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3D printing of individualized cranial PEEK implants – saving costs and following regulatory pathways

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Abstract: This paper describes a complete workflow to produce individualized cranial implants using additive manufacturing. The workflow includes design regulations, definitions of part orientation and support generation as well as process parameter definitions and post-processing steps. In addition to technical feasibility, clinical requirements and regulatory pathways are described.

I. Cranial implants

Patient specific implants (PSI) also labelled as patient matched implants (PMI) can be found in numerous applications such as orthopaedic, neurosurgery and craniomaxillofacial (CMF) surgery. Established techniques for surgical treatment of cranial defects include the use of autologous bone material, intraoperatively moulded bone cement, titanium plates or titanium meshes, or ceramic implants. Disadvantages such as temperature sensitivity, cost-intensive production, impossibilities of pre-operative planning or complication and revision rates of 22% [1] and more have been accepted to date due to the lack of alternatives.

Currently, approximately a minority of individualized cranial implants are made of PEKK or PEEK. This is mainly due to high machine costs as well as the complex manufacturing of PSI. Polymer implants in cranial applications show clinical advantages such as high wearing comfort, acceptance by the patient, millimetre accuracy of fit, excellent biocompatibility and lower revision rates than bone grafts [2]. Currently the majority of all commercially available polymer implants are milled from PEEK (Polyetheretherketone).

This paper describes Kumovis approach to 3D print PSI in PEEK fulfilling both the technical and the regulatory challenges for hospitals as well as for medical device companies.

The workflow uses Evonik VESTAKEEP® i4 3DF PEEK as filament material which is approved for long-term body contact and may be used for implant manufacturing.

II. Additive manufacturing process

A controlled workflow includes design regulations, specifications of part orientation in the build chamber of the printer, a strategy for support structure placement as well as definitions on printing process parameters and post-processing steps. Support structures (Fig. 1) in filament printing are required for multiple reasons:

Positioning and orientation of the part in the build chamber and minimizing warpage during the printing and cooling process. The vertical positioning in the build chamber ensures minimal support structures only on the bottom of the implant. Inner structures and most of the surface remains originally printed and does not require additional post-processing steps. In addition, Kumovis developed a strategy to minimize the efforts to remove the support structure in the required post-processing steps.

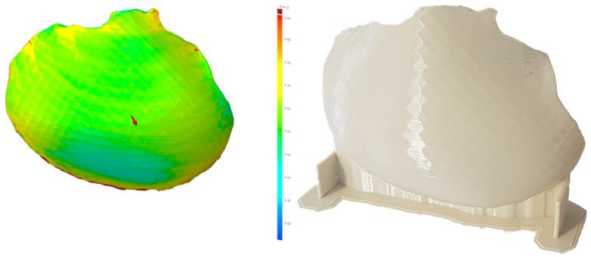

Figure 1: Intelligent strategies for support structure placement allow for material saving, time saving during post-processing and for minimizing warpage to ensure an optimal anatomical fit.

Kumovis uses the methodology of a design envelope to describe the patient population which is covered in the developed workflow to manufacture cranial plates. Multiple criteria such as curvature, thickness, surface, cross section, and diameter of the implant have influence on the printing parameters.

Kumovis gathered a critical quantity of implant designs to understand the variations and allows to define worst-case geometries which represent the boundaries of the design envelope (Fig.2). All geometries within the boundaries of

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the design envelope will be printed reliably and reproducibly following the regulatory pathway of medical device manufacturing.

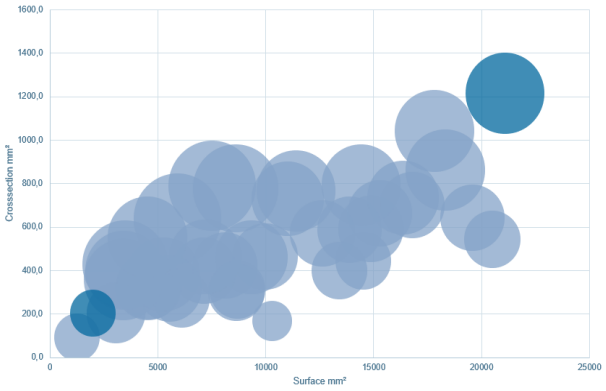

Figure 2: Definition of the patient population based on different parameters such as surface and cross-sections create the design envelope for cranial plates. The darker spheres represent the boundaries of the design envelope.

III. Qualification and validation

Kumovis provides a regulatory pathway including machine qualification, mechanical validation, and biological validation. Both static compression and impact test results of 3D printed worst case geometries fulfil the mechanical requirements for cranial plate manufacturing [Fig.3].

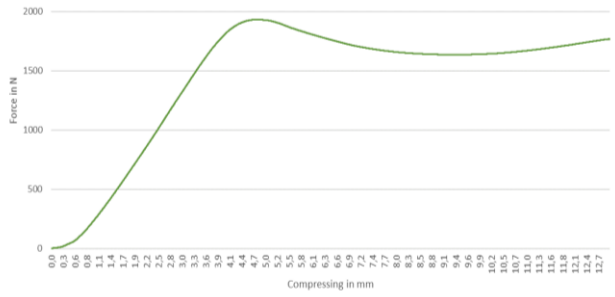

Figure 3: compression testing for cranial plates reaching a force up to 2000 N with Evonik VESTAKEEP® i4 3DF PEEK printed on Kumovis R1.

During the process of machine qualification acceptance criteria on mechanical properties, density and size accuracy are defined. In addition, the influence of part orientation and part position in the whole build envelope is documented and verified.

The regulatory requirement of biological validation includes test according to various norms. Kumovis covers multiple norms – named Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), Implantation (ISO 10993-6) and chemical characterization and toxicological risk assessment (ISO 10993-18) as excerpt. Kumovis as provider of the printer to 3D print cranial plates in PEEK provides an end-to-end solution from CT scan to sterilization including the regulatory and technological topics.

IV. Conclusion

The described workflow has the potential to accelerate the distribution of personalized medical care while saving material compared to milling processes.

In addition, the described technology provides for the first time to achieve mechanical properties (Fig.3) equivalent to those achieved by milling [3].

Cost savings with filament printing compared to other 3D printing technologies for cranial plate manufacturing will further accelerate the acceptance of patient matched implants. Comparable low initial investments in printer hardware and reduced post-processing requirements make the overall costs shrink in comparison to titanium printing based on powder bed technology. Kumovis workflow makes individualized cranial implants affordable for a hospitals and industry partners.

In addition, it accumulates the clinical benefits of high-performance polymers such as high wearing comfort, patient`s acceptance, millimetre accuracy of fit, optimal biocompatibility and low revision rates.

Author's statement

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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