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Investigation of achievable form tolerance of parts produced by polymer additive manufacturing processes for biopharmaceutical industry

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Abstract

Polymer Additive Manufacturing (AM) has been increasingly used to produce end-use parts and products in recent years. Continued technological advances have enabled certain polymer AM processes to make significant inroads into the biopharmaceutical industry. In Sartorius, a multinational biopharmaceutical equipment manufacturer, the three mainstream polymer AM processes, including laser powder bed fusion, vat photopolymerisation and material extrusion have been adopted for series production. A critical step to accelerate the uptake of polymer AM in new product development is to provide concrete tolerance information to product design and production departments. However, unlike established international standards for tolerances for machining and injection moulding, little information is available on form tolerance for polymer AM. Thus, this study investigates the form tolerance capability of the above three processes. An artefact was designed, which included six typical features, i.e. boss, pocket, cylinder, hole, thin wall and underside surfaces. Ten artefacts for each AM process were produced, and the form tolerance, including cylindricity, flatness, coaxiality, angularity, perpendicularity and parallelism, were measured using a Coordinate Measuring Machine. It was revealed that vat photopolymerisation achieved the best form tolerance in most cases. Coaxiality of cylinder and hole is the highest among all tolerance types, which is primarily due to accumulated deviation when printing two features combined as compared to a single feature. The achievable tolerances by the three processes vary depending on the tolerance type, but they were all found to be capable of producing parts with excellent and consistent parallelism and angularity.

Form tolerance, Polymer additive manufacturing, Laser powder bed, Material extrusion, Vat photopolymerisation, biopharmaceutical industry

1. Introduction

Additive Manufacturing (AM) has evolved from rapid prototyping to the production of end use products [1]. In particular, polymer AM techniques have been used for series production of parts for not only consumer products, but also aerospace and automotive applications, and more recently biopharmaceutical applications [2, 3]. Sartorius, a biopharmaceutical equipment manufacturer, has now adopted three mainstream polymer AM processes for series production, including laser powder bed fusion (L-PBF), vat photopolymerisation (VP) and material extrusion (ME). A fundamental requirement in the new product development and quality assurance stages is to specify proper tolerances in the final part drawing ready for production [4].

Understanding dimensional accuracy and surface finish of AM fabricated parts have been a popular research area. Kaveh *et al*.[5] investigated the impact of process parameters of Fused Deposition Modelling (FDM), such as extrusion temperature and raster width, on the dimensional accuracy of the finished part. Spitaels *et al*. [6] compared the achievable dimensional and form tolerances of two FDM machines by two manufacturers. Vyavahare *et al*. [7] assessed dimensional accuracy and surface roughness by using different layer thicknesses and build orientations. Zharylkassyn *et al*. [8] and Sheoran and Kumar [9] pointed out that dimensional accuracy is not only affected by process parameters but also materials. Leach *et al*. [10] further reviewed the research on geometrical dimensioning and tolerancing for AM. Minetola *et al*. [11] evaluated the dimensional tolerance of parts fabricated by plastic freeforming, ME and L-PBF processes.

However, there has been little information in the literature on form tolerance for polymer AM, particularly for materials used in the biopharmaceutical industry [12]. This significantly hinders the wider adoption of polymer AM for production. In the biopharmaceutical industry, form tolerance is critical as it guarantees a proper assembly (e.g. good sealing controlled by flatness, surface perpendicularity etc.)

This study is thus aimed at investigating the form tolerance capabilities of the above three mainstream polymer AM processes, i.e. L-PBF, VP and ME, with the materials widely used in the biopharmaceutical industry. This will form the foundation for new product development and production. Section 2 presents the methodology used in this study, including artefact design, polymer AM machines and materials investigated as well as the measurement protocol. This is followed by the discussion of the measurement results as detailed in Section 3.

2. Methodology

2.1. Polymer AM processes, machines and materials

The three AM processes investigated and the machines used in this study were L-PBF (EOS, Formiga P110 Selective Laser

Sintering, SLS), VP (Carbon 3D M2, Digital Light Synthesis, DLS) and ME (Ultimaker S5, FDM). The materials used for these three processes were Polyamide 2200 (PA12), CE221 and Ultimaker Polypropylene, respectively. Please note given that different AM processes have their own processable materials, it was not possible to choose a single material for all the three AM processes. The chosen materials are widely used materials for the processes and also biocompatible, which is essential for biopharmaceutical products.

The EOS SLS machine has a continuous laser of 25W and a build volume of 200×250×330 mm^3. The melting temperature for PA12 powder is 180°C. The average powder size was 56 µm and *d*90 was 90 µm. The powder bed preheat temperature was set at 168°C. The typical layer thickness was used, namely 0.1 mm. The Ultimaker S5 has a build volume of 330×240×300 mm^3. It has a dual extrusion heads and is fitted with a 0.4mm diameter nozzle. The build plate was heated to and maintained at 85°C during printing. The feedstock material, i.e. 2.85mm diameter polypropylene filament, was extruded at 225°C at the layer thickness of 0.1mm. Carbon 3D's M2 printer is able to create feature details of minimum 75 µm in a build volume of 189×118×326 mm^3. To keep consistent, the layer thickness was kept at 0.1mm for all three processes.

2.2. Artefact design

The artefact was designed (as shown in Figure 1) to allow for the investigation of a wide range of form tolerance types, including cylindricity, flatness (top and underside surfaces), coaxiality, perpendicularity (axis and surface perpendicularity), parallelism and roundness. The size of the artefact is 90×90×20 mm^3. The artefact also covered four typical feature types, namely cylinder, hole, pocket and boss (this also included four pairs of thin walls and wedges). Underneath steps were also designed. This was to explore the flatness of underside surfaces, which is important to Sartorius in applications where sealing is needed between two parts/surfaces. In addition, As reported in the literature [10], printing accuracy varies in different planes. Therefore the features were designed to be in different directions in the XY, XZ, YZ and XYZ planes, which allowed for the investigation of form tolerance in different planes. The build direction was along the Z-axis. Ten artefacts were produced for each AM process.

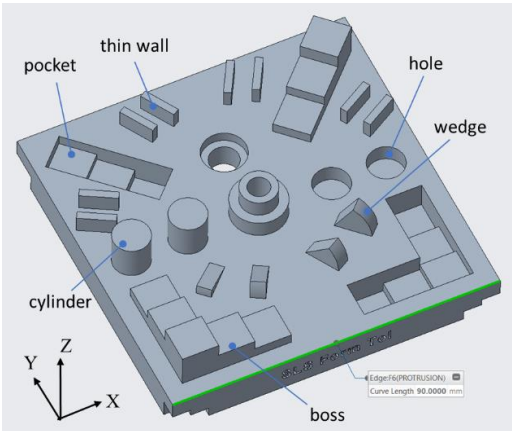

Figure 1. The artefact for investigation of form tolerance.

2.3. Measurement protocol

The dimensional and geometrical evaluation of the artefact was conducted using a Zeiss Prismo Access Coordinate Measurement Machine (CMM), with the Calypso measurement software to acquire and process the GD&T data according to ISO 286-1 [13]. A 2 mm diameter spherical tip was fitted on the Zeiss Vast probe. It was chosen due to the accessibility to small size geometries. The probe had a tolerance of 3 µm, and the standard deviation after the CMM calibration was within 0.2 to 0.4 µm. Before the measurements, the 2 mm probe stylus was recalibrated and overridden. A T probe was used to measure the underside surfaces. All geometries were probed in a scanning model to enable the capture of dense measurement data and cover the measurand surface as large as possible. The collected form tolerance data were further processed by calculating the average and standard deviation based on the measurements of ten specimens for each process.

3. Results and discussions

3.1. Form tolerance capability of SLS

The form tolerance of the SLS process is shown in Figure 2. The blue bar represents the achievable form tolerance and the orange bar represents the standard deviation of the measurement results. It was found that among all form tolerance types, coaxiality is the highest with the highest value (coaxiality of cylinder and hole) being 0.569 mm. When creating features, it is inevitable that deviation occurs. Coaxiality refers to two features and controls the central derived median points of the referenced feature to a datum axis. As a result, the measured coaxiality is higher than other tolerance types. It is also noted that standard deviation of coaxiality is also the highest among others, indicating that there is a large variation in the measured coaxiality values. In addition to coaxiality, as shown in Figure 2 top right (which was derived by averaging measurement results in each tolerance type), cylindricity is the second highest, averaged at 0.124 mm. Roundness is the 2D version of cylindricity, which turns out to be consistently high along with cylindricity. It is noted that the standard deviations of coaxiality and cylindricity are at a similar scale with the mean values. It is partially because that in SLS, the laser spot size is approx. 70 µm and the average powder size is 56 µm. When the laser beam continues to circle around to melt and create a cylindrical feature layer by layer, it causes heat accumulation, leading to over coalescence of surrounding particles, which further increases the achievable form tolerance. The measurement results also reveal that SLS is less capable of creating cylinders and holes with good cylindricity and axis perpendicularity, particularly for holes. Axis perpendicularity is a tolerance that controls how perpendicular a specific axis of the measrand needs to be to a datum, in this case, the horizontal XY plane. The measured axis perpendicularity and the associated standard deviations are 0.114 mm and 0.171 mm, respectively. The printed holes and cylinders are less vertical, thus proper specification of axis perpendicularity is needed during product design to ensure the success of assembly of SLS-processed parts.

On the other hand, parallelism was found to be the lowest, which is 0.057 mm. The parallelism in the XY plane (i.e. top surface of boss/pocket) and in the XZ and YZ planes (i.e. side surface of boss/thin wall) were measured. It was discovered that the parallelism of the side surfaces of thin walls was constantly lower than the side surface parallelism of bosses. The reason for this remains unknown and requires further investigation. A possible explanation is that when creating thin walls, there is less amount of energy that is input into the feature, resulting in fewer surrounding unsintered powder particles adhered to the wall, leading to better surface finish. A potential consequence is the improved parallelism. This explanation can be further supported by surface perpendicularity where thin wall's surface perpendicularity is less than half of the boss' surface perpendicularity.

In addition to parallelism, angularity is the second lowest among other form tolerance types, which is 0.061 mm. In order

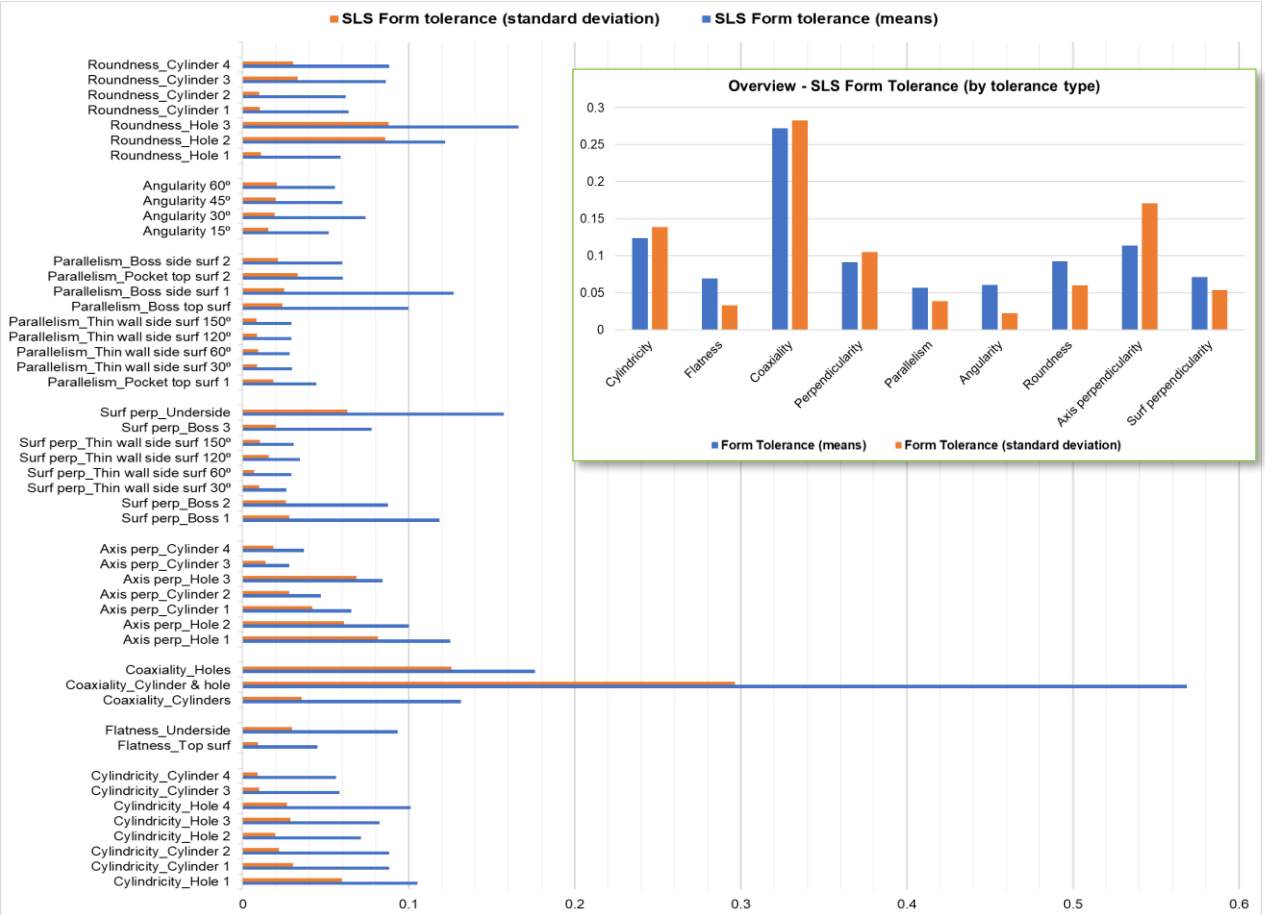

Figure 2. Laser powder bed fusion (SLS) form tolerance by tolerance type (unit: mm).

to evaluate angularity, four wedges were designed to be inclined at varying angles, i.e. 15°, 30°, 45° and 60°. The results show the standard deviations of the angularity of these four wedges are the lowest across all standard deviations of other tolerance types, indicating that the SLS process can reliably and repeatedly produce features with excellent angularity. Additionally, it is noted that there is a significant difference between the flatness of the top and underside surfaces (both in the XY plane), which are 0.045 mm and 0.093 mm, respectively. Furthermore, the top surface flatness is generally better than the flatness of the underside surface for all the three processes evaluated. For FDM and DLS, this is partially due to printing overhangs as well as support structures. Support removal can sometimes cause a slight damage to the surface. For SLS, the overhanging surface sits above loose powder, which is at a lower temperature, i.e. slightly above the preheated temperature. When melting the overhanging surface, there is less amount of heat from the layer below, leading to less particle coalescence [14]. Thus underside surface is usually found to be more porous than the top surface which has undergone the cyclic heating and reheating process. This could contribute to the better flatness of the top surface.

3.2. Comparison of form tolerance capabilities between FDM, SLS and DLS

Classed by tolerance type, Figure 3 compares the form tolerance across the SLS, FDM and DLS processes. DLS achieved the best form tolerance, except perpendicularity. One of the drawbacks of DLS is the tension built up during the solidification process, which causes the part to warp slightly. This could result in the slightly increased axis perpendicularity of cylinders and holes as well as the surface perpendicularity of the bosses and pockets. Having said that, it is noted that, unlike FDM and SLS where the form tolerance varies to a large extent for different tolerance types, DLS is able to achieve consistently low form tolerance across all tolerance types. This is primarily attributed to the material forming mechanism where the cross-section of the part is imaged by a high-resolution projector and solidified by the UV light in one exposure, rather than nozzle or laser movement in the XY plane. As a result, the geometric form of the feature is significantly less affected by the feature type and the motion accuracy in the XY plane.

Coaxiality is the highest for both FDM and SLS, followed by cylindricity and roundness. FDM performed the worst in these three tolerance types, which are 0.434, 0.194 and 0.129 mm, respectively. This is not surprising as the FDM machine used in this study is a desktop printer and the nozzle movement is driven by pulleys and belts, which is inferior to the laser galvo system in the industrial grade SLS system. In addition, all three processes were found to be able to manufacture parts with excellent and consistently low parallelism and angularity.

Furthermore, there is no clear trend of tolerance variation that all the AM processes follow. In other words, there is not a single process that always outperforms the others and vice versa. It is the perception that FDM is generally worse than DLS and SLS in the aspect of dimensional and form tolerance. However, it was revealed that in some instances, FDM surpassed SLS, such as angularity (0.052 mm), and achieved the lowest tolerance over both SLS and DLS, i.e. axis perpendicularity (0.062 mm).

In addition, it should be noted that the above results reported in sections 3 are based on specific materials. Using different materials could affect the form tolerances of the printed parts. Using different printing parameters (e.g. layer thickness, build orientation) could also have a noticeable impact on form tolerances, which has been reported in the literature [6-10]. This

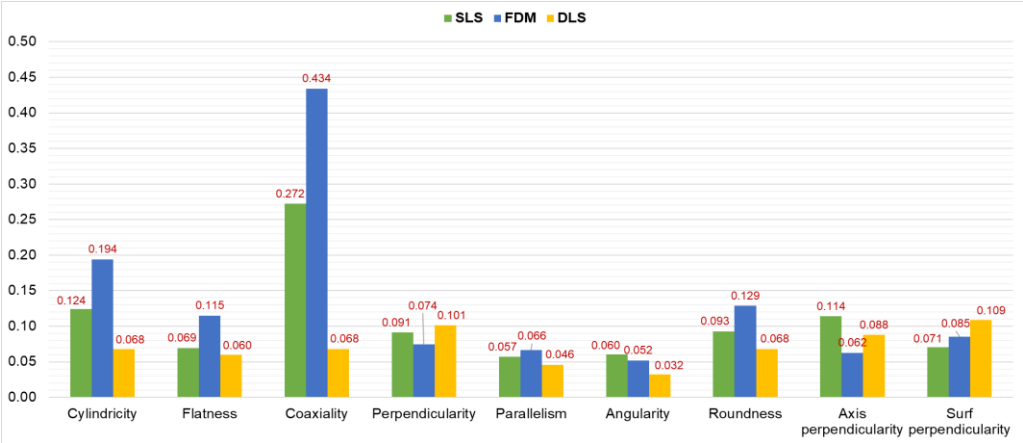

Figure 3. Comparison of form tolerance capabilities between SLS, FDM and DLS (unit: mm).

study was focused on biocompatible polymers and the manufacturer's recommended printing parameters, which have been internally qualified within Sartorius for daily serial production practice.

4. Summary

The form tolerance capabilities of the three polymer AM processes (SLS, FDM and DLS) were investigated. The achievable form tolerance by both SLS and FDM varied to a relatively large extent across different tolerance types, such as coaxiality (0.272 mm for SLS and 0.434 mm for FDM) and parallelism (0.057 mm for SLS and 0.066 mm for FDM). Coaxiality was the highest geometric deviation observed, followed by cylindricity (0.124 mm for SLS and 0.194 mm for FDM) and roundness (0.093 mm for SLS and 0.129 mm for FDM). By contrast, DLS was found to be able to reach the lowest tolerance values for most tolerance types with the lowest value on angularity averaged at 0.032 mm.

5. Conclusions

In this study, the form tolerance capabilities of the SLS, FDM and DLS processes were examined. Results show that DLS achieved the best form tolerance in most tolerance types, apart from axis and surface perpendicularity, which is partially due to minor warping as a result of continued tension built up during the solidification process. The warping also contributed to the increased perpendicularity. Coaxiality is significantly higher than other tolerance types for FDM and SLS. The combined and accumulated deviations in printing cylinders and holes resulted in the high coaxiality. It was also discovered that FDM and SLS were incapable of creating cylindrical features with excellent form tolerance. However, FDM achieved better perpendicularity than SLS and DLS, and also decent parallelism and angularity similar to SLS and DLS. Furthermore, for all three processes, flatness of underside surface was found to be up to two times higher than the top surface, which resulted from various factors such as support removal (for FDM and DLS) and less sufficient coalescence of particles (for SLS). Overall, DLS was found to have a more balanced performance among various form tolerance over the other two AM processes. The findings of this study can be used in part designs for biopharmaceutical products to ensure the desired design functions can be realised in production.

Acknowledgements

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