FURTHER DEVELOPMENT OF THE DESIGN PROCESS FOR HYBRID INDIVIDUAL IMPLANTS

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ABSTRACT

Additive manufacturing (AF) is characterised by a high degree of individuality and flexibility with regard to design and product layout. This enables the integration of different functions in a component. Due to these properties, AM has established itself in medical technology for the production of implants. Depending on the application, parameters such as resilience, biocompatibility and manufacturing restrictions play a varying role. So far, however, only limited research has been done on the design, manufacturing and application of hybrid implants (use of several materials). Although initial design and manufacturing guides exist, the problem of removing the hybrid implant from the shaping negative is hardly addressed.

The aim is to analyse and evaluate an existing procedure for the design of hybrid implants depending on individual requirements and to further develop it regarding the removability from the shaping negative. In this context, the extent to which the adhesive properties between the elements can be influenced by design changes is to be investigated.

Keywords: Design methodology, Additive Manufacturing, Design for Additive Manufacturing (DfAM), Implantology

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1 INTRODUCTION

1.1 Motivation

The further development of processes and technologies in product development is an ongoing process. Advances in manufacturing technology pave new ways in the production of components and products that continuously expand the current state of the art. Additive manufacturing (AM) is one of these technologies.

Compared to conventional processes, additive manufacturing is characterised by a high degree of individuality and flexibility in terms of design and product layout. Such design freedom enables the integration of different functions both within a component and on its surface. These properties are of critical importance in medical technology for the use of implants. Depending on the application, parameters such as resilience, biocompatibility and manufacturing restrictions are of varying relevance. The combination of these parameters suitable for the individual patient case is often not realisable with one material only. Therefore, the use of several materials as a hybrid composite can be useful. The advantage of such a hybrid system, which consists of at least two different materials, is that the implant can meet both the requirements for mechanical strength and the synthesis between the patient's body and the implant. (Wintermantel and Ha, 2009; Loew, 2010; Tidow, 2016)

1.2 Problem definition

Apart from sex-specific differences, the human anatomy is basically the same. However, the composition, shape and size of individual bones differ from one human being to another. Hardly any bone exists identically in its kind a second time (Waldeyer and Streicher, 2012). Consequently, all bone defects, regardless of their type of origin, are unique in their shape. Therefore, in situations that require the use of an implant, a customised implant should be fabricated for the defect location. In addition to the individualisation, another challenge exists in the context of hybrid individual implants. So far, only little research has been done on the design, manufacture and application of hybrid implants. The manufacture and design of hybrid individual implants face challenges such as the constructive and material structure, the individual adaptation and the stability of the design. In addition to the lack of geometric adaptation of conventional implants, which is responsible for poor ingrowth behaviour, among other things, unfavourable materials or material combinations are sometimes used. However, in order to be able to exploit the advantages of a hybrid system, a skilful constructive design and a combination of materials suitable for the individual case are absolutely necessary.

Although there is currently no generally valid procedure for this, the previously mentioned points have already been addressed in Pendzik et al. (2021). However, this does not take into account the difficulties in removing the hybrid structure after the manufacturing process. The conflict is that the biocompatible part adheres to the hybrid partner element as well as to the moulding support structure. This makes the separation of the hybrid connection from the support structure significantly more difficult. The consequence is the destruction of the biocompatible structure during the removal process and thus the complete lack of usability of the implant.

1.3 Research goal

In this paper, a process for the design methodology for hybrid individual implants will be presented, which considers the removal of the hybrid structure in the design process. Specifically, an existing process, which was developed in Pendzik et al. (2021) on the basis of a skullcap (cranial) defect, will be analysed and evaluated. In this context, the boundary conditions are going to be supplemented and extended according to the newly formulated requirement for improved removability. Based on this, the constructive design of the hybrid elements will be adapted and subsequently the hybrid individual implants will be manufactured. Finally, the hybrid implant is going to be removed from the shaping support structure and the results are going to be evaluated.

The aim is to clarify how the previously mentioned aspects, such as synthesis between implant and body, stability of the design - before, during and after production - and individual requirements, can be covered in a useful and targeted manner and how this can be implemented in the design process. The aim is thus to further develop the existing process for designing hybrid implants depending on individual requirements and to make it consistently quality-assured. The questions to be discussed are

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whether design changes can simplify the removal of the hybrid implant from the support structure and whether the design changes can be integrated in favour of better removability without neglecting other boundary conditions.

2 STATE OF THE ART

2.1 Hybrid individual implants

Hybrid implants are used in oral and maxillofacial surgery, among other fields, and are characterised by a variety of positive properties with regard to load and shape adaptation. The successful development of hybrid, customisable implants and their prospective use in various treatments of damaged bone enables better integration into the body's own bone structure and thus avoids previous deficits as well as patient discomfort. Furthermore, the novel treatment approach can significantly reduce the number of necessary follow-up interventions, e.g. through revisions, and thus contributes to resource conservation and cost reduction in the health care system. According to Schiffner (2019), however, this hybrid constellation still results in a few design criteria that need to be taken into account, since the combination of two very different materials can lead to failures. These failure cases are influenced by the adhesive properties of the two materials and the stresses in the component (Schiffner, 2019).

2.2 Skull plates

With the increase in manufacturing and software possibilities, the trend in implant production is moving more towards patient-specific implants. Conventional implants such as metal bars, plates and grids are only used in individual cases. They are available in variations and can be easily adapted to the defect site. They are cut according to the defect size and adapted to the surface contour as closely as possible by bending. The advantages are immediate availability and easy fixation with bone screws. However, the method can only be used to a limited extent, as no actual reconstruction of the defect site takes place. Standard solutions are not an adequate substitute, especially for large bone defects. Such larger or, due to their special shape, more specialised defects require more complex implants, which are designed and manufactured exclusively for one defect site. One example is the "evo_SHAPE" cranial implant from Evonos GmbH. This is a patient-specific implant derived from CT data. The most aesthetic appearance possible, the good fitting accuracy and the mechanical protective function need to be emphasised here, with Polyetheretherketone (PEEK) being used as material. Figure 1 shows the solutions for cranial implants. (Schiffner, 2019; Scheibner, 2019)

Figure 1: (a) Examples of use for BIONIKA skull plate systems (BIONIKA, 2021); (b) evo_SHAPE cranial implant from Evonos GmbH (Evonos, 2021)

2.3 Material and manufacturing

The use of implants has so far been limited to the use of compact metallic, ceramic or polymer blanks and the associated technologies for manufacturing. Efforts and successes in the individualisation of implants made of metal and ceramics, which are manufactured by additive manufacturing, can be

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noticed in some companies (Wild et al., 2013; Habijan et al., 2013). Advantages over conventional processes are: high potential for customisation, cellular volume and surface design during production, without subsequent coating, and the use of biocompatible materials that are difficult or impossible to chip.
Common additive manufacturing processes for metallic materials (usually Ti64) are laser and electron beam melting (LBM, EBM). These processes work by sequentially fusing individual powder layers in a powder bed and are therefore almost unlimited in their possible design freedom. Above all, the integration of rough, structured surfaces for improving the ingrowth behaviour of cells needs to be mentioned as an advantage. The disadvantage is that after shaping, a sintering step and corresponding post-processing steps (e.g. removal of powder residues) are necessary, which has a negative impact on cost structure, quality, variety of shapes, surface structure, porosity and biocompatibility. The inert materials processed with them cannot be biodegraded and converted into the body's own bone. Furthermore, metallic implants are known to cause disturbances in the sensation of cold as well as loss of bone load-bearing capacity in the contact area due to high differences in stiffness, thus causing high point loads (stress-shielding). (Wintermantel and Ha, 2009; Roth, 2018; Schmitt, 2013) Plastics such as PEEK have also been used in medical implants for some time. PEEK is inert, sterilisable and similar to human bone in its mechanical properties. In addition, implants made of polymethyl methacrylate (PMMA) can be adapted during surgery. However, disadvantages of the plastics are the manufacturing costs and non-existent integration possibilities of the surrounding bone, which means that they do not form a direct connection with it. (Lethaus et al., 2012; Ng and Nawaz, 2014)
Implants made of several different components are also being used and researched. In the field of non-individual implants, there are systems that offer hybrid implants made of a metallic base structure with a biologically compatible coating (e.g. calcium phosphate). There are also customisable implants made of lattice-like titanium bearing structures and biocompatible matrix (OssDesign AB, 2021). In contrast, there exist pasty calcium phosphate preparations (CPC) that allow the near-net-shape production of cellular shaped bodies without additional post-processing by means of 3D printing processes (INNOTERE GmbH, 2021; Heinemann et al., 2013; Schulz et al. 2019; Kilian et al., 2021). By using filling structures made of biocompatible plastics, complex near-net-shape implants can be manufactured (Holtzhausen et al. 2019). The positive properties related to the integration behaviour of cells and absorbability have been proven (Reitmaier et al., 2017). The technology is suitable for the restoration of non-load-bearing closed bone defects (Holtzhausen et al., 2019; Sembdner et al., 2019). For widespread use, a combination with load-bearing, individualised implant components made of polymers or titanium is required. So far, there don’t exist solutions for the combination of additively manufactured bearing structures and filling structures (bone cement).

2.4 Manufacturing process

The manufacturing process of patient-specific implants is currently very time-consuming and costly. A complex diagnostic and planning process, a considerable design effort and an often time-consuming production are always necessary. Focusing on a specific application of customisable implants enables a significant reduction of the effort (Sembdner, 2017). There are currently neither a defined design process nor common guidelines for the design of hybrid implants. However, Schiffner (2019) was able to compile essential aspects for this: For the hybrid implant design itself, defined dimensions of the bearing structure according to the load and bone cases, filling structures according to the bone thickness and structure as well as an effective combination of the two implant structures are mandatory, among other things. Furthermore, additional steps must be integrated within the process chain. This includes, among other things, the breakdown of the implant construction into sub-steps such as the design of support structures, support struts, fastening elements and wire and filling components as well as the separate but at the same time integral production of the two implant sub-structures (support and filling structure). (Schiffner, 2019)

3 PROCESS FOR THE DESIGN OF HYBRID IMPLANTS ACCORDING TO PENDZIK ET AL. (2021)

3.1 Process chain

The digital process (Figure 2) begins with the determination of patient-specific data (CT, MRI, etc.) and data preparation. For example, CT data is converted into segmented and derivable 3D data. Based

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on these data, elements such as contours, surfaces, etc. can be generated and transferred to a CAD software and can thus be made available for the implant design. In this way, the marginal area of the defect can be remodelled and the raw implant model can then be derived. This phase is called data processing. Subsequently, the design of the raw implant model is defined in the planning phase depending on the location of the defect and the patient-specific conditions, and is divided into load-bearing and filling structure. In the last phase, the modelling phase, first the raw implant model and then the hybrid structures are designed.

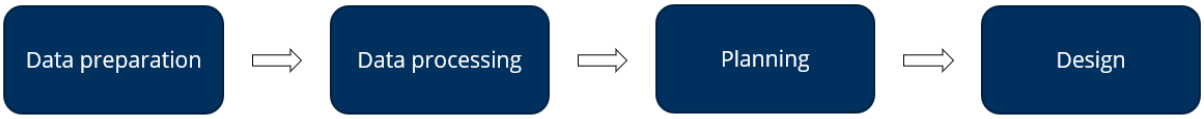

Figure 2: Process chain for the creation of hybrid implants

3.2 Design process for an individual hybrid implant

The developed process for the design of a hybrid individual implant consists of a multi-step design procedure, which is explained in more detail below.

3.2.1 Modelling of the defect location

In the first step, the defect site geometry is derived with a prototypical and non-commercial segmentation and image data processing software. For this purpose, a sufficient number of reference points on the bone surface in and around the defect site are manually created as a polyline in a number of choice (Figure 3).

Figure 3: (a) Generated reference points on skull surface; (b) Closed polyline; (c) Closed polylines on skull surface outside; (d) Closed polylines on skull surface inside

These curves are placed in such a way that edges and borders of the defect location can be reproduced as accurately as possible. The derivation of the immediate surroundings of the defect is also relevant in order to ensure sufficient contact area for the integration of fastening elements into the supporting material that takes place in the further course. After creating the reference objects, these 3D curves are transferred to the CAD software via the SolidWorks interface of the segmentation software. Using these curves, individual surface patches are created and then merged to form a closed surface. The volume body of the defect site of the skullcap defect is shown in Figure 4a.

3.2.2 Design of the raw implant model

In the next step, the raw implant model is designed. For this purpose, 3D sketches with guidelines are created on the basis of which the curved implant shape can be reconstructed. Using these guidelines as constraints and the recreated defect site as a surface boundary, two freeform surfaces are created - one on the inside and one on the outside of the implant. Figure 4b and 4c show the constructed inner surface of the implant volume and the final volume body, which is the basis for the hybrid implant.

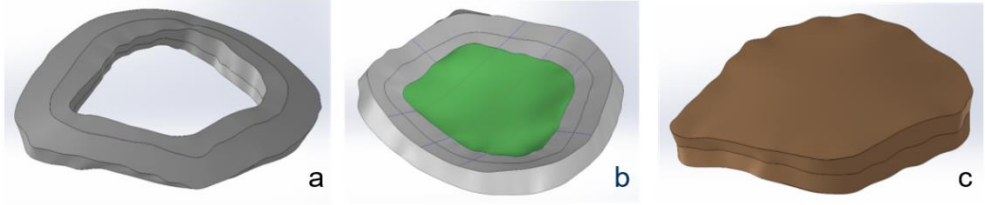

Figure 4: (a) Reconstructed defect site as volume body; (b) Surface on the inside of the implant (green) & guidelines (blue); (c) Volume body of the implant

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3.2.3 Splitting into and design of the hybrid elements

The design of the hybrid structure requires, as a preceding step, the division of the shell geometry into load-bearing components (bearing structure) and bone-forming components (filler structure). The first step is to determine the shape and design of the bearing structure. The following boundary conditions must be taken into account:

- Build direction
  - Consideration of geometric peculiarities (e.g. slopes on contact surfaces of implant and bone)
  - Using the build direction to avoid or create the staircase effect in a targeted manner
  - Consideration of manufacturability (e.g. holes for fixation screws)
- Defect contour and location (e.g. skull or zygomatic bone)
  - Orientation and number of sides facing the bone (analogous to a cube, maximum 6 sides)
  - Bone thickness (for integration of fixation elements)
  - Sensitivity of the surrounding tissue (skin, muscle, soft tissue, sensory organs, etc.)
- Print direction of the CPC paste during the manufacturing process
  - Bevels of the CPC structure: can only be considered in one direction (tapering in z-direction)
  - Takes the implantation direction into account
  - Conditional orientation of the bevels of the support structure (tapering in z-direction)
- Potential contact area between filling structure and bone
  - Maximise contact area between both
- Potential contact area between bearing structure and filling structure
  - With as little support structure as necessary, maximise contact area to ensure adhesion of the two to each other and protection against loads on the CPC structure (influenced by size of the form slopes, width of the support arms, etc.)

Based on the listed boundary conditions and the patient-specific requirements of the defect, a three-armed model was selected as the bearing structure, in particular to meet both the targeted high contact area of bone und filling structure and the stable anchorage in the skull as well as the protection against external forces. One focus of hybrid implants is the integration of fixing elements into the load-bearing material. In principle, a screw connection is to be preferred for this. For the design of screw connections, variants have been developed that allow screws to be recessed in the bearing structure (use of pockets) so that they do not protrude from the skullcap. On the one hand, this serves an aesthetic purpose, but on the other hand, it is primarily intended to prevent subsequent injuries through external contact. Different volume models were used to describe the geometries for the bearing structure and the filling structure. These result from the Boolean intersections of the raw implant model and the geometry of the bearing structure. Both models can be exported in an exchange format and can be manufactured by additive processes. The resulting design for the hybrid cranial implant is shown in Figure 5.

Figure 5: (a) Designed hybrid structure of the implant: completely; (b) Filling structure; (c) Bearing structure

4 EVALUATION OF THE CURRENT METHOD

According to the method shown in chapter 3, a hybrid individual implant can be designed and manufactured on the basis of CT data. The filling structure is imprinted into the bearing structure. For a form-fitting surface of both structures, a support structure is necessary as a shaping base, which thus forms the negative of the defect. All three elements can be seen in figure 6.

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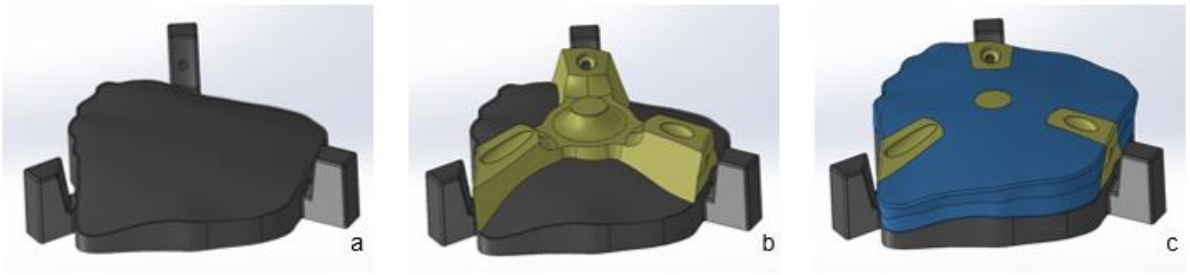

Figure 6: (a) Support structure; (b) Support and bearing structure; (c) Support, bearing and filling structure

The manufactured specimens of these constructions (Figure 7a) can be considered as promising. The filling structure adheres to the bearing structure and does not detach from it when small external forces are applied. The contact of the filling structure to the bone is considerably greater than that of the bearing structure to the bone. The anchoring screws also do not protrude from the implant. The final hybrid implant thus fulfils all relevant requirements. However, it is noticeable that the filling structure strongly adheres to the support structure after curing and can sometimes only be separated from it with great effort and this can even lead to the destruction of the implant during removal (Figure 7b and 7c).

Figure 7: Additively manufactured hybrid implant: (a) Specimen 1 - not destroyed; (b) Specimen 2 - destroyed; (c) Specimen 2 on the building plate with negative - destroyed

This problem can probably be attributed to the large contact area of the filling structure (cured CPC) and the shape-giving support structure. The procedure can therefore serve as a basis for the design and manufacture of hybrid individual implants, but it is mandatory to work out further boundary conditions in order to simplify the removability of the hybrid structure and minimise the probability of failure.

Reducing the adhesion of the filler and support structure is hardly possible without a significant reduction in the contact area between these two. However, this would also greatly reduce the proportion of new bone-forming structure. The central requirements are to maintain the greatest possible contact between the bone and the filling structure and to ensure the greatest possible formation of new bone. In order to fulfil these requirements and at the same time allow for better removability, the adhesion between the bearing and the filling structure must be increased by means of constructive adaptations. This results in the following new boundary conditions:

- Increasing the contact area between the filling structure and the bearing structure
- Anchoring of the filling structure in the bearing structure through:
  - Texturing the bearing structure
  - Enclosing the filling structure by the bearing structure

5 CONSTRUCTIVE IMPLEMENTATION OF ADAPTED BOUNDARY CONDITIONS

The enclosure of the filling structure by the bearing structure and the increase of the contact area between the two can be combined through one design change. The approach here is to extend the bearing structure along the side facing the bone by additional arms and at the same time to reduce the height of the flat elements of the bearing structure. Although the contact between the filling structure and the bone is somewhat reduced, the proportion of the filling structure and thus of the new bone-

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forming structure is only reduced from 1892.81 mm³ to 1748.89 mm³. Thus the filling structure is only reduced by 7.6 %.
Due to the complexity of the individual free-form surface constructions, the integration of a linear texture pattern is difficult to implement. Therefore, evenly distributed hemispherical sections were applied to the surface of the part of the bearing structure, which is in contact with the filling structure. The following figure 8 shows the old as well as the revised version of the bearing structure - both designed and manufactured.

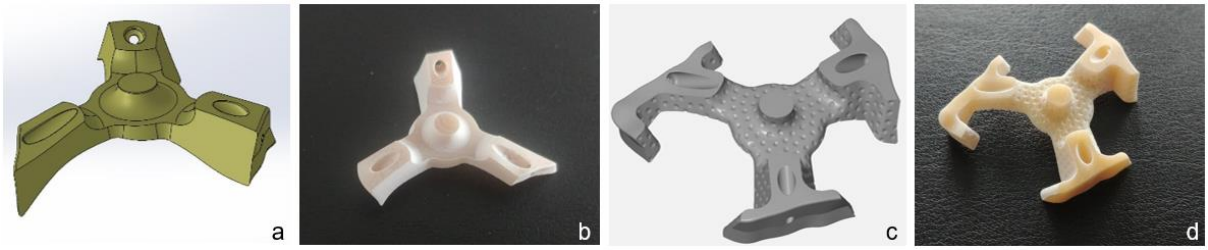

Figure 8: Bearing structure according to the old method: (a) Designed, (b) Manufactured; Bearing structure according to new the method: (c) Designed, (d) Manufactured

6 RESULTS

The filling structure was also printed onto the bearing and support structure using the revised design data. After the curing process, the hybrid composite consisting of the filler and bearing structure was removed from the shaping support structure. It has been shown that although the removal of the new hybrid implants still proves challenging, the hybrid composite of the two structures can be removed from the support structure without destruction. In addition to the skullcap implant, the new method was successfully tested on another very complex and geometrically very different implant. The final hybrid implants (1 - skullcap implant; 2 - zygomatic implant) are shown in Figure 9.

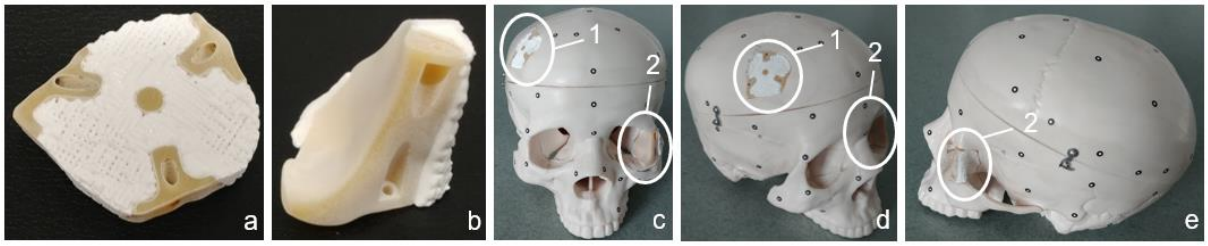

Figure 9: (a) Hybrid skullcap implant; (b) Hybrid zygomatic implant; (c) and (d) Skull with (1) und (2); (e) Skull with (2)

7 DISCUSSION

The adaptation of the existing process has proven to be a further development and a quality assurance measure and thus achieving the desired purpose. It has been shown that despite the design changes, the proportion of the new bone-forming structure is only slightly less (92.4 %) than with the old method. At the same time, the removability was improved and the hybrid implants were successfully separated from the form-giving support structure. New boundary conditions could thus be taken into account without significantly neglecting the existing requirements. Only the contact area of the filling structure to the bone was slightly reduced by the new arms on the support bars. However, there is still sufficient contact between both.
This is where future work needs to be done. In order to fully meet the central requirements for ingrowth and new bone formation, simple design changes are not sufficient. The influence on the bonding behaviour is therefore limited. A larger design of the bearing structure and less contact surface of the filling structure to the bone only seems to make sense if a higher stability is desirable due to the requirements of the defect location. Therefore, starting with the method described above, further approaches must be developed and evaluated in order to increase the adhesive properties between the filling and bearing structure or to reduce them between the filling and support structure.

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It remains to be seen to what extent the method can be applied to very large defects, especially in the cranial region, on a design and manufacturing level. Both external and endogenous forces, such as chewing, have a significant influence on the design of the hybrid elements for very large defects, especially since a larger defect site means a longer bone resorption period. If a hybrid design makes sense, a load simulation must be carried out for larger cranial defects and, if necessary, alternative hybrid models must be considered. One possibility could be a pure CPC structure as a defect site implant, which is protected by an outer cover plate.

8 SUMMARY AND OUTLOOK

Additive manufacturing is a good prerequisite for the development and production of individual bone replacement implants. By using several materials, different functions can be integrated. Geometries tailored to the patient can also be implemented. A promising approach is the division of the components into a load-bearing and a bioactive structure.

Within the scope of this work, an existing process was further developed that can be used as a guideline for the design of hybrid individual implants, taking into account the removability of the manufactured elements. In addition to the design and fabrication of a hybrid skullcap implant, a zygomatic implant was also designed and fabricated using the developed method. Both were successfully removed from the support structure and inserted into the demonstrator skull. Both the design of the bearing structure and the dimensioning of the filling structure proved to be suitable.

Building on these findings, further approaches need to be developed and investigated. One approach could be to investigate the different design and manufacturing parameters and their influence on the adhesive properties in general. For example, can cured CPC be removed better or worse on more curved surfaces? What influence do parameters such as height and print direction of the CPC paste have? Does the curing time correlate with the adhesion properties? If correlations can be established here, these findings could already be taken into account in the design process and the adhesive properties of the bearing and support structure could be manipulated in a targeted manner. In this way, quality assurance can be ensured right up to the provision of the hybrid implant.

Furthermore, a developed design of a hybrid implant needs to be validated. In subsequent investigations, a meaningful evaluation criterion must be determined to verify the suitability of the developed design. For this purpose, the possibility of a load simulation needs to be investigated and the robustness of the design needs to be analysed on the basis of potential load cases.

Furthermore, the demonstrator spectrum needs to be expanded. In further investigations, the method will be tested on considerably larger cranial defects. Alternative hybrid models will be developed and validated using a load simulation. In addition, the extent to which an adaptation of the method is suitable for other areas of application within additive manufacturing must be investigated and evaluated using suitable demonstrators.

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