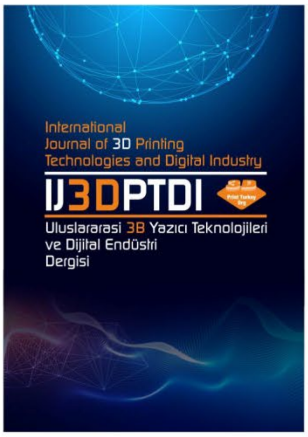

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Yazarlar (Authors): Fatih KÖSE*, Alper TEZCAN

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REDESIGN AND FABRICATION OF STENT DESIGNS PRODUCED BY COMMON METHODS BY OPTIMIZING FOR MELT ELECTRO WRITING (MEW) METHOD

Fatih KÖSE[a]*, Alper TEZCAN[a]

[a]İstanbul Arel University, Engineering Faculty, Mechanical Engineering Department, TURKIYE

* *Corresponding Author: fatihkosemakine@gmail.com*

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ABSTRACT

The main discussion is about the differences compared to other methods. The aim is to observe the advantages and disadvantages of the stent produced using the MEW manufacturing technique and to apply the production principles. This study presents the design of a mesh-patterned stent and details the production stages using a Mew manufacturing method. Melt Electro Writing (MEW) method is a 3D writing method that is progressing and developing day by day with its use in many fields from industry to medicine. With this method, semi-flexible structures can be produced with rigid polymers. Polycaprolactone (PCL) material is preferred due to its low melting temperature and degradable structurein this production technique based on electrohydrodynamic principles to produce highly efficient, micron fibers . New methods and solutions are emerging in line with the studies carried out in this field. Stents made of nitinol are the most commonly used stents. Nitinol stents cannot be removed again as a result of placement. For this reason, various difficulties may occur in cases of recurrent blockage in the same area. It is also disadvantageous in terms of material and production costs. In the ongoing studies, it is observed that the focus is on stents that can be absorbed by the body and perform mineral supplementation. Biodegradable stents provide absorption by melting in the vessel. In this study, a stent with a grid pattern design made of Polycaprolactone (PCL) material was produced with a melt electro writing device with a rotary table. The comparison of the 316L metal stent produced by conventional production methods with the same dimensions and designs and the stent produced by MEW method from PCL material is explained by simulation and analyses, and it is shown in which cases it is more efficient and in which cases it is dysfunctional. It has been shown that stents produced with polycaprolactone (PCL) in MEW method are more efficient in terms of flexibility, biocompatibility and biodegradability than 316L metal stents produced by conventional methods. While PCL stents are suitable for short-term applications with their flexibility and biocompatibility advantages, 316L stainless steel stents can be preferred for situations requiring long-term performance and mechanical durability. The specific advantages and disadvantages of both materials are important points to be considered during stent selection. In addition to the modification and improvement of PCL materials, it has been observed that design is one of the most important factors in stent efficiency, and future studies can contribute to the development of stents that provide better performance, especially by focusing on the ability and technology of MEW devices to produce every design based on design-oriented production.

Keywords: Melt Electro Writing, Cardiovascular Stent, Cardiovascular Stent Manufacturing Techniques, Cardiovascular Stent Production with Melt Electro Writing Method.

1.INTRODUCTION

This study presents the design of a mesh-patterned stent and details the production stages using a Mew manufacturing method. The ease of production and the functionality of the material are discussed, and the advantages and disadvantages of PCL material are identified. Comparisons are made with metal stents, which are among the traditional methods. It is concluded that PCL stents have a bright future in terms of processing parameters and biocompatibility, indicating they will have a larger market share in the industry in the future. While PCL stents are suitable for short-term applications due to their flexibility and biocompatibility advantages, 316L stainless steel stents may be preferred for situations requiring long-term performance and mechanical durability. The unique advantages and disadvantages of both materials are important points to consider during stent selection. Future studies focusing on the modification and improvement of these materials may contribute to the development of stents with better performance.

Stents are used to restore circulation by expanding the vessel after occlusion of the vessels. It is widely used because it has advantages over other methods applied to open the veins. It is frequently used in the brain, kidney and leg vessels, as well as in the heart vessels.

One of the most commonly used stents is stents made of nitinol. It is not possible to remove nitinol stents again as a result of their placement. For this reason, various difficulties may occur in cases of recurrent occlusion in the same area. It is observed that the focus is on stents that can be absorbed by the body and supplement minerals in the ongoing studies. Biodegradable stents dissolve in the vessel and provide absorption. However, the excessive accumulation of minerals contained in the material in the body also poses different risks. The general purpose of the studies is to eliminate the risk by minimizing it.

Melt Electro Printing (MEW) technique is a frequently used and continuously developed 3D printing technique in this field. It enables the production of cardiovascular stents with rigid polymers with high resolution flexible structures. Especially in the MEW method, it is seen that stents produced with Polycaprolactone (PCL) are efficient in terms of flexibility, biocompatibility and biodegradability. 4D printing and smart materials could positively change the future of cardiovascular stent design [13-15].

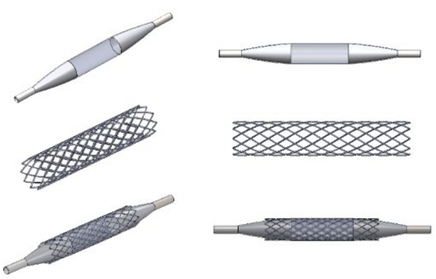


Figure 1. Stent, balloon and stent-balloon design.

Stents, which can be produced in different sizes and thicknesses according to the vascular structure in which they are used, are generally produced in 2-4 mm thickness and 10-30 mm in length. Before the procedure, there is a deflated stent balloon in the stents in the shrunken form. The balloon, which is attached to a long thin tube, is 1-2 mm wide. Stent, Balloon and Stent-Balloon Design is shown in Figure 1.

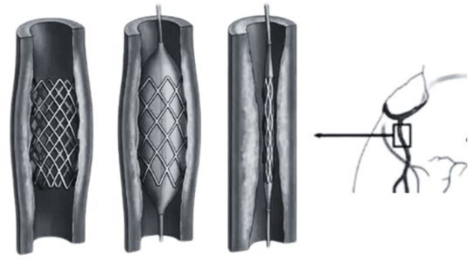


Figure 2. Stent application in the occluded vessel.

The stent, which is placed in the occluded part of the vessel, provides the crushing of the elements that cause the obstruction by inflating the balloon. The main purpose is to remove the obstruction and provide blood flow at standard values. During the procedure, the crushing or fragmentation of the elements that cause occlusion in the vessel is perceived as damage by the body and creates an intervention reflex in that area. Therefore, narrowing may occur in the same area after a short time. The placed stent prevents re-narrowing. Stent application in the occluded vessel is shown in Figure 2.

It is essential not to damage the vein during the procedure. The stent to be used should be selected according to the vascular structure. It is important that the stent is flexible and can be placed. In addition, it must have the strength to meet the pressure in the vein. It must have biocompatibility, corrosion resistance, back collapse strength and high fatigue strength.

Cardiovascular Stents are used to restore circulation by expanding the vessel after occlusion of the vessels. It is widely used because it has advantages over other methods applied to open the veins. It is frequently used in the brain, kidney and leg vessels, as well as in the heart vessels.

With the development of materials science, treatment techniques and new manufacturing processes, a variety of stents have been developed. In this way, the development has shifted from the initial bare metal stents (BMS) to drug-eluting stents (DES) and bioabsorbable stents (BRS) made of biodegradable polymers or metals [10]. The MEW method provides a great advantage in terms of integrating biodegradable or drug-eluting properties through polymeric materials used in stent manufacturing. MEW (MEW) method in the production of stents is developing day by day with the studies carried out and its preferability is increasing. MEW method is a technique using biological tissue production. Cell-encapsulated hydrogels and (sub)micrometer fibres are used as raw materials. This method enables the production of mechanically durable structures by combining bioprinting and MEW techniques . As a result of the processing of thermoplastic biopolymer materials, especially PCL, under high voltage by reaching the required parameter values, a micron-scale, high resolution and precise product emerges. Basically, the MEW technique provides high-resolution production using melt extrusion and electrohydrodynamic fibre extraction. High yields are achieved by processing micro-nano ribbons in layers. Melt electroprinting (MEW) is a solvent-free (i.e. without volatile chemicals), high-resolution three-dimensional (3D) printing method that enables the production of semi-flexible structures with rigid polymers [3].

The material generally used in MEW production technique is polycaprolactone (PCL). PCL material is widely used especially in medical applications and tissue engineering field due to its biocompatible and biodegradable properties. In addition, its low melting temperature and good processability make it suitable for use in MEW technique.

Looking at the studies in the literature, it is observed that one of the important factors in stent efficiency is the design structure, based on the comparison of PCL material and finite element analyses between the most commonly used grid pattern, ellipse pattern and circle pattern designs. Based on the current MEW Device technology, the grid pattern stent, which is the most optimal pattern that can be produced in these devices, will be designed and manufactured with the standard and workflow sequence shown in the study, and the finite element analyses will be compared by simulating the stents with 316L material produced by the traditional production method with the same dimensions of the grid pattern and the stents produced from PCL material.

1.1. Stent Types

Stents vary according to their application areas, according to the practitioner system, according to their structure and according to their design. According to the application areas; There are four types of stents: Carotid, Coronary, Renal and Peripheral stents. According to the implementing system; There are two types of stents: balloon and self-opening stents. According to their structure; There are three types of stents: Drug-eluting stents, Bare metal stents, and Dissolvable stents. According to their design; There are five types of stents: Grid, Circular, Spiral, Cylindrical and Special type stents. In this study, stents that can be expanded with a balloon with a grid pattern design will be produced. Stent types are shown in figure 3.

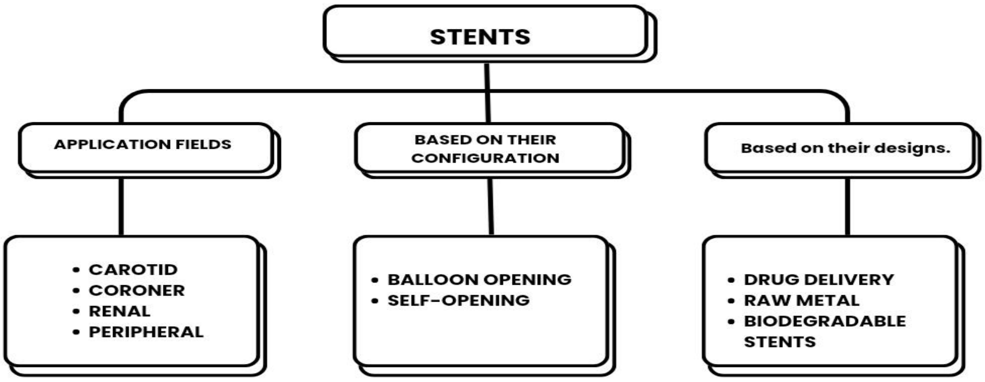


Figure 3. Types of stent

1.2.Melt Electrowriting (Mew) Production Technique

Melt electroprinting (MEW) technique is called a new manufacturing technique that is developing day by day used for 3D printing. Semi-flexible structures can be produced with rigid polymers. The most important rule in this technique can be said to be able to apply the most appropriate printing parameters. It is of great importance that it can be highly functional in the processing and production of biomaterials such as PCL. Widely used in manufacturing, PCL is preferred in terms of thermal efficiency, mechanical suitability, design flexibility and biocompatibility. The MEW technique creates micron-scale fibers, ensuring precise production with high resolution. In summary, it can be said that it is a production technique based on electrohydrodynamic principles to produce high-efficiency, micron fibers. Melt electrowriting technique shown in figure 4.

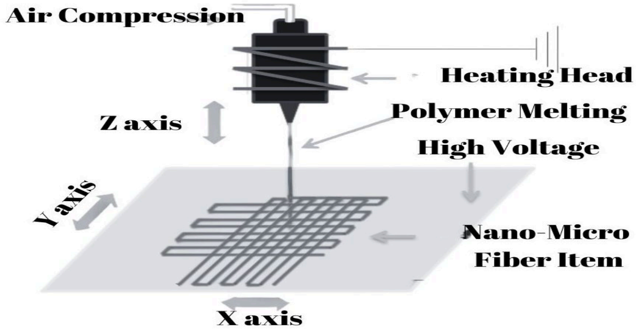


Figure 4. Melt electrowriting technique.

1.3.Traditional Bare Metal Stent Production Technique

With the spread of cardiovascular diseases, the demand for the production and use of different stents has increased. The common point of the studies is to achieve more efficient and safe results. With material science, treatment techniques and new manufacturing techniques, the transition from simple Bare Metal stents to Drug-eluting stents and Biodegradable stents has been achieved. The leading brands of commonly used stents are approved by the necessary organizations. Again, many of them are stents made of stainless steel tubes that expand with balloons. These stent designs, which are between 8-38 mm in length, can be manufactured as open or closed cell. The mechanical behavior and strength of these stents are specified by standards. Traditional Bare Metal Stents can be manufactured with 316 L stainless steel, CoCr (Cobalt-Chromium) Alloys, Nitinol (Nickel-Titanium) or Ti (titanium) alloys. Alloys containing iron, such as 316L, degrade as a result of a decrease in corrosion resistance in long use. Due to their behavior in the body environment, the producibility of more resistant and durable stents with CoCr alloys has been specified. However, both the excellence in corrosive resistance, high strength results and material lightness reveal that stents produced with Ti and Nitinol alloys are more efficient. Although the densities and weights of 316L and CoCr alloys are higher than Nitinol and Ti Alloys, their processing costs are lower [4,5].

Table 1. Mechanical strength of materials used in the production of traditional bare metal stents.

Material	Intensity (g/cm3)	Elongation at Fracture (%)	Yield Strength (MPa)	Tensile Strength (Mpa)	Young's Modulus (GPa)	Temperature (°C)
Nitinol	**6.45**	**50**	**690**	**895**	**83**	**1310**
Titanyum	**4.429**	**14**	**786**	**950**	**110**	**1660**
CoCr	**10**	**20**	**560**	**960**	**210**	**1454**
316L	**8**	**40**	**310**	**668**	**193**	**1390**

Mechanical strength of materials used in the production of traditional bare metal stents shown in Table 1.

For example, 100 µm thick stainless steel sheet plates are laser cut using cut-out geometry. The plates are formed into cylindrical form and joined by laser spot welding. Or it can be manufactured by cutting Steel Cylinder Tubes of appropriate size and thickness using laser. Afterwards, the final product is reached by electropolishing. Traditional bare metal 316l steel stent shown in Figure 5.

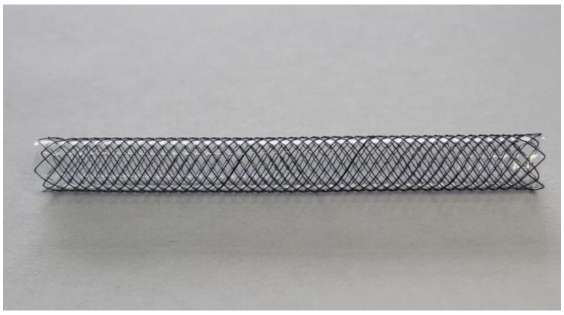


Figure 5. Traditionally manufactured 316l steel stent.

2.MATERIALS AND METHODS

2.1.Device Selected For Production

In this study, Melt Electro Writing device was used for production. Melt electro writing (MEW) device and its technical specifications are shown in figure 6 and table 2 respectively.

(A) Melt Electro Writing Device **(B) Rotary Table**

Figure 6. (A) Melt electro writing (MEW) Device, (B) Rotary table.

Table 2. MEW device technical specifications.

Melt Electrowriting Technology	:	Pneumatic Driven Extrusion
Melt Electrowriting High Voltage Range	:	0kV- 15kV DC
Melt Electrowriting Current Range	:	0 µA- 150 µA
Printing Pressure Resolution	:	0.1 psi
Air Pressure Range	:	0 kPA- 800 kPA
Z Resolution Per Microstep	:	1 µm
XY Resolution Per Microstep	:	1 µm
Printhead Tempature Range	:	Room Temperature - 265°C
Layer Resolution	:	<10 µm
Collector Rotation Speed Range	:	0-5000

2.2. Stent Design

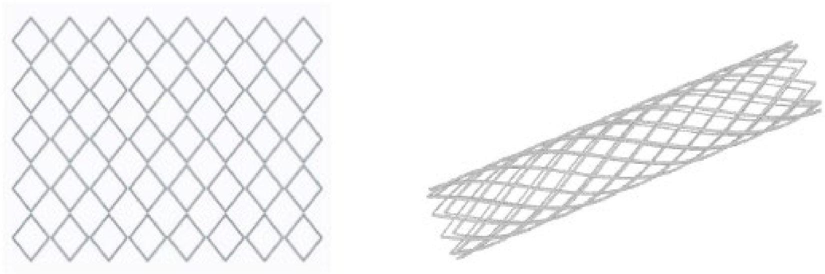
Stent sizes vary according to the vascular structure where the stent will be placed and the needs of the patient. When the products of the manufacturers are examined, it is seen that the diameter of the stents varies between 2.0 mm and 5.0 mm, while their length varies between 8 mm and 38 mm, and the wall thickness varies between 0.1 mm and 0.3 mm. However, smaller or larger diameters and different lengths and wall thicknesses may also be available if required. The choice of diameter depends on the diameter of the intervened vessel. Which length is used depends on the length of the lesion and the anatomy of the vessel in the area where it will be placed. Thickness can affect the stent's durability and ability to maintain patency. In the ISO25539-2:2012 standard, the design, performance and size requirements of standard stents are specified. During stent placement, doctors usually use angiographic images and imaging techniques such as intravascular ultrasound (IVUS) to determine the optimal stent diameter and length. Since each patient's anatomy is different, personalized planning is important. In this study, a grid pattern stent design with a diameter of 3 mm, a length of 30 mm and a wall thickness of 0.125 mm was selected. In the selection of this pattern, the most optimal production between the functionality of the stent product and the capabilities of the device used was taken into consideration. Among the most commonly used grid pattern, ellipse pattern and circle pattern designs, based on the comparisons of PCL material and finite element analysis; It is observed that one of the important factors in stent efficiency is the design structure [6]. In this study, it was concluded that the most suitable pattern that can be produced in various trials according to the movement and speed of the nozzle in xyz directions, the voltage of the rotary table and the rotational speed parameters in the current MEW device used for stent production may be in the form of a grid. The selected design was drawn with the help of the Solidworks program and modeled in 3D.

The stent design was made in the Solidworks program as defined below.

- Drawing the circle with a diameter of 3 mm, which forms the cylindrical diameter of the stent.
- In order to create the geometry of the stent design, drawing a clockwise 1-revolution arc with a diameter of 3 mm and a length of 30 mm, perpendicular to the circle wall, with an initial angle of 180 degrees.
- With the Sweep command, the drawn spring is brought to the solid cylindrical solid form with a thickness of 0.125 mm, which is the wall thickness of the design.
- In order to create the geometry of the stent design, drawing a 1-revolution, 3 mm diameter and 30 mm long arc perpendicular to the circle wall, counterclockwise with an initial angle of 180 degrees.
- With the Sweep command, the drawn spring is brought to the solid cylindrical solid form with a thickness of 0.125 mm, which is the wall thickness of the design.
- Selective reproduction of arcs in solid form

with geometry duplication at 360 degree equal intervals.

The two-dimensional version of the stent design is shown in Figure 7, and the design stages listed above are shown in Figure 8.



(A) Open Display Of The Stent **(B) Folded Closed Form Of The Stent**

Figure 7. Design of the stent with diamond pattern.

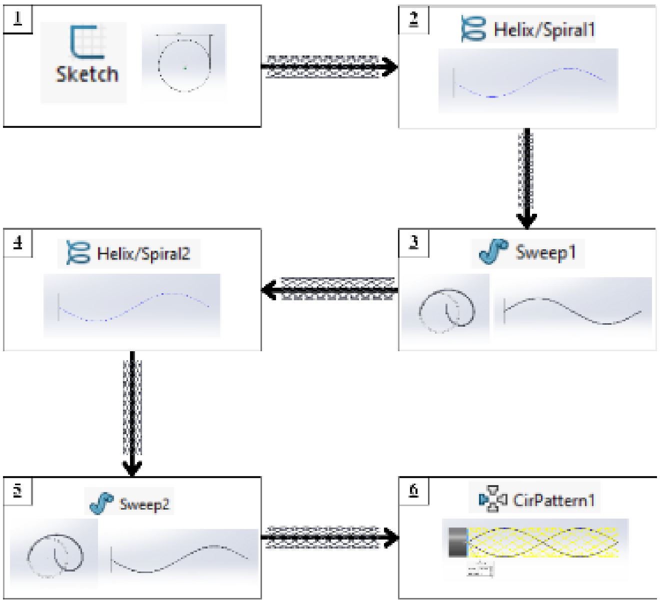


Figure 8. Stent design workflow chart.

2.3.Use Of Pcl In Melt Electrowriting Technique

Most thermoplastic materials can be used in the MEW production technique. However, due to its low melting temperature and degradable structure, Polycaprolactone (PCL) is the most commonly used material. PCL is known as a biodegradable and biocompatible polymer with high mechanical strength properties. PCL polymer, which has advantages such as less immune reactivity after implantation and suitability for mechanically supporting bone cells, has flexibility in design and is widely used in biomedical applications [1,2,7]. The Physical Properties of PCL Material are shown below in Table 3.

Table 3. Physical properties of pcl material.

Polymer	Solvent	Melting Temperature (°C)	Glass Transition Temperature (°C)	Elastic Modulus (GPa)
PCL	Chloroform: Hexafluoroi, sopropanol, Dichloromethane, Toluene	58-63	-60	0.3- 0.6

The long-term degradation time of the PCL material, which is in the class of synthetic polymers, its ability to be produced in different pore sizes and its easy shaping behavior can also be listed among the reasons for preference. These features cause more functional results in the human body in line with the stent structure and usage purposes. Criteria such as Polymer Melting Temperature (°C), Glassy Transition Temperature (°C), Young's Modulus (GPa), Solvent Polymer Used, Unit Structure are in accordance with the MEW production technique compared to other polymers. For these reasons, in this study, PCL material was determined as the production material.

The long-term degradation time of the Polycaprolactone (PCL) material, which is in the class of synthetic polymers, its ability to be produced in different pore sizes and its easy shaping behavior can also be listed among the reasons for preference.

2.4. Stent Productıon Wıth Melt Electrowrıtıng Technıque

The diamond patterned stent commonly used in this study is made of PCL material with a width of 3 mm and a length of 30 mm by Melt Electro Writing method. The work flow chart for production is shown in figüre 9.

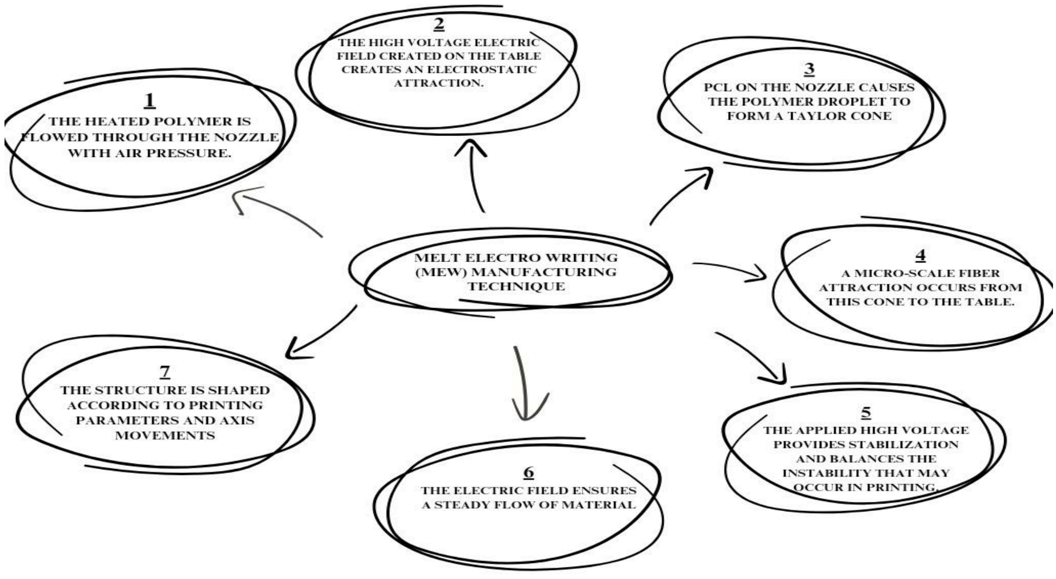


Figure 9. Work flow chart for melt electro writing technique and stent manufacturing process.

Melt Electro Writing (MEW) method can be used in stent production. As a result of the processing of thermoplastic biopolymer materials, especially PCL, under high voltage by reaching the required parameter values, a micron-scale, high-resolution and sensitive product emerges. Basically, the Melt Electro Writing (MEW) Technique provides a high-resolution production using melt extrusion and electrohydrodynamic fiber drafting. High efficiency is achieved by processing micro-nano strips in layers.

The production process is respectively; The heated polymer is flowed through the nozzle with air pressure, the high-voltage electric field created on the table creates an electrostatic attraction. The polymer on the nozzle causes the droplet to form a Taylor cone. From this cone to the table, a micro-scale fiber attraction occurs. The applied high voltage provides stabilization and balances the instability that may occur in printing. The electric field ensures that the flow of material occurs in a constant manner. The structure is shaped according to the printing parameters and axis movements.

The most important element in the MEW Technique can be defined as the determination of the correct parameters. The melting temperature of the polymer, the applied pressure and nozzle feed speed, the speed of movement of the print head on the axes used, and the distance between the nozzle and the table directly affect the quality of production.

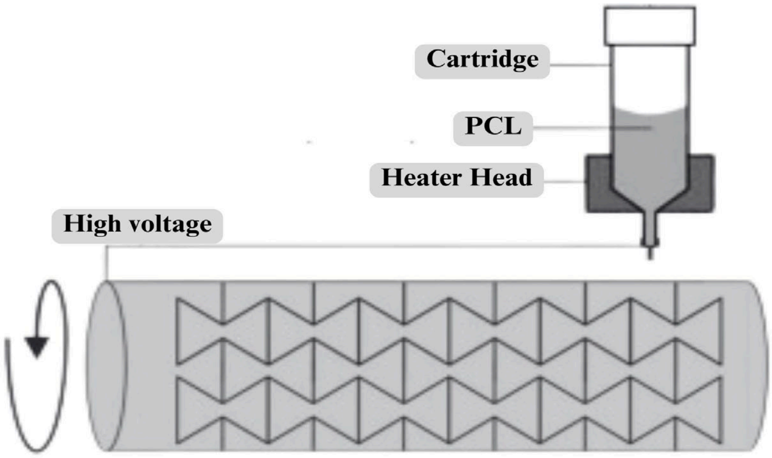


Figure 10. Melt electrowriting technique stent production principle.

Melt electrowriting technique stent production principle is shown in Figure 10. In order for the stent or any material to be produced by the MEW method, the 3D design of the relevant material must be made in a computer environment and a 3D design file must be created. After the 3D design file is created, the G-codes that determine the movements of the MEW production device, the working conditions, and the position of the part on the table are determined with another interface program and transferred to the MEW device. G-code can be defined as a programming language that guides work on all CNC machines. G-code stands for "Geometric Code". This programming language is used to command a machine or device what to do or how to perform a process during production. The G-code tells the machine or device how much it will move on which axis, how much the movement speed will be and which path it will follow for manufacturing In standard 3D printers or electro writing devices, additive layers are created on the table and the specified shape or product is revealed with G-code commands. For flawless manufacturing, G-codes suitable for the design and device should be written and transmitted to the device. An example of the Standard MEW Technique G-Code is shown in Figure 11.

```
%
G92 X-4 Y-4  F500
G1 X30 Y-4  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X30 Y30  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X-4 Y30  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X-4 Y-4  A[#<_A>+0.1] B[#<_B>+0.39]

G1 X0 Y0   A[#<_A>+0.1] B[#<_B>+0.39] F500
G1 X0 Y26   A[#<_A>+0.1] B[#<_B>+0.39]
G1 X3
G1 X3 Y0   A[#<_A>+0.1] B[#<_B>+0.39]
G1 X6
G1 X6 Y26   A[#<_A>+0.1] B[#<_B>+0.39]
G1 X9
G1 X9 Y0   A[#<_A>+0.1] B[#<_B>+0.39]
G1 X12
G1 X12 Y26  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X15
G1 X15 Y0   A[#<_A>+0.1] B[#<_B>+0.39]
G1 X18
G1 X18 Y26  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X21
G1 X21 Y0  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X24
G1 X24 Y25.5  A[#<_A>+0.1] B[#<_B>+0.39]

Z1

G1 X0.5 Y25.5  A[#<_A>+0.1] B[#<_B>+0.39]
```

```
G1 X12
G1 X12 Y26  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X15
G1 X15 Y0   A[#<_A>+0.1] B[#<_B>+0.39]
G1 X18
G1 X18 Y26  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X21
G1 X21 Y0  A[#<_A>+0.1] B[#<_B>+0.39]
G1 X24
G1 X24 Y25.5  A[#<_A>+0.1] B[#<_B>+0.39]

Z1

G1 X0.5 Y25.5  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y22
G1 X23.5 Y22  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y19
G1 X0.5 Y19  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y16
G1 X23.5 Y16  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y13
G1 X0.5 Y13  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y10
G1 X23.5 Y10  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y7
G1 X0.5 Y7  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y4
G1 X23.5 Y4  A[#<_A>+0.1] B[#<_B>+0.39]
G1 Y1
G1 X0 Y1   A[#<_A>+0.1] B[#<_B>+0.39]
```

Figure 11. example of g-codes entered into the device for production by melt electro-writing technique

After entering the correct parameters, the molten polymer in the heater printhead is properly printed directly on the table. Printing is carried out via software compatible with the MEW device and a computer connection. Designs saved in the appropriate format can be produced by transferring them from the computer to the device.

The production of cylindrical microfiber stens produced by the MEW Technique is carried out with a rotating tubular thrust bed connected to the rotary system. While the rotary table, which is placed in place of the standard table, performs a constant rotational movement in the direction of the entered speed and direction, the print head moving in the direction of the x-axis on the table performs production as in the basic principle. In this system, it is important to optimize the table rotation speed and printhead speed based on the number of layers in order to realize the production at the desired quality. After being designed in 3D in the computer environment in accordance with the MEW device, grid pattern stents produced from PCL material with diameters of 2 mm, 3 mm and 4 mm, 30 mm length and 0.125 mm wall thickness were produced with G-codes produced by entering the parameters such as placement, nozzle temperature, rotary table rotation speed, placement of the stent on the table, feed rate of the nozzle in the x, y direction, etc., together with the shape obtained in accordance with the MEW technique. Examples of grid pattern stents of different diameters produced in the MEW device are shown in Figure 12.

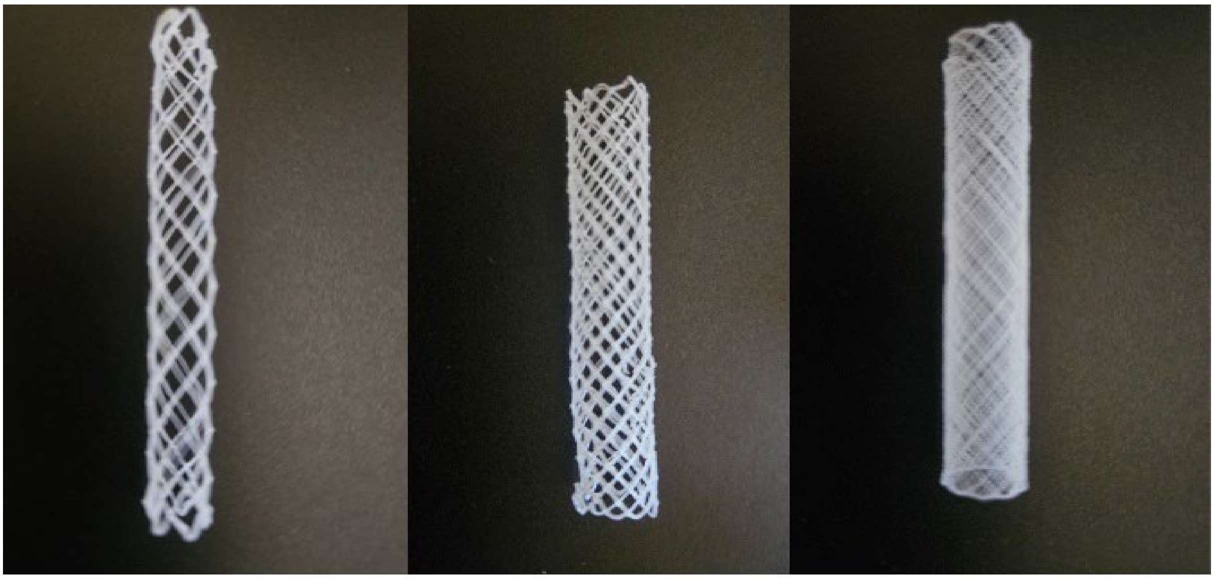


Figure 12. Stent models made of PCL material with (A) 2 mm, (B) 3 mm and (C) 4 mm diameter, 30 mm length and 0.125 mm wall thickness with a grid pattern produced in the MEW device.

2.5. Finite Element Analysis (FEA)

The high prevalence of cardiovascular diseases has increased the demand for the use of different stents. It is important to design and manufacture safer stents for coronary angioplasty to prevent stent narrowing. However, prototyping and mechanical testing of new stent designs are challenging, time-consuming and costly procedures. Therefore, parametric models and finite element simulations are used to help designers improve stent designs [12]. (FEA) to predict Equivalent Von-Mises Stress, Radial Recoil and Factor of Safety using ANSYS work bench software. Stent of different geometry are modeled using SOLIDWORKS and then structural analysis is performed on Stents of seven different materials viz. SS 316L Stent, Cobalt Chromium L-605 Stent, Bio-Degradable Stent (PCL), Nitinol Stent (Austenite), Elgiloy Stent, Tantalum Stent, Cobalt Chromium MP35 N Stent under normal blood pressure. The 'Radial recoil', Equivalent 'Von-Mises Stress' and 'Factor of Safety' of various stent materials using same stent design and same boundary conditions are compared. The results reveal that the L-605 Cobalt Chromium has low radial recoil and 316 L Stainless Steel is having highest factor of safety among the selected stent materials[19].

The designed stent design was subjected to static simulation in Ansys programme using 316L and PCL material values. The ISO 25539 standard is a standard that specifies general requirements and test procedures for stents. It includes different tests used to evaluate the mechanical properties of stents as well as biocompatibility, safety and efficacy. To test the durability of stents against external influences, their resistance under a certain force is evaluated. these tests are performed with loads ranging from 10 N to 100 N. Adhering to the above-mentioned standards, it was aimed to investigate the stresses at the grid intersections on the -y and +y surfaces when pressure is applied from the inside, assuming that the balloon in the stent is inflated, assuming that there is a blockage in the upper and lower parts of the vessel. The ends of the design were considered fixed and subjected to a force of 10 N distributed along the stent from the designed outer surface points [8]. The fixed surfaces and applied forces are shown in Figure 13.

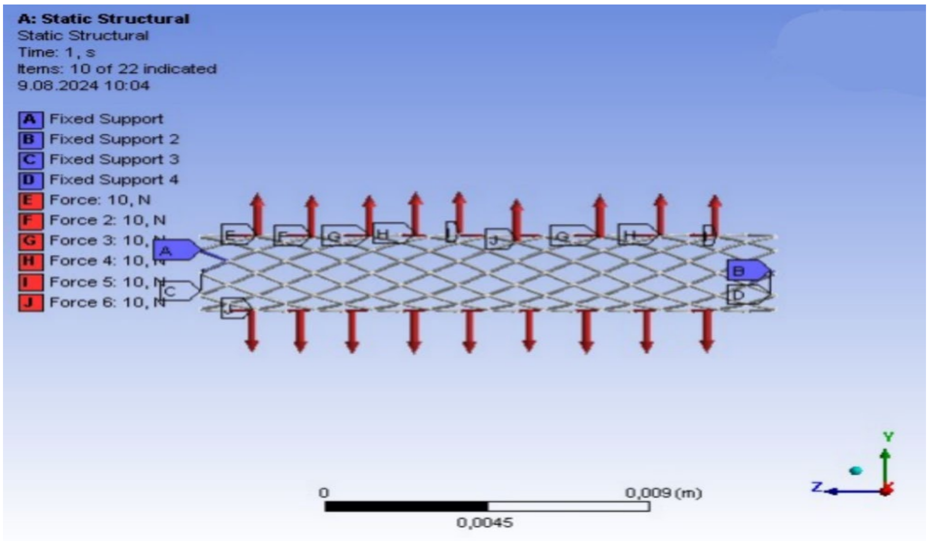


Figure 13. Fixed points and applied forces for FEA static analysis.

Equivalent Elastic Stress (Von Mises) and Displacement results of the finite element analysis performed in Ansys are shown in Figure 14.

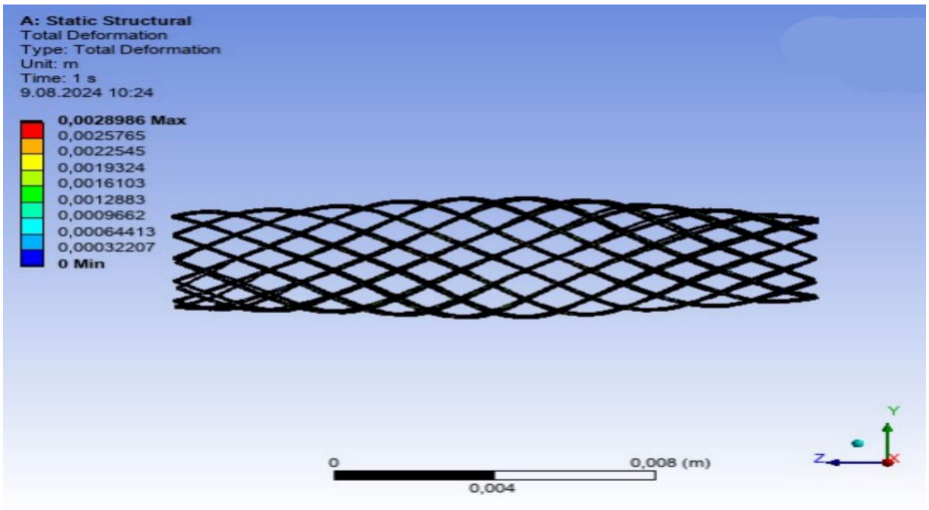


Figure 14. 316L material displacement results for FEA static analysis.

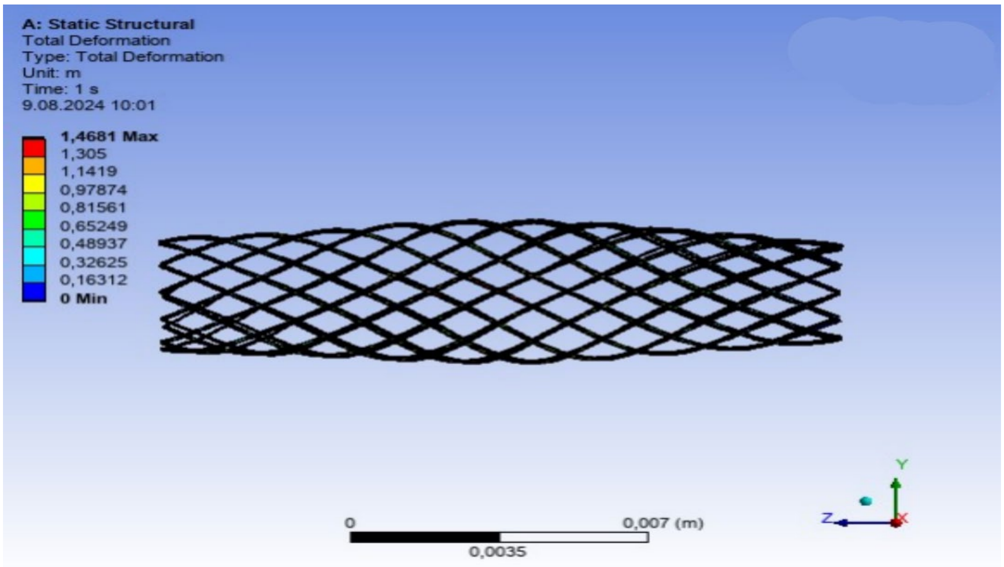


Figure 15. PCL material displacement results for FEA static analysis.

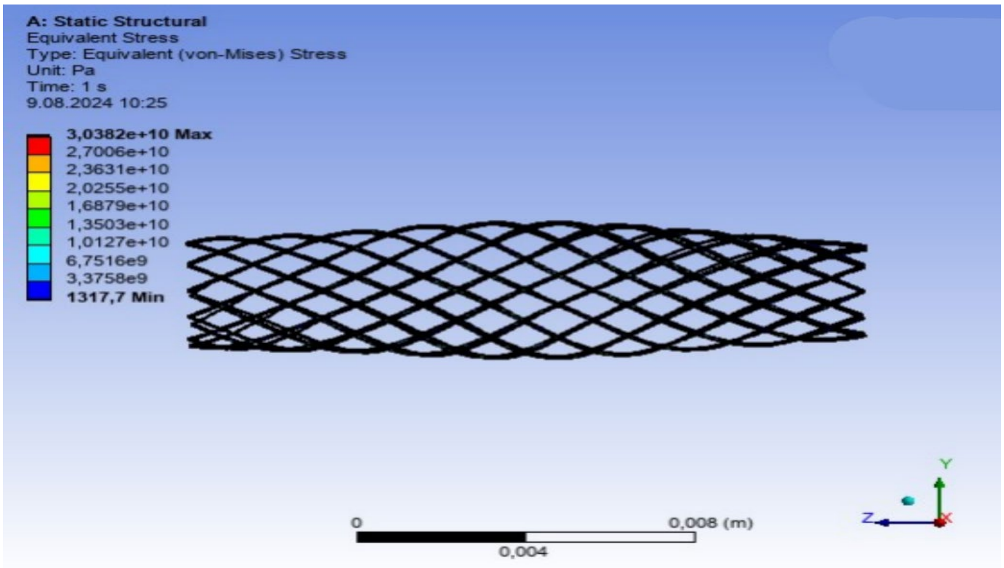


Figure 16. 316L material Von Mises results for FEA static analysis.

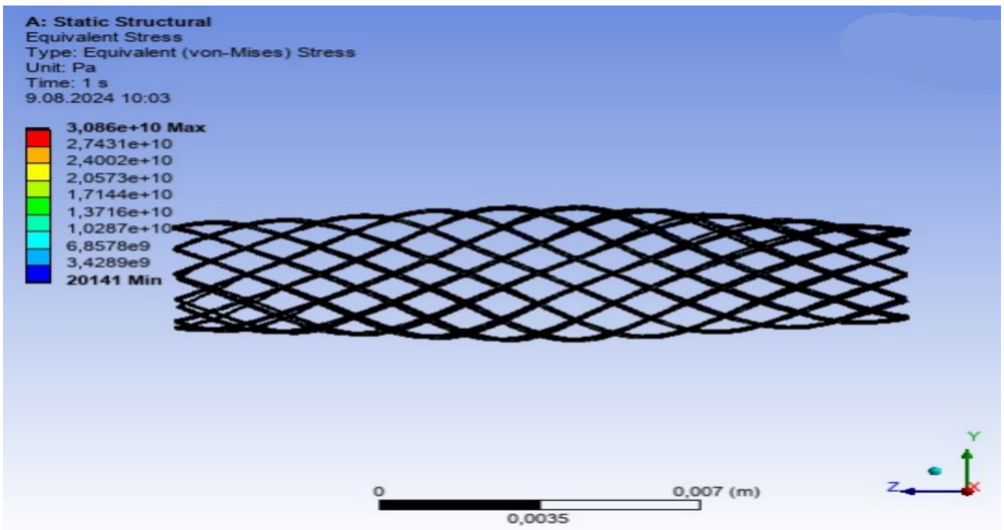


Figure 17. PCL material Von Mises results for FEA static analysis.

3. FINITE ELEMENT ANALYSIS (FEA) RESULTS

Detailed information and results of the simulation and finite element analysis of the identical design of a metal stent with a grid pattern made of 316L material, which is one of the commonly used stent types, and a stent with a grid pattern made of biodegradable PCL material with biocompatibility by MEW method are shown in Table 4. The ends of the design were considered fixed and the design the PCL stent can undergo severe plastic deformation under applied loads and potentially lose its structural integrity. The maximum displacement value of 1.4681 m is very high, which is an advantage in terms of flexibility in biomedical applications, but a major disadvantage in terms of mechanical durability. PCL Stent Advantages, Biodegradability provides an advantage for long-term implantation. It offers flexibility thanks to its low elastic modulus and has high adaptability in intravascular applications. Disadvantages, High deformation and low mechanical strength can lead to rapid deterioration of structural integrity. Due to the very low yield stress, there is a risk of structural failure when exposed to high loads. 316L Stent, Advantages: High mechanical strength and low deformation characteristics provide long-term stability. The high yield stress indicates that the stent can maintain its structural integrity even under high loads. Disadvantages, Non-biodegradability may lead to possible complications in long-term permanent implantations. It is more limited in flexibility than PCL, which may lead to adaptation difficulties in intravascular applications. Although the PCL stent offers some advantages due to its biodegradability, it was subjected to a force of 10 N distributed along the stent from the grid intersection points on the upper and lower outer surfaces. PCL Equivalent (Von-Mises) Stress 3,086e+010 Pa, 316L Equivalent (Von-Mises) Stress 3,0382e+010 Pa, PCL Result Displacement Maximum 1,4681 m, 316L Result Displacement Maximum 2,8986e-003 m results were observed. According to these results; the following conclusions were reached. The results of the finite element analysis show that has major disadvantages in terms of mechanical durability due to its low yield stress and high deformation capacity. This may cause the stent to lose its structural integrity and functionality in a short time. However, its biodegradability turns this disadvantage into an advantage.

The 316L stent, on the other hand, offers a longer-lasting and more stable option with its high mechanical strength and low deformation properties. However, its non-biodegradability may pose potential risks in long-term implantations. Therefore, additional strategies such as biocompatible coatings or surface modifications may need to be considered in the design of the 316L stent. This adds to the already high cost and manufacturing difficulty. In conclusion, both materials have advantages and disadvantages in specific applications. Depending on the field of application and duration of use, the choice of material and stent design should be optimised. In the field of biomedical engineering, supporting such designs with further analyses and experimental verifications will contribute to the development of safe and effective implants.

Table 4. Analysis Results

		316L STENT	PCL STENT
MASS	:	2,3783e-005 kg	3,7196e-006 kg
VOLUME	:	2,9901e-009 m³	2,9901e-009 m³
DENSITY	:	8.007,89 kg/m^3	1.021,01 kg/m^3
MESH NODE COUNT	:	157209	157209
NUMBER OF MESH ELEMENTS	:	69870	69870
MESH PASS RATE	:	0,272	0,272
MAXIMISED LAYERS	:	5	5
GROWTH RATE	:	1,2	1,2
TARGET MESH QUALITY (DEFAULT)	:	5,e-002	5,e-002
APPLIED FORCE	:	10 N	10 N
YIELD STRESS	:	200 MPa	30 MPa
EQUIVALENT (VON-MISES) STRESS	:	3,0382e+010 Pa	3,086e+010 Pa
RESULT DISPLACEMENT MAXIMUM	:	2,8986e-003 m	1,4681 m

4. CONCLUSION AND EVALUATION

In this study, the design of a stent with a grid pattern and its production with the mew production method is described together with its stages. the ease of production and the functionality of the material are explained, and a comparison with the metal stent, which is one of the leading traditional methods, is made. the reason for not going into detail in the finite element analysis is that the main purpose of the study is the production of stents from PCL material by MEW method and also to open the door to detailed scans and analyses that we will perform in future studies.

In future studies, it is aimed to produce different models and production techniques together, to produce medicated and timed stents in coordination with the medical and biomedical fields and to test them in the laboratory environment. In the future, when biodegradable medicated stents are produced for vascular damage and treatment, timely and most accurate treatment can be applied in diseases.

Based on the results of this study, it is understood that the MEW method has a bright future in terms of advantages in terms of ease of production, processing parameters and biocompatibility and will have a higher share in the sector in the future. In terms of disadvantages, it is seen that it is not possible to work in every design with the current possibilities due to deficiencies such as low mechanical strength results and the inability of the device to produce every design in production.

Since the production of the most optimal design will best serve the general purpose of the material, the method that can produce the design in the easiest and most efficient way comes to the fore. This problem will be eliminated with the development of MEW devices in the future. Maximum benefit will be achieved with devices that can produce the most ideal designs.

When we reach the point where we can produce the design we want with technological corrections such as easier movement of the print head in different axes in line with device mechanical and software developments, development of the rotating drum system and optimisation with software, it will become possible to make instant and fast productions suitable for the vessel structure, occlusion structure or usage structure with the MEW method. The ability to produce all design models in devices will lead to the emergence of more efficient and effective designs, faster development of existing technology through trial and error, and easier fight against diseases in the field of medicine [11].

Design-oriented development of the devices used in MEW Technique will provide maximum benefit with more specific designs of this method, which already provides high efficiency.

Stainless steel is the most popular material for conventional stents and has excellent mechanical behaviour during deformation. However, stents made of stainless steel remain permanently in the body and can cause complications or lead to blockage of the vessel. To overcome these shortcomings, biodegradable stents that dissolve and disappear in the body over time should be developed [16].

In conclusion, the choice of stent should be balanced according to the specific requirements of the application. While PCL stents are suitable for short-term applications with their flexibility and biocompatibility advantages, 316L stainless steel stents may be preferred for situations requiring long-term performance and mechanical durability. The specific advantages and disadvantages of both materials are important points to be considered during stent selection. Future studies focusing on modification and improvement of these materials may contribute to the development of stents with better performance [17-18].

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