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Micro-injection moulding of polymer locking ligation systems

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Abstract

In recent years, there has been an increment on micro-components for medical purposes, diseases treatment and surgical equipment, requiring biocompatible materials such as some engineering polymers. Nonetheless, the micro size of these parts impose challenges for fabrication using high production processes, like polymer injection moulding submitted to high cooling rates and variability of the process, in addition to the complex design of precise mould micro-cavities. This paper presents the development of a complete mould for a polymer locking ligation system fabrication, a medical device selected as a case study for micro-injection moulding tooling. This development includes the prediction of appropriate injection parameters and process conditions using computer simulations and a comparison with real values of pressure and temperature during the process, due to data acquisition with piezoelectric sensors. The results show a moderate error between experimental and simulated results, in terms of pressure (0.05% prediction error) and average cycle temperature at the sensor location (13% prediction error), which proves that the proposed approach can be used for precision micro-injection moulding applications.

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1. Introduction

Micro-injection of polymers presents different phenomena comparing to conventional injection processes. In the process of micro-injection moulding, flow behavior and polymer transition phase perform differently than in macro-injection moulding in terms of shear rates, mould temperatures and cooling rates. Consequently, the study of micro-injection moulding requires to make emphasis on certain parameters like dependent viscosity, surface tension and wall sliding [1]. The forecasting of the process performance considering the polymer behavior during injection moulding cycles, involve the combined use of numerical simulation methods and fusion sensor in order to prevent irregularities in the final shape of the moulded part at micro scale.

There are some physical aspects associated with the reduced scale of polymer micro-parts that need to be considered which are [2]:

- Sliding of the chilled layer of the polymer due to high shear near the wall of the cavity.
- High cooling rates of the polymer inside mould cavities, due to the relationship mass/volume at the micro-scale.
- Complex rheological behavior of the cast polymer that flows at the micro geometry, especially in sub-micro/nano geometry with three-dimensional cavities.

Although similar works [3] have made comparisons between simulated and actual performance of the filling of micro-cavities, however some aspects have not been studied for medical devices, surgical equipment, implants and valves. The lack of knowledge and publications on this specific topic, added to the growing demand of these products, discover a

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field of research with impact on the industry of micro-parts made with bio-polymers.

The work presented in this paper analyzes the micro-cavities design features and considerations by computerized simulations and a real time monitoring of the most important parameters during micro-injection cycle; resulting in a case study of a polymeric medical device, a locking ligation system for surgery.

2. Literature review

Micro-injection moulding is a technology for low-cost production of a variety of micro-parts. Particularly the weight of micro parts is just a few milligrams and its dimensions are in the millimeters to microns range [4]. There are in in the literature several studies regarding this recent process. Annicchiarico et al. [5] implemented a statistical methodology in order to attempt optimization for both shrinkage and part mass in micro-injection moulding. The material studied was polyoxymethylene (POM). Related to this work, previously the same authors proposed a method for measuring shrinkage in micro-injection moulded (m-IM) parts [6]. Similar research was carried out by Packianather et al. [7] using Polypropylene (PP), Acrylonitrile-Butadiene Styrene (ABS) and Polyoxymethylene (POM). Griffiths et al. [8] performed an experimental investigation of process parameters effect on the release conditions in micro-injection moulding. The material used in this research is Cyclic Olefin Copolymer (COC). Regarding to rheological behavior of polymers, Zhang and Gilchrist [9] measured the rheological behavior of polyether block amide using a micro-injection moulding machine and a process monitoring system. For characterizing the filling conditions, Piotter et al. [10] made investigations about factors that affect the replication of quality surface in micro injection changing parameters of mould temperature, injection speed, distance between pieces, and barrel temperature for different polymers. Sha et al. [11] investigated the performance and simulation of thermoplastic micro injection moulding about cavity filling from qualitative means. Gava and Luchetta [12] worked on the performance of viscoelastic constitutive models for micro injection moulding simulations using weld lines as line flow markers; they also characterized the micro moulding pattern flow fusion. Shen et al. [13] elaborated an extension method and numerical simulations of micro gears and the influence of parameters on filling. Lin et al. [14] studied the filling of nano-structures in micro injection moulding with analytical model and verification of filling distance. In order to have a broader scope of research, there is the need to explore some works regarding cooling systems, even in the macro-scale. Li [15] worked on a feature – based approach to injection mould cooling system design using decomposition surfaces methods for macro parts; Hassan et al. [16] investigated about the position of cooling channels to reduce cycle time and for improving the solidification polymer behavior. Agazzi et al. [17] made a design of cooling channels using optimal flow temperature on cooling surfaces based on morphological surfaces. Dilma et al. [18] designed and optimized conformal cooling channels in injection moulding using FEA on conventional parts. Quiao [19] developed a systematic computer aided approach for the cooling system optimal design in plastic injection moulding for micro-parts. Gao et al. [20] worked in monitoring injection moulding using self-energized dual parameters sensors for monitoring temperature and pressure variations inside mould cavity without batteries and cables for transmission. Zeatier et al. [21] made a multivariate regression modeling for monitoring quality of injection using pressure sensors in real time to ensure the quality of each part. Zhang [22] used an unvaried signal, fingerprints and neural network for monitoring and fault diagnosis. Kurt [23] reported experimental investigation of plastic injection moulding and the effects of cavity pressure and mould temperature on the quality of the final product. Other works were made in the cavity monitoring field, but until now there is a lack of research works about monitoring systems for micro-injection moulding. The usefulness of the previous literature review will be in terms of adapting the reported monitoring systems in a case study of micro-injection moulding of small surgical devices.

3. Experimental setup

3.1. Part selection

A locking ligation system commercially known as Hem-o-Lok© (Fig. 1) was selected for this work because it fits within the aim of this research of characterizing micro-injection moulding of surgical devices. The device is a small part that is used in surgeries when a ligation of vessels for different procedures in organ transplants and tissue repairs is needed. The system is inserted into the body by laparoscopic procedure and the device is made with a non-absorbable biopolymer.

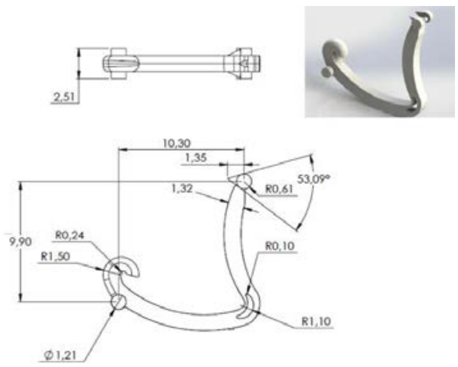

Fig. 1. Study part: Locking Ligation system (dimensions in mm).

The weight of the part is 0.04 gr approximately, the volume of the part is 47.23 mm^3 and the material is flexible and tough. Special appliers are required to introduce and close the device into the body, these appliers can be manual or automatic but it is mandatory that both must have the same size of the part to match properly with the holes on the appliers. Figure 2 shows how the device and appliers match and how the system works.