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From Injection Molding to 3d Printing of Patient-Specific Implants



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Abbreviations: GDP: Gross Domestic Product; PEEK: Poly-Ether Ether Ketone; SLS: Selective Laser Sintering; FDA: Food and Drug Administration

Editorial

The number of patients suffering from damaged or diseased tissues has increased due to an aging population. The result has been a greater socioeconomic burden on society. For example, the United States alone spends 17.1% of its gross domestic product (GDP) on health care [1,2]. Hence, there is a pressing need to develop novel cost-effective methods for tissue reconstruction using medical grade implants. Historically, such implants have been manufactured using traditional manufacturing technologies such as injection molding. Unfortunately, these technologies have certain drawbacks, namely they are often reserved for mass production due to the high initial costs involved and part design restrictions. Moreover, medical implants are often produced in generic sizes that are commonly based on an "average" patient. One solution to these problems is to manufacture patient-specific implants using 3D printing. This allows precise control of size, shape and geometry of the implant to better mimic native tissues [3,4]. Compared to traditional manufacturing, however, the 3D printing of medical implants is still in its infancy. Pro tempore, titanium alloys and polyether ether ketone (PEEK) implants are sporadically manufactured using selective laser sintering (SLS) printing technologies [5,6]. However, both titanium and PEEK have certain drawbacks.

For example, they both require high printing temperatures above 300°C, and therefore such implants are more expensive to manufacture. Furthermore, such materials are difficult to sculpture during surgery due to their rigidity (>120 GPa) [7]. Hence, novel printable, implant-grade materials are still sought. Polymers

have several advantages over titanium. These include lower cost, reduced weight, and excellent biocompatibility [8]. Furthermore, there are a plethora of possibilities for tailoring the material, processing, and product properties of polymers [9]. However, the lack of printable polymers suitable for medical applications still remains [5,10]. Very few printable polymers currently comply with American Food and Drug Administration (FDA) and European medical device regulations. Fortunately, the FDA 510(k) clearance process allows changes to be made to the manufacturing processes of existing polymers that have initially been developed for traditional manufacturing technologies such as injection molding [11]. As a consequence, the FDA approval time required to change the manufacturing process of an existing implant- grade polymer from injection molding to 3D printing can be markedly shortened. However, printing medical constructs that have qualities comparable to those acquired during injection molding remains a challenge [12,13].

In 3D printing, the print properties and quality largely depend on the material flow behavior, which can be characterized by the viscosity function using rheology. The viscosity function of a polymer is known to be influenced by extrusion temperature, flow rate, molecular weight, and chain structure. In this context, it must be noted that polymers will not be able to flow or take shape if the extrusion pressure and temperature are too low but can also degrade if the temperature is too high. Therefore, the operation window has to be carefully chosen and adjusted accordingly.

However, flow instabilities such as melt fracture or surface distortions may arise within or outside the printer extruder setup, e.g., in cases of high processing rates or internal stresses. Another challenge that remains in the 3D printing of polymers are the temperature differences between the adjacent layers in the build. These differences in temperatures mean that cooling occurs when the heated nozzle moves from one build area to another. Uneven cooling can lead to a reduction in mechanical properties such as the tensile strength of the printed construct, particularly in the Z-direction of the build [14-16]. This problem could be solved by properly re-heating the previously printed layer, and thus allowing the large polymer chains to diffuse across the layer interface. The diffusion speed (D) of the polymer chains is inversely related to the molecular weight, $M_{w'}$, of the polymer chains ($D \propto 1/(M_w)^3$ also strongly dependent on the melt temperature ($D \propto T_2$) [17].

Therefore, layer adhesion can be improved by lowering the molecular weight and raising the melt temperature of polymers. Another option is to enhance the interfacial strength by applying adhesive possibilities that "glue" the layer interfaces by means of reactive chemistry. An even more advanced option would be to use photopolymers, which offer better intrinsic adhesion between successive layers. However, to the best of our knowledge no ISO-10993 implant-grade photopolymers are currently available on the market. In conclusion, 3D printing of patient-specific implants using existing FDA-approved polymers is feasible. However, achieving the corresponding physical, structural and mechanical properties of injection-molded constructs still remains a challenge. Future research should focus on optimizing both the material and processing parameters of polymers and developing novel (photo) polymers for 3D printing.

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