Cranial polyetheretherketone implants by extrusion–based additive manufacturing: state of the art and prospects

Abstract
Extrusion–based additive manufacturing appreciates rising attention in the medical area due to its material flexibility, ability to fabricate complex, patient–specific parts and investment costs in the low to medium range. Thus, amongst other medical deployments, the application of the technology to fabricate permanent cranial implants is investigated for several years now. This mini–review gives an overview on the status quo of cranial implants by extrusion–based additive manufacturing with focus on the polymer polyetheretherketone (PEEK) and elucidates general requirements for an adequate implementation. Intra–operative AM to minimize the number of operations and/or operation time is revealed as important goal in the literature. However, this target is yet not satisfyingly accomplished by clinic–internal extrusion–based AM because of insufficient print qualities, the lack of clinical studies and undefined risk sharing. Further investigations should include a systematic evaluation of the complete benefit chain from data generating to clinical study including quality documentation and risk management. Consecutively, a successful result of such investigations would be a vital step towards clinical acceptance of extrusion–based AM for cranial implants made of PEEK.

Keywords: extrusion–based additive manufacturing, material extrusion, implants, cranial defects

Abbrevations: PEEK, polyetheretherketone; CT, computer tomography; AM, additive manufacturing; PSIs, patient–specific implants; CNC, Computer Numerical Control; CAD, computer aided design; DICOM, digital imaging and communications in medicine; STL, stereolithography.

Introduction
Additive manufacturing (AM) has been recognized as potential fabrication process for several industrial sectors such as automotive, aerospace, consumer goods and medical products. Especially in the medical field, the freedom of product design combined with patient customization for low output production makes AM very interesting for the implant industry. Cranial implants are usually fabricated externally by commercial providers based on patient–specific computer tomography (CT) and mainly using titanium, hydroxyapatite bone cements and polyetheretherketone (PEEK). Those patient–specific implants (PSIs) can be generated from 3D models by either a subtractive or an additive process (Figure 1). In contrast to AM the cost and material intensive subtractive process employs milling of the 3D–modell from a material block in a computer–controlled CNC (Computer Numerical Control) milling machine. Although the reconstruction of complex bone defects is challenging due to the unique anatomy and the variety of deficits, recent improvements in the field of computer aided design (CAD) could lead in combination with the compact technology of extrusion–based AM to precis PSIs in very short production time. Thus, shorter operation times by a clinic–internal intra–operative implementation of CAD/AM would lead to less patient stress and faster healing. In addition, time–related changes in the bone structure and the extent of the lesion (bone growth) can be addressed. Furthermore, to avoid the medical risk of introducing yet not tested new materials the use of the established polymer PEEK has dealt in literature as first material selection approach.

Discussion
Data preparation/modelling
In general, CT scan images of cranial defects are converted into 2D digital imaging and communications in medicine (DICOM) files and converted again to the 3D stereolithography (STL) format using CAD software. According to the common design method for cranial PEEK implants is as follows: a mirror image of the unaffected skull side is adapted to the affected skull side across the symmetry plane and the design of the 3D implant is virtually manipulated then by edit and sculpt tools etc. to fit precisely to the defect. In several modeling...
software are listed comprising Mimics (Materialise, Leuven, Belgium), SolidWorks (Dassault Systemes, Velizy–Villacoublay, France), Amira (FEI Visualization Sciences Group, Merignac, France), Rhino (Robert McNeel & Associates, Seattle, WA, USA) and SurgiCase CMF (Materialise, Leuven, Belgium). A more recent approach is given by 3D Systems, Inc., Rock Hill, SC, USA,13 that applies voxel modeling to sculpt, detail and deform virtual clay models into any free form. Thus, the limitation of symmetry requirement is resolved and large defects reaching across the symmetry plane can be reconstructed accurately. After virtual implant construction, the data is transferred as STL to computer aided manufacturing (CAM) software.1 Commonly used CAM software is presented in13 and includes ZPrinter and Projet (3D Systems) and Alaris (Objet Limited, Rehovot, Israel).

Extrusion–based AM approaches for PSIs

PSIs can be constructed directly by AM or can be produced by shaping indirectly from a printed skull model referring.1,5,13 The review–related direct fabrication approach “Extrusion–based AM” can be understood thereby as drawing with a precise hot glue gun. Base principle is the extrusion of material through a hot nozzle to melt the polymer, print one cross–section of an object and then rise vertically to repeat the process for a new layer.1 The extruded polymer then hardens immediately as it bonds to the layer below it. Repeating this process builds up the object one layer at a time, thus additively.1,16,20 Regarding17 processing PEEK needs specific machine configurations including full metal hot end with heating up to approximately 500°C and build chamber isolation system for sensitive components like stepper motors. Currently, AM of PEEK cranial implants is limited to cartesian printers referring Gebhardt et al.,4 and Thieringer et al.,25 which means the use of 3–axis–kinematics. The raw material for extrusion–based AM of PEEK is delivered in filament form for direct–fed extruders or as pellets for screw extruders. A commercial filament–based cartesian system especially build for medical use of PEEK is currently presented by the company Apium Additive Technologies GmbH, Karslruhe, Germany, (Apium Series M)24 and by the company VSHAPER, Rzeszow, Poland, (VSHAPER MED).24 A granulate–based system with potential medical application is given as prototype by Tseng JW.24 Focusing on process parameters studies regarding PEEK in extrusion–based AM are very rare,20 while several investigations in the field of laser sintering of PEEK took place,27–29 where for instance part positioning, part orientation or powder bed temperatures have played an important role for the part quality.

Clinical evaluations

While a couple of studies have presented a positive clinical impact of laser–based AM (powder bed fusion) regarding cranial PSIs,20,32 at present clinical tests of extrusion–based AM of cranial PEEK implants, especially internally implemented as intra–operative option, are still in its very early stages. Nevertheless, the research group MAM–Medical Additive Manufacturing located at the University of Basel, Switzerland, has evaluated the medical approach as very promising.23,33,34 In contrast, in11 extrusion–based AM was displayed as still not ready for clinical entry because of insufficient print results.

Conclusion

Based on literature and market research extrusion–based AM of cranial PEEK implants is very promising due to the potential of clinical–intern, in best case intra–operative applying. Today that approach to reduce the number of operations and operation time seems yet not achieved. The authors recommend a systematic evaluation of the complete benefit chain from data generating to clinical study including quality documentation and risk management. A successful result would be a vital step towards clinical acceptance of extrusion–based AM for cranial implants.

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Conflict of interest

The authors declare there is no conflict of interest.

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