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Biomedical Material for Stent Application: Current Status and Future Challenges

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Abstract: Cardiovascular disease is the leading cause of death worldwide. Arterial stenting as a transluminal angioplasty procedure allows re-opening of narrowed vessels and restoring normal blood flow with stent placement. The development of stents ed at the end of 19 century with bare-metal stents (BMS). Now, it has been based on the application of biodegradable or natural decomposed and coated stents. The coated stent has been found to improve BMS properties in terms of biocompatibility, cytotoxicity, and better mechanical and biophysical properties. Also, a biodegradable stent may support the blood micro-vessel during the estimated period of time before downgraded constituents. The biodegradable stent also allows a reinsertion for several months to improve the vessel wall's quality. This paper focuses on developing materials for stents, which describe the possible materials for stents and their properties. Furthermore, the current clinical trial of the new proposed stent will also be highlighted.

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Keywords: cardiovascular stent; blood micro-vessels; biocompatibility; coating technology

1. Introduction

Cardiovascular disease (CVD) is the leading cause of death globally, a disease related to the heart and blood vessels [1]. Arterial stent placement is becoming a standard cardiovascular treatment, allowing re-opening of narrowed vessels and restoring normal blood flow. The current technology, especially the up-and-coming and rapidly developing drug-eluting stent (DES), shows good effectiveness with a low treatment failure rate, making it possible to expand the application of stents in patients with severe disease [2].

Usually, a metallic stent is used for this purpose. However, typical metal stents are not biodegradable (non-biodegradable) in the human body. It is realized that the stent metals such as the Taxus (Boston Scientific Co.) drug elution stent have several disadvantages, such as temporary local antiproliferative drug therapy; permanent scaffolding may not be helpful after 3-6 months (time required for vascular remodeling 66 post dilatation), leading to further thrombosis.

Therefore, some experts question the need for scaffolding vessels for long-term application [3]. The stent that can be absorbed and dissolved at a particular time can overcome various problems on metal stents. The concept of biodegradable stents is not new. It has been actively used experimentally since metal stents were introduced, but the improvement has been relatively slow. So nowadays, many researchers focus on the breakthrough of new biodegradable materials for vascular stents, which dissolve in the biological environment after some practical use. Biodegradable

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implants are the right solution for cost, convenience, and aesthetics beneficial for the patient. In the field of biodegradable stents, there are two groups of materials, namely biodegradable metallic materials and biodegradable polymers [4], which will be discussed in detail in this article.

2. Stent Design Criteria

A lot has happened in stent design in recent times. Innovations occur in the application of stents and stent design technology. Metallic materials are an important class of materials used for stents such as Stainless Steel 316L (316L SS), platinum-iridium (Pt–Ir) alloys, tantalum (Ta), nitinol (Ni-Ti), cobalt-chromium (Co–Cr) alloys, and titanium (Ti) [3]. The material used as a lynchpin stent must meet the strict physical, mechanical and chemical properties. The material of the expandable stent must contain sufficient plasticity to remain at the required size when installed. Similarly, self-expanding stents shall be made of metal with adequate elasticity to be compressed and then expanded and maintain sufficient radial loop strength to prevent the vessel from recoiling or closing once attached. The properties of the metals are discussed in Table 1 [3, 4].

Table 1. Materials for stent applications

Logam	Modulus Elasticity (GPa)	*Yield Strength* (MPa)	*Tensile Strength* (MPa)	Density (g/cm3)	Ref.
316L *stainless-steel* (ASTM F138 dan F138; *annealed*	190	331	586	7.9	[5, 6]
Tantalum (*annealed*)	185	138	207	16.6	[5]
Cp-Titanium (F67; 30% *cold worked*)	110	485	760	4.5	[5, 6]
Nitinol	83 (Austenite phase) 28-41 (Martensite phase)	195-690 (Austenite phase) 70-140 (Martensite phase)	895	6.7	[5, 7]
Cobalt-chromium (ASTM F90)	210	448-648	951-1220	9.2	[5, 6, 7]
Pure iron	211.4	120-150	180-210	7.87	[8]
Mg alloy (WE43)	44	162	250	1.84	[9, 10]

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Stent needs to demonstrate excellent corrosion resistance and be biocompatible. Stent must quite radiopaque and creates minimal artifacts during magnetic resonance imaging (MRI). The most widely used stent material is stainless steel (SS316L). Characteristics like corrosion resistance, low carbon content, easy to deform SS316L as standard material for balloon-expandable stents. Other materials such as tantalum, platinum alloys, niobium alloys, and cobalt alloys are used in stents because of their better radiopacity, higher strength, better corrosion resistance, good MRI compatibility, and higher strength allow the design of low-profile stents. Usually, stents can be classified according to several engineering variables [11] that affect the stent's characteristics, biocompatibility, and outcome.

Nevertheless, the classifications most often based on the delivery system are expandable (balloon-expandable) or self-expandable. Biodegradable stents also have the exact delivery mechanism, except for the REVA (REVA Medical Co.) stent, which is balloon-expandable with a locking delivery mechanism. To design an ideal biodegradable stent, a materials engineer must

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consider several factors such as high radial strength in the period of degradation, low elastic radial recoil, good flexibility, low stent profile, suitable travers ability, minimal initial sorting, good scaffolding. Optimally, and has degradation over time as well as good biocompatibility properties. These are all design factors that influence the nature and outcome of the stent [12]. In producing stents, of course, many aspects must be considered so that: the manufacture of stents can meet the criteria, especially from a medical point of view. When entered the vein, the configuration of the stent is crimped (not yet developed). After arriving at the intended point, the crimped stent is then inflated with a certain amount of pressure until it reaches the required expansion diameter to support the plaque on the blood vessel wall. According to Beule [15], the ease of delivery is indicated by the flexibility of a stent, namely the ability of the stent to accommodate the bends and angles of the blood vessels. In addition, good flexibility is also needed to reduce the stress that occurs between the expanded stent and the surrounding tissue. Meanwhile, the expanded stent can adjust its shape to the end of the blood vessel while minimizing the incidence of injury to the vessel wall.

3. Development of Stent Application Biomaterials

The first generation of stents, bare-metal stents (BMS), are generally made of Stainless steel (316L), Cobalt-Chromium (Co–Cr), and Platinum-Iridium (Pt–Ir), Tantalum (Ta), Nitinol (Ni) alloys, as well as Titanium (Ti)- based stent have shown many problems causing tissue hyperplasia, restenosis within the stent (narrowing of the back), and the propensity of the organ to treat it as a foreign body during life. These considerations prompted the development of coating-stents of drug-eluting stents (DES) and BMS and the development of biodegradable stents (BDS) [16].

Yoon et al. [17] have demonstrated the potential of coated-stent, while others using DES as well as BDS for applications in the future [18, 19]. This type of stent will be discussed in this review article. The ideal stent should have the properties as formulated by Mani et al. [3], they are including: (1) the ability to be crimped on a balloon catheter; (2) good expandability ratio; (3) sufficient radial loop strength and negligible recoil; (4) good flexibility; (5) adequate radiopacity/magnetic resonance imaging (MRI) compatibility; (6) high thrombo-resistivity; (7) absence of restenosis after implantation; (8) non-toxic; and (9) good drug delivery capacity. Optimization of mechanical, Physico-chemical, and biological properties of newly developed stents is a challenge and should lead to attaining the characteristics mentioned above.

3.1 Layered Stent

Coated-Stent (layered stents) have been developed to improve the properties of BMS for better biocompatibility, non-toxicity, suitable surface roughness, and surface free energy, regulate the ability of the stent surface to absorb biological molecules and cells, ensure chemical stability by regulating the corrosion rate [17] or provide the desired biodegradable properties and serve as a platform for drug delivery. Various materials have been evaluated for application as stent coatings, as discussed in several publications [17, 20]

Several classes of materials have been tested as potential coatings for the manufacture of stents (see Figure 1). The stent surface can be modified using metal oxides and nitrides, wherein the metal and polymer are deposited using different Physio-chemical methods. Some methods include magnetron sputtering, pulsed laser deposition, and matrix-assisted pulsed laser evaporation. The surface can be modified to avoid or reduce undesired corrosion that could compromise the integrity of the stent and its function and cause ion release, which causes a significant impact on the surrounding vascular cells, as presented on Fig. 1.

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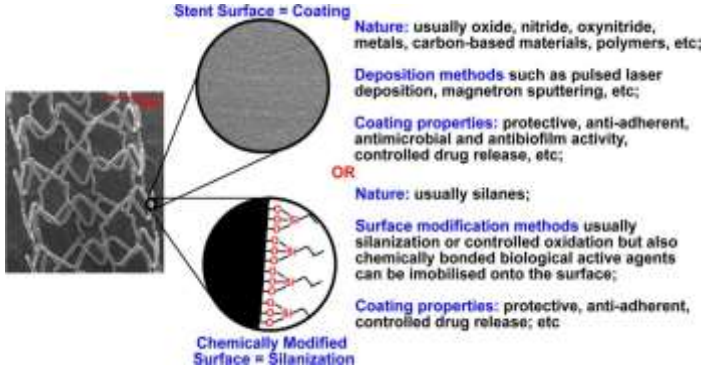

Figure 1. Stent Surface modification technique

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Polymer materials were used as stent coatings, either with or without drug-eluting, with varying success [23, 24]. The main problem of biodegradable and non-biodegradable polymer layers lies in their degradation products, which arise from contact with biological fluids and trigger inflammation followed by thrombosis formation. The susceptibility of the polymer to fracture can lead to the release of material fragments into the bloodstream, creating a hazard to seal some narrow areas of the damaged vessel. Polyethylene (PE), polyurethane (PUR), polyglycolide (PGA), and polylactide (PLA) have been evaluated as stent coating materials [25], which have been used for implants or other medical devices [26]. Polyurethane has been established as a scaffold material for vascular grafts due to its excellent hemocompatibility well [27,28]. PGA is commonly used as a suture material for different surgical applications [29,30].

Furthermore, the scaffold containing PGA was mixed with polycaprolactone (PCL) [31], which was used for a PGA-based drug delivery system [32,33]. Biodegradable polymers such as PLA have been extensively tested as temporary stent materials in cardiology due to their excellent track record of in vivo biocompatibility [34-36]. While another study conducted by Bognar et al. [22] evaluated three types of polyurethane (carbothane, tecothane, and chronoflex) deposited on the surface of a stainless steel BMS stent (L316) by immersing them in solution. Experiments have shown appropriate adherence of the PUR layer to the stent surface and improved biocompatibility and long-term stability compared with uncoated stents [37,38].

3.2. Biodegradable Stent

The advantage of DES technology has brought its advantages to overcome the limitations of conventional BMS. However, the influence of DES on clinical practice sometimes has risks, such as incomplete reendothelialization and hypersensitivity reactions to polymer coatings, which are the main subject of debate regarding implantation risks [39-41]. All these shortcomings caused the first generation of DES to fail. Late thrombosis and delayed healing are two potential risks associated with the use of DES. In addition, its long-term efficiency is questionable because some of the coating materials are not biodegradable, and there is a hypersensitivity to DES implantation [42,43].

Biodegradable stents (BDS) or bioresorbable stents are made of materials that can be dissolved or absorbed in the body. The idea of stent bioresorbable was considered revolutionary (third-generation stent) and attracted strong interest from engineers and medical teams. Due to the side effect of non-biodegradable materials in the stent, in the long term, it causes further complications such as thrombosis, neo-hyperplasia, and chronic inflammation [44]. To avoid the problems associated with polymer-coated DES stents, the modified second-generation DES uses a biodegradable polymer to improve clinical performance. This new treatment has the following properties, as on the Fig. 2.

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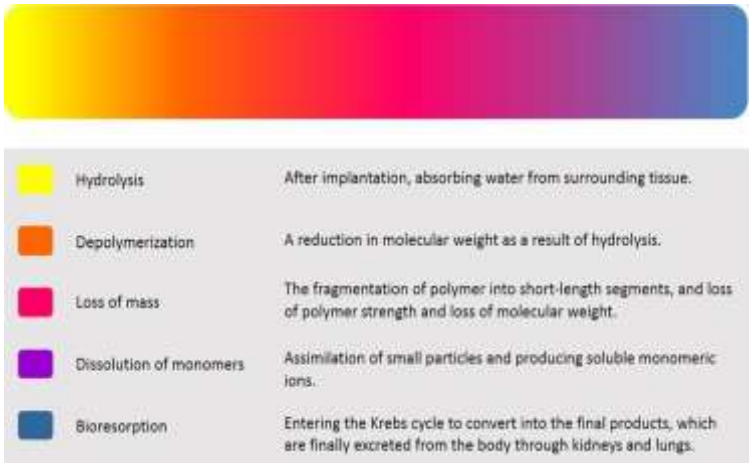

Figure 2. Biodegradation phase of stent [45,46]

Three phases occur in BDS, namely revascularization, restoration, and resorption (see Figure 2) as follow:

1) Revascularization is related to the narrowing of blood vessels that become open return. This is due to the greater flexibility and suitability of polymers biodegradable such as PLA. Its superiority in maintaining normal vessel curvature makes it a good stent material as an alternative to metal-based BMS and DES.

2) Restoration is the second phase for BDS to be fully functional. In this phase, there is a loss of total molecular mass that appears due to a decrease in molecular weight. Hydrolysis and depolymerization are followed by the metabolism of the initial production of lactate to carbon dioxide and water. The degradation process causes a decrease in the weight of the polymer structure.

3) The last and third phase, resorption, is a complementary phase for full recovery of vascular structures to their initial normal function, as shown on Fig. 3 [47].

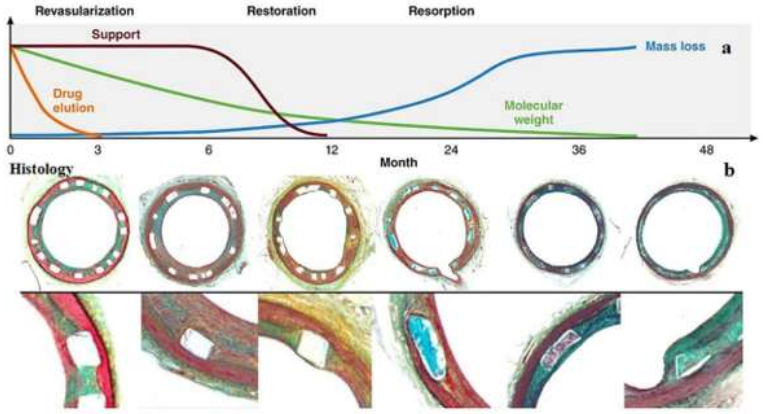

Figure 3. Three phases of biodegradable stent functionality [47]

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From Figure 3, it is observed that the three phases of BDS function include mechanical support and drug delivery function during the revascularization phase; loss of radial stiffness and mechanical restraint during the restoration phase; and resorption caused by mass loss with the return of the adaptive vascular remodeling response. The time graphs for these phases are specific to the biodegradable vascular scaffold. The molecular weight decreased immediately after implantation, and drug elution was almost complete within three months. Radial support decreased at about six months and the smallest at 12 months. Histological images at 24 months, the significant mass loss occurred, the abutment sites were replaced by a transient matrix (through histology). Further test for 36 months, the mass loss is completed [47].

4. Conclusions

Many aspects must be considered in the manufacture of materials for stents, as discussed in the design sub-criteria in this paper. Many problems have been reported in the early stent generation BMS, which causes hyperplasia and restenosis within the stent (narrowing back), and the tendency of the organ to make it a foreign object to the detriment of the patient. Because of that, the development of stent materials is currently leading to Coated-Stents (stents). layered) and biodegradable-stent. Established materials such as polyurethane as a scaffold for vascular-grafts due to their excellent hemocompatibility; PGA scaffold mixed with PCL was used for PGA based drug delivery system; polyurethanes coated on the surface of the stainless steel BMS (L316) stent exhibited good adherence from layer to surface of the stent which improves biocompatibility and long-term stability (compared to uncoated stents); and biodegradable polymers such as PLA as stent material in cardiology due to its good track record of biocompatibility.

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Abstract: Cardiovascular disease is the leading cause of death worldwide. Arterial stenting as a transluminal angioplasty procedure allows re-opening of narrowed vessels and restoring normal blood flow with stent placement. The development of stents ed at the end of 19 century with bare-metal stents (BMS). Now, it has been based on the application of biodegradable or natural decomposed and coated stents. The coated stent has been found to improve BMS properties in terms of biocompatibility, cytotoxicity, and better mechanical and biophysical properties. Also, a biodegradable stent may support the blood micro-vessel during the estimated period of time before downgraded constituents. The biodegradable stent also allows a reinsertion for several months to improve the vessel wall's quality. This paper describes the possible materials for stents and their properties such as design criteria, degradation behavior, disadvantages, and advantages with clinical and preclinical trials to date. Stent degradation allows reinsertion of the stent after several months and improves the vessel wall quality. This paper focuses on developing materials for stents, which describe the possible materials for stents and their properties. Furthermore, the current clinical trial of the new proposed stent will also be highlighted.

Keywords: cardiovascular stent; blood micro-vessels; biocompatibility; coating technology

1. Introduction

Cardiovascular disease (CVD) is the leading cause of death globally, a disease related to the heart and blood vessels [1]. Arterial stent placement is becoming a standard cardiovascular treatment, allowing re-opening of narrowed vessels and restoring normal blood flow. The current technology, especially the up-and-coming and rapidly developing drug-eluting stent (DES), shows good effectiveness with a low treatment failure rate, making it possible to expand the application of stents in patients with severe disease [2].

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Therefore, some experts question the need for scaffolding vessels for long-term application [3]. The stent that can be absorbed and dissolved at a particular time can overcome various problems on metal stents. The concept of biodegradable stents is not new. It has been actively used experimentally since metal stents were introduced, but the improvement has been relatively slow.

So nowadays, many researchers focus on the breakthrough of new biodegradable materials for vascular stents, which dissolve in the biological environment after some practical use. Biodegradable implants are the right solution for cost, convenience, and aesthetics beneficial for the patient. In the field of biodegradable stents, there are two groups of materials, namely biodegradable metallic materials and biodegradable polymers [4], which will be discussed in detail in this article.

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A lot has happened in stent design in recent times. Innovations occur in the application of stents and stent design technology. Metallic materials are an important class of materials used for stents such as Stainless Steel 316L (316L SS), platinum-iridium (Pt–Ir) alloys, tantalum (Ta), nitinol (Ni-Ti), cobalt-chromium (Co–Cr) alloys, and titanium (Ti) [3]. The material used as a lynchpin stent must meet the strict physical, mechanical and chemical properties. The material of the expandable stent must contain sufficient plasticity to remain at the required size when installed. Similarly, self-expanding stents shall be made of metal with adequate elasticity to be compressed and then expanded and maintain sufficient radial loop strength to prevent the vessel from recoiling or closing once attached. The properties of the metals are discussed in Table 1 [3, 4].

Table 1. Materials for stent applications

Metals	Modulus Elasticity (GPa)	*Yield Strength* (MPa)	*Tensile Strength* (MPa)	Density (g/cm3)	Ref.
316L *stainless-steel* (ASTM F138 dan F138; *annealed*	190	331	586	7.9	[5, 6]
Tantalum (*annealed*)	185	138	207	16.6	[5]
Cp-Titanium (F67; 30% *cold worked*)	110	485	760	4.5	[5, 6]
Nitinol	83 (Austenite phase)	195-690 (Austenite phase)	895	6.7	[5, 7]
	28-41 (Martensite phase)	70-140 (Martensite phase)			
Cobalt-chromium (ASTM F90)	210	448-648	951-1220	9.2	[5, 6, 7]
Pure iron	211.4	120-150	180-210	7.87	[8]
Mg alloy (WE43)	44	162	250	1.84	[9, 10]

Stent needs to demonstrate excellent corrosion resistance and be biocompatible. Stent must quite radiopaque and creates minimal artifacts during magnetic resonance imaging (MRI). The most widely used stent material is stainless steel (SS316L). Characteristics like corrosion resistance, low carbon content, easy to deform SS316L as standard material for balloon-expandable stents. Other materials such as tantalum, platinum alloys, niobium alloys, and cobalt alloys are used in stents because of their better radiopacity, higher strength, better corrosion resistance, good MRI compatibility, and higher strength allow the design of low-profile stents. Usually, stents can be classified according to several engineering variables [11] that affect the stent's characteristics, biocompatibility, and outcome.

Nevertheless, the classifications most often based on the delivery system are expandable (balloon-expandable) or self-expandable. Biodegradable stents also have the exact delivery

mechanism, except for the REVA (REVA Medical Co.) stent, which is balloon-expandable with a locking delivery mechanism. To design an ideal biodegradable stent, a materials engineer must consider several factors such as high radial strength in the period of degradation, low elastic radial recoil, good flexibility, low stent profile, suitable travers ability, minimal initial sorting, good scaffolding. Optimally, and has degradation over time as well as good biocompatibility properties. These are all design factors that influence the nature and outcome of the stent [12]. In producing stents, of course, many aspects must be considered so that: the manufacture of stents can meet the criteria, especially from a medical point of view. When entered the vein, the configuration of the stent is crimped (not yet developed). After arriving at the intended point, the crimped stent is then inflated with a certain amount of pressure until it reaches the required expansion diameter to support the plaque on the blood vessel wall. According to Beule [15], the ease of delivery is indicated by the flexibility of a stent, namely the ability of the stent to accommodate the bends and angles of the blood vessels. In addition, good flexibility is also needed to reduce the stress that occurs between the expanded stent and the surrounding tissue. Meanwhile, the expanded stent can adjust its shape to the end of the blood vessel while minimizing the incidence of injury to the vessel wall.

3. Development of Stent Application Biomaterials

The first generation of stents, bare-metal stents (BMS), are generally made of Stainless steel (316L), Cobalt-Chromium (Co–Cr), and Platinum-Iridium (Pt–Ir), Tantalum (Ta), Nitinol (Ni) alloys, as well as Titanium (Ti)- based stent have shown many problems causing tissue hyperplasia, restenosis within the stent (narrowing of the back), and the propensity of the organ to treat it as a foreign body during life. These considerations prompted the development of coating-stents of drug-eluting stents (DES) and BMS and the development of biodegradable stents (BDS) [16].

Yoon et al. [17] have demonstrated the potential of coated-stent, while others using DES as well as BDS for applications in the future [18, 19]. This type of stent will be discussed in this review article. The ideal stent should have the properties as formulated by Mani et al. [3], they are including: (1) the ability to be crimped on a balloon catheter; (2) good expandability ratio; (3) sufficient radial loop strength and negligible recoil; (4) good flexibility; (5) adequate radiopacity/magnetic resonance imaging (MRI) compatibility; (6) high thrombo-resistivity; (7) absence of restenosis after implantation; (8) non-toxic; and (9) good drug delivery capacity. Optimization of mechanical, Physico-chemical, and biological properties of newly developed stents is a challenge and should lead to attaining the characteristics mentioned above.

3.1 Layered Stent

Coated-Stent (layered stents) have been developed to improve the properties of BMS for better biocompatibility, non-toxicity, suitable surface roughness, and surface free energy, regulate the ability of the stent surface to absorb biological molecules and cells, ensure chemical stability by regulating the corrosion rate [17] or provide the desired biodegradable properties and serve as a platform for drug delivery. Various materials have been evaluated for application as stent coatings, as discussed in several publications [17, 20]

Several classes of materials have been tested as potential coatings for the manufacture of stents (see Figure 1). The stent surface can be modified using metal oxides and nitrides, wherein the metal and polymer are deposited using different Physio-chemical methods. Some methods include magnetron sputtering, pulsed laser deposition, and matrix-assisted pulsed laser evaporation. The surface can be modified to avoid or reduce undesired corrosion that could compromise the integrity of the stent and its function and cause ion release, which causes a significant impact on the surrounding vascular cells, as presented on Fig. 1.

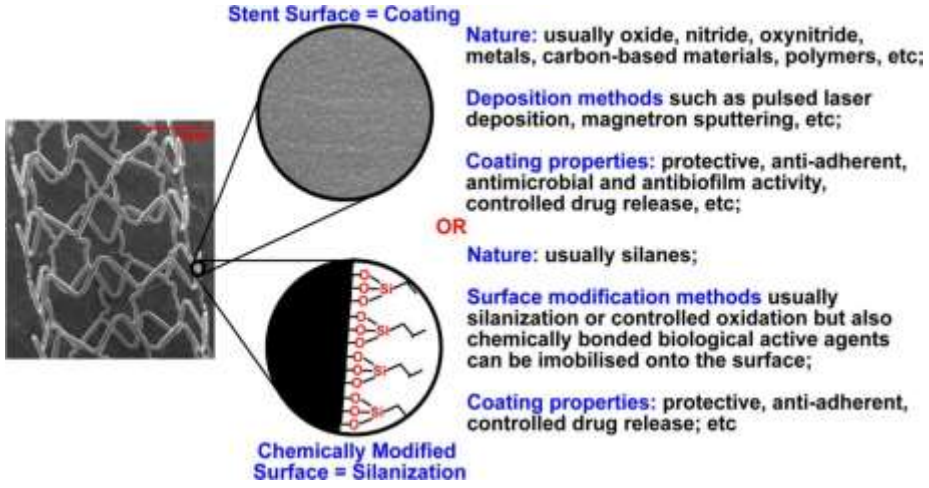

Figure 1. Stent Surface modification technique [21,22]

Polymer materials were used as stent coatings, either with or without drug-eluting, with varying success [23, 24]. The main problem of biodegradable and non-biodegradable polymer layers lies in their degradation products, which arise from contact with biological fluids and trigger inflammation followed by thrombosis formation. The susceptibility of the polymer to fracture can lead to the release of material fragments into the bloodstream, creating a hazard to seal some narrow areas of the damaged vessel. Polyethylene (PE), polyurethane (PUR), polyglycolide (PGA), and polylactide (PLA) have been evaluated as stent coating materials [25], which have been used for implants or other medical devices [26]. Polyurethane has been established as a scaffold material for vascular grafts due to its excellent hemocompatibility well [27,28]. PGA is commonly used as a suture material for different surgical applications [29,30].

Furthermore, the scaffold containing PGA was mixed with polycaprolactone (PCL) [31], which was used for a PGA-based drug delivery system [32,33]. Biodegradable polymers such as PLA have been extensively tested as temporary stent materials in cardiology due to their excellent track record of in vivo biocompatibility [34-36]. While another study conducted by Bognar et al. [22] evaluated three types of polyurethane (carbothane, tecothane, and chronoflex) deposited on the surface of a stainless steel BMS stent (L316) by immersing them in solution. Experiments have shown appropriate adherence of the PUR layer to the stent surface and improved biocompatibility and long-term stability compared with uncoated stents [37,38].

3.2. Biodegradable Stent

The advantage of DES technology has brought its advantages to overcome the limitations of conventional BMS. However, the influence of DES on clinical practice sometimes has risks, such as incomplete reendothelialization and hypersensitivity reactions to polymer coatings, which are the main subject of debate regarding implantation risks [39-41]. All these shortcomings caused the first generation of DES to fail. Late thrombosis and delayed healing are two potential risks associated with the use of DES. In addition, its long-term efficiency is questionable because some of the coating materials are not biodegradable, and there is a hypersensitivity to DES implantation [42,43].

Biodegradable stents (BDS) or bioresorbable stents are made of materials that can be dissolved or absorbed in the body. The idea of stent bioresorbable was considered revolutionary (third-generation stent) and attracted strong interest from engineers and medical teams. Due to the side effect of non-biodegradable materials in the stent, in the long term, it causes further complications such as thrombosis, neo-hyperplasia, and chronic inflammation [44]. To avoid the problems associated with polymer-coated DES stents, the modified second-generation DES uses a biodegradable polymer to improve clinical performance. This new treatment has the following properties, as on the Fig. 2.

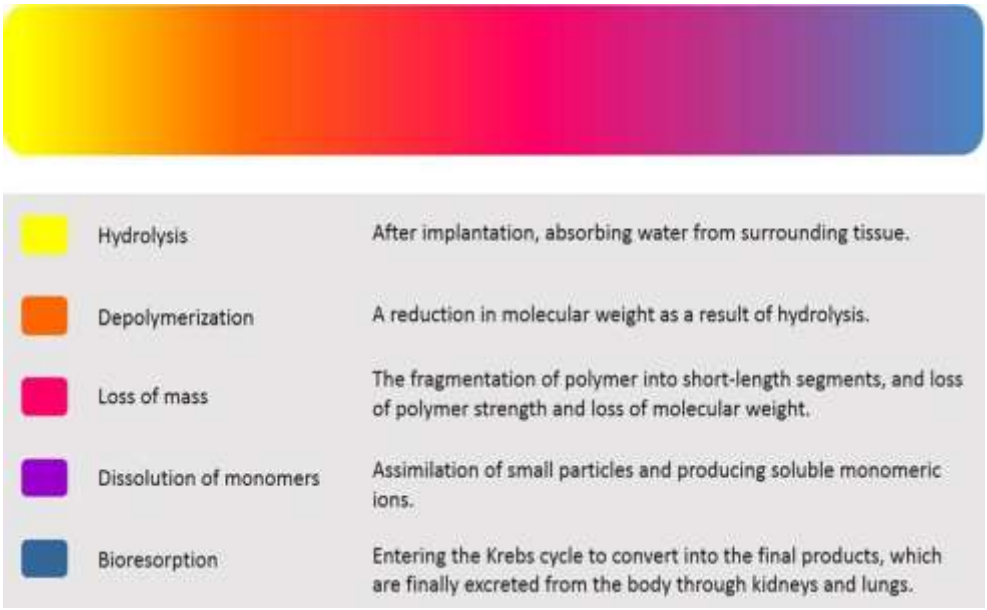

Figure 2. Biodegradation phase of stent [45,46]

Three phases occur in BDS, namely revascularization, restoration, and resorption (see Figure 2) as follow:

1) Revascularization is related to the narrowing of blood vessels that become open return. This is due to the greater flexibility and suitability of polymers biodegradable such as PLA. Its superiority in maintaining normal vessel curvature makes it a good stent material as an alternative to metal-based BMS and DES.

2) Restoration is the second phase for BDS to be fully functional. In this phase, there is a loss of total molecular mass that appears due to a decrease in molecular weight. Hydrolysis and depolymerization are followed by the metabolism of the initial production of lactate to carbon dioxide and water. The degradation process causes a decrease in the weight of the polymer structure.

3) The last and third phase, resorption, is a complementary phase for full recovery of vascular structures to their initial normal function, as shown on Fig. 3 [47].

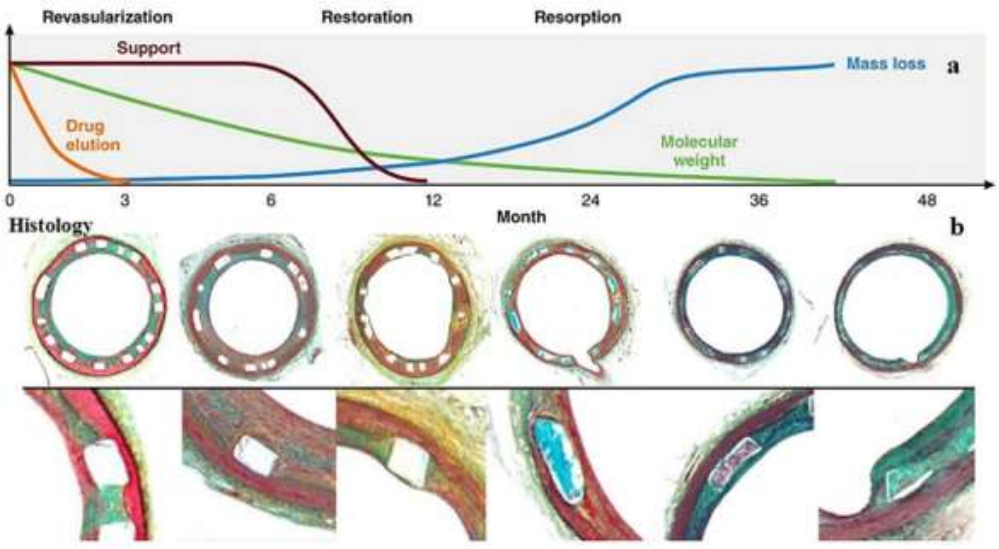

Figure 3. Three phases of biodegradable stent functionality [47]

From Figure 3, it is observed that the three phases of BDS function include mechanical support and drug delivery function during the revascularization phase; loss of radial stiffness and mechanical restraint during the restoration phase; and resorption caused by mass loss with the return of the adaptive vascular remodeling response. The time graphs for these phases are specific to the biodegradable vascular scaffold. The molecular weight decreased immediately after implantation, and drug elution was almost complete within three months. Radial support decreased at about six months and the smallest at 12 months. Histological images at 24 months, the significant mass loss occurred, the abutment sites were replaced by a transient matrix (through histology). Further test for 36 months, the mass loss is completed [47].

4. Conclusions

Many aspects must be considered in the manufacture of materials for stents, as discussed in the design sub-criteria in this paper. Many problems have been reported in the early stent generation BMS, which causes hyperplasia and restenosis within the stent (narrowing back), and the tendency of the organ to make it a foreign object to the detriment of the patient. Because of that, the development of stent materials is currently leading to Coated-Stents (stents). layered) and biodegradable-stent. Established materials such as polyurethane as a scaffold for vascular-grafts due to their excellent hemocompatibility; PGA scaffold mixed with PCL was used for PGA based drug delivery system; polyurethanes coated on the surface of the stainless steel BMS (L316) stent exhibited good adherence from layer to surface of the stent which improves biocompatibility and long-term stability (compared to uncoated stents); and biodegradable polymers such as PLA as stent material in cardiology due to its good track record of biocompatibility. Coated-stent and biodegradable stents have been currently developed to improve the properties of previous stents. They include the biocompatibility properties, cytotoxicity, surface compatibility, clinical stability, corrosion properties, and possibility for drug delivery system.

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