Application Note
LR-58

Small Scale Catheter Production

Keywords:

- Catheter die
- Polydrive
- Biodegradable
- Polystyrene
- Polycaprolactone

Application Notes

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Abstract

Catheters were produced of Polystyrene (PS) and Polycaprolactone (PCL). A PolyDrive extruder system, as stand alone extruder was used with the catheter die. For stable extrusion it was necessary to use a water bath and the take off system. By varying take off speed and output different sizes of the catheter were obtained.

Introduction

Catheters are widely used for medical applications, new developments focus on biodegradable materials and compounding of contrast media for x-ray depiction. Though the commercial products are highly sophisticated and produced on "pharma" extrusion lines, proof of concept studies and first developments can be run on a standard PolyDrive single screw extruder.
Obviously, in the same way a PolyLab OS with Single screw extruder 19/25 OS can run the same application.

Materials and Methods

Materials:
Polystyrene, PS
Polycaprolactone, PCL
Both pellets, app. 300grs required

Method:
Single Screw Extrusion
PolyDrive System, consisting of:

- PolyDrive 252 (557-8300)
- 3:1 Standard metering screw (557-2025)
- Pressure transducer 500 bar
- Hopper with closure
- Catheter die diameter: 4.5 mm, gap 1 mm, compressed air supply
- Cooled feed zone by circulator: DC30 K20, 20°C
- Water bath
- Conveyor belt

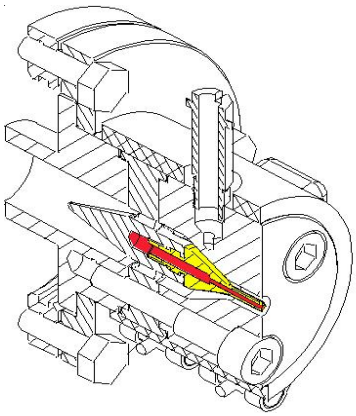

Fig. 1: catheter die (sketch)

Fig. 3: PolyLab OS

The molten extrudate exits the die and a slight air supply in the center of the catheter prevents collapsing.

The water bath is useful for the PCL. This material requires a quick cooling for crystallization. Many other polymers e.g. (HDPE) will produce good results just with the conveyor belt.

Fig. 2: running the PolyDrive R252 with catheter die

Results and Discussion

Material 1: Polycaprolatone
Caprolactone homo polymers offer a unique combination of properties resulting in hard crystalline, biodegradable polymers that melt at low temperatures (58-60°C) and have very good hot melt adhesive characteristics [1]. The Polycaprolactone is a quite expensive material, so it was important to operate the extruder with small amounts. With the low melting point and the adhesive properties the water bath is a must.
To find the right set point, e.g. speed and temperature profile (note the low die temperature of 90°C) 300 g were needed. Once the processing conditions are known 150 g are enough to produce a catheter. After reaching a stable processing the take off speed was ramped up to change the diameter.

Material 2: Polystyrene
Polystyrenes are standard engineering plastics with excellent optical properties [2]. Attractive light-transmission properties, chemical resistance and radiation stability make them well suited for a variety of applications including food packaging, lighting, packaging, dinnerware, medical ware, toys, gloss laminations and bottles.
With the good experience of the water bath and conveyor belt combination as take of the Polystyrene was easy to run in the complete speed rage of the take off. With a constant output of 2 kg/h outer diameters of 5 to 2.5 mm could be produced.

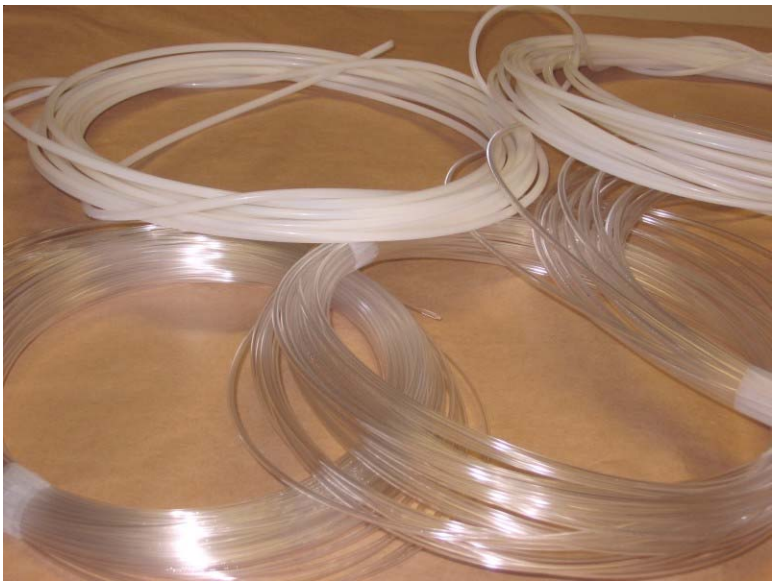

Fig. 4: final product

Table 1: Polycaprolactone Temperature profile: feed zone cooled, 150/150/140/90 °C (die)

Test Nr.	PCL 1	PCL 2
Speed [rpm]	30	50
Pressure at die p1 [bar]	115	130
Torque [Nm]	39	53
Take off speed [m/min]	1.1	2.95

Table 2: Polystyrene Temperature profile: feed zone cooled, 150/150/160/160 °C (die)

Test Nr.	PS 1	PS 2	PS 3
Speed [rpm]	50	50	50
Pressure at die p1 [bar]	87	87	87
Torque [Nm]	55	55	55
Take off speed [m/min]	3.17	4.75	11.4

Summary

Two materials were tested, both produces catheters for tests. Compared to the polystyrene the PCL is stickier and more difficult to handle, so pre trials make sense to find out correct processing conditions.
With more advanced equipment, such as a PolyLab OS system with melt pump, even more accurate and reproducible catheters can be produced. For pharmaceutical applications Thermo Electron Karlsruhe offers dedicated equipment.

Literature

[1] www.solvaycaprolactones.com
[2] http://plastics.dow.com/plastics/na/prod/polystyrenelsty_poly.htm

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LR-58_31.07.06