3D Printing of PEEK Implants

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Introduction

3D printing has many applications in medicine and surgery, ranging from patient specific tools to biofidelic, patient-specific models, to facilitate complex surgical planning. Of course, 3D printing is also expected to revolutionize medical device manufacturing by enabling more geometrically complex and patient-specific implants.[1-5] In orthopedics, these patient-specific implants have, thus far, seen broadest applications in complex devices needed for revision surgeries or oncology cases. In addition to patient-specific implants, 3D printing has also been successfully commercialized for mass manufacturing of complex titanium alloy implants with porous bone ingrowth surface for the hip, knee, and spine. 3D printing of implants is here, and it is here to stay.

So what, exactly, is 3D printing? Unlike conventional *subtractive* manufacturing, in which material is machined from a stock cast or forged shape to arrive at a final part, in 3D printing, also known as additive manufacturing (AM), components are fabricated by depositing successive, often microscopic layers, adding layer upon layer to a device from the bottom up. Today there are many additive manufacturing methods under development, but the most widely used techniques reported in the literature for biomedical applications are either based on sintering microscopic powder particles together, which are collectively referred to as powder-based fusion, for example using laser energy (referred to as Selective Laser Sintering, SLS);[6-9] or based on extrusion of filaments, known as Fused Filament Fabrication (FFF).[10] In the literature, FFF is synonymous with Fused Deposition Modeling (FDM). Because FDM is trademarked by a single manufacturer, FFF was introduced as a noncommercial alternative nomenclature for the same AM technology.

Although AM has been used in nonmedical industries for over a decade, it is still a new and growing technology for implant applications, especially so for implants fabricated from PEEK. This article reviews the current state-of-the-art for 3D printing of PEEK implants. The article considers the motivation and key drivers for 3D printing, some noteworthy papers describing AM of PEEK implants, and concludes with some considerations regarding the regulatory aspects of 3D printing.

Why 3D Print PEEK?

AM is not a panacea, and from the perspective of a device manufacturer, certainly not all products warrant commercialization using a 3D printing approach. Indeed, a key aspect of professional certification in AM technologies is the economics of production relative to traditional subtractive manufacturing techniques. From the manufacturer's perspective, with production of implants having standard sizes, important considerations include start-up manufacturing costs, raw material cost, the cost of any secondary finishing processes, as well as the time necessary to complete all the required steps for producing a finished part. These factors all contribute to the cost of a final implant component. Consider, for example, an orthopedic or spinal device with a porous surface for bone ingrowth. At a conceptual level, the device itself needs to be manufactured, and the porous coating needs to be produced and applied to the outside of the device. There are time delays in all the steps to make the device, as well as time delays before the device can be coated. The longer the process takes, the further in advance a manufacturer needs to plan their production or create a backlog of inventory to satisfy short-term demand.

AM of PEEK implants has the potential to address many of these limitations. Medical grade PEEK is expensive, and machining results in expensive waste when turning down a rod or extruded plate to create an implant. Injection molding produces less waste, but has a high start-up expense to produce the necessary molds. Finally, not all implants are suitable for machining or injection molding, and specific requirements in the molding equipment are necessary to process a high temperature polymer such as PEEK. For example, porous implants with complex parts are challenging to produce with conventional techniques. If, however, it were possible to simultaneously 3D-print a device and its porous coating at the same time, even with post-processing, the economics may favor 3D printing over a staged traditional production process. After a decade of investment in metal AM, these obstacles have already been overcome, as evidenced by selected orthopedic and spine devices already clinically available by major manufacturers and third-party service providers, such as Materialise (http://www.materialise.com/en/medical/3d-printed-implants).

Maxillofacial and dental surgeons have been leaders in the field of patient-specific implants.[11] In these fields, matching a patient's specific anatomy is essential for a satisfactory outcome. Not content with waiting the weeks necessary for 3D part manufacturers to make patient-specific implants, surgeons and their patients are investigating ways to bring AM into the hospital or clinic. With PEEK, we are still in the early stages of researching how to effectively and economically apply AM to produce load-bearing implants, such as spinal cages.

Studies / Literature Review

There are few studies describing AM techniques for PEEK. SLS was the first commercially relevant AM processing

route developed for polyketones such as PEEK.[12,13] SLS processing of PEEK is further complicated by particle morphology and size distribution. In addition to the complexity of powder production and handling, SLS equipment is costly and generates gaseous laser sintering powder material waste.[12,14] Lastly, residual powder, which is unsintered is not fully reusable, and is thus considered as waste. The structure-property relationships for PEEK fabricated using SLS have been studied.[13,15] Researchers have investigated the effect of build orientation on the mechanical behavior of cranial plates,[16] and found that printing in the horizontal and inverted horizontal orientations exhibited the highest geometrical accuracy and compressive strength.

The limitations of SLS have fueled both commercial and academic interest in FFF of PEEK as an alternative. As yet, relatively few studies discuss FFF of PEEK.[10,14,17] Wu *et al.*, developed a PEEK 3D printing system and defined optimal heated bed and print head nozzle temperatures for FFF of PEEK.[14] Vaezi *et al.*, later compared a syringe-based extrusion system and FFF for PEEK to manufacture porous structures.[17] Rahman *et al.*, on the other hand, investigated the mechanical properties of dog-bone PEEK specimen printed via FFF.[18] Finally, Cicala *et al.*, used FFF in a survey of high-temperature engineering polymers including PEEK.[10]

The recent advances of FFF techniques to include high processing temperature polymers, including PEEK, motivated our research group to examine spinal cages produced with this manufacturing technique.[19] The compressive and torsional mechanical properties were found to be sensitive to printing speed. We were able to achieve static compression and shear strengths for 3D-printed cages that reached 63-75% of that for machined cages (Fig. 1). The static strength of the printed cages was limited by the adhesion of successive layers in the AM process.

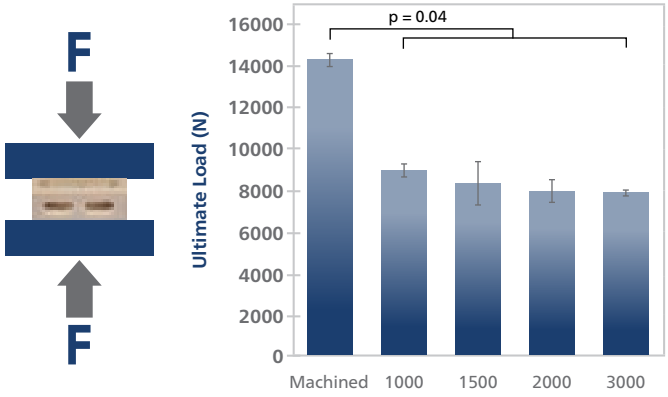

Figure 1: Ultimate strength of FFF printed PEEK spinal cages, compared with machined PEEK cages, adapted from Başgül.[19]

Although there are relatively few studies on AM PEEK implants published in the peer-reviewed literature, the 3rd International PEEK Meeting in 2017 had a special emphasis on 3D printing of PEEK and porous PEEK structures for medical applications (for abstracts, see http://www.medicalpeek.org). We welcome researchers to attend and submit to the 4th International PEEK Meeting in 2019, where AM of PEEK implants will once again be featured. Details about the upcoming conference can be found online at http://www.medicalpeek.org.

Regulatory Considerations

The explosion of medical applications of AM instruments and implants has created a need for careful preclinical testing and evaluation to ensure such devices are reasonably safe and effective, prior to clinical introduction. In the US, the regulatory pathway for AM products has been described in a recent FDA Guidance Document.

For example, patient-specific implants fall under a category of patient-matched devices, which require an entire envelope of designs to be verified and validated under the regulatory framework overseen by the FDA.

> *"Technical Considerations for Additive Manufactured Medical Devices, Guidance for Industry and Food and Drug Administration Staff."*
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> FOR MORE INFORMATION, PLEASE VISIT HTTPS://WWW.FDA.GOV/MEDICALDEVICES/PRODUCTSANDMEDICALPROCEDURES/3DPRINTINGOFMEDICALDEVICES/DEFAULT.HTM

For most existing spinal and orthopedic implants, AM of PEEK represents an achievable innovation with a clearly defined regulatory pathway in the US as a Class II implant requiring 510(k) FDA clearance, much in the same way that SLS Ti cages are Class II and have already been cleared with a 510(k) process. Beyond the technical issues associated with the AM process and its ramifications on strength, fatigue resistance, biocompatibility, and bone ingrowth, which can be assessed with well accepted techniques (and addressed in FDA guidance), AM PEEK implants do not introduce any new issues of safety and effectiveness that do not already apply to traditional manufactured PEEK implants, provided they are already Class II devices. As stated in the recent FDA guidance on Additive Manufactured Medical Devices, "It is anticipated that AM devices will generally follow the same regulatory requirements as the classification and/or regulation to which a non-AM device of the same type is subject." Thus, the regulatory risk associated with AM PEEK implants, at least in the US, is both clearly defined and, unless the device is already Class III, reasonably low.

The regulatory considerations of hospital-produced implants are more complex, and country specific. In Europe, the situation is currently more lenient than the US, with hospitals falling outside the Medical Device Regulation, provided they produce implants using biomaterials that are standardized for implant applications. Surgeons are aware of this loophole in the regulation and are encouraging the manufacture of

patient-specific implants in hospitals, at least so long as the regulatory loophole still exists.[20] It is expected, naturally, that European regulators will be eventually working to close this loophole at some point in the future. ▲

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Perspective from Invibio Biomaterial Solutions™

As you can see from the article, additive manufacturing is an exciting new area for innovation. However, due to the potential complexity of the process, FDA has already issued a guidance document, *Technical Considerations for Additive Manufactured Medical Devices* in December of 2017. Within this document FDA provides advice on the considerations device manufacturers should have regarding the materials used in the additive manufacturing process. This states that any submission should include the identity of the starting material, the material supplier and the incoming material specifications with certificates of analysis, including test methods used.

Clearly the parameters included in any specification will be dependent upon the nature of the raw material, the requirements of the finished device and the specific additive manufacturing technology being used. However, the guidance provides some examples of parameters for inclusion, such as particle size and distribution for solids, and viscosity for liquids. For polymers there is a list of possible parameters such as their composition, purity, molecular formula, molecular weight, thermal transition temperatures and monomer content. All of this information for our implantable materials is already included in Invibio's master file.

Provided by Craig Valentine, Director of Quality and Regulatory Affairs

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Dr. Steven Kurtz serves as a part-time associate Research Professor and Director of the Implant Research Center at Drexel University's School of Biomedical Engineering, Science, and Health Systems. He is a Corporate Vice President and the Director of Exponent's Biomedical Engineering practice. Dr. Kurtz has expertise in the clinical performance of polyethylene, ceramic, and metal-on-metal hip implants.

His professional career has involved the evaluation of medical device technologies, from a combined analytical, experimental, and clinical perspective. His research activities have emphasized real world clinical performance of medical devices, including orthopedic, spine, and cardiovascular implants, as assessed by human implant retrieval specimens and national health care databases; mechanical behavior of synthetic biomaterials; contact mechanics of artificial joints; and structural evaluation of bone-implant systems.

Dr. Kurtz is active in many professional societies, including the American Academy of Orthopedic Surgeons, the American Association of Hip and Knee Surgeons, the Hip Society, the Knee Society, and the American Society for Testing and Materials (ASTM). Dr. Kurtz has edited seven books and written over 200 journal articles and 460 conference abstracts. He is the founding editor of two educational websites: the UHMWPE Lexicon (http://www.uhmwpe.org) and the Medical PEEK Lexicon (http://www.medicalpeek.org). He has co-edited STP 1560: Metal-on-Metal Total Hip Replacement Devices for the ASTM in 2013 and recently completed the UHMWPE Biomaterials Handbook, 3rd Edition, published in October 2015.

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