The challenges associated with fused deposition modelling of high-density polyethylene for facial augmentation implants: a review

Rebakakgosi Mohutsiwa1*, Jacobus van der Walt2, and Hercules van den Heever3

123Department of Mechanical and Mechatronics Engineering, Central University of Technology, Private Bag X20539, Bloemfontein, Free State 9300, South Africa.

Abstract. High-density polyethylene (HDPE) implants are widely employed in craniomaxillofacial augmentation surgery because of their unique ability to bond with tissues for bone repair and functional recovery of the facial areas which are affected by acquired or congenital facial deformities. The direct manufacturing of HDPE implants as patient-specific implants through fused deposition modelling (FDM) has the potential to enhance their clinical performance. However, this approach is restricted by issues such as material shrinkage and part warpage when HDPE is processed through the FDM technology. This review paper presents an overview of FDM of HDPE to produce facial reconstruction implants.

1 Introduction

Facial areas affected by deformities can be functionally, structurally, and aesthetically restored through craniomaxillofacial augmentation surgery to improve the patients’ quality of life, boost their self-confidence and strengthen their social roles [1, 2]. The field of craniomaxillofacial augmentation surgery has advanced from using gold and silver plates in ancient civilization to using biologic tissue, ceramics, polymeric materials, and metal alloys in recent times [1, 3 – 7]. High-density polyethylene (HDPE) is one of the polymeric materials which can be used in craniomaxillofacial augmentation surgery [8 – 11]. HDPE as an implant material is usually used for permanent augmentation of cheek bone deformities, orbital floor defects, jawbone defects, and nasal tip anomalies, amongst others [4, 5, 8 – 11]. Ideally, HDPE implants need to be customized according to the facial anatomies and health care needs of each individual patient to ensure their success. These implants can now be effectively produced through additive manufacturing (AM) technologies, which can use modified geometrical information of the patient’s face from medical imaging technologies such as computed tomography (CT) scans to produce customized medical implants [1, 8, 12, 13].

Additive Manufacturing (AM) technologies, which can also be referred to as three-dimensional (3D) printing, are advanced manufacturing methods which fabricate 3D components by joining the material layer-upon-layer using computer-aided design models [12, 14]. These technologies have improved and grown since their inception in the 1980s and are now grouped into seven major categories viz., vat photopolymerization, binder jetting,
sheet lamination, powder bed fusion, direct energy deposition, material jetting, and material extrusion [8, 12 – 14]. When it comes to the types of raw materials that can be used and how they are deposited layer-upon-layer to create 3D objects, these technologies are different from one another. Nonetheless, the layer-upon-layer material addition technique of fabricating 3D objects remains the same [15]. For instance, in vat photopolymerization, light is used to cure and solidify photo-sensitive resin materials as they are stacked one layer at a time to produce 3D objects. In contrast, during powder bed fusion (commonly referred to as laser sintering), polymeric powder particles are deposited in a thin layer and joined together by a laser beam. The process involves building up layers of powdered particles on top of one another to produce 3D objects. In material extrusion, 3D objects are fabricated layer-upon-layer by the selective deposition of molten or semi-molten raw paste, gel, solution, or polymeric material through a nozzle or orifice [14, 16 – 18]. Fused deposition modelling (FDM) and semi-solid extrusion are two examples of AM methods which are part of the material extrusion AM category [12].

The purpose of this paper is to review various studies which have been conducted on the processability of HDPE through the FDM technology to enable the manufacturing of HDPE implants and to identify the approaches which have been taken to deal with problems that arise during the processing of HDPE through FDM. This review paper will also aim to provide helpful guidelines that may be used for the direct manufacturing of HDPE implants through any AM process besides the FDM technology.

2 High-density polyethylene as a craniomaxillofacial augmentation solution

High-density polyethylene (HDPE) is a semi-crystalline thermoplastic material from the polyethylene family of polyolefin polymers and is often obtained by the polymerization of the ethylene monomer [11, 19]. HDPE is a rigid and hard material with excellent mechanical properties such as high tensile strength, high compressive strength, and good impact strength. HDPE material is also non-degradable, chemically inert, and compatible to the human biological environment and does not cause inflammatory and harmful response when used inside the human body as a synthetic facial implant solution [8 – 11].

The clinical success of HDPE implants is mainly due to the fact that these implant structures can be produced as porous structures. The use of porous synthetic implants, including HDPE implants, came as a result of the need to improve implant stability and fixation with the surrounding tissues over the use of screws and bone cements [20, 21]. In tissue engineering, porous implant structures can be called lattice structures or solid tissue scaffolds. These porous implant structures are generally complex geometry design structures that provide pathways for cell proliferation, cell penetration, and surrounding tissue ingrowth [8, 22]. All physiological tissues and organs naturally have a unique non-cellular support structure called the extracellular matrix [23]. During tissue rehabilitation, this extracellular matrix serves as both structural support and aids in the initiation of the stimulation for cell proliferation, cell penetration and surrounding tissue ingrowth. In this context, porous HDPE implants are created to behave as and resemble the extracellular matrix of tissues to remedy facial defects [8, 23 – 25]. Porous HDPE implants allow for superior cell proliferation, cell penetration and surrounding tissue ingrowth when compared to medical implants made from other polymeric materials such as silicone rubber, polymethylmethacrylate (PMMA), polyether etherketone (PEEK), and expanded polytetrafluoroethylene (ePTFE). Hence, porous HDPE implants rarely suffer from implant slipping and extrusions where the implant starts being visible and poking through the skin [7 – 10, 24, 26 – 28]. Porous HDPE implants can be identified by the distribution and configuration of roughly equal open pores that are joined to one another. The key factors that allow for cell proliferation, cell penetration and
surrounding tissue ingrowth into porous HDPE implants are the location of open pores, their connectivity, shape, and size [8, 20, 23, 25].

Porous HDPE implants are favoured over metallic implants because the majority of the latter implants are usually produced as solid synthetic implant designs with stiffness (Young’s modulus) that is much higher than that of the surrounding bones as shown in Table 1 below [8, 20, 24]. It is well known that solid implant structures that are much stiffer than the host bone produce the stress-shielding effect. During stress shielding, the surrounding bone gradually decomposes into its constituent components, which are then scattered and allow the bone to regenerate into new bone. When the new bone forms, the implant gradually moves out of place and becomes loose [8, 20]. An alloy consisting of 90% titanium, 6% aluminium, and 4% vanadium called Ti6Al4V extra low interstitial is the only metallic material that is still widely used in clinical applications and has properties which are competitive with HDPE implants. The properties of Ti6Al4V alloy which makes it suitable for facial augmentation include high strengths, high corrosion and impact resistances, non-degradability, and compatibility with the human biological environment. As a result, Ti6Al4V alloy is usually applied during augmentation of loadbearing bony facial features where high strength implants are required such as for jawbone reconstructions. For augmentation of non-loadbearing bony tissues such as cheek bones, the use of Ti6Al4V alloy is not necessary and flexible materials such as HDPE are more suitable. Other issues which relate to the use of Ti6Al4V include some patients claiming that their Ti6Al4V implants feel cold during the winter season, and that there is possibility of the implant being visible through the facial skin of light-skinned individuals. In addition, medical imaging of implants made with Ti6Al4V alloy is also known to produce artifacts that lower the quality of the images, which are frequently required for postoperative follow-up checks and potential radiotherapy planning [12, 20, 29 – 32].

**Table 1.** Mechanical properties of metallic materials in comparison to those of bioactive glass, cortical bone, and polyethylene [11, 20, 33, 34].

<table>
<thead>
<tr>
<th>Material</th>
<th>Young’s Modulus (GPa)</th>
<th>Yield Strength (MPa)</th>
<th>Ultimate Tensile Strength (MPa)</th>
<th>Density (g/cm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless steel 316L</td>
<td>205 – 210</td>
<td>170 – 750</td>
<td>465 - 950</td>
<td>8.4</td>
</tr>
<tr>
<td>Cr – Co alloys</td>
<td>220 – 230</td>
<td>275 – 1585</td>
<td>600 – 1785</td>
<td>8</td>
</tr>
<tr>
<td>Pure titanium</td>
<td>110</td>
<td>485</td>
<td>760</td>
<td>-</td>
</tr>
<tr>
<td>Titanium alloys</td>
<td>105 – 125</td>
<td>840 – 1100</td>
<td>590 – 1024</td>
<td>4.5</td>
</tr>
<tr>
<td>Bioactive glass</td>
<td>22</td>
<td>500</td>
<td>56-83</td>
<td>-</td>
</tr>
<tr>
<td>Cortical bone</td>
<td>3 - 30</td>
<td>45 - 55</td>
<td>70 – 230</td>
<td>1 - 2</td>
</tr>
<tr>
<td>HDPE</td>
<td>0.2 - 1.2</td>
<td>20 - 40</td>
<td>-</td>
<td>0.94 - 0.97</td>
</tr>
</tbody>
</table>

Porous HDPE implants are preferred over implants made from ceramic materials such as bioactive glass, hydroxyapatite, glass ceramic apatite-wollastonite, and tricalcium phosphate, which are most suitable for non-loadbearing facial augmentation just like HDPE. In contrast to non-degradable materials such as HDPE, most ceramic materials are usually used to augment non-loadbearing bony tissues of the face where the implant is used to promote bone growth and after some time degrades while the bone remains. This is because ceramic materials are known to be fragile and prone to fracture because of their inherent brittleness and poor mechanical qualities (e.g., low fracture toughness) when utilized as synthetic facial implants. Their brittleness and poor mechanical properties also makes it difficult for surgeons to manually modify during a surgical procedure to create an acceptable patient fit and this further limits their clinical use as facial implants [8, 20, 29, 33, 35].
Porous HDPE implants also stand in contrast to biologic tissue implants such as autografts, allografts, and xenografts. Autografts are biologic tissue implants harvested from non-essential bones of the face and head regions of the patient receiving the graft. Allografts are biologic tissue implants which come from human donor patients who are not the patient receiving the graft while xenografts are biologic tissue implants obtained from other species besides the human species [7, 8]. Biologic tissue implants are usually chosen for facial augmentation because of their intrinsic propensity to be easily compatible to the human biological environment. Also, these implants have the power to activate the body's recruitment of immature and unspecialized cells as well as their differentiation and stimulation into cells that promote bone growth. Moreover, they can also provide scaffolding and structural support during cell proliferation and surrounding tissue ingrowth. However, the clinical use of biologic tissue implants is constrained by the necessity to remove bone tissue and transfer it to the primary site during a different surgical procedure. As a result, the patient goes through a longer surgical procedure, loses more blood, feels uncomfortable afterward, and needs to stay longer in the hospital. Other constraints for biologic tissue implants include risk of infections, limited donor tissue availability, and unfavourable implant failure rates which were reported to be almost 25% in the 1980s and during the past decade have remained over 20% [7, 8, 36 – 38].

Porous HDPE implants have been proven to be effective substitutes for implants made from other polymeric materials, biologic tissues, metallic materials and ceramic materials in order to improve facial regions affected by facial deformities [8]. However, the main issue with currently available HDPE implants is their lack of patient-specificity. This is due to their commercial availability as sheets, blocks, and standard shapes which necessitates manual modification by the surgeon in the operating room in order to get an appropriate patient fit [8, 39, 40]. When implants that are not patient-specific and require further modifications are used in reconstructive surgery for augmentation of facial defects, the operating theatre time is increased. This results in a more expensive surgical procedure, the patient is exposed to increased risk of infections, and the implant fit may be less than ideal [1].

3 Fused deposition modelling for patient-specific and porous implant structures

One of the AM techniques, known as fused deposition modelling (FDM), aims to produce accurate and patient-specific 3D porous structures which can be employed as medical implants and tissue scaffolds during tissue engineering [1, 8, 12, 15, 41]. In the early 1990s, Scott Crump of the Stratasys corporation in the United States of America invented and made FDM technology commercially available as material extrusion AM process [15, 16, 41, 42]. The technology has since developed and it is now widely used in prototyping, modelling, and production applications [15]. This is due to the process having shorter production cycle times, low production costs, and not requiring the use of organic solvents, the presence of sticky resins or inks, and micron to sub-micron sized powder particles which may pose safety, occupational, and environmental concerns [43]. In addition, when compared to conventional manufacturing methods which produce porous structures on average terms (average pore size, average pore-to-pore opening size, and average porosity), FDM technology has the ability to consistently produce porous implant structures and accurately manipulate and control their internal geometry designs as well as their porosities to tailor for their superior mechanical properties and enhance their clinical performance for each individual patient [12, 16, 17, 22, 43]. Other porous structures that have been created using FDM in addition to tissue scaffolds and medical implants include schwarzite structures, seashell-inspired architectures, tubulance 3D structures, lightweight sandwich structures, honeycomb cellular structures, lumbar fusion cages, and boxception architectures. These examples further
highlight the technology’s capacity to create porous structures [41]. FDM may therefore be adopted and used for the fabrication of porous patient-specific HDPE implants. However, to successfully produce porous patient-specific HDPE implants through the FDM process, the science and process requirements for fabricating porous structures through the technology need to be well understood.

3.1 The science of fused deposition modelling when fabricating patient-specific porous structures

The FDM process can produce porous implant structures using a solid filament which is normally made from a medical-grade thermoplastic material using traditional extrusion method. In the FDM process, a filament material is constantly hauled off a spool and fed into a print head which can move in the X-Y plane. The print head contains two counter-rotating driving wheels, one with a smooth surface and the other with a grooved surface. The counter-rotating driving wheels are used to pinch and prevent the material from slipping during its transportation from the spool to the heating liquefier and printing nozzle which are also situated inside the print head. The heating liquefier is responsible for heating the material to a state at which it is less viscous and can easily flow through the printing nozzle. For semi-crystalline materials, such as HDPE, the heating temperatures are usually above the material’s melting point and are used to turn the material to a molten state. The printing nozzle on the other hand is used to deposit the filament onto a heated printing platform as a molten material according to the computer-controlled manufacturing toolpath to commence building the first layer of the porous 3D structure. Upon completion of the first layer, the printing platform will move one layer downwards in the Z-direction and another layer of the molten filament material will be deposited and fused with the previous layer. The process will continue this way, layer-upon-layer, until a 3D object is manufactured [12, 16, 43]. The schematic representation of the FDM process is illustrated in Figure 1 below.

![Schematic representation of the FDM process.](image)

The fabrication of 3D implant structures through the FDM process is made possible by the use of medical imaging technologies and 3D modelling and design applications. Medical imaging technologies (such as computed tomography) are used to gather geometric information of the patient’s facial features. A 3D model of an implant is then designed using 3D modelling and design applications (such as Materialise Mimics and 3-matic) from the patient’s geometrical data of the face. The 3D model of an implant is normally saved in stereolithography file format. Advanced build preparation applications such as Materialise Magics can be employed when generating the manufacturing path, otherwise build preparation applications which are normally in-built within FDM technologies can be used.
for this purpose although their functionalities as far as porous implant structures are concerned may be limited [1, 8, 12, 13, 16].

### 3.2 Fused deposition modelling process requirements for producing patient-specific porous structures.

There are essentially three main aspects which need to be considered for the successful fabrication of patient-specific porous implant structures through the FDM technology, viz., filament material, 3D structure geometry, and process parameters [41]. The filament material’s properties such as its solubility, degree of crystallinity, rate of crystallization, molecular weight, viscoelastic and thermal behaviour play a crucial role in the quality of implant structures hence they need to be considered when porous implant structures are to be fabricated with FDM technologies [8, 44]. For filament materials to be flawlessly processable through the FDM process to fabricate implant structures, they should satisfy certain material requirements. These filaments should firstly be made from a medical-grade thermoplastic material which can be melt processed, and in terms of dimensions, be within a certain diameter and ovality tolerance to fabricate porous structures [16, 43]. Ideally, filament diameters should correspond with currently available commercial filaments which have an approximately round cross-section and have diameters which are either $2.85 \pm 0.1$ mm or $1.75 \pm 0.1$ mm. If filaments do not correspond with these diametric limits and tolerances, they are likely to cause inhomogeneous deposition of the material or clog the nozzle and interrupt the build job [43].

Filament materials should also have the right mechanical properties which will be suitable for withstanding the pinching effect from counter-rotating driving wheels. For a reliable and continuous transport through the counter-rotating driving wheels, the filament material should reveal roughly 5% of the minimum strain at yield under tensile load and have sufficient compressive modulus to withstand buckling which is often experienced at the entrance of the liquefier [16, 43]. The viscosities of filament materials should also be sufficient to avoid material backflow (often seen with stiff and highly viscous materials) or material dripping (often seen with less viscous materials). Material backflow occurs at the end of the heating liquefier and entrance to the printing nozzle and can result in under-extrusion which can lead to damage of the extrusion system of the machine and ultimately interrupt the build job. Material dripping, on the other hand, occur at the tip of the printing nozzle during material deposition and can result in over-extrusion which can lead to uncontrolled material deposition and undesired part geometries since deposited molten filaments are unable to retain their shape after they have been extruded [16]. Viscosities and melt flow indices of filament materials which are normally used in the FDM technology can therefore be used to establish a suitable range which can be used as a guide when new materials are to be used in the FDM technology to fabricate porous structures. From literature, this range was found to be between 5000 Pa.s and 10 000 Pa.s [43]. Furthermore, filament materials should have the right thermal properties for withstanding the heating conditions in the liquefier without degradation. To be specific, semi-crystalline filament materials should have extrusion temperatures which are roughly $20 - 40 \, ^\circ C$ higher than their glass transition temperatures to soften their amorphous sections [43]. To melt the crystalline regions of these semi-crystalline filaments, their extrusion temperatures should ideally range between $180 - 260 \, ^\circ C$. Mathematical models can also be utilized when there is a need for more information on the processability of filament materials through the extrusion system of the FDM technology. These analytical models are often used in combination with computational simulation programs for deeper comprehension of the interaction between the filament material and the extrusion systems of FDM technologies [43].
The 3D geometry of structures to be manufactured with the FDM technology depend highly on the ability of the process to accurately deposit the neighbouring molten filaments which are now rasters or beads of the material layer-upon-layer [43]. For part consolidation to occur and ultimately end up with a physical 3D porous structure, the freshly deposited material rasters need to maintain a stable geometry, adhere to the printing platform, and fully support itself during first layer modelling [43, 45]. In addition, the freshly deposited material rasters need to be strong enough after first layer fabrication and be able to serve as support substrate for the fabrication of subsequent layers and handle their resulting weight [45]. Moreover, the freshly deposited material rasters should also be able to fuse and bond with the pre-existing material rasters during and after any layer modelling. Fusion and bonding between material rasters are ensured by the sintering action and healing process. Sintering action refers to the neck formation and growth when neighbouring material rasters bond with each other and it is activated by the hot freshly deposited material raster when it touches the previously deposited material raster which is now already cold. Healing process refers to molecular diffusion and the disappearance of the neck that formed between material rasters as a result of the sintering action. Part consolidation is therefore achieved by establishing large neck growth and the appropriate control of the rate of molecular diffusion before the glass transition temperature is reached. The sintering action and healing process needed for part consolidation are highly dependent on the cooling rate which has the ability to hinder the completion of the healing process if it is too fast or encourage sufficient healing if it is reasonably slow [43]. Sintering, healing, and cooling rate are dependent on the filament material properties and on the process parameters of the FDM technology. Since the FDM process is a highly complicated technology and has conflicting parameters which may present much difficulty when porous implant structures are to be fabricated with the technology, these parameters can be classified into three main groups, viz., slicing, build orientation, and temperature parameters. These groups may be effective when selecting suitable FDM process parameters for fabricating porous implant structures [15, 41, 46, 47]. Slicing parameters are used to specify the manufacturing path and to define the cross-sectional area of each layer that makes up the 3D object. These parameters may include layer thickness, nozzle diameter or road width, print speed, air gap, number of contours, contour width, contour to contour air gap, raster angle, material flow rate/extrusion multiplier, stacking section length, infill pattern, and the infill density amongst others. The build orientation parameters, on the other hand, orient the 3D model of the part to be manufactured according to the cartesian coordinate system and in relation to the printing platform of the FDM technology. The only parameter which belongs to this category is part orientation. The temperature parameters are responsible for setting the thermal conditions for the appropriate building of the part and fusion of each layer. Extrusion or nozzle temperature, build chamber temperature, and bed or build platform temperature all form part of the temperature parameters for the FDM process [15, 41, 46 – 48]. When fabricating porous polymeric implant structures, such as HDPE implants, through the FDM process, careful consideration of the material filament properties, optimal selection of process parameters, and appropriate knowledge of the design of the 3D geometry that must be fabricated may be beneficial. In the next section, these requirements will be considered while analysing the studies which have been conducted on the FDM of neat HDPE material.

4 Fused deposition modelling of neat high-density polyethylene for use in craniomaxillofacial augmentation surgery: Success and challenges

HDPE material is still in its infancy stages as far as FDM technologies are concerned. Wampol [49] is one of the researchers who have successfully processed neat non-medical
grade HDPE filament through the FDM process. From Wampol’s study, it was reported that extruded neat HDPE material rasters fail to adhere to the printing platform. This was due to material shrinkage and aggressive part warpage [49, 50]. Tarres et al. [51] and Chong et al. [52], also reported similar issues of material shrinkage and aggressive part warpage after they have tested neat non-medical grade HDPE for processability through the FDM process. Material shrinkage is a phenomenon observed when a material's temperature rises over its glass transition point and the volume of a polymer melt decreases as it cools, including the free volume between the macromolecular chains and their vibrational volume. Materials such as HDPE have high crystallization rates and high degree of crystallinity and are more likely to experience material shrinkage [16, 50]. In FDM technologies, these materials facilitate rapid and inhomogeneous cooling, shorten the time needed to achieve the glass transition temperature, and impede the progression of the healing process during component consolidation. Warpage is a direct consequence of materials that shrink and is associated with parts that are bent, distorted or twisted out of shape resulting in part delamination and break-off from the printing platform during the building process [43, 50]. In addition to warpage caused by material shrinkage, anisotropic material deposition and complex temperature distribution, both of which are FDM process characteristics, cause contractual forces within the deposited material rasters, resulting in residual stresses that worsen the warpage of HDPE parts. Even if there is sufficient component adherence to the printing platform, HDPE parts undergo warpage after the FDM process is completed. This form of warpage is caused by significant residual tensions which developed inside the material rasters during the FDM process [16]. In addition to material shrinkage and part warpage, HDPE filaments also suffer from poor interlayer bonding, void formation, and under-extrusions during the FDM process. This is because of material backflow associated with its high viscosities and high molecular weights [50, 51, 53]. As a result of these findings, both neat non-medical grade and neat medical-grade HDPE filaments continue to be among the filament materials which are not widely available in the filament material market for commercial use in FDM processes as illustrated in Figure 2 below.

**Fig. 2.** List of polymeric materials which can be used in the FDM process and those are suitable for FDM process but have not been used at the commercial level. Adapted from [16, 17].
5 Strategies to overcome the challenges associated with fused deposition modelling of high-density polyethylene for use as facial implants

Despite the challenges associated with its processability through the FDM technology, HDPE remains a suitable candidate material for this process. This is because HDPE has material properties which are suitable for the FDM process such as high strength-to-weight ratio, resistance to moisture and solvents, and is widely available and reasonably priced [8, 49]. According to Table 2 below, HDPE has melting points, extrusion temperatures, and melt flow indices that fall between those of polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS), which are two materials that are frequently used in the FDM process [34]. HDPE also has extrusion temperatures which are within the needed range for softening its amorphous regions (20 – 40 °C range above glass transition temperature). Its specific extrusion temperatures are also in the needed range of 180 – 260 °C for melting its crystalline regions [34]. In light of these factors, the FDM process can therefore be modified and optimized to suit the processability of materials such as HDPE. The HDPE material can also be optimized to make it more processable through the FDM process. These approaches are the focus of the following subsections.

Table 2. Comparison of material properties between polylactic acid, acrylonitrile butadiene styrene, and HDPE [34].

<table>
<thead>
<tr>
<th>Material Properties</th>
<th>PLA</th>
<th>ABS</th>
<th>HDPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melt flow rate (g/10 min)</td>
<td>2.4 – 4.3</td>
<td>22 - 48</td>
<td>4 - 8</td>
</tr>
<tr>
<td>Tensile Strength (MPa)</td>
<td>50 - 55</td>
<td>30 - 52</td>
<td>20 - 40</td>
</tr>
<tr>
<td>Strain at yield (%)</td>
<td>10 - 100</td>
<td>3 - 75</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Young’s Modulus (GPa)</td>
<td>3.5</td>
<td>1.7 – 2.8</td>
<td>0.12 – 1.2</td>
</tr>
<tr>
<td>Melting temperature (°C)</td>
<td>120 - 170</td>
<td>200 - 230</td>
<td>120 - 190</td>
</tr>
<tr>
<td>Glass transition temperature (°C)</td>
<td>55 - 60</td>
<td>100</td>
<td>80 - 110</td>
</tr>
<tr>
<td>Crystallinity (%)</td>
<td>~37</td>
<td>Not applicable</td>
<td>70-80</td>
</tr>
<tr>
<td>Cooling time</td>
<td>Long</td>
<td>Medium</td>
<td>Medium</td>
</tr>
</tbody>
</table>

5.1 Direct strategies: Optimizing the process for processing neat HDPE material

5.1.1 Extrusion mechanism modification

Challenges such as filament material slippage on the pinch wheel, material buckling and under-extrusions seen when materials such as HDPE are processed through FDM technologies have resulted in efforts to modify the traditional extrusion mechanism of FDM systems [54]. In more recent developments, syringe-based and screw-based extrusion mechanisms have been recognized as valuable methods for AM applications that enables the processing of a broader range of materials than traditional pinch-wheel-based FDM because they use polymer granules and/or powders as raw materials instead of polymer filaments [54, 55]. Syringe-based extrusion systems in FDM technologies enables the use of granulated and/or powdered materials and works by making use of a plunger for material deposition and a heating barrel for melting the material [54, 56]. The main drawbacks of using syringe-based extrusion systems in the FDM process include possible material degradation which results in poor material properties after long periods of process runs, inhomogeneous temperature
distribution inside the barrel which leads to differences in melt viscosity, potential air-block when there is inappropriate filling of the material in the syringe, and the constant need to keep refilling the barrel during the production of large parts which disturbs the process and causes the part and syringe to cool, resulting in inadequate adhesion between the affected layers [54, 56, 57]. Despite the disadvantages associated with using syringe-based FDM technologies, Yin et al. [58] used neat powdered HDPE material in syringe-based FDM technology and were able to successfully fabricate 3D scaffolds with satisfactory pore size and connectivity. The 3D scaffolds which were fabricated in this study were used for in vitro and in vivo animal studies and the results enabled the potential use of syringe-based FDM technologies for the direct manufacturing of HDPE implants for use during facial augmentation surgery [58].

The use of screw-based extrusion mechanisms in FDM technologies, came as a result of the need to overcome both the challenges associated with pinch-wheel-based FDM technologies and the syringe-based FDM technologies [54]. Screw-based FDM technologies work similar to industrial polymer extruders where a screw situated inside a barrel and in front of a heated nozzle acts as the material melting mechanism and the feeding mechanism. This extrusion mechanism is especially intriguing for use in FDM technologies because it allows the direct use of commercially available granules, ensures continuous feeding of granulated materials and enables precise control over the extrusion process as well as improved capacity to generate suitable extrusion pressures to allow the material to melt and be deposited homogeneously and avoid material backflow [54, 59, 60]. In screw-based FDM systems, there is less material degradation due to homogenous material melting and homogeneous material flow [54]. Setiawan et al. [61] successfully processed neat HDPE granules in a screw-based FDM technology and reported that the extrusion system was able to consistently extrude the molten plastic material at relatively low melting temperatures. The study reported no inhomogeneous material deposition and no under-extrusions. Montoya-Ospina et al. [62] also successfully processed neat HDPE and HDPE-vitrimer granules through screw-based FDM to fabricate 3D scaffolds and compared the printability of neat HDPE with the printability of HDPE-vitrimers. From the study, when using neat HDPE granules, no inhomogeneous material deposition, content voids, and distortions of the resultant filament were reported. However, for HDPE-vitrimers, problems with material flow and filament distortions were initially reported [62].

Screw-based FDM can be made more suitable for processing HDPE material by the incorporation of infrared heaters near the deposition nozzle. This extrusion system setup enables the FDM technology to process highly viscous polymeric materials and helps prevent part delamination and warpage during the FDM process and it has been used successfully before by Tseng et al. for PEEK which is one of the most viscous polymeric materials [59, 60]. Another adaptation to the screw-based FDM technology which may make the technology more suitable for processing HDPE is the addition of piezoelectric actuators between the plasticisation screw mechanism and the extrusion nozzle to enable the deposition of the material as droplets for part fabrication instead of the usual filament strands. As far as porous facial implants are concerned, this approach can ensure that the correct porosity is achieved without neglecting mechanical stability. Paxton [8] mentioned that a compromise between mechanical stability and good porosity is a need in medical implants. Therefore, to know if a porous HDPE implant structure will be successful in its application the pore size range of 150 to 400 µm from previous successful HDPE implants can be used as a guideline. When using ABS to compare traditional FDM technology with screw-based FDM technology which had a piezo-electric actuator mechanism, Pinter et al. [63] found components fabricated with screw-based FDM technology to have better mechanical properties and had more controlled porosity than components produced through the traditional FDM technology. Despite the fact that HDPE was not employed in this study, the results demonstrate that
screw-based FDM technologies have superior control over the porosity of structures. In a study by Chen et al. [64], neat medical-grade HDPE granules were successfully processed through screw-based FDM technology which had piezo-electric actuators and the 3D models which were manufactured were used for implant surface treatment studies with the aim of improving the stability of HDPE. This study remains the only study in which HDPE was successfully processed through screw-based FDM technology where issues related to inhomogeneous material deposition, material shrinkage, part voids and defects, as well as part delamination and warpage were not mentioned as drawbacks of using HDPE in the FDM technology.

5.1.2 Optimisation of process parameters:

To reduce material shrinkage and part warpage associated with the use of the HDPE material when processed in the FDM technology, the process parameters can be optimised to improve the flowability of the HDPE material and suit the process for the production of porous HDPE implants without changing the conventional extrusion system setup of the FDM process [48]. The current goals for processing HDPE through the FDM technology has been to achieve control over the temperature parameters of the process since these parameters have the capacity to promote adhesion and prevent part warpage. Therefore only these parameters have been rigorously optimised for processing HDPE and can be used as preliminary checks when fabricating porous HDPE implant structures through the FDM process [48]. Schirmeister et al. [50] successfully optimized FDM process parameters for processing neat HDPE filaments and were able to fabricate 3D objects for mechanical, dimensional accuracy, and morphological analyses. From the study, issues such as material shrinkage, under-extrusions, part voids, and part warpage were eventually overcome and complex objects were finally fabricated to illustrate the dimensional accuracy of the FDM process when the process parameters are appropriately optimized [50]. To compensate for material shrinkage and avoid void formation around HDPE 3D parts, the study reported that the extrusion volume rate should be raised from 100% to 107% during the process. The extrusion temperatures of 240 °C for 0.2 mm nozzle and 220 °C for 0.8 mm nozzle were also reported as the most suitable for achieving lack of anisotropy, enhanced mechanical properties, and improved surface finish when fabricating HDPE parts. The nozzle diameter and the printing speed were found to have an impact on the part surface quality but had no effect on the mechanical properties of parts produced. To achieve part adhesion without experiencing part delamination and part warpage, printing platform made from styrene-block-ethene-co-butene-block-styrene (SEBS), was found to be the best. This was in comparison to printing platforms made from polypropylene (PP), HDPE (one with smooth surface and the other with roughened surface), glass (one with cleaned surface and the other combined with adhesive hairspray or polyetherimide), as well as platforms made from random and block ethylene/1-octene copolymers. Using SEBS as a printing platform not only improved part adhesion but it also allowed easy detachment of the part from the printing platform without damaging it unlike when HDPE itself was used as a platform [50]. However, according to Jeyachandran et al. [65], using SEBS as a printing platform, incurs additional costs during its preparation, and the platform manufactured from such a material loses its dimensional integrity when used frequently. As a result, in their study, they proposed using SEBS as an adhesive which is prepared and applied over a Kapton tape already stuck on a glass substrate. The study reported that a printing platform prepared this way still provided good part adhesion during the FDM process and allowed easy part detachment when the process was done. Their study also reported that extrusion temperature of 200 to 240 °C, printing platform temperature of 110 °C, and build chamber temperature of 70 °C were more suitable for processing neat
 HDPE material and avoid insufficient diffusion and print induced voids as well improve the dimensional stability of parts produced [65].

For the optimisation of most of the FDM process parameters, statistical design of experiment methods such as response surface methodology, gray relational, artificial neural network, fuzzy logic, genetic algorithm, full factorial, fractional factorial, and Taguchi method in combination with analysis of variance may be used to ensure the successful fabrication of porous HDPE implants through the FDM technology and avoid the trial-and-error method. However, the effective implementation of these process parameter optimization methods is dependent on a well-defined experimental setup. For instance, the Taguchi method is most suitable when a large number of process parameters are to be studied but it is ineffective when the objective is to identify critical process parameters which are often few. This problem may be avoided by using the response surface methodology. Fractional factorial method, on the other hand, is appropriate when a small number of tests are required for process parameter optimization and there are less chances of experimental error. However, if there are many chances of experimental error and precision is needed, full factorial method is preferable to fractional factorial [15, 53]. Through the use of the knowledge of existing FDM process parameters and process parameter optimization methods, layer thickness, air gap, build orientation, raster angle, and raster width were found to be the other significant FDM process parameters and may be used as the first quality evaluation indicators for enhancing material response and mechanical properties to obtain porous HDPE implant structures with high qualities through the FDM process without encountering material shrinkage and part warpage [15, 17, 48]. When PP, which has material properties similar to HDPE, was processed in FDM, it was reported that smaller layer thickness combined with higher extrusion temperatures improves the degree of diffusion and results in a part with fewer voids when only these two parameters were studied. However, when the same material was used again in the FDM technology, it was reported that higher layer thickness, lower extrusion temperatures, and increased printing speed together with short stacking length resulted in minimal part warpage. In another study, when PP was used again, higher stacking lengths led to reduced residual stresses in a part and resulted in a part with improved dimensional stability and low warpage. These findings show that there is no thumb rule for processing materials in the FDM process and the performance of the technology varies from material grade to material grade [48]. Notwithstanding, the statistical design of experiment method can reduce the difficulty of selecting appropriate parameters for processing difficult materials such as HDPE in the FDM technology and they can do this while considering more than two process parameters at once.

Other strategies which can be used together with the process parameters to combat the challenges associated with processing HDPE in the FDM technology include simulation tools. These tools can provide a visual image of the material behaviour by predicting how the HDPE material will behave when exposed to simulated FDM process conditions prior to the actual processing of the material. These tools can be effective when information about overcoming defects such as material shrinkage, part warpage, void formations, and under-extrusions, is needed. For warpage analysis, the free-form deformation method is the most useful and can be used to pre-deform the 3D model data from 3D modelling and design applications in the opposite direction to the expected warpage deviations. Information from free-form deformation can be used to manipulate and modify the 3D model to avoid warpage. While free-form deformation is useful for warpage analysis, finite element analysis may be better for thermal analysis of materials. When information about the mechanical properties of parts is needed, computational fluid dynamics method can be used [16, 48, 66]. All three tools can be useful for overcoming challenges associated with the processability of HDPE through the FDM technology.
5.1.3 Slicing Strategy:

Material shrinkage and part warpage seen when HDPE is processed through FDM technologies can also be overcome by an appropriate slicing strategy. At the most basic level, this requires the use of the shrinkage compensation factor which is normally used to fix the shrinkage effect in the X-, Y-, and Z- directions. The shrinkage compensation factor varies from material to materials and needs to be determined experimentally by evaluating for the dimensional error through comparing the dimensions of the computer-aided design model of the part with the dimensions of physical 3D part of the same model after it has been produced through the FDM technology [67]. The dimensional error found may be used as shrinkage compensation scaling factor normally found in AM slicing programs to scale the 3D model in all three directions and compensate for shrinkage as well as improve the dimensional accuracy of parts produced [68]. Another slicing strategy which may be used for overcoming material shrinkage and part warpage seen when HDPE is processed in the FDM technology is to restrict the shrinkage effects to the interior parts of the 3D model by using its interior structures [16, 68]. Yaman [68] successfully used this strategy for a different polymeric material and reported that when one circular interior structure was used, dimensional error improved by 80%. When stretching lines, rectangular interior structures and multiple circular interior structures were also used, dimensional accuracy of parts produced still improved. These findings were found to be satisfactorily in agreement with the results from shrinkage analysis done with numerical models and the measurements taken with a coordinate measurement machine [68]. The shrinkage compensation scaling factor is mostly suitable for solid design structures and when shrinkage is not anisotropic while the use of interior structures to restrict shrinkage to the interior parts of the model is more suitable for porous structures as needed for HDPE implants. Reduction of the stacking section length which is often used to specify the vertical distance between each deposited material layer during the FDM process may also avoid HDPE material shrinkage and part warpage [16, 69]. Guerrero-de-Mier et al. [69], used a different polymeric material and found that splitting the geometrical features of the 3D model into smaller bricks limits the maximum value of the stacking section length and therefore reduces deformations caused by part warpage. From the study, it was also reported that deformations caused by part warpage were reduced significantly when hexagonal bricks were used than when squared bricks were used [69].

5.2 Indirect Strategies: incorporation of filler materials

Since the discovery of the shrinkage and warpage properties of HDPE material when processed through FDM technologies, some research studies have shifted their focus to the incorporation of low aspect ratio filler materials into the HDPE polymer matrix to make the material more isotropic when processed through this technology [43]. Filler materials have the ability to impede the tendency of HDPE material to shrink and warp when used in FDM technologies by decreasing the molecular mobility of the HDPE matrix. This reduction in the molecular mobility of the HDPE matrix inhibits the arrangement of the molecular chains into orderly crystalline regions which, if they grow, facilitate rapid cooling which may lead to material shrinkage and part warpage. Reduced molecular mobility of the HDPE matrix is achieved if there is a good interfacial adhesion between the filler particles and the polymer matrix. Good interfacial adhesion between the filler particles and the polymer matrix in turn can be achieved when smaller filler particles are used because they exhibit a larger specific surface area at the interface between the filler and the matrix compared to when larger particles are used. Good interfacial adhesion between the filler material and the polymer matrix is a characteristic which is needed for materials to be flawlessly processable through the FDM technology and improve the dimensional stability of the 3D objects [16, 43]. Filler
Filler materials such as bioactive glass, hydroxyapatite, and apatite-wollastonite glass ceramic (A-W) have been incorporated into the HDPE material for the fabrication of facial augmentation implants. As previously mentioned, the innate brittleness and low fracture toughness of ceramic materials have limited their clinical use [8, 19, 20, 35, 65, 70, 71]. However, this limitation can be overcome by the incorporation of these materials into HDPE matrix as fillers to improve their brittleness and enhance the properties of the HDPE materials for use as facial augmentation implants [19, 35, 65, 70, 71]. These ceramics materials can also reduce the material shrinkage and part warpage to enable the direct manufacturing of HDPE facial implants through the FDM technology. Jeyachandran et al. [65] successfully processed HDPE/Bioactive glass composite through the FDM technology to study the rheological, thermal, impact, and warpage behaviour of parts produced for potential use in craniofacial augmentation applications. The composite was prepared using a melt compounding process and the filament material was prepared using a conventional extrusion process. The thermal analysis from the study reported negligible change in peak melting temperature, increase in crystallization temperature, and a decrease in the degree of crystallization from the thermal behaviour analysis. The warpage and rheological analyses on the other hand reported enhanced temperature parameters and the addition of bioactive glass reduced part warpage and print induced defects. It furthermore improved the first layer adhesion and the dimensional stability of parts produced [65]. Park et al. [70] used neat HDPE and a composite made from HDPE matrix and nano-Hydroxyapatite(n-HAp) to fabricate 3D scaffolds using the FDM technology for in vitro animal studies. From the study, it was reported that 3D scaffolds fabricated with HDPE/n-HAp performed better under in vitro studies than scaffolds made from neat HDPE. The study also reported that 3D scaffolds were successfully fabricated through the FDM technology using HDPE/n-HAp composite but reported difficulties of processing neat HDPE through the FDM technology to fabricate 3D scaffolds [70]. Of the three composite materials, A-W added to the HDPE matrix remains the only material which is yet to be tested for processability and for warpage reduction in the FDM technology. Nonetheless, Juhasz et al. [35] and Rea et al. [71] have reported that the HDPE/A-W composite material is suitable for craniofacial augmentation because of its excellent mechanical properties and bio-performance seen from their in vitro animal studies.

6 Conclusions

HDPE has shown promising clinical success when used as a medical implant material for facial augmentation. However, the clinical success of these implants can be improved upon by tailoring them for each patient. FDM is one of the manufacturing methods which may be used for this purpose due to its ability to directly manufacture implants using information from medical imaging technologies. The adoption of this technology is however restricted by the difficulties of processing HDPE through FDM. These difficulties can be overcome by using strategies which have been used to overcome similar difficulties when other materials were processed through FDM technology.

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