VASCULAR STENTS – MATERIALS AND MANUFACTURING TECHNOLOGIES

Klaudia Malisz*, Beata Świeczko-Żurek

Institute of Machines and Materials Technology, Faculty of Mechanical Engineering and Ship Technology, Gdańsk University of Technology, 11/12 Narutowicza Str., 80-233 Gdańsk, Poland
*e-mail: klaudia.malisz@pg.edu.pl

Abstract

The objective of this article is to present materials and technology for the manufacture of vascular stents with appropriate design requirements. The use of the right material is very important in implantology. A biomaterial introduced into the circulatory system must be biocompatible and hemocompatible. At the same time, it should not initiate toxic, mutagenic, or immunological reactions. Currently, 316L stainless steel (316L SS), nitinol (Ni-Ti alloy) and cobalt-chromium alloy (Co-Cr) are used as standard stent materials. Additionally, drug-containing coatings are used to provide antithrombotic properties. Nowadays, scientists are trying to create biodegradable stents (BDS) using magnesium (Mg) or zinc (Zn) alloys.

Laser methods are generally used to manufacture stents using Nd:YAG lasers with a pulse length in the range of several milliseconds. Material removal is based on the ejection of the melt using a high-pressure gas. The result is remelting and heat-affected zones. Various post-processing procedures are necessary to remove residues, including etching and electropolishing. Minimizing the heat-affected zone could be achieved by using femtosecond lasers. Additionally, immersion of the material in water prevents the deposition of residues on the workpiece. Interesting alternatives used in the manufacture of vascular stents are electrospinning or additive techniques. 3D printing enables obtaining of geometrically complex and personalized implants and reduces the consumption of materials and the production of waste.

Keywords: *vascular stents, biomaterials, laser processing, 3D printing, electrospinning, post-processing*

Introduction

The development of interventional medicine has revolutionized the treatment and prevention of ischemic diseases. Cardiovascular diseases are one of the main causes of death in our century, and percutaneous coronary angioplasty is one of the most popular methods of their treatment. In Poland, more than 80% of such procedures involve stent implantation. The cause of ischemic disease is atherosclerosis of blood vessels resulting from long-term inflammation in the vascular wall [1,2].

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Stents are a type of metal, elastic scaffold with a spatial cylindrical structure and small size. They are implanted in place of a critically narrowed section of the coronary artery to support its walls and widen its lumen. The initial experience with stent implantation was not very encouraging, i.e. blood clotting was common, resulting in secondary arterial occlusion and acute complications. This led to myocardial ischemia and even death of a patient [1]. Today, the phenomenon of restenosis has been reduced due to the use of drug-eluting stents (DES). Still, restenosis may occur as a result of damage to the blood vessel wall during stent implantation, thrombosis, and allergic reactions caused by ion release. Hyperplasia (hypernormal proliferation) of fibroblasts and smooth muscle cells is another potential cause of stent restenosis. Restenosis can be observed in the angiographic examination as a sudden reduction in vessel diameter by at least 50% compared to the value obtained during the angioplasty procedure [1,3-5].

The endovascular implant must be characterized, among others, by flexibility, ease of movement in the catheter and arteries, low thrombogenicity (protecting against blood clots and relapses), tissue neutrality, good extensibility (facilitating the expansion mechanism), resistance to external forces, small total stent surface, and good coverage of the vessel wall. Materials intended for a given type of an implant include austenitic steel, nitinol, tantalum, cobalt alloys, and polymer stents, which can be divided into two groups: self-expanding elastic vascular stents implanted in arteries exposed to movement and bending, and non-deformable elastic cardiological stents implanted in arteries running inside the heart muscle [1,2,6].

Biomaterials used for vascular stents

The first types of stents used for coronary applications were bare metal stents (BMS). These stents are typically made of 316L stainless steel, platinum-iridium alloy (Pt-Ir alloy), cobalt-chromium alloy, and nitinol. They exhibit outstanding mechanical properties and improved corrosion resistance [7]. In previous studies, intracoronary stent restenosis was reported to be between 10% and 20% during a 6-month follow-up, leading to myocardial infarction and angina, which required revascularization. Healing with bare metal stents has very beneficial results, and restenosis were observed in 20-30% of patients in 6-12 months [8].

Drug-eluting stents are composed of a metallic stent, a polymeric coating, and an immunosuppressant or antiproliferative compound as a pharmacological agent [7]. The elution from polymers is influenced by a variety of factors. The release and duration of its elution are significant in the design of a drug-eluting stent [8]. Antiproliferative drugs released from DES (such as rapamycin, paclitaxel, etc.) not only inhibit excessive smooth muscle cell proliferation and prevent in-stent restenosis, but they also prevent the adhesion and growth of the endothelial cells, leading to delayed endothelial healing, late thrombosis, late restenosis, and other clinical complications. Furthermore, the polymer-drug carriers used for DES are not sufficiently biocompatible, and after long-term implantation, degradation, aging, and peeling of the coating can put patients at risk [9-12].

The use of totally bioresorbable stents, the fourth revolution in interventional cardiology, has attracted much interest over the past ten years. The most significant innovations in biodegradable stent technology include magnesium and its alloys, which have high biodegradability, biosafety, and promising mechanical properties with a low risk of restenosis [7]. Furthermore, in addition to magnesium alloys, biodegradable stents can also be made of zinc alloys and some biodegradable polymers, i.e. poly(lactic acid) (PLA) and polycaprolactone (PCL).

These materials degrade into products, which are later metabolized by the patient. Biodegradable metal stents are designed to keep the vessel open and maintain its physiological function. As the name suggests, biodegradable stents must be able to be degraded or absorbed by the human body. They do not affect subsequent treatment, have excellent mechanical properties, that guarantee stable transfer during stent compression, and maintain a sufficient radial force to support the vessel after complete expansion of the stenotic portion. The mechanical properties and degradation time of biodegradable stents can be improved by the synthesis of various types of polymers [13-15]. Additionally, the degradation rate of the biodegradable polymer is uncontrollable, and degradation products can be caused by immune and inflammatory reactions [9,16].

The use of pure iron (Fe) as biodegradable stents is advantageous due to its good mechanical properties, radiopacity, biocompatibility, and degradability. Fe is also essential for human life if it is kept at a moderate value. Because of its high elastic modulus, it possesses greater radial strength. Consequently, the design of stents can make use of thinner struts. Studies reported no inflammation, neointimal proliferation, or thrombotic events during the follow-up of 6-18 months, but the higher degradation rate is desired for Fe stents so without any changes to their corrosion rate, they cannot be used in stent applications, because they would face similar problems as permanent stents [17,18].

Researchers are also investigating zinc alloys for BDS. Many studies have shown that Zn degradation rate is slower than that of Mg and faster than Fe, which makes it a good candidate for this application. In addition, it has acceptable biocompatibility but low mechanical properties, preventing the use of Zn in stents. It is possible to add alloying elements; however, it should be taken into account, that some elements cannot exist in the human body, and others affect the rate of degradation, corrosion homogeneity, and elongation to failure [17]. Despite the advantages of zinc-based materials, the aging of zinc alloy makes the mechanical properties of zinc stents unstable. Vascular stents exhibit heterogeneous deformation during compression and expansion. Work-softening can prevent the stent from being firmly fixed on the balloon during compression and makes it easy to move during implantation while work-hardening can cause the stent to expand and deform unevenly. On the other hand, low density and good in vivo support performance are all characteristics of the magnesium alloy. Jiang J. et al. [19] fabricated biodegradable Zn-2.0Cu-0.5Mn alloy microtubes and vascular stents to improve the mechanical properties of pure Zn elements. The microtubes and vascular stents were manufactured by a combined process of extrusion, drawing, laser cutting, and electrochemical polishing. As-drawn microtube demonstrated appropriate mechanical properties as a stent material with an ultimate tensile strength of around 298 MPa and an elongation of approximately 26%. Additionally, the processed stent with a thickness of about 125 μm possessed sufficient radial strength of about 150 kPa and good balloon expandability. This research suggested that the biodegradable Zn-2.0Cu-0.5Mn alloy is a good candidate for this application [19]. Another solution was proposed by Niu J. et al. [20]. They developed a new Zinc-4 wt% copper alloy (Zn-4Cu) as a biodegradable material. Cu was selected for its ability to promote the proliferation of vascular endothelial cells, thereby accelerating the revascularization process. Hot extrusion was applied to Zn-4Cu to refine the microstructure. It should improve the mechanical properties and corrosion resistance of the Zn alloy. After extrusion, the dendritic CuZn5 phases were broken and distributed along the extrusion direction. In vitro studies showed that Zn-4Cu presents acceptable toxicity to human endothelial cells. Additionally, it could effectively inhibit bacteria adhesion and biofilm formation. Moreover, the Zn-4Cu alloy exhibits excellent strength and ductility; it is also characterized by uniform and slow degradation, good biocompatibility, and a significant antibacterial effect [20].

The magnesium alloy is biodegradable and may provide advantages over conventional non-biodegradable metal stents in preventing chronic inflammation, late thrombosis, and long-term use of antiplatelet medications. Effective solutions are used to solve the poor mechanical properties and high rate of corrosion of magnesium-based materials, e.g. heat treatment can change the second phase's shape, distribution, and internal structure. Additionally, plastic deformation can improve mechanical properties by improving dynamic recrystallization grain quality and reducing structure segregation. Furthermore, surface modification may protect the substrate from corrosion by preventing direct contact with body fluids. However, Mg alloys produce a large amount of hydrogen during the degradation process, which causes an increase in pH in the environment of the surrounding tissues. This phenomenon is disadvantageous; it can reduce the adhesion and growth of endothelial cells on the surface, and thus may cause acute and long-term complications [9,21,22].

To improve the biocompatibility and corrosion resistance of the magnesium alloy, Pan C. et al. [23] used chitosan functionalized graphene oxide loaded with Zn^{2+} and propranolol. They also evaluated anticorrosion properties, hemocompatibility, and endothelial cell growth behavior. Research [23] shows, that multifunctional coating can significantly enhance the corrosion resistance and minimalize the degradation rate of the Mg alloy. Additionally, the blood compatibility of the coating was improved due to the inhibition of platelet adhesion, activation, and reduction of hemolysis rate [23]. However, Wang Y. et al. [24] constructed a nanocoating on Mg alloy for vascular stent application. A rapamycin-loaded nanocoating consisting of the MgF_2 layer, the polydopamine layer, and targeted rapamycin-loaded nanoparticles was constructed on Mg-Zn-Y-Nd alloy (ZE21B) to improve its corrosion resistance and especially modulate smooth muscle cells. The results showed that rapamycin-loaded nanocoating reduced the degradation rate of the Mg alloy, but also improved the hemocompatibility of the material. Rapamycin-loaded nanocoating on ZE21B alloy, according to the results of in vitro cell tests, selectively inhibited the proliferation and migration of vascular smooth muscle cells, while having only marginal effects on the proliferation of vascular endothelial cells [24].

In recent years, there has been a lot of interest in functional coatings as a way to improve the performance of implants. Saadatlou G. et al. [25] presented, prepared, and characterized a tetra-functional coating exhibiting anticorrosion, antibacterial, biocompatible, and anticoagulant properties. Poly(2-ethyl-2-oxazoline)-co-polyethyleneimine (PEOX-co-PEI) stabilized silver nanoparticles (AgNPs) and heparin were used to prepare the multifunctional multilayers. The coatings were deposited on nitinol and 316L stainless steel substrates using the layer-by-layer technique, which involves sequential adsorption of complementary species with intermolecular forces such as hydrogen bonding and electrostatic interactions. Anticoagulation is generally provided by heparin. Heparin has the potential to enhance the hemocompatibility of surfaces because it inhibits blood clotting by attaching to and deactivating thrombin, a blood protein that causes coagulation. AgNPs provide antibacterial properties, and polycationic polymers, such as polyethyleneimine attracted great attention to inhibit metal corrosion.

The copolymer (PEOX-co-PEI) is temperature and pH-responsive and can provide the conditions for hydrogen-bonded assemblies. Such a combination of materials meant that the prepared coatings showed anti-corrosion, antibacterial, biocompatible, and anticoagulant properties at the same time [25].

Another way to improve the biocompatibility of stents was proposed by Li P. et al. [26], i.e. novel co-immobilization of molecules for the multifunctional coating of cardiovascular materials via layer-by-layer self-assembly. They created a phospholipid-based multifunctional coating with phospholipids-based polymers, type I collagen (Col-I), and Arg-Glu-Asp-Val (REDV) peptide. Their results showed that the multifunctional coating (Ti-PMMDA-Col-I-POMDA-REDV) could not only strongly inhibit platelet adhesion and smooth muscle cell proliferation, but also promote endothelial cell proliferation [26].

Among thin coatings, those containing titanium dioxide (TiO_2) are gaining a lot of interest. Thin films of titanium dioxide do not corrode or release harmful ions into solutions. As a result, it can be regarded as bioinert and may even stop the release of metal ions (Cr, Ni) from underlying bulk material (e.g. nitinol). Nickel and aluminium ions should be avoided because they can promote oxidative effects within body fluids. TiO_2 is characterized by low cost, non-toxicity, but also appropriate physical, mechanical, and dielectric properties for medical applications. In addition, it shows high biocompatibility [5,27,28]. Sun Z. et al. [5] used nitrogen doping of titanium dioxide thin films to improve the biological properties and biocompatibility of the coating. The titanium oxide thin films were fabricated by magnetron sputtering in a reactive gas atmosphere consisting of argon and oxygen in the first case and argon, nitrogen, and oxygen in the second case. Control of the nitrogen and oxygen gas flow rates and their mixing ratios allow adjustment of the nitrogen-doping level within the titanium dioxide thin films. The surface energy, wettability, cell adhesion, and consequently cellular proliferation on top of the thin films were all impacted by different nitrogen doping amounts. The results showed that the 1.5 times more nitrogen-doped titanium dioxide thin film can be used to modify the surface of stents to reduce the risk of vascular stent restenosis [5].

Diamond-like carbon (DLC) coatings have excellent mechanical properties, a low coefficient of friction, wear resistance, strong adherence to the substrate, and high biocompatibility. Furthermore, DLC films can enhance endothelization on vascular stents and reduce thrombotic clots [29,30]. Modern DLC-coated Co-Cr stents demonstrated more effective fibrin deposition and platelet activation prevention and more comprehensive and uniform endothelization, which reduced the incidence of thrombotic clots. Due to the coating's decreased inflammatory activation, the vascular repair was stabilized within 30 days [30,31]. Numerous studies have suggested a connection between surface energy, wettability, and cell adhesion in DLC films. They claimed that blood cell adsorption was commonly prevented by hydrophobic surfaces. Fluorocarbon polymers are well known for having exceptional water-shedding properties when it comes to hydrophobicity [30,32,33]. Additionally, platelet adhesion and activation on the surface of the F-DLC films were significantly reduced. Saito T. et al. [32] showed that the addition of fluorine considerably increased the antithrombogenicity of DLC coatings [32].

Design requirements for the manufacture of vascular stents

Vascular stents should be scientifically and rigorously designed and developed to ensure, that the stent can effectively treat blocked blood vessels, open up thrombi, and restore vascular functions [34]. Specific design requirements must be met and appropriate material properties must be ensured to safely introduce the stent to the target site and minimize the risk of restenosis.

Radial force plays a key role in preventing stent retraction by providing radial or structural support to the vessel. The ability of the stent to move through the vessel to its destination using the recommended accessories is also important. It depends on the low friction and high flexibility of the stent body. The profile of the stent defines the maximum diameter along the device. To avoid disruption of blood flow during implantation, the stent should have a minimal profile. Accurate placement of the stent is very important during vessel dilation, so it should have minimal foreshortening. Another important aspect is the optimal scaffold that minimizes the aggressive thrombotic response to the stent material, for this purpose, the smallest possible contact surface of the stent with the blood vessel should be ensured [35].

Each material must also be evaluated in terms of biocompatibility, as it must not cause adverse reactions in the body. Evaluation for stent visualization by fluoroscopy is also required both during insertion and after withdrawal of the delivery system. To place the stent in the correct position, the absorption of X-rays by the material is very important to obtain a good image and minimize the risk of vessel damage. It is also necessary to evaluate the stent's susceptibility to corrosion in a real or simulated environment. Corrosion mechanisms can include pitting, crevice, and galvanic corrosion. Each corrosion mechanism should be properly evaluated for the specific stent design. For example, fretting corrosion should be evaluated for stents that can be used with a tab. Another evaluation criterion is fatigue safety. Fatigue stress or strain analysis requires the determination of average and cyclic stresses or strains and comparison with the corresponding properties of the material. The selection of the stent material is such that it can withstand at least 380 million cyclic loads, i.e. up to 10 years of presence in the body. The resistance to the occurrence of cracks on the stents is particularly important from the point of view of their safe use. Stent ruptures can be initiated by all kinds of structural defects in the volume of the material, as well as by defects on the surface (notches, cavities, pits) [35].

The requirements for the biodegradable metallic stent tube include aspects such as degradations, biocompatibility, and mechanical properties. For degradation, scaffold integrity of 3-6 months and complete dissolution of 1-2 years are important. Biocompatibility requirements are non-toxicity of the material, no tissue inflammatory response, and no harmful release and/or residence of particles. The requirements for mechanical properties include tensile yield strength TYS > 200 MPa, tensile strength UTS > 300 MPa, tensile elongation > 15-18%, and elastic recoil < 4% [17]. The mechanical properties of the metals used for vascular stents are shown in TABLE 1.

Stent manufacturing technologies are most often based on laser cutting of an openwork structure from tubes of a specific diameter [35]. Other methods include the braided technique, electrospinning generation, and additive production generation [8].

TABLE 1. Mechanical properties of metals used for stents [36-40].

Material	Elastic modulus [GPa]	Yield strength [MPa]	Tensile strength [MPa]	Elongation [%]
Ti6Al4V	110	795	860	10
Ta	190	138	207	30
316L SS	196-210	205	515	40
CoCrMo	210	450	655	8
Ni-Ti	20-50 martensitic phase; 40-90 (approx. 83) austenitic phase	70-140 martensitic phase; 195-690 austenitic phase	895	25-50
Magnesium	41-45	65-100	207	2
Iron	200	150	210	40

Laser processing in the manufacture of coronary stents

The most typical technique used to make a vascular stent is laser cutting. During the laser cutting process, a high-power laser canvas focuses on the tubular material, the material melts, evaporates, or wears out rapidly, and then the material is blown away by high-velocity airflow [8].

Due to the requirements for precise coronary stent sizes, e.g. diameter 2.5-4.0 mm, length 8-38 mm, and wall thickness 80-100 μm, high accuracy is essential in its production. Nd:YAG, fiber, and disk lasers are used for this purpose. Process parameters include average power, pulse repetition rate, pulse width, processing speed, and energy. The heat-affected zone is proportional to the laser-matter interaction time. Lasers with short pulse duration, such as picosecond and femtosecond lasers, have no or minimal heat-affected zone, offering the best quality in stent fabrication [35].

Typical laser cutting processing involves CAD design with an optimized stent configuration, then the design is transferred to the laser processing system. The metal tube is mounted on the lathe with a Teflon rod passing through the inner diameter of the tube. The tube is then rotated and moved longitudinally relative to the laser to produce the desired programmed pattern [35].

After laser processing, it is common to encounter abrasive sticking to the underside of the cut as a result of the temperature gradient, beam divergence, and turbulent gas stream. To remove the abrasive and the oxide layer, etching is used, i.e. the laser-processed part is immersed in a thermoplastic tank containing dilute HCl. The use of ultrasound can improve the efficiency of digestion. The state-of-the-art surface finishing process for metallic stents is electropolishing, used to remove abrasive and contaminants, as well as metallic and non-metallic inclusions (introduced during production) and the heat-affected zone, eliminating surface irregularities, but also rounding off sharp edges and increasing corrosion resistance. In addition, electropolishing improves reflectivity and surface brightness [35]. Examples of the electrolyte composition and operating conditions used for electropolishing of the stent are shown in TABLE 2.

A new approach to stent processing using a 100 fs pulsed laser uses immersion of the treated material in a liquid. It has been shown that femtosecond lasers can provide high-quality cut surfaces without a heat-affected zone with optimal selection of parameters in both cutting environments. However, the main obstacles to the use of this technology in the air environment are the residues (in the form of deposits of previously evaporated material) and the remelted layer.

TABLE 2. Composition of solutions used for polishing and working conditions [35,41,42].

1 [35]		2 [41]		3 [42]		4 [42]	
Solution	Contents, parameter values	Solution	Contents, parameter values	Solution	Contents, parameter values	Solution	Contents, parameter values
H_3PO_4 (85%)	650 ml/l	H_3PO_4	42 wt%	H_2SO_4 (95-97%)	40 ml	H_3PO_4 (85 wt%)	42 wt%
H_2SO_4 (98%)	250 ml/l	Glycerol	47 wt%	H_3PO_4 (85 wt%)	45 ml	Glycerol	47 wt%
CrO_3	80 g/l	H_2O	11 wt%	H_2O	14 ml	H_2O	11 wt%
Addition	10 g/l	Current density	1.3 A/cm^3	Cathode	Stainless steel sheet	Cathode	Stainless steel sheet
Temp.	70-80°C	Time	1 min	Temp.	75°C	Temp.	90-95°C
Tension	18 V	-	-	Time	0.5 min	Time	1 min
Time	2 min	-	-	Applied voltage	3.5 V	Applied voltage	10-12 V
Cathode and anode surface	4:1	-	-	Anodic current	0.4 A	Anodic current	1.2 A
Cathode material	Stainless steel	-	-	-	-	-	-

Residues can be removed by ultrasonic cleaning, while the melted part is permanently attached to the material and requires subsequent treatment [43].

The presence of water around the workpiece minimizes the redeposition of material, resulting in a better cut surface finish and eliminating the need for residue removal. In addition, it has been observed that the use of water can reduce emissions of gases and particulates into the atmosphere. High-quality machining with well-defined edges, no chipping, and no remelting is achieved immediately after the cutting process. This indicates that underwater cutting can reduce the cost of the production process by reducing the need for cleaning and finishing, but it is a more energy-intensive solution [43].

Electrospinning

Electrospinning is a unique technique that uses an applied voltage for the liquid atomization process. The electrospinning technique has undergone rapid development in recent years. This technique can provide the unlimited potential to achieve vascular implants [8]. Electrospinning is a representative technology for producing various polymer solutions into fibers using an electric field. A multifunctional stent, such as one with a biodegradable coating and a drug-release mechanism, can be created using electrospinning. However, there are several disadvantages, such as weak mechanical properties and peeling from the stent due to the features of the electrospun fiber [44,45]. Electrospinning can be used to create drug-loaded stents in a variety of ways. After electrospinning, the fiber membrane is immersed in the drug solution to adsorb the drug. Emulsions for electrospinning, which can be used to create micro/nanofibers with core-shell structures, can be produced by combining the water and oil phases [46].

Chan Lee J. [44] used silicone to fabricate a silicone/polycaprolactone (PCL) multilayer film for stent coating. They received a multilayer membrane with high mechanical properties. Furthermore, the multilayer membrane cured at a low temperature had no problem with cell growth [44]. Chalony C. et al. [47] tried to create a drug-free coating on vascular stents that prevents cellular and platelet adhesion. To achieve this goal, they used co-axial electrospinning of Poly-ethyl2-cyanoacrylate (PECA) and Polyurethane (PU). This drug-free stent coating was developed that attenuates biological element adhesion. Furthermore, the coating was characterized by hemocompatibility and biocompatibility, and it also had adequate mechanical strength [47].

3D printing technologies in the production of vascular stents

Additive techniques use material addition, resin curing, or powder sintering a specific model by applying successive thin layers of material. The accuracy of technological machines creating real “layer-by-layer” models is determined, among others, by the thickness of the built layer. Incremental methods include, among others: stereolithography (SLA, Stereolithography), Selective Laser Sintering (SLS), Selective Laser Melting (SLM), modeling with liquid thermoplastic (FDM -Fused Deposition Modeling) [48].

Stereolithography consists of polymerization (photocuring) of liquid acrylic or epoxy resin with a UV laser beam. The platform on which the model is created is lowered by a layer thickness, while the scraper levels and applies a new layer of liquid resin. The accuracy of the model is affected by the thickness of the hardened layer, the type of resin, or the diameter of the laser spot. In the FDM method, the model is built in layers from a polymer extruded from the nozzle. The material (round plastic wire, wrapped on a spool) is melted in a heated nozzle to the appropriate flow temperature and then applied to the build platform, where it merges with the previous layers as it cools. Selective laser sintering of powders of various materials, i.e. polymers or metals, consists in combining powders as a result of their melting. Some materials (e.g. metal powders) require additional coating with substances that are a kind of binder melted with the use of a laser and binding powder particles. Sometimes, to increase the strength or density of the material obtained by the SLS technique, it is required to infiltrate the pores remaining between the particles, e.g. in the case of steel, infiltration is performed using copper alloys. Using SLM methods, components can be produced from virtually any material that can be powdered and melted. Most often, stainless steel, titanium, and its alloys are used; it is also possible to use low-melting materials, e.g. zinc alloys. Thanks to the full remelting of the material, no pores are formed and infiltration is not required [48].

Metal stents, due to the inability to dissolve in the body, remain permanently in the human blood vessel. Chronic exposure of the vessels to the presence of a foreign body may result in a decrease in their elasticity, which leads to restenosis in the stent. Therefore, biodegradable stents are of interest to scientists. 3D printing is of great importance in their production, which is economical and allows the development of innovative stent models, and gives the possibility of implant personalization [13,49]. Despite its exceptional accuracy and precision, laser cutting is a thermal process that can lead to structural problems such as residual stresses, micro-cracks, or, more commonly, heat-affected zones. In addition, surface finishing further increases the price of stents. Despite many advantages of additive methods, the SLM technique involves the use of high processing temperatures, which can cause damage to the material similar to laser cutting and requires subsequent surface finishing [14].

Due to the growing interest in printed implants, scientists investigated the effect of nozzle temperature, material flow, and speed on the accuracy of FDM printing. They found that both material flow and nozzle temperature strongly influenced the fineness of the process, as opposed to speed. Due to the ultrashort pulse emission duration of femtosecond lasers as well as the fact that the majority of the heat is removed by gas-phase evaporation, the area of the workpiece surface affected by thermal diffusion is incredibly small. Additionally, femtosecond lasers can achieve great processing precision and postprocessing workpiece surface quality and are applicable for use in micromachining [13]. When considering bioresorbable stents, it is necessary to evaluate the degradation of the material. For a lower fill percentage, the number of pores inside the printed structure will be greater. As a consequence, it will facilitate the degradation process, thanks to a larger contact surface, which easily allows the diffusion of water molecules, and thus the hydrolysis of the material and its resorption. However, an increase in percentage fill leads to a higher tensile strength value. In addition, the bending properties depend on the percentage of filling.

Furthermore, as the layer thickness decreases, the load resistance increases, which means that vascular stents should be printed with a minimum layer thickness to achieve better radial strength and withstand the loads imposed by arterial walls. The reduction of layer thickness correlates with greater bending strength, which is important due to the good fit of the stent to the blood vessel [14].

Coronary artery stents can be as small as 1 mm in diameter, so there is a technical challenge in 3D printing these implants. Virtual testing using finite element analysis makes it possible to predict the material behavior of selected nonresorbable polymers in a closed artery. A virtual testing framework is a numerical platform designed to realistically reproduce the characteristics of a physical experiment/study. This method makes it possible to improve processes and assess the behavior of materials. In addition, it also helps to shorten the time needed from the conceptualization of the project to market launch [50].

Conclusions

A stent implantation is associated with the risk of restenosis, which is why scientists continue to improve the properties of stents and research is conducted on new manufacturing technologies, surface modification, and methods of drug release. The coating is supposed to enhance antithrombotic properties and reduce the possibility of migration of alloy metals to the surrounding tissues. Nowadays, biodegradable materials, such as magnesium and polymers, which are supposed to reduce the risk of late complications, are becoming more and more popular.

The production of vascular stents has been dominated by laser processing methods, where the Nd:YAG laser is mainly used. It works well for steel and nitinol stents. Before introducing new materials to the market, the stent is tested and evaluated in many ways to ensure that it is as demanded. Manufacturing technology must ensure appropriate surface smoothness, edge rounding, and high dimensional accuracy. The main problem of laser processing is the heat-affected zones, which significantly reduce the strength of the material, to minimize their occurrence, the duration of the pulses should be shortened – that is why femtosecond lasers are characterized by the best results. In addition, immersion of the material in water prevents the deposition of residues on the workpiece. Another possibility for producing vascular stents is the use of additive techniques, which by adding thin layers of material, i.e. by hardening the resin or sintering powders, to build a specific model. Due to the many technological problems encountered in the 3D printing of coronary stents, virtual testing becomes useful, which allows examining the material's behavior in the occluded artery and shortens the time of introducing the appropriate project to the market.

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ORCID iD

K. Malisz: https://orcid.org/0000-0003-0596-3140
B. Świeczko-Żurek: https://orcid.org/0000-0001-7742-0052

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