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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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Keywords: micro-injection moulding; ligation system; micro-cavity design

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.

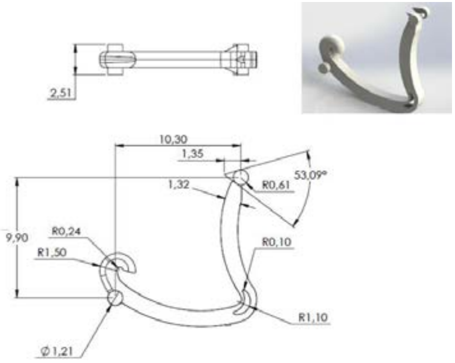


Fig. 1. Study part: Locking Ligation system (dimensions in mm).

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.

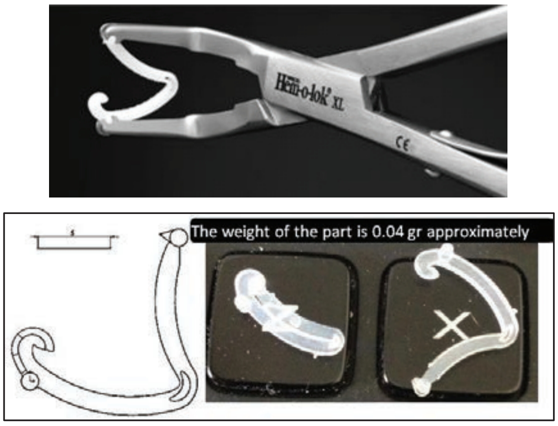


Fig. 2. Locking ligation system and appliers.

3.2. Material selection

With the intention to perform an appropriate comparison between computerized simulations and the data acquired with mould sensors, the rheological properties of the virtual and physical material must be as close in order to have reliable comparisons. The material injected was a Polypropylene (PP) for which Table 1 summarizes the characteristics.

Table 1. Characteristics of material.

Material	Melt flow index [dg/min]	Density [g/cm^3]
Pro-fax SL262MW (Commercial name)	1.8	0.9

This thermoplastic satisfies FDA (Food and Drug Administration) requirements according the specifications mentioned in the code of federal regulations number 21 CFR 177-1520 [24]. The rheological testing of this material was provided through Monsivais et al. [25]. This information contains: shear modulus (G*), storage modulus (G´) and loss modulus (G”) for three different temperatures 170, 180 and 190 °C. The data was acquired using an oscillatory rheometer according to the expressions of the Eqs. (1-2).

$$G^*(\omega) = G'(\omega) + i\,G''(\omega) \tag{1}$$

$$\eta^*(\varpi) = \frac{\sqrt{|G^*(\omega)|}}{\omega} \tag{2}$$

and with the assumption of Cox Mertz Rule, expressed in Eq. (3):

$$\eta^*(\omega) = \eta(\dot{\gamma}) \tag{3}$$

Where ω is the frequency of the rheometer, $\eta*(\omega)$ is the complex viscosity and $\eta\ (\dot{\gamma})$ is the steady shear viscosity. According of the previous expressions, several plots were obtained in order to characterize the viscosity of the selected polymer at different temperatures and rheometer frequencies (Figure 3).

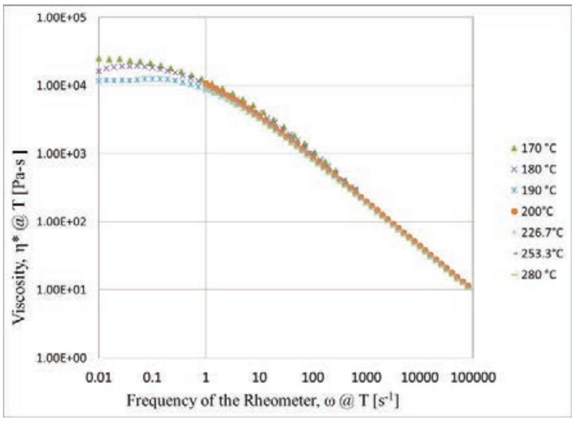


Fig. 3. Viscosity curves for the selected polymer at different temperatures and rheometer frequencies.

In order to perform accurate numerical simulations Moldflow© was selected as the software most appropriate, due among other reasons to the fact that it has in the polymer library several resins with the characteristics of the selected polymer. The material that fits these characteristics is Propathene HSM and corresponds to the same polypropylene family.

3.3. Mould design

To elaborate the mould design, it is essential to define some conditions and framework conditions that allow preparation of the proper solutions for each particularly case. Some of these conditions to establish or known previously are: injection machine available, polymer used for the injection, number of cavities, draft angle permitted, parting line definition, size and shape of runners and gates.

3.3.1. Parting line

The clamping zone and parting line position are shown in Figure 4. It is important to mention that there was the need of using sliders in the clamping zone of the mould, where are located the geometric features that allow the locking of the device.

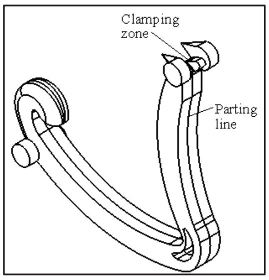


Fig. 4. Parting line and clamping zone.

The parting line was established in the middle of the part with symmetric distribution and equal cavities on each side of the mould with one slider for the clamping zone. The slides were designed as a combination of locking heel and angle pin; and the angle pins move the slides during the mould opening and closing and the locking heel supports the slides when mould is closed. In Figure 5 a two-plates mould configuration can be seen, indicating that the core sections, the cavity sections, and the runner system are contained within the two plates.

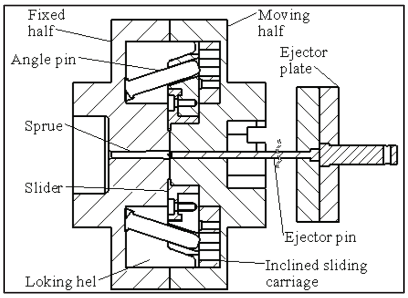


Fig. 5. Cross section of the mould, including the angle pin slide activator.

3.3.2. Number of cavities

According with the machine technical data, part characteristics and standard mould parts, it was decided to construct a mould with four cavities and cold runners (Figure 6). The number of cavities was chosen for the following reasons:

- The mould has to be balanced, the layout of the mould should be homogenous; the distance between parts; size and length of runners should be equal; the distance along the end of the sprue to the port gate of each cavity should be the same; and the time lapsed during the filling phase had to be the same for all cavities.
- The best utilization of available space and use of standard mould parts.

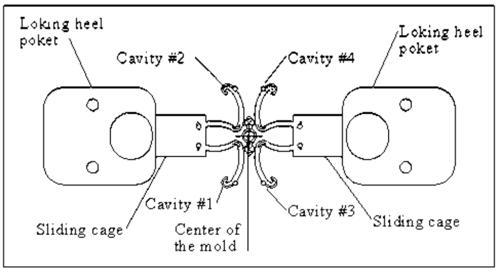


Fig. 6. Cavities distribution.

3.3.3. Runners and gates

The runner shape selected was a semicircular channel in each half mould with 1.4 mm of diameter (Figure 7). The gate was designed as circular tapered with 1.4 mm of diameter at the side of the runner and 0.76 mm at part side with 0.5 mm length. In addition, a Moldflow© simulation correlates and validates the sizes of those elements.

The length of measure (1) 4.8 mm shown in Figure 7 was defined with the intention to use standard sliders and measure (2) of 1.3 mm is related with the wall thickness. The remaining measure (3) of 11.34 mm is to support radial forces ejected by the slide units.

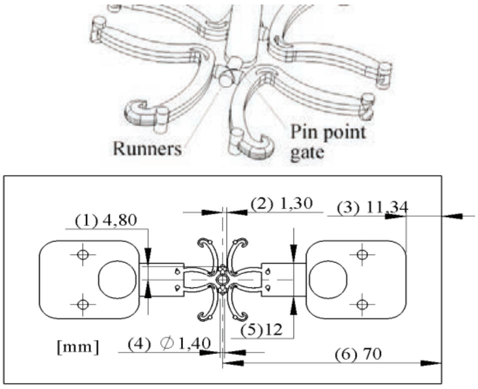


Fig. 7. Runners and gates (dimensions in mm)

3.3.4. Draft angle analysis

According with the size of the part and well-known design recommendations, a draft angle of one degree for the work piece and two degrees of draft angle for the sprue were established. Figure 8 shows the draft angle analysis made by Solid Works© using the middle of the part as parting line and one degree as comparative parameter of draft angle. The cylinder at the bottom of the part marked in yellow has 0 draft angle and is used to pull the part when the mould initially opens. On the other hand, the ejector pin ejects the part when the mould is completely open.

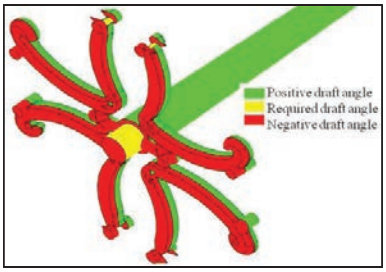


Fig. 8. Draft angle analysis.

3.4. Numerical Simulation

The numerical simulations were made for various purposes such as: validate the calculus of runners and gates, check the balance of the cavities, calculate injection process variables, predict possible failures and compare with the information in real time. For the polypropylene Propathene HSM available in the Moldflow© library the optimum combination of process variables are listed in the Table 2.

Table 2. Optimum injection conditions.

Mould temperature	63.3°C
Melt temperature	226.8°C
Injection time	1.526s

After establishing the part, machine, number of cavities and parting line, it was needed to design the layout and to check the required force clamp and filling time in all the cavities. The calculations of clamping force were verified with different methods including the projected area, thickness and simulation. Figure 9 shows the lay out of the mould and the time lapsed until the last corner of the part were filled. Proper balance in cavities causes equal filling time for all cavities, and same zones in different cavities are filled at same time as is shown in the Figure 9.

The maximum injection pressure showed in Figure 10 according with simulation is 41.85 MPa, and the projected area of all cavities runners and sprue is 4.98 cm^2. Those simulations required a clamping force of 122 Kg/cm^2, lower than maximum clamping force of the machine, which is 6,250 Kg/cm^2.

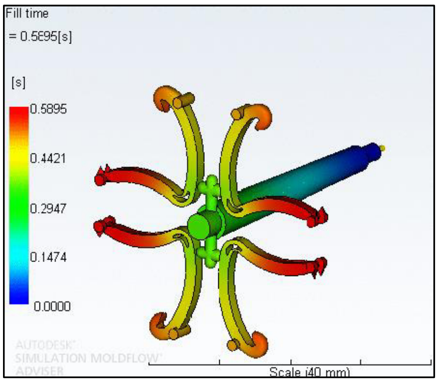


Fig. 9. Filling time.

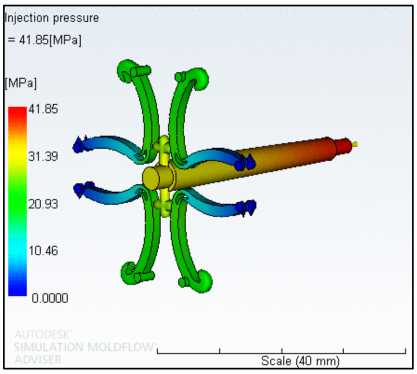


Fig. 10. Injection pressure.

3.5. Mould and micro-cavity manufacturing

The manufacturing of cavities and other mould components was performed by a mixed process of micro end milling and electro discharge machining. After corroborating the distribution and sizes of cavities, runners and gates with simulations analysis, CNC programs were elaborated for machining holes, pockets channels and electrodes. The electrodes were made of electrolytic copper for runners and gates, and were made of graphite for the cavities machining. This last because it enables machining in small pockets with end mills with diameters lower than 1 mm, reducing the risk of break mills and scratches. The manufacturing process was developed trying to reduce the number of parts required for the cavities and prevent misalignment on injected parts and mould assemblies. Some standard parts were acquired and modified according to the case of study, the sliders were machined using wire EDM due to the material hardness (up to 52 HRc) and limited spaces for direct machining (Figure 11).

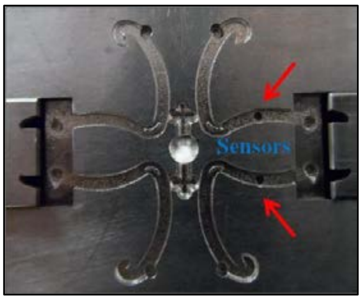


Fig. 11. Machined cavities.

3.6. Machine setup

The injection machine is a Babyplast model 6/10P with 1340 Kg/cm^3 of injection pressure and 62.5 KN of clamping force. The properly use of the micro-injection machine requires specific parameters of the injection cycle as injection pressures, number of injection pressure steps, time for injection, screw displacement, holding pressure, time of holding and temperature of the three different zones (hopper, plasticization area and nozzle). The injection conditions of the simulation were set and updated according to the actual machine specifications (Table 3).

Table 3. Micro-injection moulding machine specifications.

Piston diameter	14 mm
Volume (injected)	9 cm^3
Injection Pressure	1340 Kg/cm^2
Clamping Force	6.250 Kg/cm^2 62.5 KN
Opening Force	4 KN
Opening Stroke	30 – 110 mm
Ejection Force	5 KN
Ejection Stroke	45 mm
Hydraulic Pressure	130 Kg
Oil Tank Capacity	16 L
Dry Cycle	2.4s
Power	2.9 KW
Weight	120 Kg

3.7. Sensor and data acquisition systems

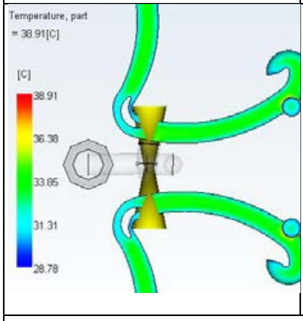
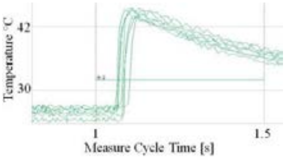
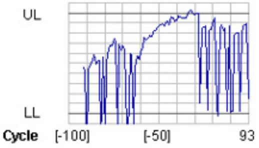
The monitoring system is composed by sensors, signal amplifiers, data acquisition board and screen. This system is required to measure pressure and temperature during the injection cycle and the data acquired was used to compare against the values predicted by the computerized simulation. The sensors selected for the mould were Kistler p-T- sensor type 6188AA. Two amplifiers, Kistler type 2205A141 were required for signal conditioning, one for the pressure signal and another one for temperature signal. The data acquisition board selected is Kistler CoMo injection basic type 2869B.

4. Results and discussion

4.1. Temperature prediction

The average predicted temperature of the region of the mould where the sensor is located was 38.91°C and the temperature acquired by the sensor was approximately 43.73°. It is important to mention that the temperature result shows the average temperature of the part side of the part/mould interface during the cycle, not the temperature of the polymer when the flow front reaches a specified point in the center of the plastic cross-section (193-200ºC).

Table 4. Temperature comparison of the part/mould interface.

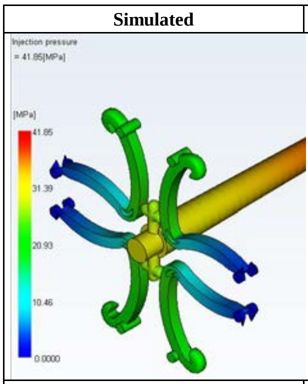
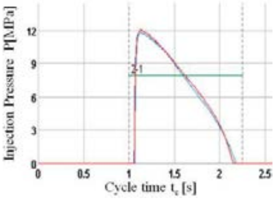
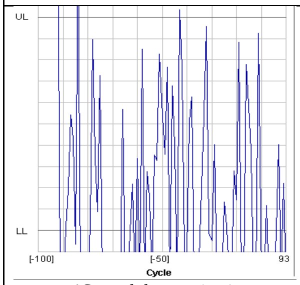
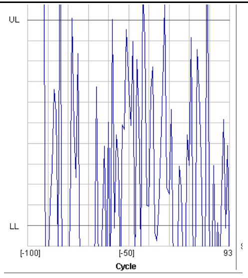
Simulated	Sensed
	
UL- Upper limit = 48 °C LL – Lower Limit = 38 °C	

4.2. Pressure prediction

Table 5 summarizes the results obtained regarding to pressure analysis. The maximum injection pressure according to the simulation was 41.85 MPa and the pressure in the region where the sensor is located was 10 Mpa. The pressure obtained by the monitoring system was approximately the same (9.979-10.079 MPa).

Differences between simulation and sensed values are reasonable considering that some process variables are not controlled as mould temperature. The average error between the numerical prediction and the experimental results are in the order of 0.05% in pressure and 13% in temperature, numbers that show a moderate discrepancy between the results and that are appropriate for micro-injection moulding design and monitoring purposes.

Table 5. Pressure analysis.

Simulated	Sensed
	
Simulated predicted injection pressures of 10 MPa on the sensor location	Injection pressures sensed on each cavities show the reduced difference between them
 *Sensed data cavity 1	 *Sensed data cavity 2
*Obtained from sensed data: Range of allowable pressure to produce accepted parts UL- Upper limit 18 MPa LL – Lower Limit 3.5 MPa	
Cavity 1 Average pressure 9.979 MPa	Cavity 2 Average pressure 10.079 MPa

5. Conclusions

The method proposed for designing and manufacturing micro-cavities for polymer injection was successful owing to the results presented in this paper, in terms of simulation capabilities and process monitoring. The methodology can be varied for specific parts, injection machines and processing conditions, but the main activities and goals are similar for a lot of microparts, focused on micro-surgical devices made of biocompatible polymers. The majority efforts should be focused on controlling mould temperatures and reduce drafts that impact directly on the mould. Due to lower pressures compared with larger injected parts, the quality of the micro-injected parts is more sensitive to burs and rest of polymers.

Future works will be focused on the study of injection profiles influence in polymer micro-injection processes, in order to find the variables that cause differences between numerical predictions and real-time monitoring.

Acknowledgements

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