RESEARCH PAPER

Evaluation of the Influence of FDM 3D Printing Process Parameters on the Physical Properties of 3D Printed Tablets

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Abstract

Fused deposition modeling (FDM) is one of the most extensively investigated 3D printing technique to design and fabricate customized drug delivery devices and dosage forms with tuned drug release characteristics. FDM 3D printing is an extrusion-based technique that requires a filament (feedstock) to be loaded into the printer, which enables the successive deposition of extruded material to form a 3D geometry from a hot nozzle head. There are certain critical parameters related to process, material, and machine that influence the quality attributes of the 3D printed product. The aim of the present investigation is to evaluate the impact of 3D printing process parameters on the physical properties of a 3D-printed tablet. In this study, a PVA tablet was designed and printed by varying the various process parameters such as infill density, infill pattern, layer thickness, printing temperature, and printing speed. The 3D printed tablets with variable process parameters were characterized for tablet size (diameter and thickness), tablet weight, density, and disintegration time. Among the various tested process parameters, infill density was identified as the most impactful parameter that influenced the tablet weight, density, and disintegration time. It has been evidenced that as the % of infill density increased, the tablet has shown a remarkable increase in weight and density. The infill density has also shown a significant influence on tablet disintegration. The results demonstrated that the tablet disintegration time increased with an increase in infill density. Thus, the precise control of FDM printing parameters is essential to develop customized drug products.

Keywords: Fused deposition modeling, 3D printing, Process parameters, Infill density, Tablet properties, Disintegration time, PVA tablets.

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Introduction

Three-dimensional (3D) printing is an additive manufacturing technology that operates on the idea of layer-by-layer deposition of materials to build the intended 3D shape. The intended 3D structure is derived from the geometrical codes generated by a 3D design software [1]. Various types of 3D printing techniques have been developed and applied to design biomedical devices, implants and drug delivery systems [2]. The 3D printing techniques have been used to design complex drug delivery systems, polypills, mini tablets in different shapes, and sizes specifically for pediatric and geriatric patients to improve patient compliance [3]. The major breakthrough in the field of 3D printing technique is its applicability to design personalized medicines according to patients need at the point of care (Hospital pharmacy). The 3D printing techniques fulfills the gap and replaces the conventional mode of drug product design which works on the principle of "one size fit for all". 3D printing techniques have the potential to design a drug product according to individual patients need. The 3D printing technique could produce computer designed complex geometries with personalized dosing and tuned drug release characteristics [4]. The various types of 3D printing techniques employed for pharmaceutical product development includes inkjet printing, binder jet printing, stereolithography, Selective laser sintering and extrusion-based 3D printing [5]. Among these,

extrusion-based 3D printing technique is one of the most extensively utilized techniques for drug delivery application. The extrusion-based 3D printing technique uses two methods of product fabrication i.e. pressure assisted microsyringes (PAM) and fused deposition modelling (FDM). PAM 3D printing technique works on the principle of material extrusion through a syringe with the help of pneumatic air pressure. In this technique, the pre-composite in the form of paste is used to fabricate a 3D printed product. various grades of commonly employed tableting excipients are used to prepare a drug loaded paste which was pre-optimized for viscosity, consistency and flow behavior for the extrusion process. PAM 3D printing technique has been utilized to develop various types of drug delivery systems with customized drug release characteristics such as immediate release tablets, bilayer tablets, polypills, sustained release tablets, gastro retentive floating tablets, and nanomedicine based printlets [6]. FDM is one of the majorly investigated 3D printing technique which works on the principle of filament extrusion through a hot nozzle. The pre-requisite for FDM 3D printing is the design and development of drug loaded filaments. For this, Hot melt extrusion (HME) technique is used to fabricate filaments. FDM is a precise, consistent, and inexpensive printing technique. A wide range of polymeric materials have been investigated for drug product development by using FDM 3D printing technique [7]. There are certain critical parameters in FDM 3D printing related to material, machine and process are essential variables that influence the product development process [8]. This research aims to evaluate the various FDM 3D printing process parameters and study their influence on the physical properties of 3D printed tablets.

Materials and methods

Materials

The PVA filament (1.75mm thickness) was purchased from Fused materials 3D filaments New York. Hydrochloric acid was purchased from Sigma-Aldrich Gillingham, UK. Autodesk fusion 360 software (version-V.2.0.14335), Utimaker Cura, a slicer software (version 5.13). All other reagents used were of analytical grade.

Design of PVA tablet

The PVA tablet was designed as round cylindrical tablet of 12 mm diameter and 6 mm thickness size by using Fusion 360 Software. The design was saved as a stl file. This design was sliced by using Utimaker Cura, a slicer software. Then this sliced design was saved as a G-code (a 3D printer readable file format). This G-code was later uploaded to the 3D printer for printing of PVA tablet.

3D printing of PVA tablet

The 3D printing was carried out by using a FDM based 3D printer (Anycubic K2 Neo). The process involves loading of filament in the printer extruder, followed by levelling the printer stage. Then the printing process was carried out at different printing process conditions which includes:

Infill density (%)

Infill density defines the ratio of the volume of voids to the volume of deposited pathways within the 3D printed item. The 3D printing process was carried out by varying the infill density from 20 to 100% (20%, 40%, 60, 80, and 100%) to study its influence on the physical properties of 3D printlets.

Infill pattern

The infill pattern is defined as the geometry of the core filling which influences the tablet internal structure and surface area. The rectilinear, honeycomb, Gyroid, grid, triangle and concentric infill pattern were used to study their influence on the physical properties of 3D printlets.

Layer thickness

Layer thickness refers to the height of each extruded layer. The 3D printing process was carried out by varying the layer thickness from 0.1 mm to 0.3mm to study its influence on the geometry and physical properties of 3D printlets.

Printing temperature

Printing temperature is defined as the temperature at which filament extrusion occurs through nozzle during the 3D printing process. The impact of varying printing temperature on fluidity of the material and physical properties of the 3D printed objects were studies. The printing temperature varied in a range of 180 ^{0}C to 220 ^{0}C based on the polymeric material used for 3D printing process.

Printing speed

Printing speed is defined as the speed or velocity at which the printer's nozzle moves while extruding material, measured in millimeters per second during the printing process which includes travel speed, base print speed, and successive layer print speed, overhang speed, speed during extrusion and retraction. The effect of layer printing speed on physical characteristics of the 3D printlets were studied by varying the printing speed between 40 to 80 mm/sec.

3D printing material and process parameters that were kept constant throughout the process and variable parameters that were kept constant and varied when the parameter itself is under test were represented in table 1

Table 1 Representing 3D printing material and process parameters that were kept constant and variable parameters that were varied when the parameter itself is under test.

Fixed parameters	**Filament used**	**PVA filament**
	Filament diameter	1.75 mm
	Nozzle diameter	0.4 mm
	Printer bed temperature	50 ^{0}C
Variable parameters*	Printing speed	40-80 mm/sec
	Layer thickness	0.1-0.3mm/sec
	Printing temperature	180-220 ^{0}C
	Infill density	20-100%
	Infill pattern	Rectilinear, honeycomb, Gyroid, grid, triangle and concentric

Twenty-four tablets were printed with five variable printing parameters at different level indicated in table 2. The influence of these 3D printing process parameters on physical properties such as diameter, thickness, weight, density and disintegration time of 3D printed printlets were studied. Table 2 Representing different 3D printing process parameters investigated at different levels.

3D printed tablet no.	**Printing parameter**	**level**
1.	Infill density	20%
2.		40%
3.		60%
4.		80%
5.		100%
6.	Infill pattern	rectilinear
7.		honeycomb
8.		gyroid
9.		grid
10.		triangle
11.		concentric
12.	Layer thickness	0.1 mm
13.		0.2 mm
14.		0.3 mm
15.	Printing	180 ^{0}C
16.	temperature	190 ^{0}C
17.		200 ^{0}C
18.		210 ^{0}C
19.		220 ^{0}C
20.	Printing speed	40 mm/sec
21.		50 mm/sec
22.		60 mm/sec
23.		70 mm/sec
24.		80 mm/sec

Characterization of the 3D printed PVA tablet

Physical characterization (weight, density, thickness, and diameter).

The influence of different 3D printing parameters on the physical properties of the 3D printed tablet was investigated based on the changes occurred in the following properties of the final printed tablets (weight, density, diameter, and thickness).

The weight of tablets and its dimensions (diameter and thickness) were measured by electronic balance and digital calliper, respectively. While the density of the printed tablets was calculated from the following equation

$$\rho = \frac{m}{v}$$

Where D=density, m= mass (g) and v= volume

The volume of the tablet was determined by the following equation:

$V=\pi r^2 h$

Where V= volume, r = radius, h = height

Tablets were weighed individually, and the average weight along with the relative standard deviation (RSD) was determined to analyze weight uniformity.

4.5.5.2 Disintegration test

The 3D printed tablets were evaluated for disintegration time and disintegration time uniformity. The disintegration test was conducted utilizing the ERWEKA disintegration test apparatus (Erweka, Germany). The disintegration test was conducted in six replicates using distilled water at 37.0 °C, in accordance with the European Pharmacopoeia monograph (2.9.1 Disintegration of tablets and capsules). Tablets were considered disintegrated when no residue was observed in the tubes or on the mesh screen.

Results and discussion

3D design and printing of PVA tablet

The PVA tablets were designed for each 3D printing process parameter under study. These designs were sliced and the generated G-code was used for each set of printing. The time taken for printing each PVA tablet varied with different process parameters. After the printing process, the 3D printed PVA tablets were stored in a desiccator for further characterization.

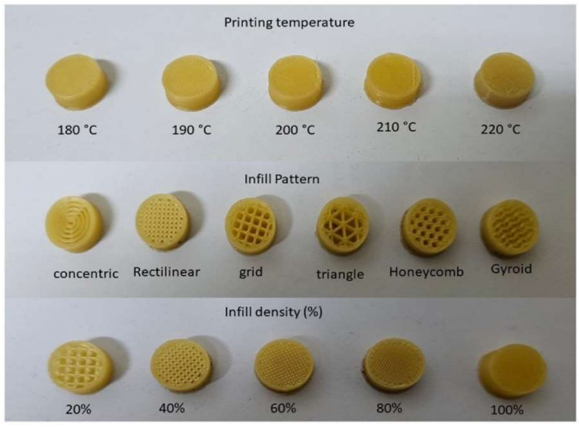

Figure 1 represents 3D printed PVA tablet at different printing process parameters.

Optimization of FDM 3D printing process parameters

Infill density (%)

In extrusion-based 3D-printing technique (FDM, SSE), infill density directly influences drug release kinetics, mechanical strength, porosity, and bioavailability [8,9]. Customization of drug release profile could be achieved by varying the infill density. 3D printlets with low infill density could achieve an immediate drug release profile whereas 3D printlets with high infill density could achieve a controlled or sustained drug release profiles [10,11]. Infill density plays an important role in designing floating or gastroretentive drug delivery systems. 3D printed drug delivery systems with low infill density are suitable to design gastroretentive systems due to low porosity and low density it impart buoyancy and causes gastric retention [12]. Whereas the 3D printed drug delivery systems with high infill density are not suitable to design gastro retentive drug delivery systems as due to high density than the gastric media that causes the tablet to sink and no gastric retention could be achieved [13].

Infill pattern

In 3D-printed drug delivery systems the infill pattern is not only a mechanical design choice, but it also serves as a pharmaceutical design variable that directly influences the mechanical strength, integrity, drug release, hydration, porosity, and dose customization of 3D prints [8,9]. The different infill patterns used in the design of 3D printed products includes Line, Rectilinear, Honeycomb, Gyroid, Cubic and Concentric. Different infill patterns creates different infill geometries, which alters the porosity, surface area, and tortuosity of the 3D printed structure. Infill patterns like honeycomb, line/zigzag and rectilinear impart high porosity to the structure and allows rapid fluid penetration and drug diffusion into the gastric fluid media thus considered ideal for the design of immediate release drug delivery systems. Whereas infill patterns like concentric, cubic and gyroid impart low porosity to the 3D printed structure and allows slow fluid penetration, controlled hydration and slow drug diffusion thus considered to the ideal patterns for the design of controlled and sustained release systems. Infill pattern also influences the swelling and erosion behavior of the polymeric matrices which in turn influences the drug release rate. For example, dense patterns like concentric and gyroid causes slow erosion of the polymeric matrix and may lead to controlled or sustained drug release. Whereas open patterns like honeycomb and rectilinear swells and erode quickly and may lead to faster drug release. Similarly, infill patterns also influences the mechanical strength and integrity of 3D printed objects. The infill patterns like line, rectilinear and honeycomb are weaker patterns that tend to crack, thus affecting the mechanical strength and integrity of the 3D printed object. Similarly, the infill patterns like gyroid, cubic and concentric are stronger patterns and may remain intact and impart good mechanical strength to the 3D printed objects. These stronger patterns are considered ideal for designing multiparticulate systems and modified or delayed release systems.

Layer thickness

Layer thickness influences the physical properties of 3D printed objects. Reduced layer height (low layer thickness) requires printing of a greater number of layers to attain the equivalent tablet height. Nonetheless, reduced layer height results in flatter layers, thus improves interlayer contact between the layers and impart mechanical strength to the 3D printed geometry [14]. Layer thickness also influences print resolution and reproducibility. A print layer with low thickness improves the print resolution and provides a finer control over geometry, thus results in high-resolution printing. However, it increases the total print time and may also cause drug uniformity issues if the drug loading in the filament is not uniform [8,15,16].

Printing temperature

Printing temperature has to be optimized based on polymeric material used for FDM 3D printing process. Different polymers require specific printing temperature for proper extrusion and printing process. A low printing temperature may result in low extrusion of material and poor layer adhesion. While a too high printing temperature may result in drug-polymer degradation, and discoloration of the 3D printed geometries. Printing temperature is a machine adjustable parameter that influences material properties specifically the flow behavior, which influences spread of the extruded material on build plate that may affect the reproducibility and dimensional precision of the 3D printed object.

Printing speed

Printing speed in FDM 3D printing process influences the dimensional accuracy and total print time required to print an object [17]. The printing speed exhibits significant impact on the quality of 3D printed objects such as printing at moderate speed results in stronger and higher quality prints. At elevated speeds, the printed layer remains inadequately solidified, failing to offer sufficient support for the subsequent layers, resulting in a compromised structure. Printing at low-speed lead to extended residence times within the heated nozzle, which in turn causes greater filament softening and may result in potential challenges during extrusion [18,19].

Influence of different 3D printing process parameters on the physical properties of 3D printed PVA tablet

Tablet thickness and diameter

Among all the tested 3D printed process parameters, layer thickness has shown a minor influence on tablet diameter and thickness. However, this variation in the tablet dimensions was within the limit of ± 5% of the size. The infill pattern, infill density, printing speed, and printing temperature has shown no remarkable variation in the diameter and thickness of the tablet as shown in the figure 2.

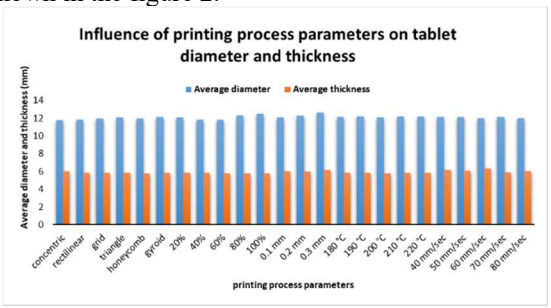

Figure 2 Influence of printing process parameters on tablet diameter and thickness.

Tablet weight and density

The influence of various 3D printing process parameters on tablet weight and density has been illustrated in figure 3. Among the various parameters, the infill density has significantly influenced the tablet weight and density. As seen in the figure, the infill density has shown a direct proportionality to the tablet weight and density. As the % of infill density increased, the tablet has shown a remarkable increase in the weight and density. The infill pattern has also shown an impact on tablet weight and density, but the variation in the weight and density of different infill pattern were found to be within ± 5% of the average weight. The weight and density of tablet in increasing order with different infill pattern was as rectilinear < gyroid < concentric < grid < triangle < honeycomb. The printing parameters such as layer thickness, printing speed and printing temperature has shown a slight variation in the weight and density of the tablet. With increase in layer height and printing temperature, it has been noticed that the tablet weight and density has also increased to a small level. Moreover, with increase in printing speed, the tablet weight and density was found to be slightly decreasing. However, these variations were non-significant.

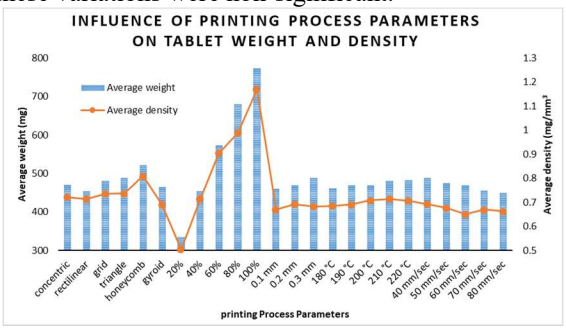

Figure 3 Influence of printing process parameters on tablet weight and density

Disintegration time

The impact of various 3D printing process parameters on tablet disintegration was evaluated and the results demonstrated that all the parameters has shown some influence on disintegration time. However, the relationship was not significant at all levels of various printing parameters. With respect to layer height, 0.1 mm layer height demonstrated a higher disintegration time, followed by 0.2 and 0.3 mm layer height. The reduced layer thickness improves interlayer contact between the layers and impart mechanical strength to the 3D printed geometry, which influences the disintegration process. The printing temperature and printing speed has not shown significant difference in the disintegration time. The infill pattern and infill density has shown a greater influence on the disintegration time. With respect to infill pattern the tablet disintegration times were in increasing order as follows: triangular < rectilinear < concentric < grid < honeycomb < gyroid. The triangular pattern provided the least disintegration time due to least supported internal structure. The denser the geometrical arrangement in a pattern causes a delayed in the disintegration of the structure. The infill density has shown a greater influence on tablet disintegration. The results demonstrated that the tablet disintegration time increased with increase in infill density (%). This result was in accordance to the literature [15,20]. The figure 4 represents the influence of various printing process parameters on tablet disintegration time.

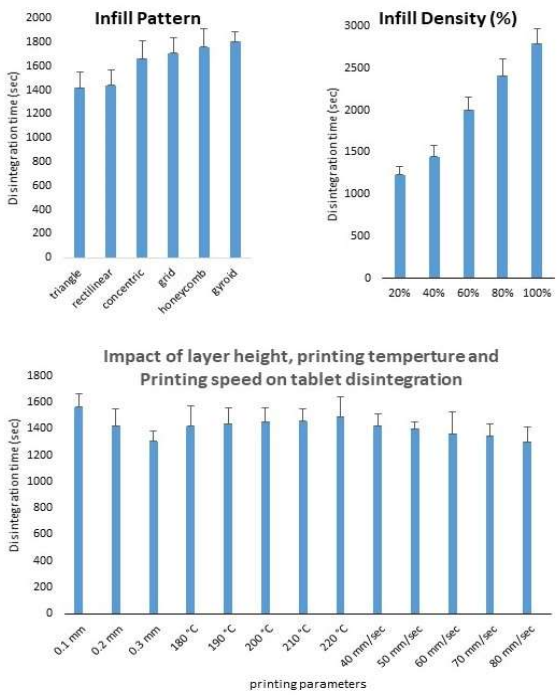

Figure 4 represents the influence of various printing process parameters on tablet disintegration time.

Conclusion

This study emphasized the necessity of optimizing printing process parameters during the FDM 3D printing process prior to the development of 3D-printed tablets and illustrates the influence of each parameter on the physical characteristics of the printed tablet. The tablet disintegration and the drug release profile are not only dependent on the formulation but are also significantly affected by the tablet design and the printing settings employed during production. From the results, it was concluded that all the 3D printing process parameters under investigation have shown no significant impact on the tablet size (diameter and thickness). Among the various tested 3D printing process parameters, infill density is one of the key parameters that has shown a remarkable effect on tablet weight, tablet density, and tablet disintegration time. Thus, this study concludes that product design has an impact on the physical characteristics and performance of a 3D printed product. Although process parameters are crucial in the printing of drug products using FDM technology, this area still remains poorly explored. Further experimental investigations should be conducted to study the impact of material, machine, and process parameters on the drug release profile and overall performance of 3D-printed tablets.

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