

Background

3D printing (3DP) of pharmaceutical formulations via commercially available FDM printers has gained interest in recent years, enabling personalisation of medicines. It also facilitates advanced control of the micro-structure of the tablet core, permitting fine tuning of product release characteristics with a single formulation. In addition, the technology also offers a platform for Dose escalation studies employing a single formulation and single manufacturing step.

Objectives

The objective of this study was to perform a mechanical characterisation of the extrusion of pharmaceutically relevant feedstock material during an FDM process.

Methods

Hot-Melt-Extrusion (HME): 5-50 % (w/w) Paracetamol (PCM) in Affinisol 15LV™ were extruded on an 16 mm Hot-Melt-Extruder (Eurolab 16, Thermofisher, Karlsruhe, Germany) equipped with a 1.6 mm die [1].

Mechanical characterisation of the extrusion process of commercial and in-house prepared filaments through an FDM print head [1] were recorded on a Texture Analyser TA-XT (Stable Micro Systems, Godalming, UK) equipped with a custom made mount for the print head (Figure 1).

Commercial filaments (ABS, blue, MAXX @240C; PLA, dutch orange, MAXX @ 190C and PVA, natural RS @ 180C) and in-house prepared filaments (5-50% w/w PCM-Affinisol 15LV™ @190C) through round nozzles (0.2, 0.4, 0.8, 1.0mm) at volumetric speeds ranging from 1.2 to 4.8 mm³/s.

Results and Discussion

Maximum forces (MF) during the extrusion process of commercial and in-house prepared filaments were recorded (Figure 1). 30 and 35% w/w PCM-Affinisol 15LV™ filaments failed to extrude. Instead, buckling of the filament in the hot end and drive gear was observed. The highest MFs (PVA - 19N, 5PCM - 16.3N) were observed for the smallest (0.2mm) nozzle size and highest volumetric speed (4.8mm³/s) (Figure 2A). With increasing the nozzle size, the MF observed during extrusion decreased (Figure 2B, 2C, 2D). The impact of speed on extrusion was negligible for the popular commercial filaments ABS and PLA with nozzle sizes of 0.8 and 1.0mm, exemplifying the suitability of the material to the FDM process. PVA, a less popular polymer used in FDM, was not as amenable to change in print speed, with notable changes in MFs.

In-house prepared filaments exhibited Affinisol 15LV™ dominated characteristics for drug loadings of 5 - 20% w/w: high impact of nozzle size and print speed on MF. 40-50% w/w drug loading showed negligible impact of nozzle size (except 0.2mm) and print speed on MF during extrusion.

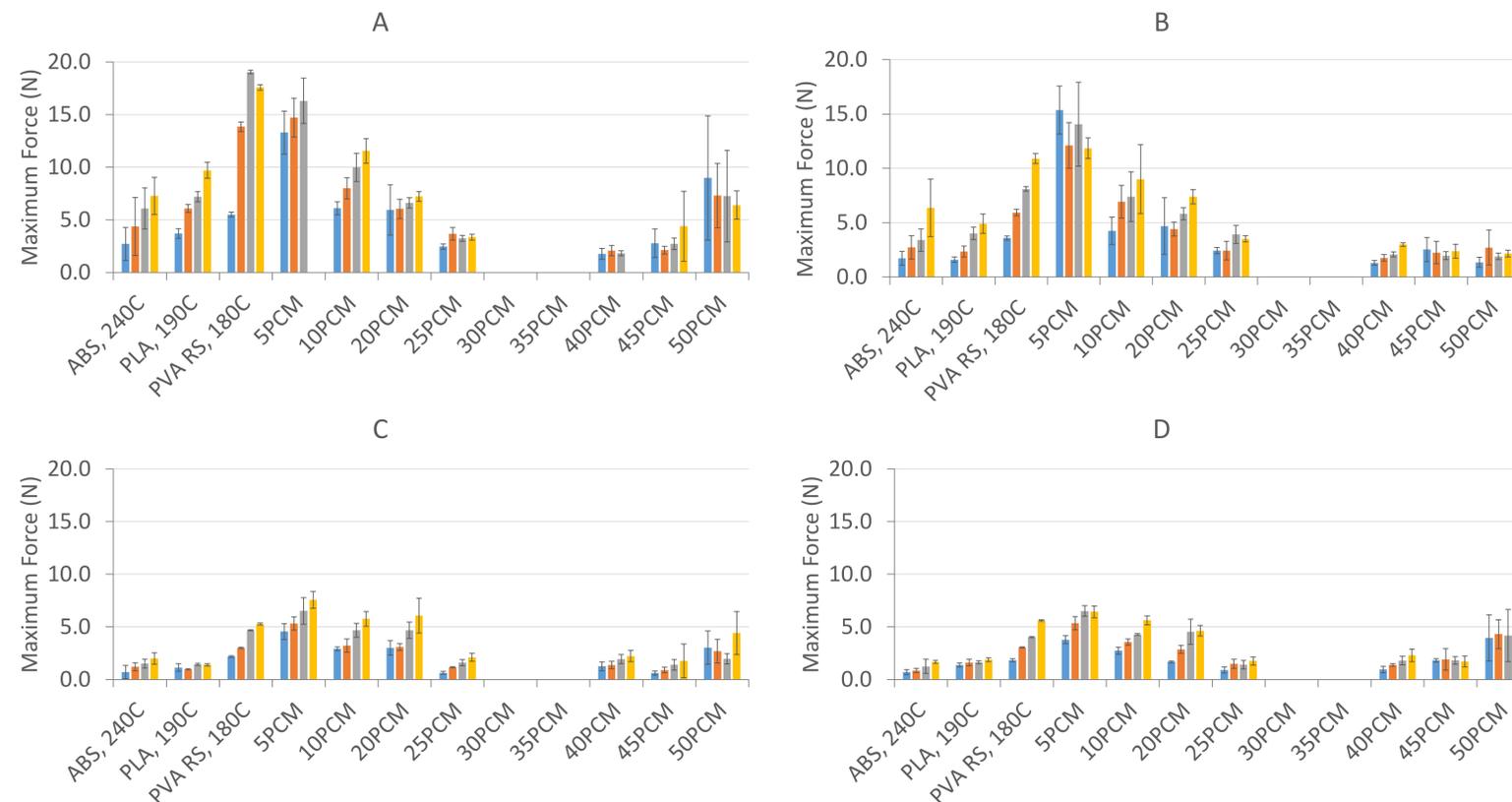


Figure 2: Maximum force recorded during extrusion of commercial filaments (ABS @240C, PLA @ 190C and PVA @ 180C) and in-house prepared filaments (5-50% w/w PCM-Affinisol 15LV™ @190C) through an FDM print head [1] equipped with different round nozzle diameters: A) 0.2mm, B) 0.4mm, C) 0.8mm and D) 1.0mm. Extrusion was performed at volumetric speeds of 1.2mm³/s (blue), 2.4mm³/s (orange), 3.6mm³/s (grey), 4.8mm³/s (yellow).

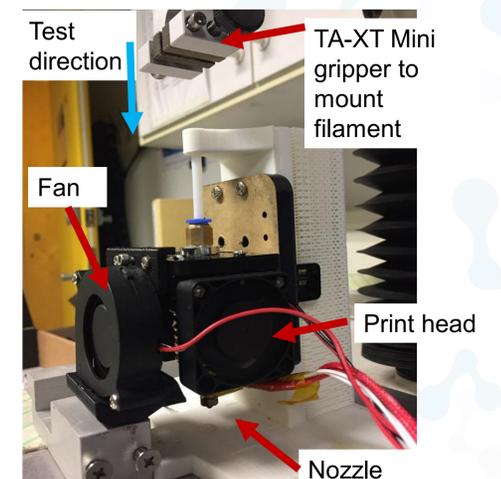


Figure 1: Custom mount for FDM print head in texture analyser.

Conclusion

Mechanical properties of an FDM process for commercial and in-house prepared pharmaceutically relevant feed stock material were investigated and have shown the material dependant impact of print geometries and print speed on the FDM process; informing future development of pharmaceutically relevant feedstock material.

References

1. Prasad E, Islam MT, Goodwin DJ, Megarry AJ, Halbert GW, Florence AJ, Robertson J 2019. Development of a hot-melt extrusion (HME) process to produce drug loaded Affinisol™ 15LV filaments for fused filament fabrication (FFF) 3D printing. Additive Manufacturing 29:100776.