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ТЕХНИКАЛЫҚ ҒЫЛЫМДАР ЖӘНЕ ТЕХНОЛОГИЯЛАР СЕРИЯСЫ / TECHNICAL SCIENCES AND TECHNOLOGY SERIES/ СЕРИЯ ТЕХНИЧЕСКИЕ НАУКИ И ТЕХНОЛОГИИ

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Computational Fluid Dynamics Study and Experimental Verification of the Proposed Procedure for Luer Fitting to Catheter Shaft Attachment

B.T.Zhali , D.Wei , A.Mussayev , D.G.Igali*

Nazarbayev University, Astana, Kazakhstan

E mail: dastan.igali@alumni.nu.edu.kz

Abstract. The objective of this study is to develop and design an efficient procedure for molding luer fittings and joining luer with an extruded catheter shaft. Unlike overmolding, this technology involves the process of injection molding the luer fittings separately from the catheter and their subsequent attachment to the extruded catheter shaft using adhesives and UV curing. The proposed methodology is empirically evaluated using an injection molding machine and manual assembly with an emphasis on evaluating the quality of the final product and manufacturing efficiency. As a result, unlike the traditional method of manufacturing fittings and connecting to catheters (via overmolding), luer fittings obtained using the proposed methodology have a low probability of short shots during the manufacturing process, do not compress the catheter lumen since they are not subject to shrinkage, and reduce labor costs by 4.9%, which makes this technology attractive. When designing the luer fitting, 3D modeling tools such as Solidworks were used, and calculations of the pressure and speed of the polymer melt inside the mold were analyzed using the finite element method in the Ansys Polyflow software. The absence of shrinkage, efficiency in labor costs, and compliance of the final product with the standards of ISO 10555-1 (2021) for intravascular catheters were experimentally verified.

Keywords: luer fittings, medical catheters, CFD, injection molding, extrusion, UV curing, materials and manufacturing, polymer processing

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*the corresponding author

Introduction

Polymers are widely used in various products that we use in our daily lives. These include apparel produced from synthetic fibers, cups made from polyethylene, fiberglass, nylon bearings, plastic bags, sheets and films manufactured from polypropylene, medical catheters, infusion lines, and silicone heart valves (Choudhury et al., 2022).

The polymer market is vast and experiencing tremendous growth due to the convenience of working with these materials. Furthermore, polymers are characterized by their exceptional mechanical and chemical attributes, including their affordability, lightweight nature, strength, flexibility, transparency, ease of sterilization, permeability, and remarkable resistance to physical aging and biological deterioration. Hence, polymer processing technologies are widely employed in several sectors such as packaging, building & construction, electronics, medicine, and aerospace. As an illustration, the automobile industry is currently focusing on decreasing the weight of its vehicles by substituting some components with polymers. This is because polymers are both cost-effective and lightweight, resulting in reduced fuel consumption for cars. Furthermore, the medical sector is increasingly adopting disposable plastic medical equipment due to their cost-effectiveness and reduced danger, in contrast to reusable medical devices, which are costly and recognized as potential sources of infections like HIV and hepatitis. (Choudhury et al., 2022; Czuba, 2014).

Injection molding is a prominent manufacturing process used to produce a variety of high-volume commercial products. These products include spools, bottle caps, vehicle dashboards, automotive parts, chairs, tables, plastic containers, medical catheter hubs, fittings for infusion lines, syringes, and other plastic-based products that are currently available (Dizon et al., 2019).

Overmolding is a specific use of the injection molding method where the molten polymer is directly poured onto the surface of a solidified substrate (Aliyeva et al., 2021). Nevertheless, the viscoelastic properties of the polymer melt as it solidifies might lead to deformation effects in the manufacturing process (Zeppenfeld et al., 2019). Overmolding or insert molding is employed to attach a polymer luer fitting to the proximal end of the extruded catheter (Kucklick, 2012). Although this process is extensively employed by catheter makers, the solidifying polymer fitting often experiences non-linear viscoelastic behavior, which leads to shrinkage and compression of the extruded catheter tubing. The shape irregularities of the fabricated part are caused by the high demolding temperature of the material (Michels, 2022). Consequently, the inner diameter of the compressed catheter decreases, making it challenging to introduce other devices via the catheter lumen.

Catheter luer fitting overmolding process steps are as follows:

1. The extruded catheter shaft is installed on mold inserts.
2. Luer fittings are insert molded around the extruded catheter shaft.

As a result, the solidifying luer fitting shrank and reduced the lumen of the soft catheter tubing (see Figure 1).

Aside from shrinkage, there exist numerous other faults in injection molding, including flow lines, sink marks, burn markings, and short shots. The faults primarily stem from factors such as excessive moisture in the material, suboptimal mold design, mold deterioration, and inappropriate machine parameter settings (Mourya et al., 2023).

Finding the ideal shape that matches the rheological properties of the melt and prevents mold deformation or external faults in the final product is the primary problem. Numerous optimization techniques for extrusion die designs that take deflection analysis and uniform polymer flow into account are equally relevant to the injection molding procedure (Igali et al., 2020; Razeghiyadaki et al., 2020; Razeghiyadaki et al., 2021; Igali et al., 2023).

Figure 1. Shrinkage of the luer fitting

For instance, it has been shown that the adjoint optimization approach helps resolve problems with die-shape optimization for polymer melt extrusion (Igali et al., 2023). The adjoint optimization approach is a potent computational methodology for extrusion dies that minimizes flow-related problems such as non-uniform velocity at the outlet and stagnation, improving die design. Using this approach, the sensitivities of an objective function (such as pressure drop or flow uniformity) concerning design factors may be computed by solving the adjoint equations obtained from the governing fluid dynamics equations. The adjoint approach allows for the exact modification of the die shape to attain ideal flow characteristics by repeatedly modifying these variables. By guaranteeing a more consistent and regulated polymer melt flow through the die, this method substantially enhances both processing efficiency and product quality, making it very effective for intricate die designs.

The objective of this paper is to numerically and experimentally create a streamlined catheter luer fitting manufacturing process utilizing 3D modeling tools, which will enable the production of catheter luer fittings of superior quality that comply with ISO 10555-1:2023 requirements for intravascular catheters, while eliminating any previously noted flaws such as shrinkage and short shots. This technology involves the process of individually injection molding the luer fittings and then attaching them to the extruded catheter shaft using adhesives and UV curing. The proposed methodology will be empirically evaluated by utilizing an injection molding machine and manual assembly, with a focus on assessing the quality of the final product and the efficiency of manufacturing. The results obtained from the suggested methodology will be compared to the results from overmolding or insert molding in terms of shrinkage and labor cost.

The methodology

This paper aims to use 3D modeling software, such as Solidworks, to generate the catheter luer fitting seen in Figure 2, while complying with ISO 10555-1:2023 requirements for intravascular catheters. In addition, a mold design with several cavities will be developed to facilitate the concurrent manufacturing of 6 to 8 luer fittings. The mold design will be tailored to suit the precise viscoelastic characteristics of the selected material, as well as the capabilities of the injection molding machine, cooling and heating systems, gate/runner design, and ejection mechanisms. The design will undergo computational validation utilizing Ansys Polyflow software, renowned for their efficacy in studying the characteristics of polymer melts (Igali et al., 2020).

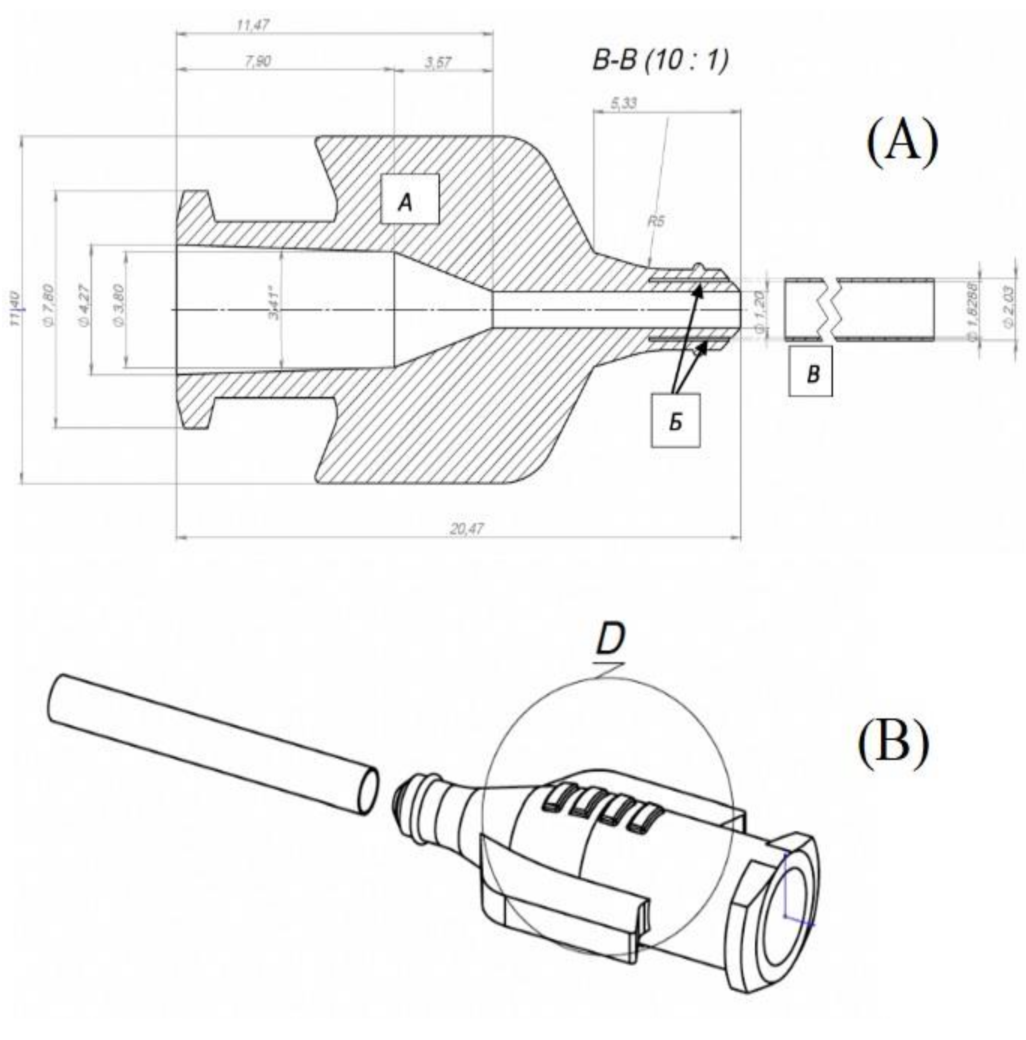

Figure 2. Cross-sectional view (A) and isometric view (B) of the luer fitting

In this study, the results of the pressure and velocity have been obtained to investigate the polymer melt behavior inside the luer fitting mold. Figure 3A illustrates that the inside of the mold comprises the sprue, runner, gates, and component cavities. Typically, the molten material flows into the mold from the nozzle of the injection machine, then passes through the sprue and fills the mold cavities through runners and gates.

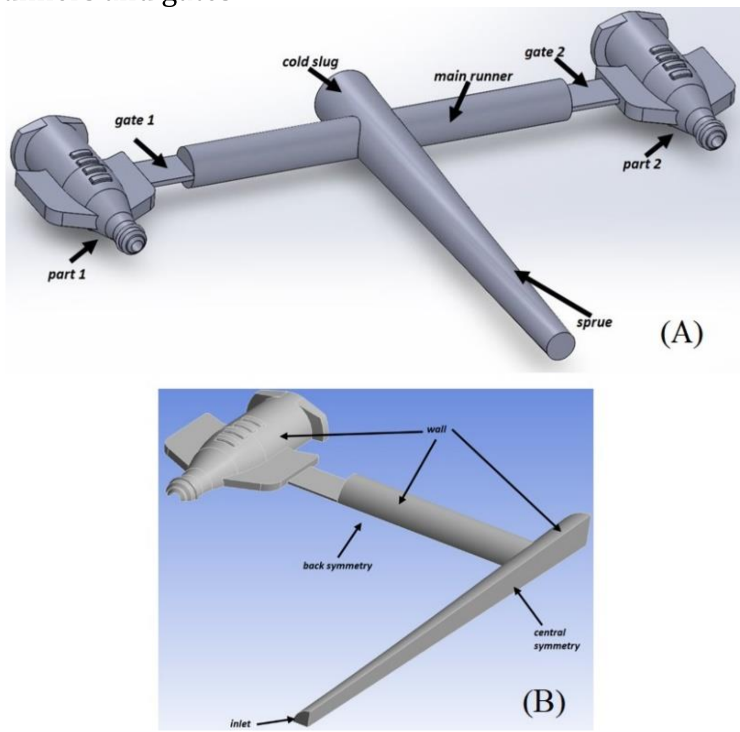

Figure 3. Interior of the mold (fluid body) (A) and one-fourth of the fluid body (B)

To minimize calculation time, just one-fourth of the fluid body's shape, which includes the inlet, wall, and symmetry faces, is evaluated due to its symmetric characteristic (see Figure 3B).

The mesh generated for this computational fluid dynamics (CFD) analysis has 165,480 nodes and 514,408 elements, as shown in Figure 4.

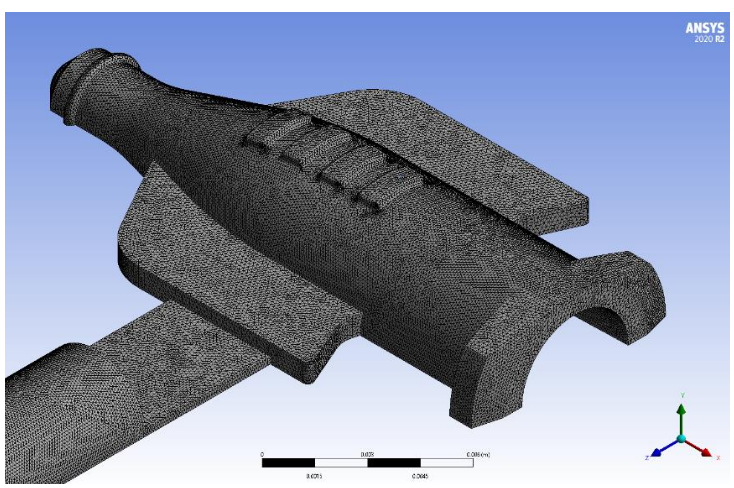

Figure 4. Mesh

Boundary conditions are as follows:
- Inlet: the flow is assumed to be fully developed with the volumetric flow rate of 1.46 m3/s;
- Wall: no-slip boundary conditions.

Some basic assumptions were made for the computations:
- Steady state flow;
- Isothermal flow;
- Hydrodynamically fully developed flow;
- Incompressible fluid;
- No external forces (e.g., the effect of gravity is neglected);
- No slip boundary condition at the walls.

In this study, the medical grade PP (LB6331) with the following mechanical properties and power-law viscosity parameters has been used:

Table 1. Simulation parameters for PP (LB6331) (Zaki et al., 2022)

Material	Medical grade (LB6331)
Inlet temperature (°C)	190.00
Inlet pressure (MPa)	38.22
Density (kg/m³)	900
Zero shear viscosity (kg/m s)	2160.00
Power law index	0.2590
Time constant (s)	0.0573

Figure 5 illustrates the pressure and velocity distribution of the medical-grade PP melt inside the mold after injection.

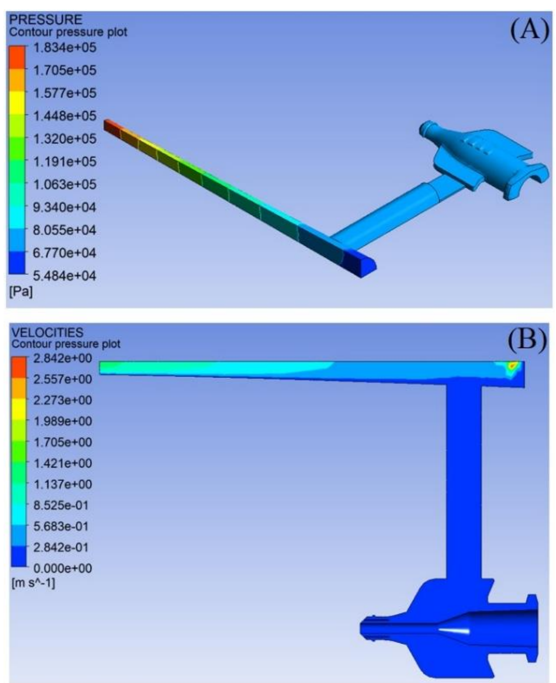

Figure 5. Pressure (A) and velocity (B) contour plots

These results have been produced using Ansys Polyflow. As anticipated, the intake experiences a maximum pressure of 0.183 MPA, which gradually decreases as it progresses into the part cavities. Furthermore, the velocity reaches its peak at the intake as a result of the substantial flow rate at the entry. However, the velocity gradually decreases from 2.842 m/s to 0 m/s as the molten material fills the cavities and eventually comes to a halt. According to the results shown in Figure 5, the luer fitting cavities are completely filled, and there are no signs of deformation and short shots, because the pressure and velocity values are distributed evenly.

This study also provides instructions for the experimental procedure of bonding a luer to the proximal end of a catheter using UV-cure adhesive. This procedure must be performed in a minimum of a Class 8 Clean room. The following equipment and fixtures were used in this procedure:

- Fixture for Holding Parts;
- Luer Lock Dispensing Tips (disposable; hooked to syringe of adhesive to control the adhesive flow);
- EFD Precision Fluid Dispenser with adapters for syringe (optional, requires pressurized air hookup);
- UV Light Source with required Light Guide;
- UV Cure Adhesive.

The proximal end of the catheter shaft is placed over the mandrel and into the bore of the luer fitting until it bottoms out, as shown below.

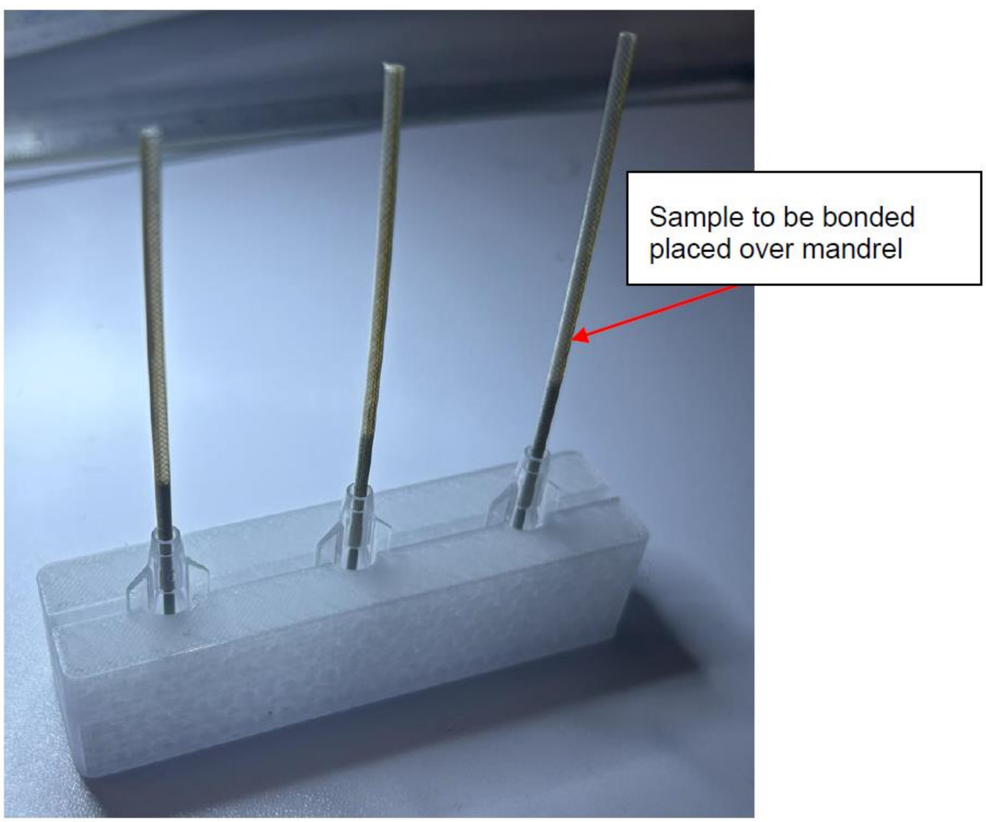

Figure 6. Loading parts into the fixture

The dispensing tip is positioned between the luer fitting and the catheter shaft.

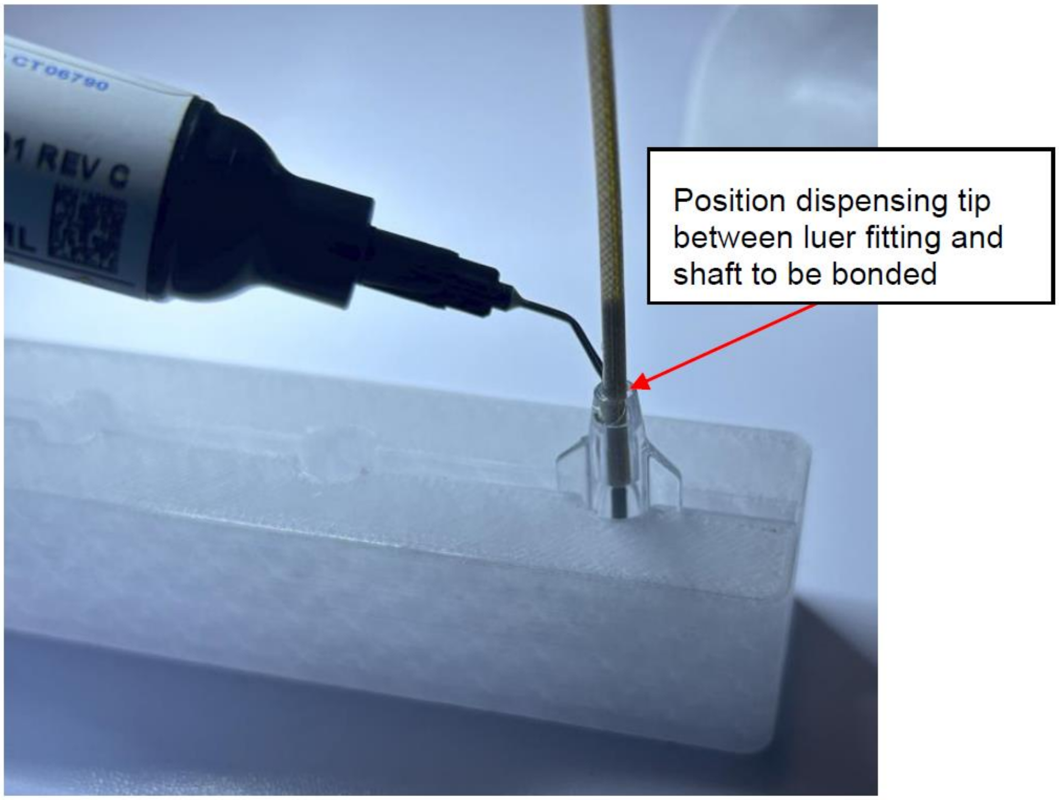

Figure 7. Adding adhesive

Slowly dispense adhesive, allowing it to flow into the gap between the luer fitting and the shaft. It can be helpful to rotate the shaft while dispensing to better distribute the adhesive around the circumference of the shaft.

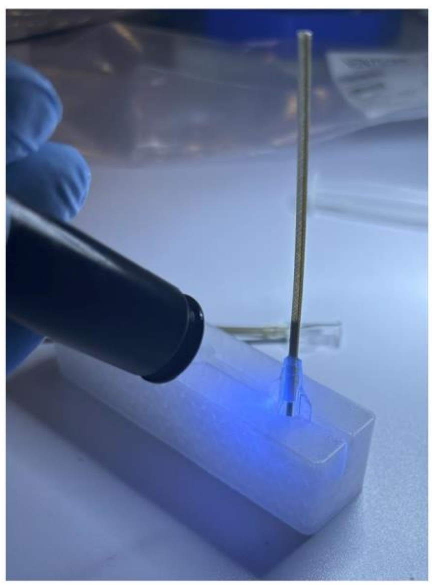

Figure 8. Curing (putting the wand too close to the part will result in the part heating up)

Note:

- Depending on the viscosity of the adhesive, adjust the dispensing speed.
- The tip may be positioned near the top or bottom, depending on the viscosity, size of the gap, and geometry of the parts.

Once the adhesive has reached the bottom of the bore/shaft, stop dispensing adhesive. Use a cleanroom swab or cleanroom wipe to clean away any spilled adhesive. Depending on the viscosity of the adhesive, it may be necessary to carry out the next UV curing step very quickly.

Position the UV Cure Wand about 25mm from the part and cure for 10 seconds as shown in Figure 8.

Then, rotate the fixture 180 degrees, and cure for 10 more seconds.

The last step is to add a fillet of adhesive around the junction of the luer and the tubing, as shown in the figure below.

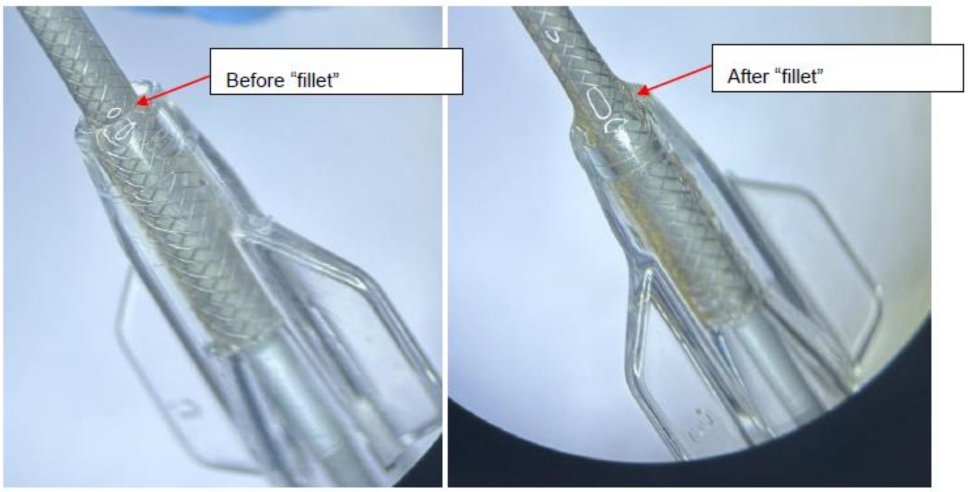

Figure 9. Adding a fillet (it may be advantageous to remove the part from the fixture for this step so that it can be done fully under a microscope)

Finding/Discussion

After visual inspection, it can be clearly noticed that the luer fitting was not subject to shrinkage since the lumen of the catheter was not compressed, as shown in Figure 8.

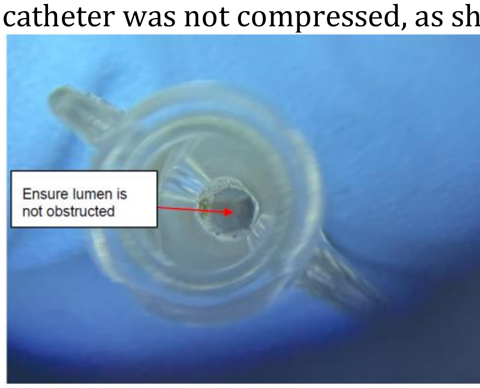

Figure 10. Observation of the catheter lumen

Also, there are no excessively large voids in the luer fittings. The figures below show examples of acceptable and unacceptable voids in the fittings because of the short shots.

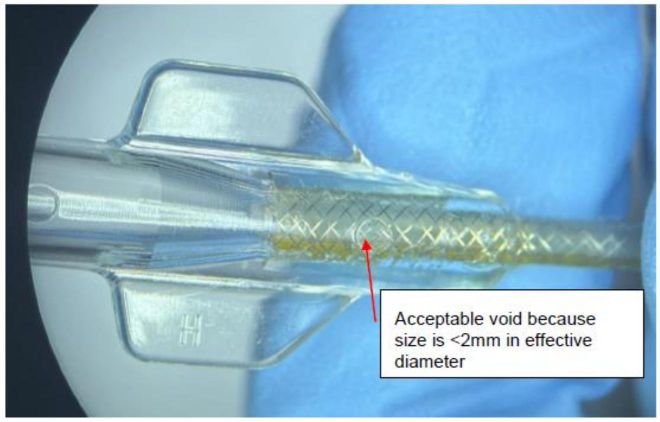

Figure 11. Observation of the acceptable voids

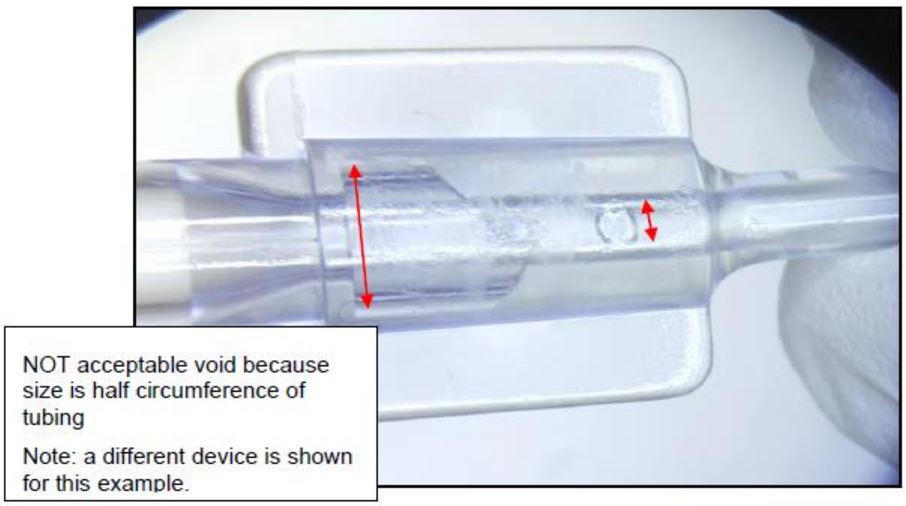

Figure 12. Observation of the unacceptable voids

According to ISO 10555-1 (2021) for intravascular catheters, the junction of the luer fitting with the catheter must withstand a load of up to 15 N. The tensile test was carried out on 11 samples, and the obtained average strength value is about 108 N. All samples passed the test successfully, as shown in the table below. Furthermore, the labor costs for manufacturing one luer fitting were experimentally estimated. The aforementioned technological process of manufacturing a luer by the traditional method (overmolding) consists of two stages: placing the catheter shaft on the insert and the luer injection molding process around the shaft. Installation of the catheter shaft on the inserts takes 3 sec. (0.00083 man-hours), while the luer molding process around the shaft takes 20 sec. (0.0055 man-hours). The technological process of manufacturing luer by the proposed method consists of three stages: the process of molding luer on an injection molding machine separately without using inserts, adding adhesive, and UV curing. The process of injection molding by this method takes 6.67 sec. (0.0019 man-hours), and the adding adhesive and UV curing processes take 15 sec. (0.0042 man-hours). It is important to consider that the overmolding process using an injection molding machine with inserts takes more production time, since this method allows you to manufacture only 2 pcs. of luer fittings at one shot, while the proposed method allows you to produce a minimum 6-8 pcs. at one shot, since the absence of an insert on the mold frees up space for additional part cavities in the mold.

Table 2. Tensile strength testing results

Sample #	Force to Failure (lbf)	Force to Failure (N)
1	23.4	104.0
2	19.8	88.2
3	23.1	102.5
4	31.6	140.6
5	25.3	112.5
6	21.1	94.0
7	14.6	64.9
8	25.6	113.7
9	30.8	136.9
10	23.5	104.7
11	28.6	127.2
Avg	24.3	108.1
Standard Deviation	4.70	20.93
Min	14.6	64.9
Max	31.6	140.6

Comparative data for the two methods of manufacturing catheter fittings are given below:
Table 3. Comparative analysis

Criteria	Traditional method of manufacturing luer fittings (overmolding)	Proposed manufacturing method of luer fittings (adding adhesive + UV curing)
Labor costs, man-hours	0.0064	0.0061
Number of cavities on the mold, pcs.	2	6-8
Compression of the internal lumen of the catheter	yes	no

Conclusion

The conducted research highlights the effectiveness of developing an alternative approach to the manufacturing of intravascular catheters by introducing a modified process for producing and assembling luer fittings. Unlike traditional overmolding, where the fitting is formed directly on the catheter shaft, the proposed methodology involves independent injection molding of the luer component, followed by its attachment to the extruded catheter shaft using medical-grade adhesives combined with UV curing. This separation of processes as only reduces technological risks associated with polymer shrinkage and dimensional instability but also provides improved control over both the quality of the fitting and the assembly procedure.

The empirical evaluation, carried out using industrial injection molding equipment and manual assembly techniques, revealed significant benefits of the new method. The probability of short-shot defects during injection molding was minimized, while the absence of shrinkage ensured that the catheter lumen remained uncompromised, thereby preserving the functional characteristics of the device. Furthermore, comparative analysis demonstrated a 4.9% increase in labor efficiency, which, although modest, represents an important contribution to overall manufacturing productivity when scaled to industrial volumes.

From a design perspective, the study integrated advanced engineering tools, including 3D modeling in SolidWorks for geometrical optimization and finite element simulations in Ansys Polyflow to analyze polymer melt flow parameters within the mold cavity. These computational analyses provided valuable insights into the pressure and velocity distribution of the polymer, enabling improved mold design and minimizing the likelihood of processing defects. The experimental outcomes validated these theoretical models, confirming that the final product consistently meets the structural and functional requirements of ISO 10555-1 (2021) for intravascular catheters.

In summary, the proposed technology offers a promising alternative to conventional overmolding by combining manufacturing flexibility, reduced defect rates, and improved cost-efficiency. Beyond the direct technical advantages, this approach also opens opportunities for further automation of catheter assembly, integration with novel adhesive formulations, and adaptation to other classes of medical devices where precise dimensional stability and lumen preservation are critical. Consequently, this study establishes the feasibility of the method but also lays the groundwork for scaling its application in modern medical device production, potentially influencing industry practices toward more reliable and resource-efficient manufacturing strategies.

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The contribution of the authors

Zhali B.T. is responsible for literature review and scientific consulting.

Wei D. developed the concept and methodology.

Mussayev A. is responsible for literature review and scientific consulting.

Igali D.G. worked on data collection, 3D modeling, CFD study, experimental verification, analysis, interpretation, drafting, editing**.**

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Б.Т.Жали, Д.Уей, А.Д.Мусаев, Д. Ғ.Иғали*

[1] Назарбаев Университеті, Астана, Қазақстан, Қазақстан

Сұйықтық динамикасын есептеуді зерттеу және катетер білігіне Луер фитингін орнатудың ұсынылған процедурасын эксперименттік тексеру

Аңдатпа. Бұл зерттеудің мақсаты - экструдталған катетердің шафтына Луер фитингтері мен қосылымдарын өндірудің тиімді процедурасын әзірлеу және жобалау. Дәстүрлі қалыптаудан (овермолдингтен) айырмашылығы, бұл технология Луер фитингтерін катетерден бөлек инъекциялық қалыптау процесін қамтиды, содан кейін оларды жабысқақ және ультракүлгін сәулелену арқылы экструдталған катетердің шафтына қосу болып табылады. Ұсынылған әдістеме соңғы өнімнің сапасы мен өндіріс тиімділігін бағалауға баса назар аудара отырып, қалыптау машинасы мен қолмен құрастыру арқылы эмпирикалық түрде бағаланады. Нәтижесінде, фитингтерді дайындаудың және катетерге қосудың дәстүрлі әдісінен айырмашылығы (овермолдингтен), ұсынылған әдіспен алынған Луер фитингтері өндіріс процесінде толымсыз құйылу ықтималдығы төмен, катетердің люменін қыспайды, өйткені олар шөгуге ұшырамайды және бұл технология жұмыс күші бойынша 4,9 %-ға тиімді. Луер фитингінің дизайны Solidworks сияқты 3D модельдеу құралдары арқылы жасалды және қалып ішіндегі полимердің қысымы мен балқу жылдамдығының есептеулері Ansys Polyflow бағдарламалық құралында соңғы элементтерді талдау арқылы талданды. Шөгудің жоқтығы, еңбек өнімділігі және түпкілікті өнімнің ISO 10555-1 (2021) тамырішілік катетерлер стандарттарына сәйкестігі тәжірибе жүзінде расталды.

Түйін сөздер: Луер втулкасы, Катетерлер, CFD, Инъекциялық құю, Медициналық құрылғылар өндірісі, Экструзия

Б.Т.Жали, Д.Уей, А.Д.Мусаев, Д. Г.Игали*

Назарбаев Университеті, Астана, Қазақстан, Қазақстан

Исследование динамики жидкости с помощью компьютерных вычислений и экспериментальная проверка предлагаемой процедуры установки Луер фитинга на шафт катетера

Аннотация. Целью данного исследования является разработка и проектирование эффективной процедуры изготовления фитингов Луер и соединения с экструдированным шафтом катетера. В отличие от овермолдинга, данная технология включает в себя процесс литья под давлением фитингов Луер отдельно от катетера и их последующего соединения к экструдированному шафту катетера с помощью клея и УФ-отверждения. Предлагаемая методика эмпирически оценена с использованием термопластавтомата и ручной сборки с акцентом на оценку качества конечного продукта и эффективности производства. В результате, в отличие от традиционного способа изготовления фитингов и соединения с катетерами (с помощью овермолдинга), фитинги Луер, полученные с использованием предлагаемой методики, имеют низкий риск недоливов в процессе производства, не сдавливают просвет катетера, поскольку не подвержены усадке, и обеспечивают снижение трудозатрат на 4,9%, что делает данную технологию привлекательной. При проектировании Луер фитинга использовались инструменты 3D-моделирования, такие как Solidworks, а расчеты давления и скорости расплава полимера внутри формы анализировались методом конечных элементов в программном обеспечении Ansys Polyflow. Отсутствие усадки, эффективность по трудозатратам и соответствие конечного продукта стандартам ISO 10555-1 (2021) для внутрисосудистых катетеров было экспериментально подтверждено.

Ключевые слова: Втулка Луер, Катетеры, CFD, Литье под давлением, Производство медицинских изделий, Экструзия

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Information about the authors

Zhali B.T. - bachelor degree in economics, Nazarbayev University, Kabanbay Batyr Avenue, 53, Z05H0P9, Astana, Kazakhstan

Wei D. - PhD in mathematics, full Professor, Nazarbayev University, Kabanbay Batyr Avenue, 53, Z05H0P9, Astana, Kazakhstan

Mussayev A. - master of science in Mining Engineering, Nazarbayev University, Kabanbay Batyr Avenue, 53, Z05H0P9, Astana, Kazakhstan

Igali D.G. - corresponding author, master of science in Mechanical & Aerospace Engineering, project manager, Nazarbayev University, Kabanbay Batyr Avenue, 53, Z05H0P9, Astana, Kazakhstan

Жали Б.Т. - степень бакалавра экономики, Назарбаев Университет, проспект Кабанбай батыра, 53, Z05H0P9, Астана, Казахстан

Уей Д. - доктор наук по математике, профессор, Назарбаев Университет, проспект Кабанбай батыра, 53, Z05H0P9, Астана, Казахстан

Мусаев А.Д. - магистр наук в области горного дела, Назарбаев Университет, проспект Кабанбай батыра, 53, Z05H0P9, Астана, Казахстан

Игали Д. Г. - автор-корреспондент, магистр наук в области машиностроения и аэрокосмической техники, менеджер проектов, Назарбаев Университет, проспект Кабанбай батыра, 53, Z05H0P9, Астана, Казахстан

Жали Б.Т. - экономика бакалавры, Назарбаев Университеті, Қабанбай батыр даңғылы, 53, Z05H0P9, Астана, Қазақстан

Уей Д. - математика ғылымдарының докторы, Назарбаев Университетінің профессоры, Қабанбай батыр даңғылы, 53, Z05H0P9, Астана, Қазақстан

Мусаев А.Д. - тау-кен ісі саласындағы ғылым магистрі, Назарбаев Университеті, Кабанбай батыр даңғылы, 53, Z05H0P9, Астана, Қазақстан

Иғали Д. Ғ. - корреспондент-автор, машина жасау және аэроғарыштық инженерия магистрі, жоба менеджері, Назарбаев Университеті, Қабанбай батыр даңғылы, 53, Z05H0P9, Астана, Қазақстан