Material Science & Engineering International Journal

Mini Review

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

Volume 2 Issue 3 - 2018

Matthias Katschnig, Clemens Holzer
Chair of Polymer Processing, Austria

Correspondence: Matthias Katschnig, Chair of Polymer Processing, Montanuniversitaet Leoben, Leoben, Austria, Tel +43 3842402 3525, Email matthias.katschnig@gmail.com

Received: February 27, 2018 | **Published:** May 01, 2018

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.[1] 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).[2]

Those patient–specific implants (PSIs) can be generated from 3D models by either a subtractive or an additive process (Figure 1).[3,4] 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.[5] Although the reconstruction of complex bone defects is challenging due to the unique anatomy and the variety of deficits,[6,7] recent improvements in the field of computer aided design (CAD) could lead in combination with the compact technology of extrusion–based AM to precise PSIs in very short production time.[8] 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.[5,9,10]

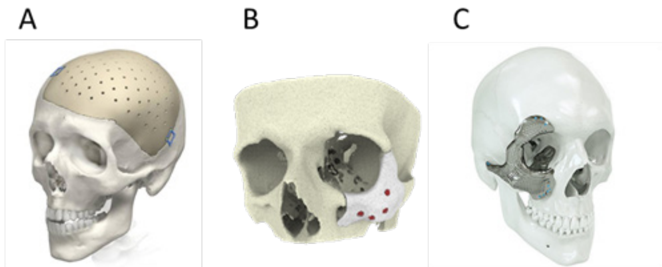

Figure 1 Examples for commercially available implants externally fabricated using different materials. (A) Milled PEEK;[3] (B) Laser-sintered hydroxyapatite (CT-Bone®),[4] (C) Laser-molten titanium.[5]

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.[5,6, 11,12] According to[5] 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[5] 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.[5] Commonly used CAM software is presented in[14] 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.[5,15] 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.[9] 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.[16–20] Regarding[21] 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 regarding Gebhardt et al.,[8] and Thieringer et al.,[22] 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)[23] 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.[25] Focusing on process parameters studies regarding PEEK in extrusion–based AM are very rare,[26] 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,[30–32] 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.[22,33,34] In contrast, in[35] 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.

Acknowledgements

This work has been done thanks to the financial support provided by the Austrian Research Promotion Agency (FFG).

Conflict of interest

The authors declare there is no conflict of interest.

References

1. Berretta S, Evans K, Ghita O, et al. Additive manufacture of PEEK cranial implants: Manufacturing considerations versus accuracy and mechanical performance. *Materials & Design*. 2018;139:141–152.
2. NN. Stryker iD™ Customized Cranial Implants.
3. NN. *Patient Specific Implants: Materials/CT–Bone*®. 2017.
4. NN. *IPS Implants*®. 2018.
5. Oh JH. Recent advances in the reconstruction of cranio–maxillofacial defects using computer–aided design/computer–aided manufacturing. *Maxillofac Plast Reconstr Surg*. 2018;40(1):2.
6. Rachmiel A, Shilo D, Blanc O, et al. Reconstruction of complex mandibular defects using integrated dental custom–made titanium implants. *Br J Oral Maxillofac Surg*. 2017;55(4):425–427.
7. Kim MM, Boahene KDO, Byrne PJ, et al. Use of customized polyetheretherketone (PEEK) implants in the reconstruction of complex maxillofacial defects. *Arch Facial Plast Surg*. 2009;11(1):53–57.
8. Gebhardt A. *Additive Fertigungsverfahren*. 5. Auflage. Carl Hanser Verlag Gmbh & S.l; 2016.
9. Thieringer FM, Sharma N, Mootien A, et al. Patient Specific Implants from a 3D Printer–An Innovative Manufacturing Process for Custom PEEK Implants in Cranio–Maxillofacial Surgery. In: Meboldt M, Klahn C, editors. *Proceedings of Additive Manufacturing in Products and Applications–Ampa, 2017*. Springer International Pu, [S.l.]. 2017;39:308–315.
10. Kim JW, Kim DY, Ahn KM, et al. Surgical implications of anatomical variation in anterolateral thigh flaps for the reconstruction of oral and maxillofacial soft tissue defects: focus on perforators and pedicles. *J Korean Assoc Oral Maxillofac Surg*. 2016;42(5):265–270.
11. Owusu JA, Boahene K. Update of patient–specific maxillofacial implant. *Curr Opin Otolaryngol Head Neck Surg*. 2015;23(4):261–264.
12. Zhao L, Patel PK, Cohen M, et al. Application of virtual surgical planning with computer assisted design and manufacturing technology to cranio–maxillofacial surgery. *Arch Plast Surg*. 2012;39(4):309–316.
13. NN. *3D Systems, Inc*. Healthcare Solutions. 2018.
14. Jacobs CA, Lin AY. A New Classification of Three–Dimensional Printing Technologies: Systematic Review of Three–Dimensional Printing for Patient–Specific Craniomaxillofacial Surgery. *Plast Reconstr Surg*. 2017;139(5):1211–1220.
15. Liu Y, Ma Q, Zhao J, et al. A Comprehensive Strategy for Reconstruction of a Missing Midface. *Plast Reconstr Surg Glob Open*. 2015;3(7):e446.
16. Brantner P, Thieringer F, Heye T, et al. From 2D to 3D: A Review of the 3D–Printing Experience in a Swiss University Hospital–A Case Series

Hinting at the Potential of this New Medium. *Annual Meeting of the Radiological Society NA*; 2016 Meeting, Chicago; 2016.

17. Fastermann P. 3D–Drucken: Wie die generative Fertigungstechnik funktioniert. *Technik im Fokus*. Springer Vieweg, Berlin; 2014.
18. Gebhardt A, Kessler J, Thurn L, et al. *3D–Drucken: Grundlagen und Anwendungen des Additive Manufacturing (AM)*. 2nd ed. *neu bearbeitete und erweiterte Auflage*. Hanser, München; 2016.
19. Katschnig M. Rapid. Tech/FabCon 2016: Bericht für den Lehrstuhl KV. 1st ed. Leoben; 2016.
20. Stansbury JW, Idacavage MJ. 3D printing with polymers: Challenges among expanding options and opportunities. *Dent Mater*. 2016;32(1):54–64.
21. NN. EN_Apium_P155_Datasheet.
22. Thieringer F, Popp U, Okolo B, et al. Custom Implants for Humans from a 3D Printer–An Innovative Manufacturing Process for Custom PEEK Implants. *Kunststoffe International*; 2016.
23. NN. Apium M Series: Fit for Medical Devices.
24. NN. Vshaper Med.
25. Tseng JW, Liu CY, Yen YK, et al. Screw extrusion–based additive manufacturing of PEEK. *Materials & Design*. 2018;140:209–221.
26. Yang C, Tian X, Li D, et al. Influence of thermal processing conditions in 3D printing on the crystallinity and mechanical properties of PEEK material. *Journal of Materials Processing Technology*. 2017;248:1–7.
27. Berretta S. Poly Ether Ether Ketone (PEEK) polymers for High Temperature Laser Sintering (HT–LS). University of Exeter; 2015.
28. Berretta S, Evans KE, Ghita O, et al. Processability of PEEK, a new polymer for High Temperature Laser Sintering (HT–LS). *European Polymer Journal*. 2015;68:243–266.
29. Ghita O, James E, Davies R, et al. High Temperature Laser Sintering (HT–LS): An investigation into mechanical properties and shrinkage characteristics of Poly (Ether Ketone) (PEK) structures. *Materials & Design*. 2014;61:124–132.
30. Guevara–Rojas G, Figl M, Schicho K, et al. Patient–specific polyetheretherketone facial implants in a computer–aided planning workflow. *J Oral Maxillofac Surg*. 2014;72(9):1801–1812.
31. Deng L, Deng Y, Xie K, et al. AgNPs–decorated 3D printed PEEK implant for infection control and bone repair. *Colloids Surf B Biointerfaces*. 2017;160:483–492.
32. Eley KA. Centralised 3D printing in the NHS: a radiological review. *Clin Radiol*. 2017;72(4):269–275.
33. Thieringer F, Zeilhofer HF, Kunz C, et al. *Patientenspezifische PEEK–Implantate zur Sofortrekonstruktion des Oberkiefers–Vor und Nachteile einer neuen Therapievariante.* Jahreskongress der SGMKG, Lausanne; 2014.
34. Thieringer F, Zeilhofer HF, Kunz C, et al. *Vor–und Nachteile der Sofortrekonstruktion des Oberkiefers mit PEEK Implantaten*. 44. DOESAK Jahrestagung, München; 2013.
35. Vaezi M, Yang S. Extrusion–based additive manufacturing of PEEK for biomedical applications. *Virtual and Physical Prototyping*. 2015;10(3):123–135.

Citation: Katschnig M, Holzer C. Cranial polyetheretherketone implants by extrusion–based additive manufacturing: state of the art and prospects. *Material Sci & Eng.* 2018;2(3):66–68. DOI: 10.15406/mseij.2018.02.00036