From Patient-Specific MRI Data to Printed Implant Demonstrators Using Multi Material Jetting

The Multi Material Jetting technology developed at Fraunhofer IKTS/DE offers the opportunity to combine up to four matched materials within one printing process. One possibility of application is individual bone.

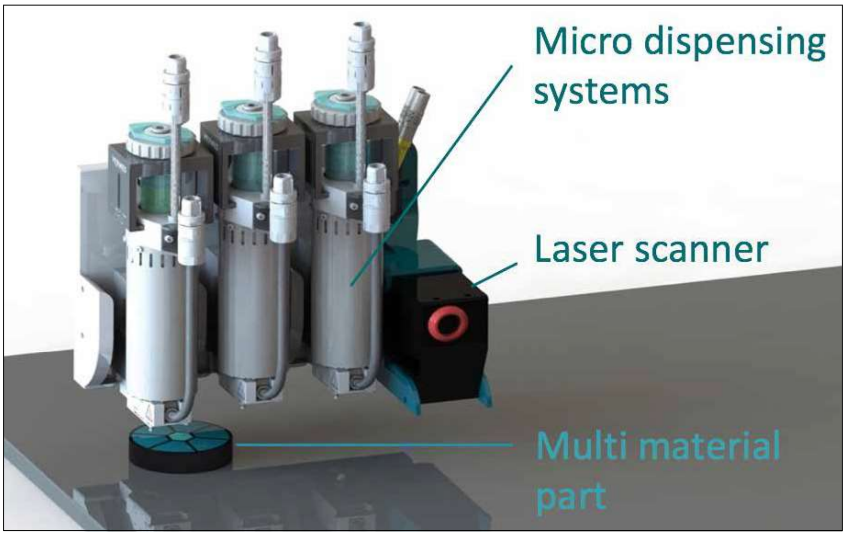

Fig. 1
Micro dispensing systems in the build space

Motivation

Due to demographic change and the increasingly aging population, the number of necessary bone reconstructions is also rising steadily. In Germany alone, more than 100 000 operations are performed on extremities and hips every year [1].

Up to now, in addition to the most commonly used autografts, synthetically manufactured implants have also been used as replacement structures in patients [2]. Due to the existing high postoperative complication rates and deficits in manufacturing, new solutions are constantly being sought. There is still a great need for research both in the choice of material and in the manufacturing process.

Keywords
additive manufacturing, multi material, multi functional, bone reconstruction

As a production method Additive Manufacturing (AM) is becoming increasingly important. On the one hand it offers the possibility to create implant structures with a porous designed interior and well-defined outer shape [3]. On the other hand, it allows the integration of medical imaging techniques, as MRI and CT, and thus the development of personalised implants. Based on this research need, the aim of this article was to implement a material that imitates the biomechanical properties of our bones and to use the advantages of Additive Manufacturing to produce an implant structure based on MRI data of a patient.

The Multi Material Jetting technology (CerAM MMJ) developed at Fraunhofer IKTS, with currently four print heads, offers the possibility to combine up to four matched materials within one printing process. With regard to the realisation of components with density gradients, this offers various possibilities. On the one hand, printing materials with different contents of pore-forming agents can be produced and combined in a defined way within a component [4]. Another possibility is the use of support material in places where there should be a greater porosity after sintering. The 3rd option is hybrid shaping, in which additively manufactured dense structures are combined with a defined porous foam.

Material

The material EvoCera® used is a novel biocompatible material powder developed in the LONGLIFE project (http://www.longlife-project.eu) funded by the European Community's 7th Framework Program (FP7/2007-2013) under the grant agreement n. 280741 and in the SISCERA project (http://siscera-project.eu), funded by E.U. (H2020-FTIPilot-2016, grant agreement n. 737954) and provided by DOCERAM: it combines the properties of high-performance ceramics with the ductility of steel [5]. The probably greatest advantage is the significantly lower strength scatter, which is reflected in a high Weibull modulus of 50 and the associated better predictability and thus possible FEM calculation. Where conventional ceramic materials break under overload, EvoCera®

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is predictably plastically deformable according to FEM calculations. This property gives the material an important reserve in safety-relevant components [6]. For this reason, it could also be of excellent use in the field of implantology. Previous artificial implant materials are often too hard or too brittle, like ordinary ceramics or bone minerals such as hydroxyapatite. EvoCera® offers a possible alternative to conventional implant materials due to its biocompatibility, its ability not to break immediately under overload, and its bending strength values similar to those of bone.

For processing the material within the Multi Material Jetting Technology, the powder was added to a thermoplastic binder system and rheologically characterised.

Shaping using Multi Material Jetting (CerAM MMJ)

The AM technology CerAM MMJ is based on the selective deposition of particle-filled thermoplastic suspensions. Filling with 75–96 mass-% or 40–60 vol.-% of ceramic or metallic particles enables the production of dense components (>99 % of the theoretical density) from ceramics such as zirconia, alumina, aluminium nitride, silicon nitride, LTCC, stainless steels such as 316L or 17-4PH or cemented carbides and cermets. Alternatively, it is possible to process pure or particle-reinforced polymers up to a melting temperature of approximately 170 °C. The droplet depositioning is performed by commercial Microdispensing Systems (MDS) which are shown in Fig. 1. Through the defined overlapping of dosed individual drops, it is possible to create line structures with defined characteristic values. These form the basis for the AM of layers and thereon more complex components.

The low viscosity in the molten state based on the binder system allows the deposition of very small volumes in the range of 0,5–1 nl and thus rapid solidification by cooling in fractions of a second. Since the components are manufactured drop by drop, it is possible to place individual droplets of different materials next to each other and thus manufacture multi-material components. This means that elements with integrated functionality can be produced quickly and easily, for example by combining insulating and electrically conductive materials.

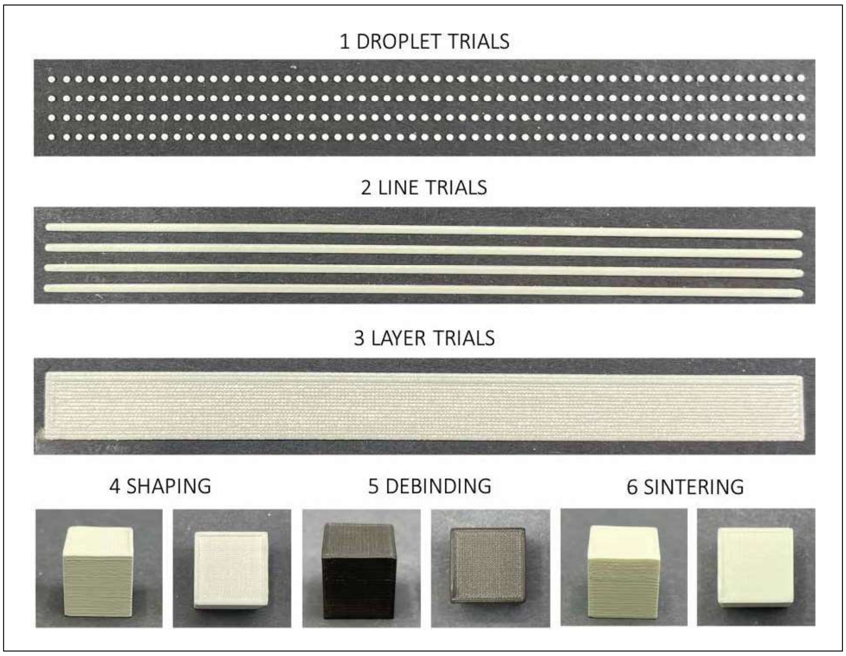

Fig. 2
Implementation of the new material EvoCera®

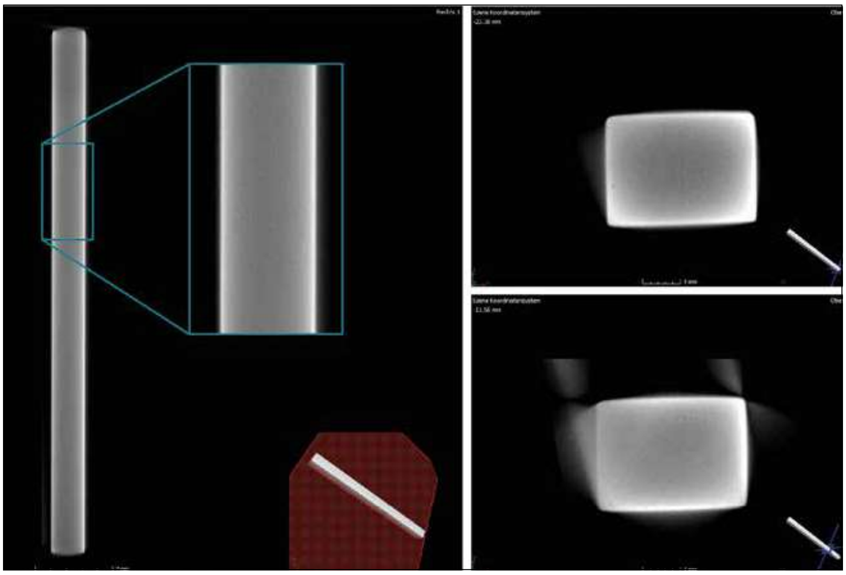

Fig. 3
CT images of exemplary sample

Prior to AM, drop characteristic value-specific process parameters are first set and rows of drops, line structures and surface segments are applied to the print bed (Fig. 2). These are scanned and automatically measured by the laser scanner implemented in the printer. Tests are carried out to determine the optimum parameter and print settings for generating a reproducible and geometrically optimal droplet [7]. The determined parameter settings are subsequently used to print test specimens for different characterisation procedures. Finally, completed tests and potential adjustments enable the production of more complex components and implant structures as demonstrators.

In order to take into account, the shrinkage caused by the removal of contained binders in thermal post-treatment, when developing an implant structure, it must first be determined. The higher the solid

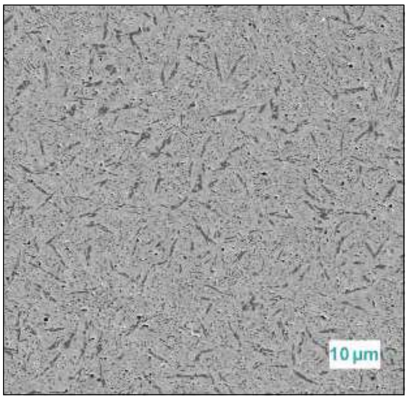

Fig. 4
FESEM Images of printed EvoCera® material

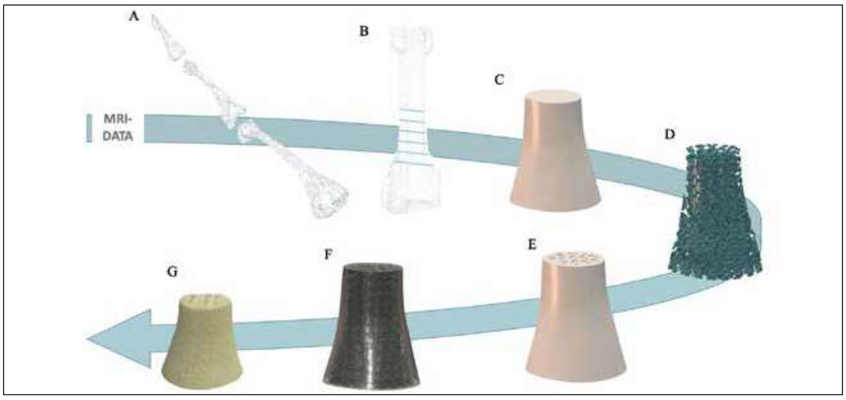

Fig. 5
Construction of an implant structure in CATIA 3D Experience®

content in the feedstock (printing material), the lower the shrinkage. The specimens were measured and compared in the green and sintered state. On average, the volume shrinks by 23 % in the x, y and z directions and the mass by 15 %.

The density of the samples is determined according to Archimedes' principle and shows a value higher than 99 %. To confirm this and to examine the samples for defects radiography and CT scans were taken. The minor overlapping errors in the slicing process could easily be adapted in following prints. Fig. 3 shows CT images of one of the bending bars. No defects can be detected either vertically to the printing direction or horizontally to it. The structure is dense and non-porous. Four-point bending tests were performed to investigate the strength. Ten bending bars with dimensions of 45 mm × 4 mm × 3 mm were printed and investigated. On average, the bars withstand stresses of up to 528,9 MPa with a standard deviation of 46,9 MPa. Thus compare very well with the manufacturer's specifications.

In FESEM analyses, the microstructure of the samples is microscopically imaged with very high resolution and precision. For this purpose, the surface to be analysed is scanned with a finely focused electron beam [8]. Fig. 4 shows a microstructure image from the center of the sample. The image shows a dense defect-free microstructure and a dominant zirconia matrix with proportions of a few other elements, like alumina. The EDX examination showed the composition specified by the manufacturer.

Preparation of the MRI data and construction of the implant demonstrator

The basic idea in producing an implant structure is to design and additively manufacture a bone implant individually adapted to the patient on the basis of MRI data. In the case of osteosarcomas, for example, the tumour-containing bone tissue must be surgically removed. If the resulting gap in the bone is too large, an implant must be inserted. In the following, a process, from the discovery of the tumour in the MRI, through the 3-dimensional reconstruction of the affected area, to additive manufacturing will be described.

The construction and development process are shown in Fig. 5. Starting with the preparation of the MRI data of a finger, a 3D model and a 3D model (A) was created, which forms the basis for the design of the implant structure. A CAD model for the actual implant (E) and for the necessary support structure (D) was created in CATIA 3D Experience®. After slicing the model, the demonstrator could be printed and thermally processed (G).

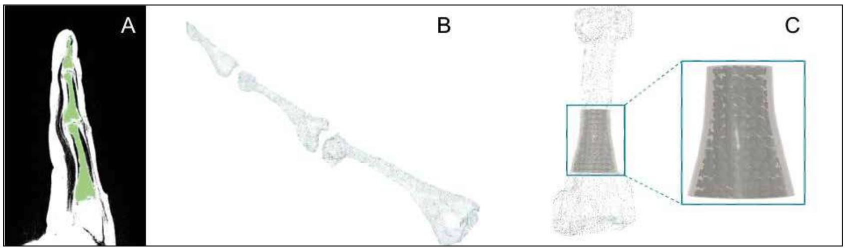

Fig. 6 A–C
Data generation

During the generation of the implant structure, the basic process steps of CerAM MMJ are run through. Beginning with the preparation of the patient data and the generation of a 3D model from the individual DICOM files created in the MRI. For this purpose, the open-source medical software InVesalius 3.1.1 is used, with which virtual reconstructions of structures of the human body can be created. The first step is to load the image files into the program and select the Region of Interest (ROI) from which the 3D model is to be generated. The program recognises differences between the various types of tissue in the body and, after setting a filter, independently selects the desired one. In this case, the relevant material is bone, which is illustrated in green in Fig. 6 A. Subsequently, individual areas that are incorrectly identified as bone material or those that are not identified by the program can be manually removed or added. After defining the ROI, a 3D model of the bone in question is generated in a STL format (Fig. 6 B). After importing this file into a design program (in this case CATIA 3D Experience®), the final bone implant can be designed based on it.

The STL file of the patient's phalanges is imported into Catia 3D Experience® in the form of a point cloud. First, the model is reduced to the relevant part of the finger by removing the points of the two unaffected phalanges, phalanx media II and phalanx distalis II.

Oriented to the circumference of the patient's bone, splines are then created, which form the basis for the construction of the implant structure. To mimic the trabeculae of the long bones, a structure is constructed to represent the air-filled cavities inside the bone.

Since the designed bone implant is based on the real MRI data of the patient's finger bone, the constructed dimensions correspond to the desired ones. Therefore, the model must be scaled in the slicer prior to printing.

After all process relevant parameters have been set, the slicing process starts. During this process, each drop is assigned a coordinate at which the microdispensing system is to deposit it. In addition, the sequence of the drops to be placed is defined. The final implant structure consists of 73 layers of EvoCera® material and correspondingly 146 of the support material. A total of 101 591 drops are dispensed.

The demonstrator implant created during the printing process receives its final structure through thermal post-treatment. Fig. 7 shows the additively manufactured implant structure after this final processing step. The pores of the implant, which were filled with support material during the shaping process are revealed in debinding. To support the extraction of the binder, the samples are embedded in Al_2O_3 powder. Due to the smaller droplet diameter of the support material and shrinkage, pore sizes between 150–400 µm can be achieved.

Hybrid structure

Since, on the one hand, a sufficient porosity for the formation of vessels and better proliferation of bone cells and, on the other hand, the precise shaping of the outer shell are of great importance for a bone implant, the two processes, CerAM MMJ and freeze foaming are combined. For this purpose, hybrid implant structures consisting of dense additively manufactured support structures and porous foam are fabricated as demonstrators. Both structures are based on the material EvoCera® provided by DOCERAM. The additively manufactured support structure provides the necessary stability and the inserted foam the desired porosity inside. Figs. 8 A–C show the formation of these hybrid structures. Fig. 8 A and Fig. 8 B show the specimens produced in the various processes individually. The combination of the foam produced in the direct foaming process with the support structure printed with Multi Material Jetting results in the hybrid structure shown in Fig. 8 C.

The two manufacturing processes of Multi Material Jetting and Freeze-direct Foaming form the basis of the produced samples. The principle of CerAM MMJ has already been described above and will not be further illuminated. The fundamentals of the freeze-direct foaming process are briefly explained below.

Freeze foaming is the direct foaming of powdered materials, in this case ceramics, from an aqueous suspension. In this process, only water vapour, introduced air and the sublimation of frozen water act as pore formers [9]. A vacuum is applied in the freeze dryer, which causes the air introduced into the suspension to rise. In combination with rising water vapour, this causes foam-

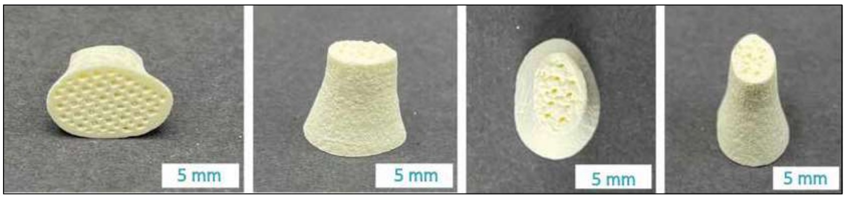

Fig. 7
Implant demonstrator after the thermal post treatment

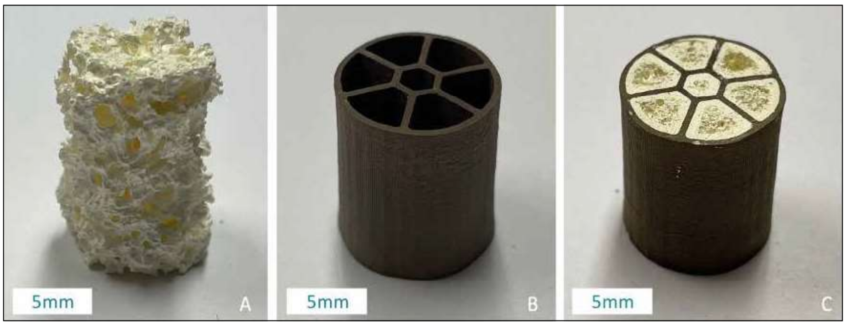

Fig. 8 A–C
Foam structure (A), Multi Material Jetting structure (B), hybrid structure (C)

ing of the suspension. A further reduction in pressure causes a sudden freezing at the so-called triple point and thus stabilisation of the resulting foam structure. This is followed by freeze-drying, where water and other solvents are removed from the sample, allowing the ice to change directly from a solid to a vapour without passing through a liquid phase. An anhydrous and porous structure is produced [9, 10].

The greatest challenge when combining two manufacturing processes is to match the process behaviour of the manufactured samples, such as thermal properties and shrinkage. Since the exact same powder is used for both processes, the debinding and sintering regime does not have to be adapted. Only the shrinkage behaviour is different, since various binders and additives are used for the different suspensions. The main base of the suspension for the freeze-direct foaming process is water. That of the CerAM MMJ suspension is thermoplastic binder. For this reason, the foams have a very high shrinkage of about 38 vol.-%, while that of the CerAM MMJ specimens is only 23 %. In order to come closer to the freeze foaming and to provoke greater shrinkage, two additional CerAM MMJ feedstocks with lower solid contents of 40 vol.-% and 30 vol.-% are produced. Accordingly, different structures are printed with each feedstock, which undergo the first step of debinding before they are filled with the aqueous suspension (Fig. 9 A and Fig. 9 C). Fig. 9 shows one of the structures after foaming (A and C) and after thermal processing (B and D). Due to a not yet perfectly adapted shrinkage there are small cracks where the foam detaches from the support structure. This is also confirmed in CT scans visualised in Fig. 10.

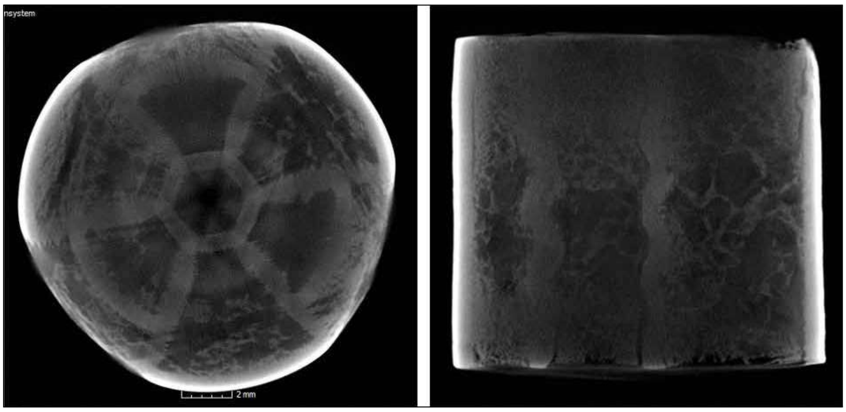

Fig. 10
CT images of the Hybrid Demonstrators

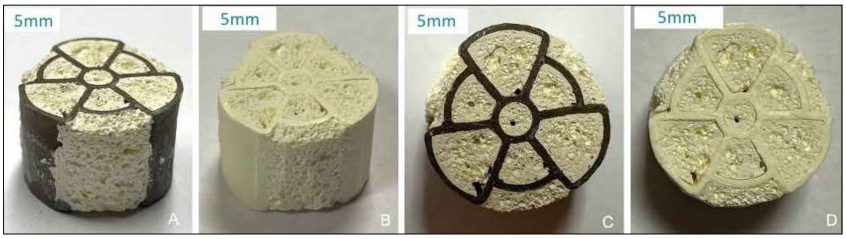

Fig. 9 A–D
Hybrid Implant Demonstrator

The combination of dense support material and open porous foam is clearly visible. The additively manufactured part is dense and transmits only little radiation, making it appear lighter. The foam has many pores that are very translucent and thus become visible as dark areas in the CT. Since minor cracking occurs even in samples printed with 30 % solids by volume, the solid content of the foams should be increased to reduce shrinkage. Alternatively, the solid content of the CerAM MMJ printing material can be slightly reduced until the shrinkage of the printed part and the foam are matched.

Conclusion

It was shown that the advantages of additive manufacturing can be used to realise personalised implant structures adapted to each individual patient by Multi Material Jetting. MRI data could be successfully processed and used as a basis for the implant generation. Purely additive manufactured implant structures with pore sizes of 150 µm and 400 µm were produced.

By combining the two processes CerAM MMJ and freeze-drying, hybrid structures with compact additively manufactured support structures and a porous foam interior could be fabricated.

In following investigations, the final implant structures should first be fully characterised and compared with natural bone. Furthermore, an interesting step would be the colonization of the implant structures with cells, which can contribute to a characterisation of the attachment and ingrowth behaviour. Based on this, the internal structure or external roughness of the implant demonstrator can be optimized.

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