OPTIMIZATION OF MICRO-INJECTION MOULDING PROCESS STABILITY IN AUTOMATIC-CYCLIC MODE CONDITIONS DURING MANUFACTURING BIORESORBABLE VASCULAR STENTS

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Introduction

Processing of biodegradable polyesters creates many difficulties due to their susceptibility to hydrolysis, especially at high temperatures and fairly poor thermal stability [1,2]. For this reason, they are quite rarely used in industry. However, thanks to their unique properties, they have found quite a wide application in medicine, e.g. for the obtaining of vascular implants – stents [3]. Production of this kind of implants, poses a special challenge due to their thin-walled, openwork structure.

Due to the relatively low energy and polymer material consumption, as well as the process rate, micro-injection moulding seems to be the best method for obtaining bioresorbable stents. As a result of carrying out the process in high temperature and generation of the high internal friction caused by injection under high pressure of molten polymer to a very small space of the injection mould cavity (wall thickness of the element 200 μm), the polyester material is exposed to thermal degradation. It causes weakening of the internal structure of the stent, which prevents its connection to the insertion system, due to span cracking.

The present work focuses on optimizing the micro-injection moulding process of vascular stents, made of poly(L-lactide-co- glycolide-co- trimethylene carbonate), in terms of maintaining mechanical properties in processing carried out in an automatic cyclic mode.

Materials and Methods

The study was based on a terpolyester poly(lactide - *co*-glycolide-*co*-trimethylene-*co*-carbonate) with a mutual molar ratio of comonomers 76 : 15 : 9 respectively [4], prepared in the form of a pellet of the dimensions 2 mm by 2 mm.

The polymeric material was processed using a MicroPower 15 micro-injection moulding machine (Wittmann Battenfeld). The mould was thermostatted with a hot water. The moisture content of the granulate was measured by Karl-Fischer titration (Metrohm). The quality of stents and regions susceptible to damage was observed with a stereoscopic microscope (DeltaOptical) working in polarized light. The mechanical properties of the implants were measured on the crimper device (tensile test machine from Blockwise Engineering) intended for measuring radial forces [RF]. The progress of thermal degradation was estimated based on changes in average molecular weights obtained by gel permeation chromatography (GPC). The influence of processing parameters on the thermal properties of stents has been examined by differential scanning calorimetry DSC.

Results and Discussion

The obtained results indicate, that the maximum moisture content in the used terpolymer, allowing to limit the hydrolysis under processing conditions (200°C and 10 min of contact time) is 250 ppm. Optimal stent geometry (FIG. 1), with minimization of degradation, was obtained by using the parameters listed in TABLE 1.

TABLE 1. Micro-injection molding parameter process.

Injection limiting pressure	2500 bar
Volumetric melt stream	4 ml/s
Holding pressure	1500 bar; 5 s
Mold cavity temperature	55 °C
Conditioning in closed mould	15 s
Injection volume	0,25 ml

The graph below (FIG. 2) shows the correlation between the radial force (RF) of the stent and the average molecular weight (Mn) in subsequent processing cycles (60 s per cycle). An average radial force value of 27.2 ± 1.5 N was obtained, with an average molar mass equal to 29.2 ± 2.2 kDa (initial molar mass of 38 kDa). Small standard deviations indicate good stability of the terpolymer micro-injection process during 13 cycles. After this time, the plasticizing system of the injection molding machine should be reloaded with a fresh portion of polymer.

Conclusions

It has been proven, that the selection of parameters allowing the cyclic production of biodegradable vascular stents with the desired utility properties is possible by micro-injection molding method. This is crucial for transferring the production scale from laboratory to industry.

Acknowledgments

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References

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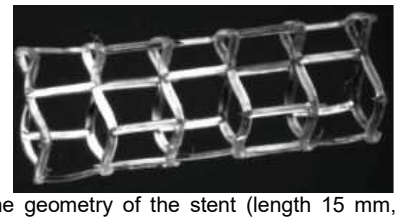

FIG. 1. The geometry of the stent (length 15 mm, diameter 6 mm) obtained with the process parameters listed in TABLE 1.

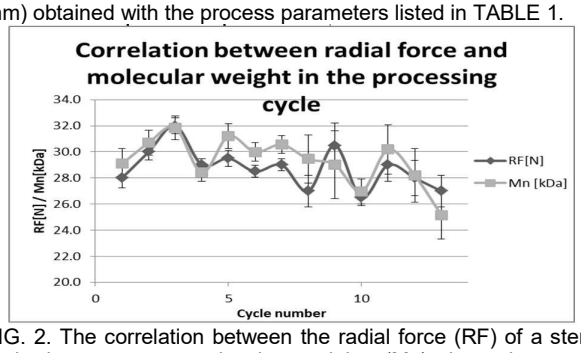

FIG. 2. The correlation between the radial force (RF) of a stent and the average molecular weight (Mn) in subsequent processing cycles (60 s per cycle).