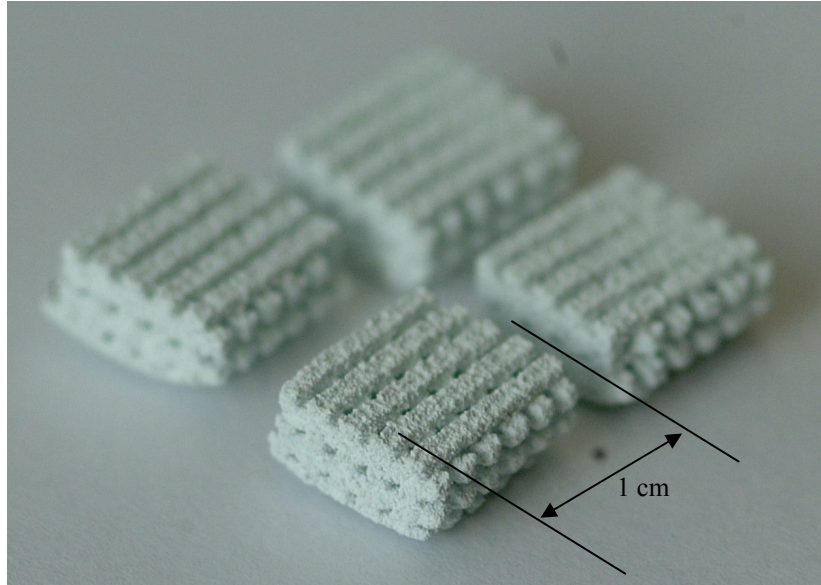
### 5.1 3D-printing

A new 3D printer was developed at the institute of “Feingerätebau und Mikrotechnik”. The first printed bodies have been fabricated without internal structure, but tests proved, that the green bodies can be sintered. On scanning electron microscope pictures (Figure 5) the sinter-necks between the agglomerates can be observed as well as the sintered powder-particles in the agglomerate. This result proves the feasibility of the process using this new material combination.



**Figure 5. Sintered necks between the spray dried particles**

The next step was the production of scaffolds with defined inner structures in three dimensions. The strength of the printed parts is low but after sintering at 1250°C they are solid enough for handling. The powder-binder interaction influences the strength of the part and the behaviour of the wetted powder. During the drying of the binder, mechanical tensions often cause warpage of the powder layer, which results in mechanical failures sometimes. By choosing the right powder-binder combination it was possible to decrease the warpage (Figure 6).



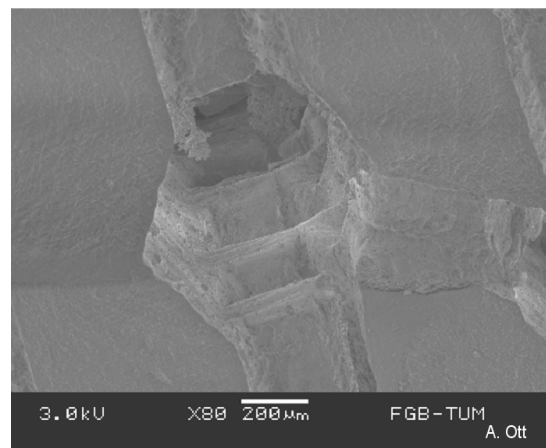
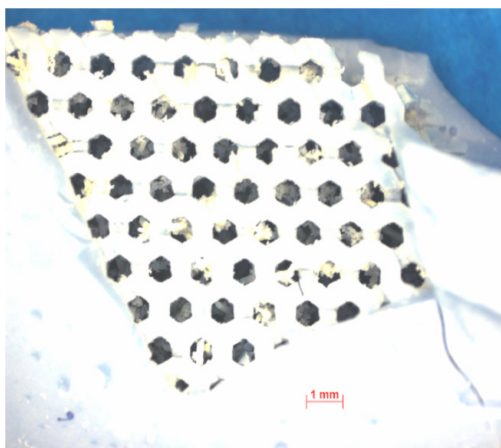
**Figure 6. 3D-printed ceramic parts with internal porosity**

Thereby the printing of the parts could be realised. Further investigation should account the physical cause of this warpage.

### 5.2 Casting

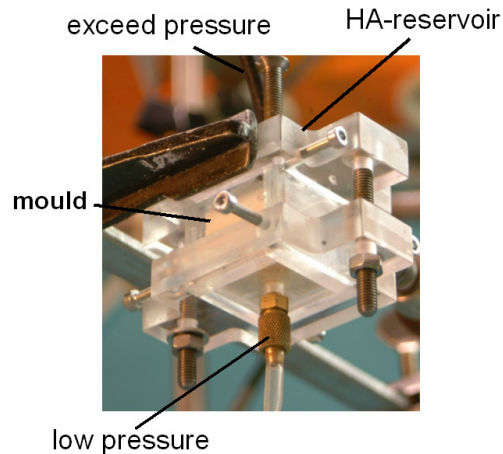
The desired channel and wall size of about 600µm can easily be achieved by using the SLS technology. But due to the thermal expansion and the exited stress it is necessary to keep the ratio of polymer to ceramic at less than 50 %.

Using a honeycomb with hollow blocks allows the reduction of the of polymer ratio dramatically and the filled mould is more suitable for the thermal process. With this design sharp edges can be avoided, which is better for cell proliferation and later filling processes.



**Figure 7. Ceramic parts with internal porosity**

Sintered probes of moulded HA implants show, that the structures of the moulds are reproduced in a very high accuracy (Figure 7). In the sintered probes single layers of the stereolithography moulds can be seen. The examined probes offer the expected characteristic of sintered ceramic.



**Figure 8. Filling station**

The pressure/vacuum method solved most of the problems during the impregnation of the moulds. The small cavities could be reasonably filled without any air bubbles. By using low pressure it became possible to dry the slurry during the filling process (Figure 8). This way swelling of the moulds by the water-based slurry was avoided.

With the EDX-analysis no toxic residues could be found at the surface of the ceramic parts. Even investigations with cell proliferation on the surface of the sintered parts show good results. The next investigations have to prove if the chosen wall and pore size are adequate for cell proliferation into the sintered implants.

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