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Abstract

Digital work flow and process for additive manufacturing of patient-specific-implants for craniomaxillofacial reconstruction

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The aim of the work presented here is to establish and test a prototypical, end-to-end digital and physical value chain for patient-specific implants from facial surgery (orbita implants), which are generated based on suitable AI algorithms and produced using additive manufacturing. In the first step, AI-based pre-processing of the medical image data of the orbita defect is performed. The segmentation is implemented with a Convolutional Neural Network. The segmentation process chain including the Dense U-Net [1] was implemented in Python and training runs were conducted. For the virtual reconstruction, an approach based on Variational Autoencoders [2] is presented along with initial trials to verify its applicability. Following imaging, an algorithm for the automated generation of implant designs is being trained. For implant manufacturing, process parameters are being developed that should lead to an optimization in AM manufacturing, especially in view of the filigree structures and component distortion. Test specimens were manufactured to validate density, microstructure and biocompatibility. A CNC blasting machine has been set up for automated post-processing to improve finished part quality. To ensure complete process traceability, a relational database structure that can import various metadata robustly was developed. Corresponding programming interfaces (APIs) were defined. To validate the complete medical workflow, it is essential to break down each process step with regard to a necessary certification [3]. For this purpose, flow diagrams were derived, based on which a conformity assessment will be carried out in a next step.

AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest. Animal models: Animal models have not been used in the present research. 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. Acknowledgments: The work presented is part of the project DigiMed and has received funding by the European Regional Development Fund in the framework of the REACT-EU program.

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