200um-class Polymeric Microneedle Fabricated by a Micro Injection Molding Technique

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ABSTRACT

Microneedles for the usage in bio-applications have been fabricated using various kinds of materials, including ceramics, metals, and polymers. The manufacturing cost must be taken into account for low-cost applications such as daily multiple usages for patients. In this work, the designs of a 200um-class microneedle and a runner system suitable for the successful fabrication using micro injection molding have been proposed. The mass-production of microneedles can be accomplished using micro injection molding.

Keywords: polymeric microneedle, micro injection molding

1 INTRODUCTION

Extensive microneedle researches have been conducted to enhance the efficiency of transdermal drug delivery. It has been expected and shown through experiments *in vivo* that microneedles can increase the skin permeability to deliver drugs by physically penetrating stratum corneum on epidermis without pain and scar.

Microneedles have been fabricated using various kinds of materials, including ceramics, metals, and polymers. For example, a combination of surface and bulk-micromachining techniques was used to fabricate micro-hypodermic needles from a silicon wafer [1]. The manufacturing cost may be, however, too high for low-cost applications such as daily multiple usages for patients. In this work, the designs of a 200um-class microneedle and a runner system suitable for the successful fabrication using micro injection molding have been proposed. The designs were examined and modified for better fabrications through virtual simulations based on CAE.

2 POLYMERIC MICRONEEDLE DESIGN

Microneedles can be divided into two types, in-plane and out-of-plane for its shape. In this research, microneedles of in-plane type will be fabricated. First of all, it has to be taken into account that the design of a microneedle is suitable for injection molding as a fabrication process of the microneedle. As shown in Fig. 1, the microneedle is composed of needle part and chamber part. Needle part has the function of pathway for drug delivery or the extraction of body fluids through skin, and chamber part has the role of space for the storage of drugs or body fluids. As initial dimensions, the thickness, width, and length of a microneedle were set to be 200um, 200um, and 1.9mm, respectively. There is an open channel of width 50um and depth 25um on the needle part. The initial design of the microneedle was made considering the functions of the microneedle and its fabricability by injection molding. The properness of the designs will be also examined by numerical analysis in the aspect of moldability.

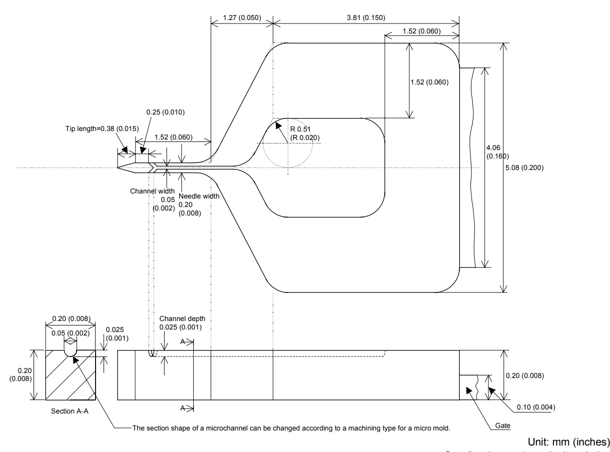


Figure 1: Initial design of a microneedle.

3 MOLD DESIGN AND SIMULATION

3.1 Mold Design

A runner system for the injection molding of microneedles is composed of a sprue, primary runners, secondary runners, and gates just before cavities for microneedles (Fig. 2). Basically the guideline suggested in the reference [2] was followed for the design of the runner system. The initial plan was based on the runner system for the 600um-class microneedle fabrication [3]. The total volume of the runner system including cavities was adjusted considering the performance of the injection molding machine for injection volume control.

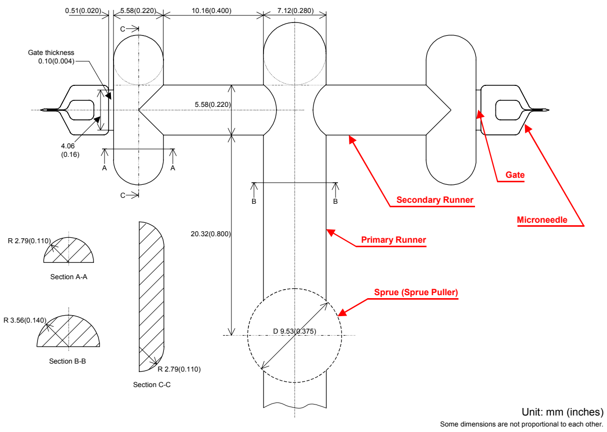


Figure 2: Initial design of a runner system for the fabrication of microneedles by injection molding.

3.2 Simulation of Micro Injection Molding

After 3-D modeling of the microneedle and the runner system for the initial design, the injection molding process for the fabrication of microneedles was numerically analyzed using the commercial software, Moldflow. Although mold and polymer melting temperatures are generally set to be 40 ~ 70°C and 220 ~ 250°C for the relevant polymer, Topas COC grade 8007, short shot was predicted in the simulation under the process conditions. Even under the extreme conditions of mold temperature higher than 80°C and polymer melting temperature higher than 300°C, it was predicted that the end part of the microneedle cavity is not completely filled. The right picture of Fig. 3 shows the predicted polymer temperature at flow front. It was predicted that the polymer temperature decreases by 15°C in the gate region. This is a kind of hesitation effect in injection molding, which can block the forward flow of polymer as the polymer cools rapidly and is solidified in the gate.

3.3 Modifications

It was predicted that the filling could not be completed. In order to fix the incompletion, the designs were modified in two aspects. As one is for the microneedle, the size of chamber part was reduced from 5mm x 5mm to 3mm x 4mm (Fig. 4). As the other is for the gate in the runner system, the shape between a secondary runner and a gate was modified into a tapered shape (Fig. 5), which was intended to remove the hesitation effect. These modifications can help to maintain polymer temperature constantly during injection molding with the control of injection speed, which can make the fabrication more easily.

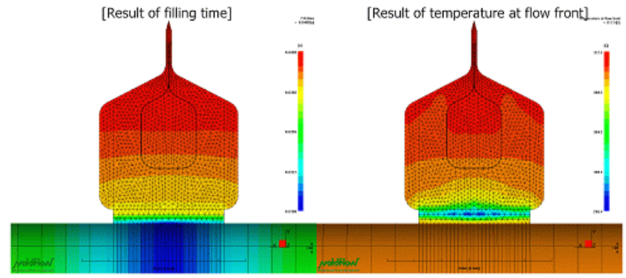


Figure 3: Predicted results of filling time and temperature at flow front.

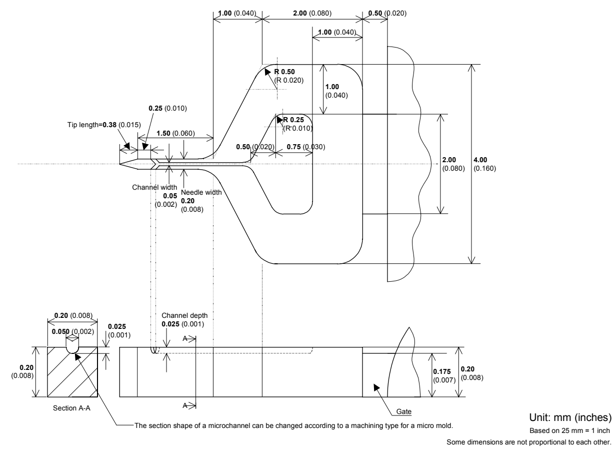


Figure 4: Modified design of a microneedle.

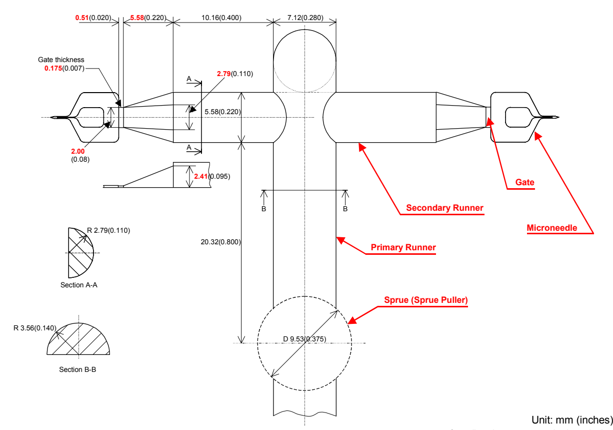


Figure 5: Modified design of a runner system.

4 MICRO INJECTION MOLDING

4.1 Mold Fabrication

The microneedle has a micro channel of width 50um and depth 25um on the needle part of width 200um. The relevant mold has the channel shape of width 75um and depth 25um. Since this shape is not easy to fabricate by conventional machining methods, the core of the mold was made by micro EDM(electro-discharge machining) using ROBOFORM 35P (Fig. 6). DC53 (improved one of SKD11) was used for the mold core material.

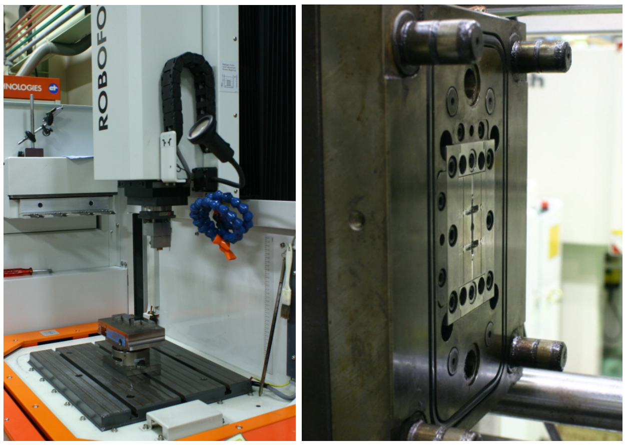


Figure 6: Micro EDM machine and the machined part of a steel mold with four cavities.

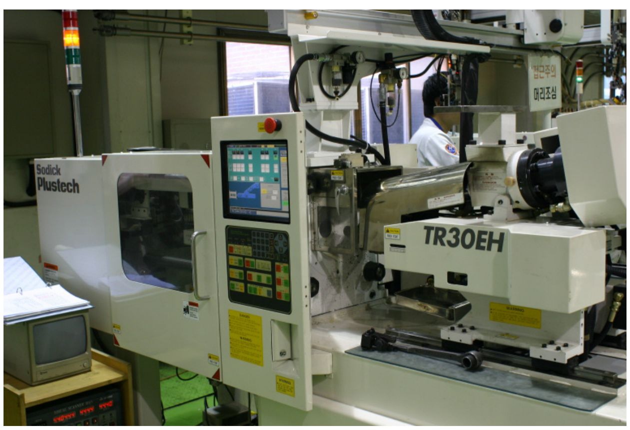


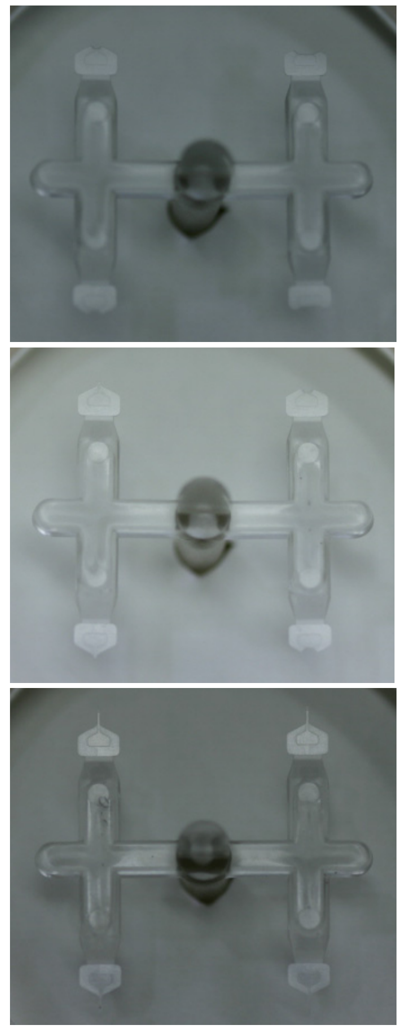
Figure 7: Injection molding machine for the fabrication of polymeric microneedles.

4.2 Micro Injection Molding

Sodick Plustech TR30EH (Fig. 7) was used for the injection molding of the microneedles with the polymer material of Topas COC grade 8007. The maximum injection volume of the machine is 4.5 cm^3 and the maximum injection speed is 500 mm/sec. It's thought that the machine is adequate for the injection molding of very thin and small parts. The mold temperature was kept at 40°C.

4.3 Molded Polymeric Microneedles

Injection speed as well as total filling time is an important process parameter to affect moldability. Fig. 8 shows injection molding results for microneedle fabrication according to the total filling time. The injection speeds just before the injection finishes were set to be 15, 30, 70 mm/sec for the filling time of 0.42, 0.33, 0.20 sec, respectively.



(a) 0.42 sec

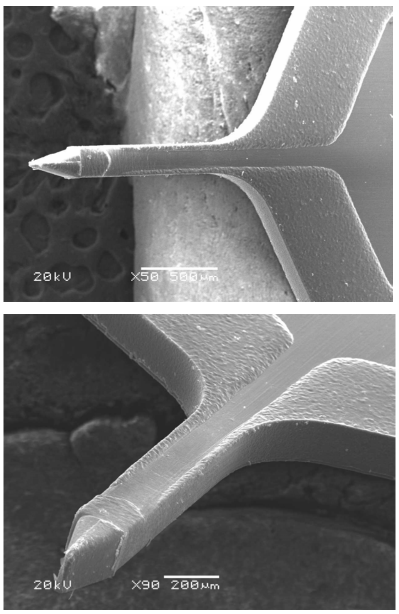
(b) 0.33 sec

(c) 0.20 sec

Figure 8: Fabricated microneedle sets (with filling time).

As shown in Fig. 8, short shots occurred and the fabrications of the microneedles were not completed in the case of the filling time is larger than 0.20 sec. If the filling time cannot be lowered below proper level by increasing injection speed, it may cause the incompletion of injection molding with the increase of flow resistance and the early solidification. When the injection speed is set to be larger than 70mm/sec and the filling time is shorter, good injection molding results could be obtained.

Fig. 9 is the SEM photo of the fabricated 200um-class microneedle. It is shown that the microneedle was fabricated finely. It is thought that the low quality of the roughness is just because the machined mark by micro EDM is replicated onto the injection molded part. The channel width of the microneedle was originally designed to be 50um. As shown in the picture, that of the fabricated microneedle is larger than 100um. It is thought that the relevant dimension of the mold core was not fabricated accurately by micro EDM and it should be improved in the future. Fig. 10 shows a digital picture of the fabricated microneedle compared with a 600um-width one(old version).



(a) Top view

(b) Isometric view

Figure 9: SEM photographs of a fabricated microneedle.

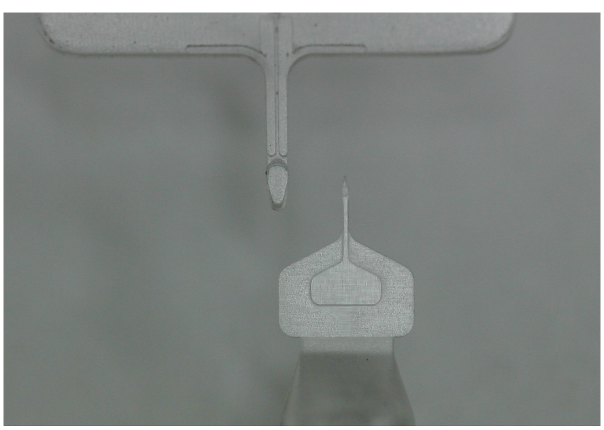


Figure 10: Fabricated microneedle (200um class) with a previous one (600um class).

5 CONCLUSION

The designs of a 200um-class microneedle and a runner system for its fabrication by injection molding were suggested. The initial plan was modified properly through the examination step by performing the numerical analysis based on CAE. The mold core for the microneedle fabrication was made using micro EDM. The 200um-class polymeric microneedle was successfully fabricated using micro injection molding with the mold. The mass-production of microneedles can be accomplished using micro injection molding.

ACKNOWLEDGEMENTS

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