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Biodegradable Polymeric Stent: Poly(lactic acid) Variation

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Abstract:
Stenting is a treatment procedure to insert an implant-like needle into the blood vessel for the purpose of removing plaque and thrombosis while supporting the weak blood vessel. This procedure will enlarge the narrow blood vessel and restore blood circulation. Specifically, stent implantation is being combined with coronary angioplasty procedure to be known as percutaneous coronary intervention (PCI), which is an approach to treat cardiovascular diseases (CVD). There are three main variations of commercialized stents: Bare metal stent, drug-eluting stent and biodegradable stent. These three variations are focusing on the utilization of metal as the base material. Biodegradable metallic stent is a metallic stent which can be degraded into the physiological environment following an implantation. Even though forthcoming complications of permanent stent can be overcome with this type of stent, the degradation products often trigger inflammation and disturb the cascaded physiological processes. Therefore, researchers are moving towards biodegradable polymeric stents that are able to degrade while not harming the implanted lesion and surrounding tissues. This review article is intended to expose the information on biodegradable polymeric stent specifically to the implementation of poly(lactic acid) (PLA) and its variation as the polymeric materials.

Keywords: Polymeric stent; Biodegradable; Poly(lactic acid)

1. Introduction

Coronary heart disease, stroke, peripheral arterial disease and aortic disease are several abnormalities in the heart and blood vessels which will lead to cardiovascular diseases (CVD) [1]. Deficit in blood flow to the heart cause rapid shortfall of oxygen and nutrients in the cardiac cells, thus promoting ischemia [2]. The prolong deficit blood flow leads to cardiac tissue necrosis and relative circulatory complication [2]. In 2021, 11.3 million of deaths have been reported due to ischemic heart diseases which can be associated to a significant narrowing of the artery caused by atherosclerosis [3]. Diabetes and obesity are among the factors that could trigger atherosclerosis [4]. It is also recognised that endothelial layer damage and inflammatory responses are two cascaded events related to the formation of atherosclerosis [5].

Percutaneous coronary intervention (PCI) is a minimally invasive non-surgical approach commonly known as coronary angioplasty, involves inserting a stent into the artery [6]. It is a procedure that restores blood circulation in narrowed or occluded arteries [7]. Stent, a small tubular structures utilized to enlarge the vessel wall and the arterial

lumen to prevent the artery wall from recoiling and to repair the cardiovascular system that has been clogged by atherosclerosis [8]. In order to increase blood circulation and prevent arteries from rupturing, surgeons may implant stents in weak arteries. Stents are often constructed of metal and polymer, although they can also be made of fabric. Stents must be flexible and possess appropriate strength to maintain artery walls and keep the lumen clear of plaque formation [9, 10]. It also serves as a temporary or permanent vascular scaffold that helps in avoiding restenosis and acute artery obstruction [10]. The restenosis rate can be successfully reduced by stent implantation, however, an in-stent restenosis becomes the forthcoming problem with the occurrence of 16.4 to 70% [11] . In general, there are three major types of stent: Bare metal stent, biodegradable stent and drug-eluting stent. Current commercialized vascular stent of bare metal stent is known as Magmaris, which is biodegradable, sirolimus-eluting and balloon-expandable with two tantalum radiopaque markers at its distal and proximal ends [12]. While Absorb BVS is a biodegradable stent in the existing market which elutes everolimus. CYPHER™ stent is another drug eluting stent composed of stainless steel 316L strut and drug (sirolimus)-eluting part [12].

Second surgery is mostly needed to remove the metal stent and to treat inflammation [13]. The revolution of biodegradable metal stent gives a promising value to overcome in-stent restenosis and stent thrombosis [10]. However, degradation of the metal products has caused inflammation and accumulation on specific organs that lead to forthcoming diseases [14]. Therefore, the attention on biodegradable metal stent has been diverged, covering the development of biodegradable polymeric stent. However, low mechanical strength and high degradation rate of biodegradable polymeric stent become major limitations for the implementation of polymeric stent to support weaken blood vessel wall [15]. It is crucial to maintain the structural of biodegradable stent at least within 6 months and to ensure element degradation instead of large compounds dissociation [16]. This review paper covers the information on biodegradable polymeric stent towards the implementation of poly(lactic acid) (PLA) as the polymeric materials.

2. Biodegradable Polymeric Stent

Biodegradable stent materials must be biocompatible, biodegradable and the degradation products must not affect the human body [17]. Moreover, stent degradation rate should be relevant to maintain the mechanical properties, required during the remodeling and repairing of the vessel [18]. It is crucial to understand that stents will lose its stability and mechanical strength during resorption phase which are compensated by newly generated tissues.

Biodegradable stents are commonly made from synthetic polymers, because of their broad range of properties [19]. Mechanical qualities, primarily characterized by radial stiffness, and biodegradability are important considerations, and should be chosen to prevent probable quick rebound [20]. Once biodegradable stents are inserted in the blood artery, their mechanical qualities must fit the application and remain sufficiently robust until the surrounding tissues heal. It is mentioned that, depending on the polymer and the manufacturing method of stents, the mechanical characteristics of stents will be altered as the polymers degrade [21]. Furthermore, when biodegradable stents are placed and undergo metabolic change, there should be harmless reactions in the body. Their biodegradable products can either enter the body's metabolic cycle or be ejected outside the body. At the same time, the polymers should be able to transport and release pharmaceuticals into blood vessels. Table 1 lists these biodegradable polymers and their important properties.

Table 1 - Common biodegradable polymers for stent development

Polymer	Modulus (GPa)	Degradation (Months)	Melting point (°C)	Biocompatibility	Ref.
PCL	0.4 - 0.6	> 24	58 - 63	Good	[23, 24]
PGA	7.0 - 8.4	2-3 or 6 - 12	225 - 230	No severe inflammatory	[23, 24]
PLA	3.5 - 3.9	12 - 16	130 - 180	Mild inflammatory	[23, 25]
PDLA	1.9	12 - 16	Amorphous	-	[26, 27]
PLLA	2.7	> 24	173 - 178	Good	[26, 28]

A period of 6 - 12 months with appropriate mechanical characteristics is required to complete the vessel's remodeling and healing process. Afterwards, when the stent's mechanical integrity declines, the degradation must proceed at a rate that does not create degradation products build-up beyond the implants physiological limits. The overall time range for stent degradation is considered to be 12 - 24 months after implantation [22]. Numerous biodegradable stents have been created and tested in clinical trials over the last couple of decades. Poly(l-lactic acid) (PLLA) is the backbone

of the Igaki-Tamai stent (Kyoto Medocal Plannin Co.) and the Bioresorbable Vascular Scaffold (Abbot Vascular) [6]. The common polymers which have been used in biomedical engineering, as reported in the literature, include PLLA, PDLA, polyglycolic acid (PGA), poly(D-lactide) (PDLA), polylactic acid (PLA) and poly (caprolactone) (PCL). Table 2 lists the current commercialized biodegradable stent of PLA variations.

Table 2 - Current commercialized biodegradable stent of PLA variations

Stent	Platform material	Strut thickness (μm)	Coating material	Drug	Observation	Ref
Absorb BVS	PLLA	150	PDLLA	Everolimus	Resorption time of 36 months and 90 days for drug elution	[29]
DESolve	PLLA	150	PLLA	Myolimus/ Novolimus	Resorption time of 12 to 24 months	[29]
Igaki-Tamai	PLLA	-	None	-	Resorption time of 24 months	[6]
Xinsor	PLLA	-	PLLA + PDLLA	Sirolimus	Resorption time of 24 to 36 months and 28 days for drug elution	[6]

3. Poly(lactic acid) (PLA)

Various types of biodegradable polymers such as PLGA, PCL and PLA have been used in biodegradable polymeric stent development [29, 30]. Poly(lactic acid) has attracted increasing attention due to its excellent overall performance of high stiffness, strength, biodegradability, biocompatibility and thermal process ability [30]. It is considered as an alternative to traditional petrochemical plastics [31]. It is a thermoplastic polymer that derived from renewable resources such as corn, starch, sugar cane and wheat [32].

Since 1970s, United States (US) Food and Drug Administration (FDA) has approved the usage of PLA materials for human application [33]. The degradation release products from PLA are water and carbon dioxide that are non-toxic to human body and environment [34]. Poly(lactic acid) can be polymerized by direct lactic acid condensation or by cyclic lactide dimer ring opening polymerization [35]. There are two different isomers of PLA with different optical configurations; L-lactic acid and D-lactic acid as shown in Figure 1. Isotactic PDLA and PLLA have been found to have equivalent physicochemical properties, such as crystallization temperature, melting temperature and crystallinity [35].

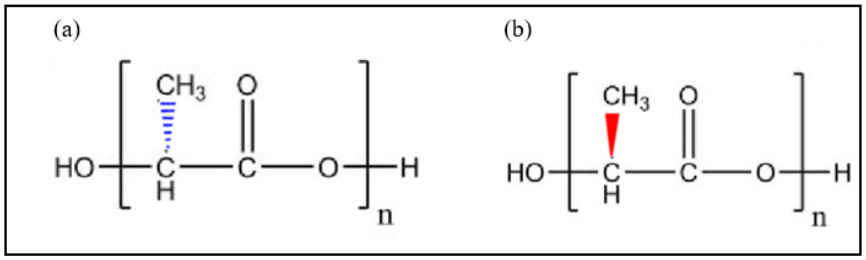

Figure 1. Chemical structures of (a) PLLA and (b) PDLA: Blue broken hashed wedge indicates the pointed of this bond or group away from the reader while red solid wedge indicates the pointed of this bond or group towards the reader

Poly(lactic acid) is considered as the best candidate for biomedical implant replacement due to its biodegradable and biocompatibility properties. Its degradation occurs through hydrolysis at molecular level whereby the breakage of backbone bonds occur by water penetration [36]. The degradation hydrolysis rate is affected by temperature conditions and stress imposed [36]. Although PLA can be considered as a decent renewable replacement for biomedical implant materials, several other characteristics are still considered lower than traditional polymer materials. It has some limitations such as having poor toughness, fragility, poor melting strength, low heat bending temperature, narrow processing window and low thermal stability [37].

Moreover, poor thermal and hydrolytic stability of PLA-based materials limit their potential for durability [38]. To overcome these limitations, various approaches have been adopted for PLA modification such as co-polymerization, blending, stereo-complexation and composition with nanoparticles [39]. Interestingly, PLA stereo-complexation, based

on the strong hydrogen bond between PLLA and PDLA enantiomers and the consequent formation of complementary structures, has become an interesting strategy for improving the mechanical strength and thermal stability characteristics of neat PLA [39].

Poly(lactic acid) containing > 99% L-lactide (PLLA) requires more than 5 years to completely breakdown after implantation in animals and humans meanwhile, PLA containing > 99% D-lactide (PDLA) requires only 1.5 years for complete breakdown [40]. The degradation rate depends on several factors such as polymer composition since with increasing hydrophilicity the degradability increases. The PDLLA degrades faster than PDLLA due to its crystalline regions. Besides, the compact crystallinity of sc-PLA makes it to be less degradable than its homopolymer [40]. With increasing molecular weight, the degradation rate decreases as the water intake is reduced. Thus, PLLA (21 000 g/mol) has the potential to degrade faster than PLA (58 000 g/mol) followed by PDLA (114 000 g/mol) [41, 42].

3.1 PLLA and PDLA stereo-complex

There are two enantiomers of sc-PLA which are PLLA and PDLA. Ikada *et al*. [35] was the first to report on stereo-complex formation between PLLA and PDLA using solution blending of the two homopolymers; individual solutions and later by melt blending. Figure 2 is a schematic illustration of the preparation sc-PLA [43]. The formation of stereo-complex occurs when PLLA with left handed helical confirmation and PDLA with right handed helical confirmation are blended by solution or melt blended where the resultant mixture is casted through van der Waals interactions [44] and/or hydrogen bonding [45].

The melting temperature of stereo-complex is 50°C higher (230°C) than that of pure PLLA or PDLA (180°C) [38]. The properties enhancement is achieved due to the unique structures between PLLA and PDLA units. The parameters of mixing ratio and molecular weight of PLLA and PDLA affect the most the sc-PLA [34]. Besides, strong interaction between PLLA and PDLA polymer are due to the presence of Van der Wall interactions following the stereo-complexation of PLA [35]. The interfacial bonding between PLLA and PDLA describes why the stere-complex has a high melting temperature and excellent mechanical properties.

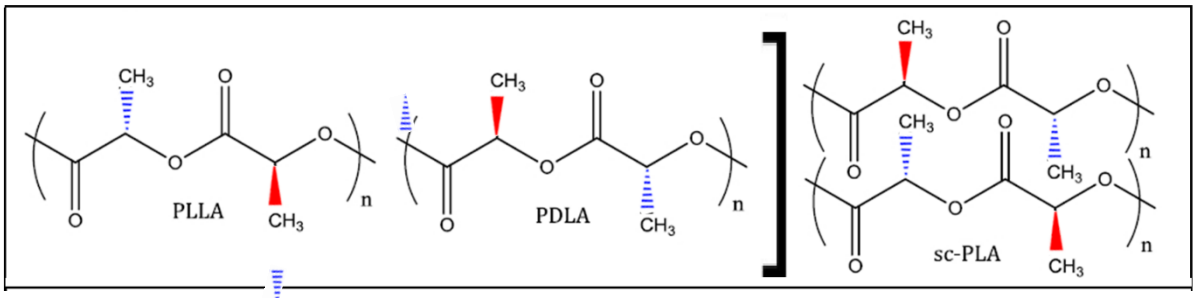

Figure 2. Chemical orientation of sc-PLA: Blue broken hashed wedge indicates the pointed of this bond or group away from the reader while red solid wedge indicates the pointed of this bond or group towards the reader

Table 3 - Physical properties of PLLA or PDLA and sc-PLA [42]

Properties	**PLLA or PDLA**	**sc-PLA**
Glass transition temperature (°C)	58	65 ~ 72
Melting temperature (°C)	170 - 190	220 ~ 230
Enthalpy of melting of crystal having infinite size (J/g)	40 - 50, 93	142, 146
Decomposition temperature (°C)	310	NA
Density (g/cm3)	1.25 ~ 1.29	NA
Tensile strength (GPa)	0.12 ~ 2.3	0.88
Young's modulus (GPa)	7-10	8.6
Elongation at break (%)	4-7	30

Table 3 summarizes the physical properties of PLLA or PDLA and sc-PLA. Numerous studies have been carried out with respect to the formation, structure, properties, degradation, and application of the sc-PLA [34, 46, 47]. Stereo-complexation enhances the mechanical properties, the thermal-resistance, and the hydrolysis-resistance of PLA based materials [38]. It has been used as biomedical materials for tissue regeneration, matrices for drug delivery system and as an alternative for commercial polymeric materials to reduce impact on the environment.

4. Conclusion

This review paper provides information on the biodegradable stent as one of the approaches to treat CVD. The utilization of metallic biodegradable stent is currently diverged towards polymeric materials due to the acute toxicity of degradation products which subsequently will trigger inflammation and disturb the cascaded physiological processes. There are several types of polymers being used as polymeric materials for the development of biodegradable polymeric stents including PLA, PCL, PGA, PLLA and PDLA. This review paper is focusing on the implementation of PLA and its variation as biodegradable polymeric materials, thus discussing on their ability to be degraded.

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Conflict of Interest

The authors declare no conflict of interest.

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