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A Study on Die Design Optimization for Microcatheter Extrusion Processes

Seunggi Jo[*,**], Euntaek Lee[*,#]
[*]Mechanical System Engineering, Kumoh National Institute of Technology,
[**]Safety System R&D Group, Korea Institute of Industrial Technology

마이크로 카테터 압출 공정을 위한 다이 설계 최적화에 관한 연구

조승기[*,**], 이은택[*,#]
[*]금오공과대학교 기계시스템공학과, [**]한국생산기술연구원 안전 시스템 연구 그룹

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ABSTRACT

Interventional radiology and minimally invasive surgery both require a precisely shaped microcatheter. Microcatheters are manufactured using polymer extrusion processes with a die and puller. The manufacturing parameters and die geometry greatly influence the profile of the extrudate and designing dies using a trial-and-error process is expensive and requires a lot of time. Therefore, predicting the profile of the extrudate is important for manufacturing microcatheters. This study investigates the effects of die design and geometry on the profile of the extrudate. The profiles of the extrudate are predicted using ANSYS Polyflow with respect to the different die geometries. The outer and inner diameters and wall thickness of the predicted extrudate are compared to those of a target extrudate. The die swell of melt polymer and the effect of the pulling are both examined. Optimized die designs are suggested for manufacturing the target extrudate.

Keywords : Catheter(카테터), Polymer Extrusion(폴리머 압출), Polymer Flow(폴리머 유동), Extrusion Die(압출 다이), Design Optimization(설계 최적화)

1. Introduction

A microcatheter is a consumable medical device in the form of a catheter based on minimal invasion and is actively used in the medical field of interventional therapy. It is a polymer-based disposable medical device used to minimize the risk and rate of infection of patients during a procedure. With the recent development of both medical technology and the medical techniques of medical staff, the need for a precise microcatheter is increasing[1].

In actual extrusion, it is difficult to simply extrude a microcatheter with the desired inner and outer diameters. Due to the limited number of

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Corresponding Author : euntaek@kumoh.ac.kr
Tel: +82-54-478-7328, Fax: +82-54-478-7319

process parameters that can be set during extrusion, the die shape for extrusion is determined through repetitive design changes. Thus, a die with parameters that can minimize trial and error is required. Furthermore, the extruded product should be stable and continuous. To satisfy these requirements, stable and precise process conditions are needed. Due to these problems, extrusion analysis using a numerical method is primarily applied, and the actual extrusion is performed based on the results[2,3]. Gonçalves et al.[2] validated the code developed to predict the flow field of polymer melts in limited channels using the generalized Newtonian model, and the developed code was used to improve the flow distribution of complex profile extrusion dies for manufacturing medical catheters. Tian et al.[3] succeeded in predicting the extrudate swelling of polypropylene and investigated the effects of flow rate, channel geometry, and the nonlinear parameters of the material on the extrudate.

A typical polymer extrusion process is performed through a die. The molten polymer flowing inside the die emerges onto the free surface. In this case, a product larger in size than the die is obtained due to the properties of the polymer. This phenomenon is called swelling. The polymer melted during the extrusion process is deformed by pressure and shear force inside the die. Deformed polymers attempt to return to their original stable state as they pass through the die and emerge onto the free surface. In this case, the residual stress does not completely disappear, inducing swelling[4-6]. Lee and Lyu[4] analyzed the tube-shaped extrusion process by using the generalized Newtonian model (cross law model) and the PTT model, which is a nonlinear viscoelastic model, and identified the effects of the relaxation time on the extrudate. Liu et al.,[5] through numerical analysis, analyzed the effects of various extrusion process variables on the cross-sectional phenomenon of the catheter extrudate and performed the optimization of the extrusion process conditions for manufacturing catheters with a uniform cross-sectional phenomenon by using the Taguchi technique. Cho et al.[6] investigated the effects of the screw speed (mass flow rate), the pulling speed, the air pressure applied to the lumen, and the varying distance between the quench and head, on the inner and outer diameters of the catheter. To prevent swelling, a method of pulling the polymer using a puller at the end of the free surface is applied[5,6]. Jin et al.[7] explored the change in the diameters of the catheter according to the temperature change of the die, the change in flow rate, and the speed of the puller. In addition, air pressure is applied into the lumen to preserve the shape of the lumen through swelling prevention[8-9]. Jin et al.[8] studied the effects of die swell and gas flow in polymer-based microtubes on the cross-sectional shape of the die, further confirming that the maximum velocity in the cross-section exists in the part with the largest area, which was found at the swell. Jo and Lee[9] examined the effects of process variables on the extrusion process of multi-lumen catheters through numerical analysis. The same study confirmed that as the puller speed increased, the cross-sectional area of the extrudate became smaller, and so did the lumen size. The study also confirmed that the effects of air pressure acting on a specific lumen were related to other lumens, as well as changes in roundness and long diameter. However, in general, the shape of the die has a great influence on that of the final extrudate. Thus, it is essential to design a suitable die to obtain the desired shape of the extrudate.

As thus far discussed above, many studies have been conducted on various process variables that affect the extrudate. However, there are few studies on the effects of the changes in die shape and size requiring repetitive design on the shape of extrudates. Therefore, this study analyzes the

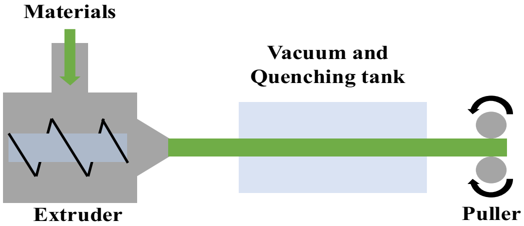


Fig. 1 Schematic diagram of catheter extrusion process

rheological flow of polymers using ANSYS Polyflow and predicts and compares the shapes of the final extrudate for dies of various sizes. Based on the results, an optimal die design method is suggested.

2. Catheter Extrusion Process

Fig. 1 is a schematic diagram of a catheter extrusion process. As raw polymer material enters the extruder, the polymer temperature is raised, and the material melts as it gets pumped along by a rotating screw. The liquid polymer emerges through the die onto the free surface to form a catheter. The extrudate, connected to a puller, is pulled at a constant speed. Subsequently, the extrudate is transferred to a vacuum and cooling tank and then cooled and hardened to possess the final shape of the extrudate.

3. Numerical Analysis Method

3.1 Numerical Analysis Modeling

The flow of the molten polymer follows the Navier Stokes equation in an incompressible steady state where temperature changes are not considered and inertia is neglected. In this study, because the length of the free surface between the die end and the vacuum and cooling tank is short, the effect on gravity is neglected. Equation (1) represents the mass conservation equation[9].

$$\frac{\partial u_i}{\partial x_i}=0 \tag{1}$$

The equation for conservation of momentum is represented as Equation (2) below,

$$-\frac{\partial p}{\partial x_i}+\frac{\partial \tau_{ij}}{\partial x_i}=0 \tag{2}$$

where u_i refers to the ith velocity, p refers to the pressure, and τ_{ij} refers to the shear stress. This study utilizes the generalized Newtonian model to show the rheological behavior. In the generalized Newtonian model, the shear stress is defined as follows[9].

$$\tau_{ij}=\eta(\dot{\gamma})\left(\frac{\partial u_i}{\partial x_j}+\frac{\partial u_j}{\partial x_i}\right) \tag{3}$$

Here, $\dot{\gamma}$ refers to the shear strain, and $\eta(\dot{\gamma})$ refers to the viscosity coefficient according to the shear strain. For the viscosity coefficient model, the cross law model is used as below[4],

$$\eta(\dot{\gamma})=\frac{\eta_0}{1+(\lambda\dot{\gamma})^m} \tag{4}$$

where η_0 refers to the initial viscosity and λ and m are the parameters of the cross law model.

3.2 Extrusion Process Analysis

The polymer used in the study is PEBAX 7233 purchased from Arkema Inc. whose density is 1,010 kg/m^3. Table 1 shows the parameters of the cross law model[4]. Fig. 2 shows the grid and boundary conditions used in the numerical analysis. Considering the symmetry condition, a quarter of the 3D calculation area was modeled and analyzed. The land length of the die is 5 mm and a no-slip

Table 1 Parameters of Cross law for PEBAX 7233

Parameters	
$\eta_0(Pa \cdot s)$	0.612515E+3
$\lambda(s)$	0.368397E-2
$m(-)$	0.627136E+0

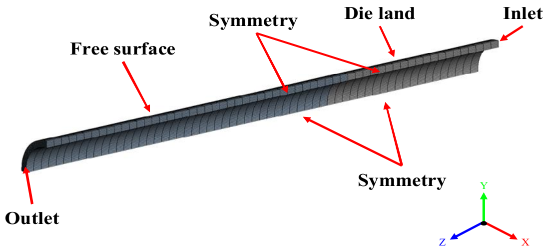


Fig. 2 Mesh and boundary conditions for numerical simulations

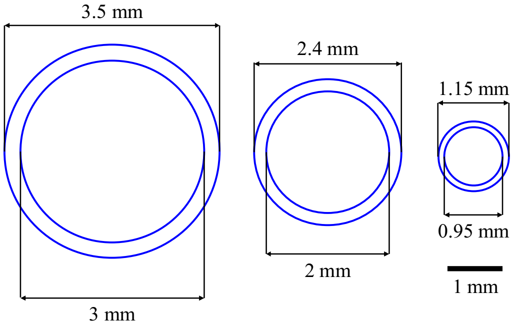


Fig. 3 Dimension of 3 target extrudates

condition is applied to the wall. The shape of the extrudate is predicted by applying a free surface condition from the end of the die land to the 10-mm position therefrom. The molten polymer enters the die land in the form of a fully developed flow through the inlet.

At the outlet of the end of the free surface, the puller speed, which is the speed at which the extrudate is pulled, is applied. The grid used for the numerical analysis consists of 352,641 nodes and 336,000 hexahedral elements.

Fig. 3 shows the sizes of three target extrudates in the form of a circular tube. The catheter size used in cardiovascular and cerebrovascular interventions usually consists of variable diameters of less than 4 mm. To find the common optimization conditions for various target sizes, three targets were set in an irregular range rather than a quantitatively increasing range. The puller speed was set as constant at 100 mm/s. The mass conservation law was applied to set the inlet flow rate according to the cross-sectional area of each target extrudate, and Table 2 shows the size and inlet flow rate of the target extrudate. Dies of various sizes were used to obtain each target extrudate. The underlying die size was determined based on a die of a shape equivalent to the extrudate, from which the sizes were increased by up to 7 times that of the extrudate.

Table 2 Geometric description of 3 target extrudates

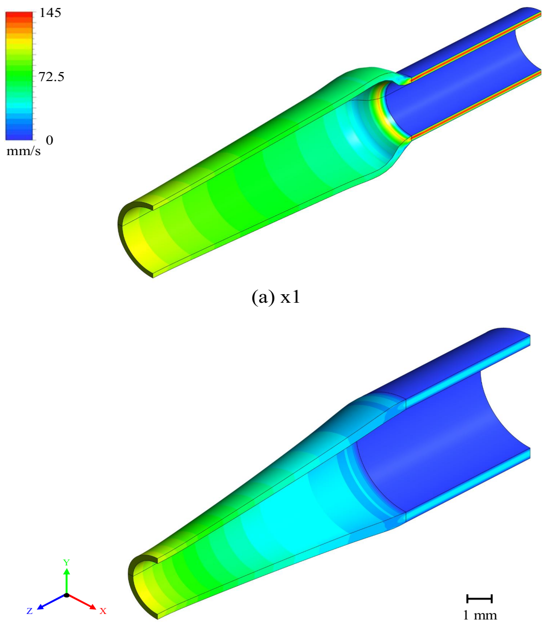
	Target 1	Target 2	Target 3
Outer diameter(mm)	2.4	1.15	3.5
Inner diameter(mm)	2.0	0.95	3.0
Wall thickness(mm)	0.2	0.1	0.25
Cross sectional area(mm^2)	1.38	0.33	2.55
Volume flow rate(mm^3/s)	138	33	255

4. Numerical Analysis Results

4.1 Die Land and Velocity Distribution on the Free Surface

An extrusion process analysis was performed by using a generalized Newtonian model. The target extrudate was Target 1, the flow rate was 138 mm^3/s, and a speed of 100 mm/s was applied to the end of the free surface during the extrusion process. To verify the results of the numerical analysis, the results of Tian et al.[3] were compared with those of this study. The accuracy of this study is ensured by the fact that almost the same results were obtained.

In this study, the velocity field at the die land



(a) x1

(b) x4

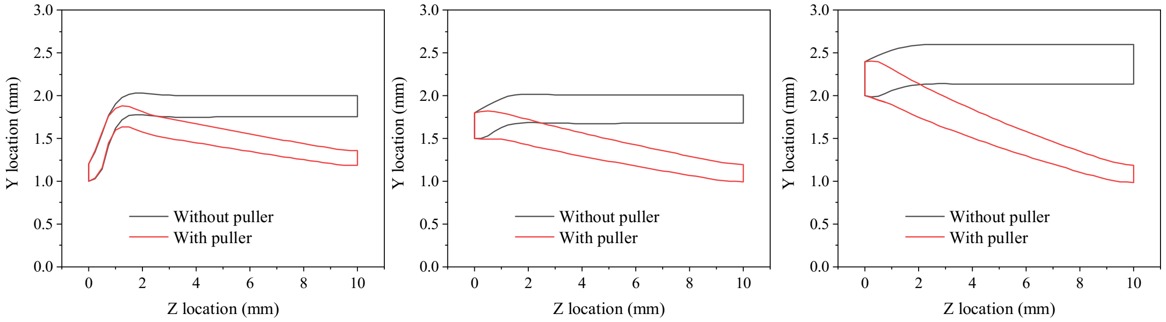
Fig. 4 Predicted velocity contour of target 1 for (a) x1 and (b) x4 with puller

and the free surface was obtained to examine the effects of the velocity distribution on the swelling at the beginning of the free surface. Fig. 4(a) indicates the velocity distribution using a die with a size equal to that of the extrudate, and Fig. 4(b) shows the results of the velocity distribution using a die with a size that is four times that of the extrudate. In the former case, because the die size is small compared with the same fixed flow rate, the polymer melting rate is high at the die land. Due to this high velocity, much swelling occurred. In the case of using a die with a size four times that of the extrudate, the polymer melting rate in the die land is relatively lower because of the wide flow path compared with the same flow rate, which causes less swelling to occur.

4.2 Influence of the Puller

To understand the effects of the puller during extrusion, the case in which the puller was not applied was compared with the case in which the puller was applied. For the target extrudate, Target 1, the shape of the extrudate was predicted while varying the die sizes.

Fig. 5(a) shows the case that uses the die with the same size as that of the extrudate, Fig. 5(b) shows the case that uses the die with a size 1.5 times that of the extrudate, and Fig. 5(c) shows the top cross-sectional profile of the extrudate using the die with a size twice that of the extrudate. In each case, the graph above represents the outer wall profile of the extrudate, and the graph below represents its inner wall profile. The left vertical line represents the die exit, and the right vertical line represents the exit at the end of the free



(a) x1 (b) x1.5 (c) x2

Fig. 5 Cross sectional profile of extrudate of target 1 for (a) x1 (b) x1.5 and (c) x2 die with and without puller

surface. The results show that the size of the extrudate increases considerably compared to that of the target extrudate due to the swelling phenomenon when the puller is not applied. This swelling phenomenon is difficult to predict.

As the die size increases, the speed and pressure at the die exit decrease, resulting in a more uniform velocity distribution. Thus, the results show that the swelling phenomenon decreases as the die size increases. On the other hand, when the puller is applied, the swelling phenomenon is alleviated in all cases, and the target extrudate shape is formed at the end of the free surface. Thus, if a die larger than the target extrudate is designed and a puller is applied, the extrudate of the desired size can be obtained.

Fig. 6 shows the cross-sectional profile of the extrudate when the puller is applied and the die size is the same, twice the size, three times the size, and four times the size of the target extrudate for Target 1. When the die size is the same, the profile is larger in size than the target extrudate, and when the die size is twice the size, the profile matches that of the target extrudate. When the die size is three and four times the size, the profile is larger in size than the target extrudate, similar to the case in which the die size is the same. To see the detailed trend, the inner diameter, outer diameter, and wall thickness of the extrudate are shown in Fig. 7. The die with the same size as the target extrudate produces an extrudate that has larger inner and outer diameters and a smaller wall thickness than the target extrudate. The results that are similar to the target extrudate can be obtained when the die size is approximately 1.5 times and twice the size of the target extrudate. In the same manner, when the die size is larger, the profile results in larger inner and outer diameters and smaller wall thickness than those of the target extrudate.

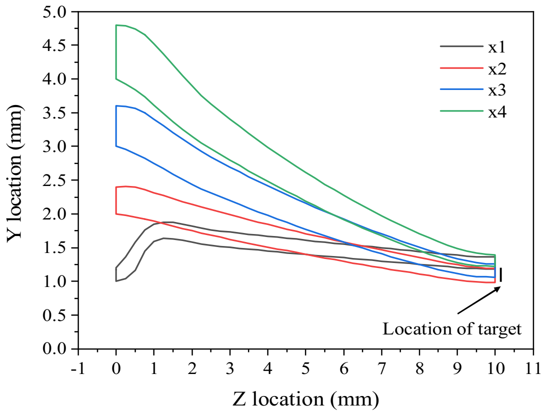


Fig. 6 Cross sectional profiles of extrudates of target 1 with puller

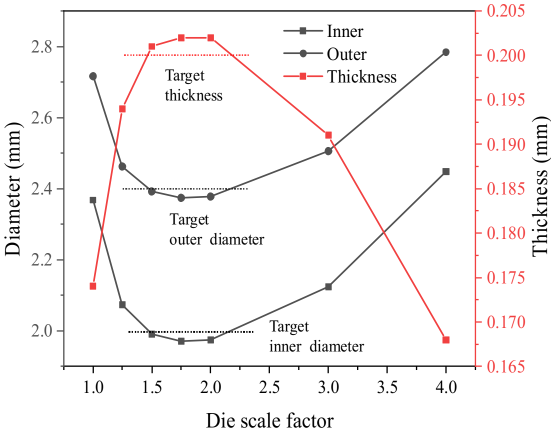


Fig. 7 Inner and outer diameters and wall thickness of target 1 for different die scale factor

4.3 Results of the Target Extrudate with Different Sizes

As shown in Table 2, the outer diameter of Target 2 is 1.15 mm, its inner diameter is 0.95 mm, its wall thickness is 0.05 mm, and its flow rate is 33 mm^3/s. Target 3 has an outer diameter of 3.5 mm, an inner diameter of 3.0 mm, a wall thickness of 0.25 mm, and a flow rate of 255 mm^3/s. Fig. 8 shows the inner diameter, outer diameter, and wall thickness for the various die

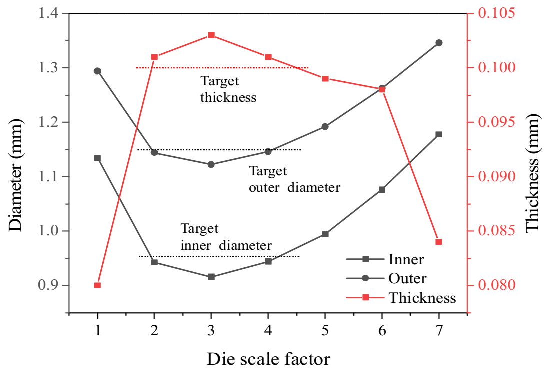


Fig. 8 Inner and outer diameters and wall thickness of target 2 for different die scale factor

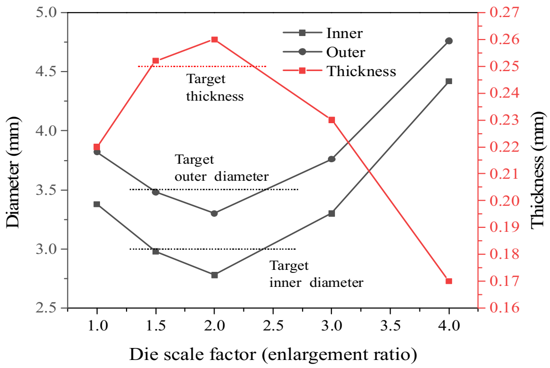


Fig. 9 Inner and outer diameters and wall thickness of target 3 for different die scale factor

sizes for Target 2. In the case of Target 2, the same results as those of the target extrudate can be obtained at the die size roughly twice and four times that of the target extrudate. As in Target 1, in smaller or larger dies, the inner and outer diameters tend to decrease, and the wall thickness tends to increase.

Fig. 9 shows the inner diameter, outer diameter, and wall thickness for the various die sizes for Target 3. In the results of Target 3, the same extrudate as the target extrudate can be obtained when the die size is approximately 1.5 and 2.5 times that of the target extrudate. Different sizes of the target extrudates result in different optimized die sizes. However, the results of the three target extrudates suggest that the target extrudate can be obtained with a die approximately twice the size of the target extrudate.

4. Conclusion

This study conducts a numerical analysis of die design optimization to obtain the target extrudate of the desired size. A microcatheter of a commonly used size is set as the target extrudate, and the molten polymer flow is analyzed by using ANSYS Polyflow. Dies of various sizes are used to obtain the target extrudate, and an optimized die design method is presented from the results.

1 Although it is difficult to predict the swelling phenomenon that occurs due to the difference in polymer melt rate at the end of the die land, the phenomenon can be alleviated by applying a puller.

2 If a die larger in size than the target extrudate is used to reduce the speed at the die land and a puller is applied, the size of the extrudate can be adjusted to be the same size as that of the target extrudate.

3 The optimized die size is influenced by the size of the target extrudate and the desired shape of the extrudate can be obtained by using a die with roughly twice the size of the target extrudate.

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