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Process and product fingerprint concept for microinjection moulding of thermoplastic microneedle arrays

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Abstract
One of the biggest challenges in micromanufacturing is the inline measurement and quality assurance of the produced parts with micro-nano scale features. Dimensional measurements of these small parts and surface structures are usually laborious and costly because of the intricate features such as micro - nanogrooves, and high aspect ratio protrusions e.g microneedle arrays. The focus of this work is to present a micromanufacturing fingerprint concept for microinjection moulding (µIM) of thermoplastic microneedle arrays for drug delivery to reduce the quality inspection efforts by introducing novel process monitoring methods and measurement strategies. The fingerprint method will be implemented by careful monitoring of the important features of process data for both ultrasonic and conventional µIM technologies and measurements of needle height and tip radius. Correlations will eventually be presented to assess which process feature is more relevant to the quality criterion of the microneedle arrays. For microneedle quality inspection purposes, confocal microscopy and a custom-built telecentric machine vision system will be used, and results will also be compared. Another fingerprinting approach is also being developed by implementing a nano-fingerprint structure into the microneedle mould tool. The ultimate goal of this work is to present a zero-defect micromanufacturing fingerprint concept and incorporate an optical inspection tool inside the µIM machines that will allow inline quality assurance of the micromoulded products.

Microneedles, microinjection moulding, replication, diffraction, process monitoring.

1. Introduction

Micromoulded parts are often used in fields such as medical technologies, energy and optics where the quality of the final product is the key consideration in the manufacturing process [1]. Hence, novel methods for quality assessment should be implemented as the need for quality assurance of micromoulded products is ever increasing with the advancement of technology.

The final quality criterion of the micromoulded parts such as surface features and mechanical properties are hugely dependent on the dynamics of the process. Therefore, in depth analysis of the process measurements could yield valuable information on the final quality of the micromoulded products. Work has been carried out in the literature for characterising a micromoulding process and measurements such as piston displacement and velocity, cavity and injection pressure were taken and correlation factors were presented [2]. It has been reported that even a slight change in the piston dynamics could have a detrimental effect on the micromoulded part in terms of its functionality.

Microneedles for drug delivery are becoming increasingly popular and microinjection moulding processes have been presented as a viable technology for manufacturing microneedle arrays for drug delivery in the literature [3]. One of the biggest challenges in the manufacturing of microneedle patches is the quality assurance of structures that have features on the micron scale with present metrology techniques. Therefore, the aforementioned process data measurements and features should be correlated with the final part quality and a so-called process fingerprint has to be developed that is in correlation with the quality criterion of the microneedles. In depth analysis of these process fingerprints can be made to correlate the variations in the process with the quality criterion of the microneedle patches paving the way to a zero-defect micromanufacturing for this new technology. Ultrasonic microinjection moulding (USM) in particular, is a novel and promising method of micromoulding of thermoplastic materials for various applications and can be an alternative to the conventional micromoulding for several reasons reported in the literature [4]. However, the literature on ultrasonic moulding has been scarce and process dynamics of this new technique must be understood thoroughly for having a zero-defect micromoulded part.

This work will present the process fingerprint concept by giving examples from ultrasonic microinjection process measurements and the methods used for geometrical characterisation of the microneedle arrays. A conceptual design that will evolve into a low-cost quality assurance setup for microneedles will also be presented.

2. Process and product measurements

2.1. Process fingerprint candidates

The only commercial ultrasonic microinjection moulding machine, Sonorus 1G (Ultrasion) was used for microinjection moulding of polypropylene microneedles in this work. The flow visualisation mould tool and microneedle design, thermal imaging, process and material details are explained elsewhere [5]. Sonorus user interface allows its users to monitor the plunger position, injection force, sonication frequency and power consumed by the ultrasonic generator for each cycle as depicted in Figure 1.

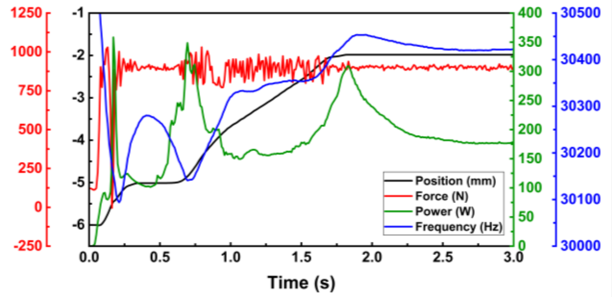

Figure 1. USM process data measured from a single cycle.

Plunger displacement and plunger velocity during injection contain useful information on how successful an USM cycle is being carried out. The total displacement of the plunger from the bottom position to where injection ends and plunger velocity during injection are defined as two of the process fingerprint candidates and will be monitored for each cycle. The fluctuation of these features versus mould cycles will allow a detailed analysis of the process fingerprint aspect.

Sonication frequency is another important parameter as it changes dramatically throughout an USM cycle. This parameter has impact on the process repeatability as the operating frequency limit is set by the manufacturer at a range of 29250-30750 Hz and it could go above or below this range that would result in ceasing the operation of the generator. It is also very likely that fluctuating ultrasonic frequency could lead to degradation in the parts due to uncontrolled heating of the feedstock. Hence, distinct peaks and changes will be extracted from the sonication frequency plots and be presented for each cycle of the USM process. Alongside with the sonication frequency, the final process measurement to be analysed is the power consumed by the ultrasonic generator, as the plots vs time show certain peaks for the start of the melting and end of the filling processes.

2.2. Product quality criteria

The most important features of a microneedle array in terms of functionality are the needles' heights and tip radii. Needle height is an important criterion for micromoulding since these high aspect ratio structures are often challenging to fill and demoulding could be problematic for certain materials. The tip radius is also critical since it directly affects the penetration forces of the microneedles into the skin. To assess the quality criteria of microneedle arrays, a telecentric machine vision system was built. The system allows the measurement of tip radii and needle heights of a 5x5 microneedle array in less than 2 minutes using a pair of motorised stages that moves in x and y directions. An example measurement from the optical apparatus is given in Figure 2.

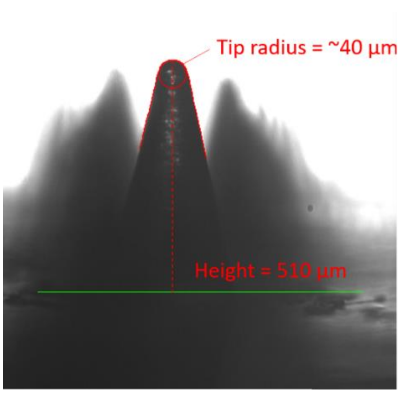

Figure 2. Telecentric optical image of a single microneedle taken from the measurement apparatus.

3. Nano-fingerprint concept for quality inspection

To reduce the product inspection efforts further for micromoulded products, a nano-fingerprint concept has been proposed. The concept suggests incorporating distinctive micro-nano patterns on certain regions of the microneedle patch for product inspection. Ultra-high precision machining techniques will be used for generation of the structures on mould walls. The quality criterion of the microneedle arrays and degree of replication of the nano-fingerprint geometery will be eventually correlated using laser scattering techniques. A conceptual drawing for the mould insert and a laser machined example pattern as a nano-fingerprint candidate is given in Figure 3.

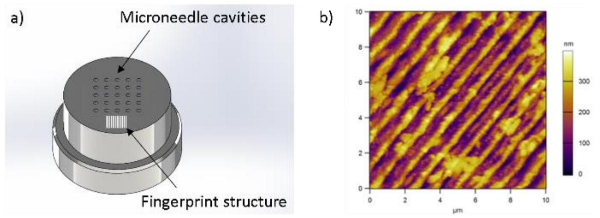

Figure 3. a) Microneedle mould insert with nano-fingerprint feature, b) AFM image of the laser machined nano-patterns with 1 µm pitch presented in a).

4. Summary and Outlook

The fingerprint concept presented in this work will provide ways of correlating micromoulding process data with the final part quality that will lower the inspection efforts made during the quality assessment stage. The investigations will be carried out selecting distinct features of the process data such as pressure peaks, curvatures and integrals. Incorporation of a nano-fingerprint inspection system into the micromoulding machines will also allow in-line product assessment in a fast and robust way. It should also be noted that this fingerprint approach for micromoulding can also be a useful tool during process monitoring for other micro-nano manufacturing technologies where lots of process data is generated.

Acknowledgement

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References

[1] M. Heckele et. al., "Review on micro molding of thermoplastic polymers," J. Micromechanics Microengineering, vol. 14, no. 3, pp. R1–R14, 2003.

[2] B. R. Whiteside et al., "Micromoulding: extreme process monitoring and inline product assessment," Plast. Rubber Compos., vol. 34, no. 9, pp. 380–386, 2005.

[3] K. Nair et al., "Investigation of plasma treatment on micro-injection moulded microneedle for drug delivery," Pharmaceutics, vol. 7, no. 4, pp. 471–485, 2015.

[4] M. Sacristán et al.,"Effects of ultrasonic vibration on the micro-molding processing of polylactide," Ultrason. Sonochem., vol. 21, no. 1, pp. 376–386, 2014.

[5] M. Gulcur et al., "Ultrasonic injection moulding of polypropylene and thermal visualisation of the process using a bespoke injection mould tool," in EUSPEN Conference Proceedings - 18th International Conference and Exhibition, EUSPEN 2018,p 243-244, 2018.