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Development of Biodegradable Stents from Polymeric Composites for Cardiovascular Applications

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Abstract

Cardiovascular diseases are still one of the leading health complications in the world, and coronary artery disease remains one of the toughest ones to crack. The introduction of stent implantation in interventional cardiology is a breakthrough concept which helps to restore blood flow and maintain patency of the arteries. On the other hand, long-term results of bare-metal stents and drug-eluting stents indicate the presence of complications, such as in-stent restenosis, late thrombosis, and chronic inflammation, which are hardly negligible. Recent biodegradable stents alleviate such concerns, providing temporary mechanical support in the vascular system, before degrading into biocompatible byproducts and hence, reducing the long-term complications associated with permanent implants. As opposed to metallic materials which are associated with inflammatory responses, polymeric composites can be custom-designed with specific values on a spectrum of structural strength and bifunctionality. Recent bioresorbable polymers – such as poly-L-lactic acid, polycaprolactone, and their composites with natural polymers or nanoparticles – exhibit improved mechanical integrity and hemocompatibility This review article is dedicated to the history of polymeric stents, which focuses on intricate cardiovascular system applications. It highlights the issues of fabricating materials and methods of degradation, the clinical advancements, and the focus on the difficulties on applying these technologies in everyday clinics. The review provides an outlook on future of next generation stents incorporating smart materials, improved design, nanotechnology, and patient-centered approaches for seamless clinical outcomes in cardiovascular healing.

Keywords: Biodegradable stents, polymeric composites, cardiovascular applications, bioresorbable polymers, coronary artery disease, drug delivery, vascular healing, nanocomposites, tissue compatibility, interventional cardiology

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INTRODUCTION

Worldwide, cardiovascular diseases (CVDs) account for almost one-third of all deaths every year, making them the foremost causative factor of all deaths [1]. Of these, coronary arteries disease (CAD) is by far the most common, ranging from the narrowing to the total blockage of coronary arteries because of an atherosclerotic plaque. Reduction of blood flow leads to an increasing risk of acute coronary events like a heart attack and sudden cardiac death [2]. A few decades ago, percutaneous coronary interventions (PCI) changed the face of cardiovascular care by treating arteries non-invasively and the placing of stents has become the focus. Angioplasty is aided using traditional bare-metal stents (BMS) and is said to be the first stent. Though putting the BMS is meant to reduce acute

closure of the blood vessels, the inflammatory response which leads to in-stent restenosis, neointimal hyperplasia, is almost unavoidable [3].

In response to this issue, drug-eluting stents (DES) were developed, and smooth muscle cell proliferation was attenuated by incorporating antiproliferative medications [4]. The rate of restenosis was significantly less with DES compared to BMS, though resulted in other complications such as late stent thrombosis, delayed endothelial healing, and prolonged dual antiplatelet therapy [5]. These drawbacks pointed out the importance of another alternative that could provide temporary mechanical support without the complications of permanent metallic devices.

Bioresorbable scaffolds (BDS), or biodegradable stents, were developed to meet these criteria. In contrast to permanent stents, biodegradable systems are designed to provide enough radial strength during the crucial healing phase and then gradually break down to non-harmful by-products that are metabolized or excreted from the body [2, 3]. This temporary presence diminishes the risk of late complications and restores the physiology of the vasculature by removing the long-term presence of a foreign body.

The first development attempts of biodegradable stents focused primarily on metallic alloys, particularly magnesium and iron. Promising as they were, metallic bioresorbable stents encountered problems with unpredictable degradation rates, poor mechanical stability, and inflammation on adjacent tissue. This prompted a more intense exploration of polymeric materials, which afford mechanically and biologically engineered structures with greater control over the degradation rate, flexibility, and bio-functionality.

Biodegradable polymers – like poly-L-lactic acid (PLLA), polyglycolic acid (PGA), polylactide (PLA), and polycaprolactone (PCL) polymers – can be designed to match the architectural and mechanical properties of arteries and spatially degrade over months to years to provide mechanical support and safe absorption [5]. Recent advancements in the development of polymeric composites, hybrid materials comprising synthetic polymers combined with specially synthesized nanoparticles, ceramics and/or even natural polymers, has brought forth materials with improved mechanical strength, hemocompatibility, and enhanced drug-loading capacity, which renders them more suitable for improved, next-generation stent designs. Furthermore, more precise fabrication of stents incorporating proper alloys and optimized geometry, porosity, and surface nanoscale features, with the use of additive manufacturing and enhanced stent nanotechnology, is becoming widely possible.

This review documents the advancements of biodegradable stents with emphasis on polymeric composites for cardiovascular applications. Subsequently, materials, stent fabrication methods, degradation, biological interaction, and other clinical advancements along with possible future outlook for this area of research will be presented.

EVOLUTION OF STENT TECHNOLOGY AND THE RISE OF BIODEGRADABLE SOLUTIONS

Technological advances have continuously improved intravascular stents in attempts to overcome shortcomings of previous models. During initial attempts at performing “Percutaneous transluminal coronary angioplasty” (PTCA), surgeons achieved vessel lumen, however vessels recoil acutely with >30–40% of acute vessel to restenosis in under 6 months [6]. Stents began the interventional cardiologist revolution by allowing angioplasty to have scaffolding that mechanically supports the vessel to avoid collapse unlike most angioplasty which have no scaffolding.

Bare-Metal Stents (BMS)

Stents Without Any Coating Stents Without Any Coating (BMS) that are made of stainless steel, cobalt–chromium, platinum–chromium alloys offer substantial decreases in restenosis rates compared to

balloon angioplasty alone [7]. Their mesh construction and radial strength ensure the vessel is unlikely to collapse. However, BMS trigger hyperplasia and in 20–30% of cases in-stent restenosis occurs. This leads to repeated interventions which reduce long-term success and are required by the patient [8].

Drug-Eluting Stents (DES)

Stent Systems Having Coating To keep restenosis to a minimum, stents with coatings were developed in the 2000s and became stents with a coating of sirolimus or paclitaxel, known as drug-eluting stents. These decreases restenosis rates to under 10% and are a major step forward in the medical world [9]. However, there were some concerns regarding reendothelialization delay, chronic inflammation, and late stent thrombosis, particularly when polymer membranes were inconsistently degraded. Managing these patients was also complicated due to the requirement for prolonged dual antiplatelet therapy, particularly in those susceptible to bleeding diathesis [10].

Fully Biodegradable Stents

Paradigm Shift Aimed at overcoming the downsides of permanent implants, some researchers designed fully biodegradable stents, also known as bioresorbable scaffolds (BRS). The guiding principle was to offer scaffolding within the vasculature for the duration of the critical healing phase and afterwards permit the stent to completely bio-resorb. As a result of no longer retaining foreign material in the body, stents of advanced design were expected to re-establish vasculature physiology, chronic inflammation, and late expansive remodeling of vessels [6, 7].

POLYMERIC MATERIALS FOR BIODEGRADABLE STENTS

Poly-L-Lactic Acid (PLLA)

Biodegradable stents have been extensively researched, and Poly-L-lactic acid (PLLA) is no exemption. It is synthesized from lactic acid monomers and is semi crystalline, biocompatible, and can be metabolically degraded to lactic acid as one of the end products of the Krebs cycle [11]. Among polymers, it has the most strength and stiffness and is, therefore, a leading polymer for vascular scaffolds. PLLA stents are, however, associated with slow degradation spans of 2–3 years, a condition that could impede vessel recovery, and brittle fracture under cyclic loads. Furthermore, stents with thick PLLA polymer struts can be difficult to deliver and poorly endothelialized. Regardless of its drawbacks, most clinical trials continue to use it as the benchmark material.

Polyglycolic Acid (PGA)

Also considered for the fabrication of biodegradable stent polymers due to biocompatibility and rapid hydrolytic cleavage is PGA (Polyglycolic Acid) [12]. It possesses a very high degree of crystallinity which reinforces the mechanical properties; however, within an in vivo setting, PGA is often over degraded, and lost, within a few months. This adverse complication results in the healing of incomplete vessels, which is a much worse case scenario. To address this, PGA is most often copolymerized and PLLA to create PLGA (A poly(lactic-co-glycolic acid)), or poly(lactic and glycolic acid copolymer) and is useful to tailor any degradation by shifting the glycolic-to-lactic ratio. Stents made of PLGA display stents and flexibility along with regulated resorption, which is a vast improvement in the PLGA stents, however, there is still a problem of optimization in the mechanical strength of the stent.

Polycaprolactone (PCL)

The degradation rate of Polycaprolactone (PCL) is 2 to 5 years. It is a semi crystalline aliphatic polyester and is classified as slow in degradation rate [13]. Due to the low glass transition temperature in PCL, it displays a flexible nature as a result and aids the improvement of stent deployment along with the vascular anatomy nebulously. The PCL is of interest when stent constituent is deployed due to the low ever shifting arterial pressure around the stent device. The mechanic strength of PCL, when used with other devices, is boosted using nanoparticles or ceramics with it. PCL is also present in stents due to propelling functions along with drug which it can hold in bound stents is releasable.

Poly(D,L-Lactic Acid) and Copolymers

PDLLA sprints faster than PLLA because the amorphous structure is more disordered, and thus less ordered [14]. PDLLA, though able to endure lower mechanical stress than PLLA, has more flexible as well as faster bio-resorption time which makes it useful for stents requiring faster degradation. In combination with PLLA or PGA, PDLLA can equilibrate strength and degradation. More freedom with mechanical and degradation properties is offered by copolymers such as PLGA and poly(lactic-co-caprolactone) PLCL). Stents have been studied for use with these copolymers and more advanced manufacturing processes such as electrospinning and 3D printing [15]. Table 1 shows Summary of major biodegradable polymers and polymeric composites used for cardiovascular stents.

Table 1. Summary of major biodegradable polymers and polymeric composites used for cardiovascular stents.

Material composite	Mechanical strength	Degradation time	Key advantages	Limitations/ challenges	References
PLLA (Poly-L-lactic acid)	High stiffness and strength	2–3 years	Excellent biocompatibility; proven clinical use	Brittle; slow degradation; poor reendothelialization	[11, 12, 16].
PGA (Polyglycolic acid)	High crystallinity, strong	<6 months	Rapid degradation; good processability	Too fast degradation; weak long-term support	[12, 14].
PLGA (Poly(lactic-co-glycolic acid))	Moderate	6–12 months	Tunable degradation rate; flexibility	Lower strength; needs optimization	[13, 14].
PCL (Polycaprolactone)	Moderate–low	2–5 years	Highly flexible; suitable for drug delivery; easy fabrication	Very slow degradation; low stiffness	[13, 15, 17].
PDLLA (Poly(D,L-lactic acid))	Moderate	<1 year	Faster degradation than PLLA; good flexibility	Reduced mechanical strength	[14].
PLCL (Poly(lactic-co-caprolactone))	Moderate	1–3 years	Combines elasticity of PCL and strength of PLLA	Optimization needed for vascular use	[14, 18].
PLLA/Natural Polymer (e.g., Chitosan, Collagen)	Variable	Tunable	Improved reendothelialization and hemocompatibility	Lower mechanical integrity	[15, 19].
PLLA/Nanoparticle or Ceramic Composite	High	Tunable	Enhanced strength and buffering capacity; reduced inflammation	Complex fabrication	[9, 20, 21].

Critical Perspective and Future Outlook

Although substantial progress has been achieved in developing biodegradable polymeric materials for cardiovascular stents, no single polymer currently satisfies all the mechanical, biological, and degradation requirements necessary for optimal clinical performance. PLLA remains the most extensively investigated material because of its favorable radial strength and biocompatibility; however, its slow degradation and relatively thick strut design may delay vascular healing. In contrast, PGA exhibits rapid degradation but often loses mechanical integrity before complete tissue repair, whereas PCL provides excellent flexibility and drug-loading capability but lacks sufficient stiffness for high-load vascular applications. Consequently, recent investigations have increasingly focused on polymeric composite systems that integrate synthetic polymers with natural biomaterials, ceramics, or nanomaterials to achieve a more balanced combination of mechanical stability, controlled bio resorption, and enhanced endothelialization. Nevertheless, direct comparative studies using standardized experimental protocols remain limited, making it difficult to identify the most suitable material for specific clinical applications. Future research should emphasize systematic benchmarking of polymeric composites, long-term in vivo validation, scalable manufacturing strategies, and patient-specific scaffold optimization through computational modelling and artificial intelligence to facilitate successful clinical translation.

FABRICATION TECHNIQUES FOR POLYMERIC COMPOSITE STENTS

Extrusion and Laser Cutting

One of the earliest approaches for rapidly prototyping polymer stents involves the extrusion of polymer tubes which are subsequently laser cut to form a predefined mesh structure [20]. Extrusion yields a polymeric tube of uniform cross section which can subsequently be laser cut to yield struts of a predefined thickness and geometry. For composites, polymer matrices can be blended with bioresorbable fillers such as metallic nanoparticles or bioresorbable metal meshes. However, during extrusion and laser cutting, polygonal structures, which can thermally degrade and microcrack, are common. The long-term mechanical properties in these cases are often compromised, surface polishing, post-annealing, and abrasion are common to mitigate these concerns.

Injection Molding

Injection molding is widely used in polymer engineering and has been adapted for stent fabrication. In this method, polymeric composites are thermally processed and injected under pressure into stent patterned molds [16]. The method's high reproducibility allows for mass production as well as the addition of reinforcing fillers. Furthermore, the injection molding method allows for the incorporation of drug reservoirs within the stent body. However, the high processing temperatures may compromise the stability of the drug; thus, limiting their use in drug-eluting stents without some alterations.

Electrospinning

Electro spinning can be used in several ways, including in the construction of nano-scaffolds that emulate the extracellular matrix [17]. The polymer matrix of stents has been modified with electrospun composites for improved endothelialization, hemocompatibility, and sustained drug release. Stents can be covered with nanofiber mats of polycaprolactone, PLLA, or bioactive polymer blend composites. Nanofibers, with their large surface area, allow for the efficient loading and release of drugs. Although mostly used for coatings, electrospinning is beginning to be used for the entire stent body, and the recent development of 3D electrospinning may allow for the construction of intricately designed, fully polymeric stents.

3D Printing and Additive Manufacturing

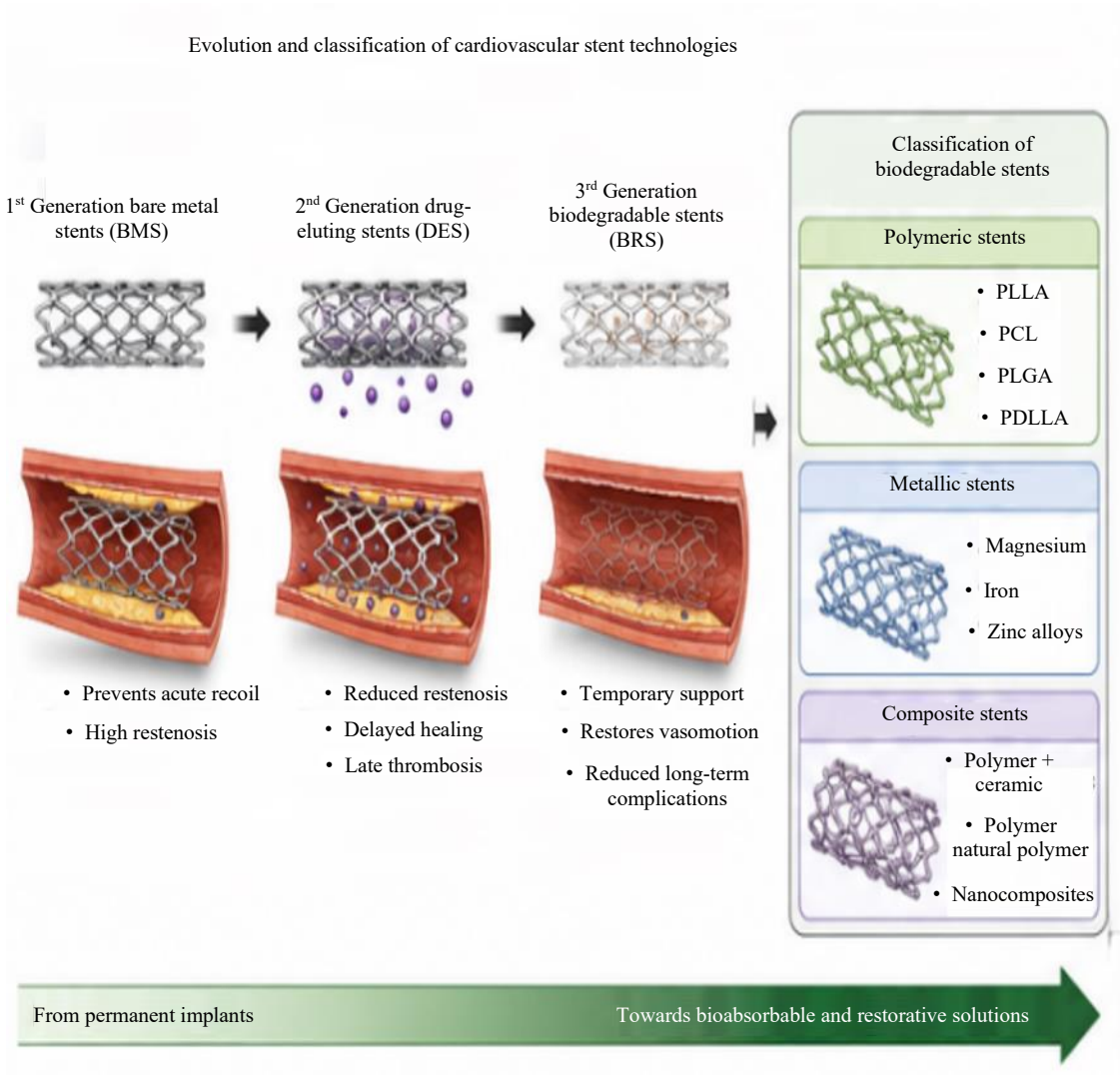
The fabrication of polymeric composite stents is easily customizable with the use of CAD owing to the precision of layer-by-layer deposition that 3D printers offer, thus, revolutionizing the stent fabrication process [18]. Successful printing of biodegradable polymers – such as PCL and PLLA – have been completed onto tubular scaffolds with wall thickness and porosity control. Performance of multifunctional stents can be improved by the addition of nanoparticles, ceramics, or drug carrier systems into the printing inks. There is also the novel area of 4D printing, where stents can change shape in response to physiological stimuli, allowing for self-deploying and stents that are adaptive in function. There is still the challenge of optimizing clinical applications in print resolution, mechanical consistency, and ease of scaling up production [21].

Comparative evaluation of fabrication technologies used for biodegradable polymeric stents, highlighting their advantages, limitations, suitable biomaterials, and potential for clinical translation (Table 2).

Graphical overview of biodegradable polymeric composite stents for cardiovascular applications. (A) Evolution and classification of cardiovascular stent technologies from bare-metal stents (BMS) and drug-eluting stents (DES) to biodegradable stents (BRS), including polymeric, metallic, and composite scaffold systems. (B) Design strategy of polymeric composite biodegradable stents illustrating the integration of biodegradable polymers with nanomaterials, natural polymers, and ceramic reinforcements to enhance mechanical strength, controlled degradation, drug delivery, reendothelialization, hemocompatibility, and anti-inflammatory performance. (C) Schematic workflow depicting material selection, fabrication techniques, stent implantation, functional performance, degradation mechanisms, vascular healing, and complete bio absorption, highlighting the translational pathway toward next-generation biodegradable cardiovascular stents (Figure 1).

Table 2. Comparative analysis of fabrication techniques for biodegradable polymeric stents.

Fabrication technique	Key advantages	Major limitations	Suitable polymers	Clinical translation potential
Extrusion + Laser Cutting	High precision, reproducible geometry, widely established	Thermal damage, microcracks, limited design flexibility	PLLA, PLGA	High.
Injection Molding	Mass production, good dimensional accuracy	High processing temperature may affect drug stability	PLLA, PCL	Moderate–High.
Electrospinning	Excellent endothelialization, sustained drug release, ECM-like structure	Limited radial strength for standalone stents	PCL, PLLA, PLGA	Moderate.
3D Printing	Patient-specific design, customizable architecture	Limited printing resolution, regulatory challenges	PLLA, PCL, PLCL	High (Emerging).
4D Printing	Shape-memory behavior, adaptive deployment	Early-stage development, limited clinical evidence	Smart polymer composites	Future Potential.



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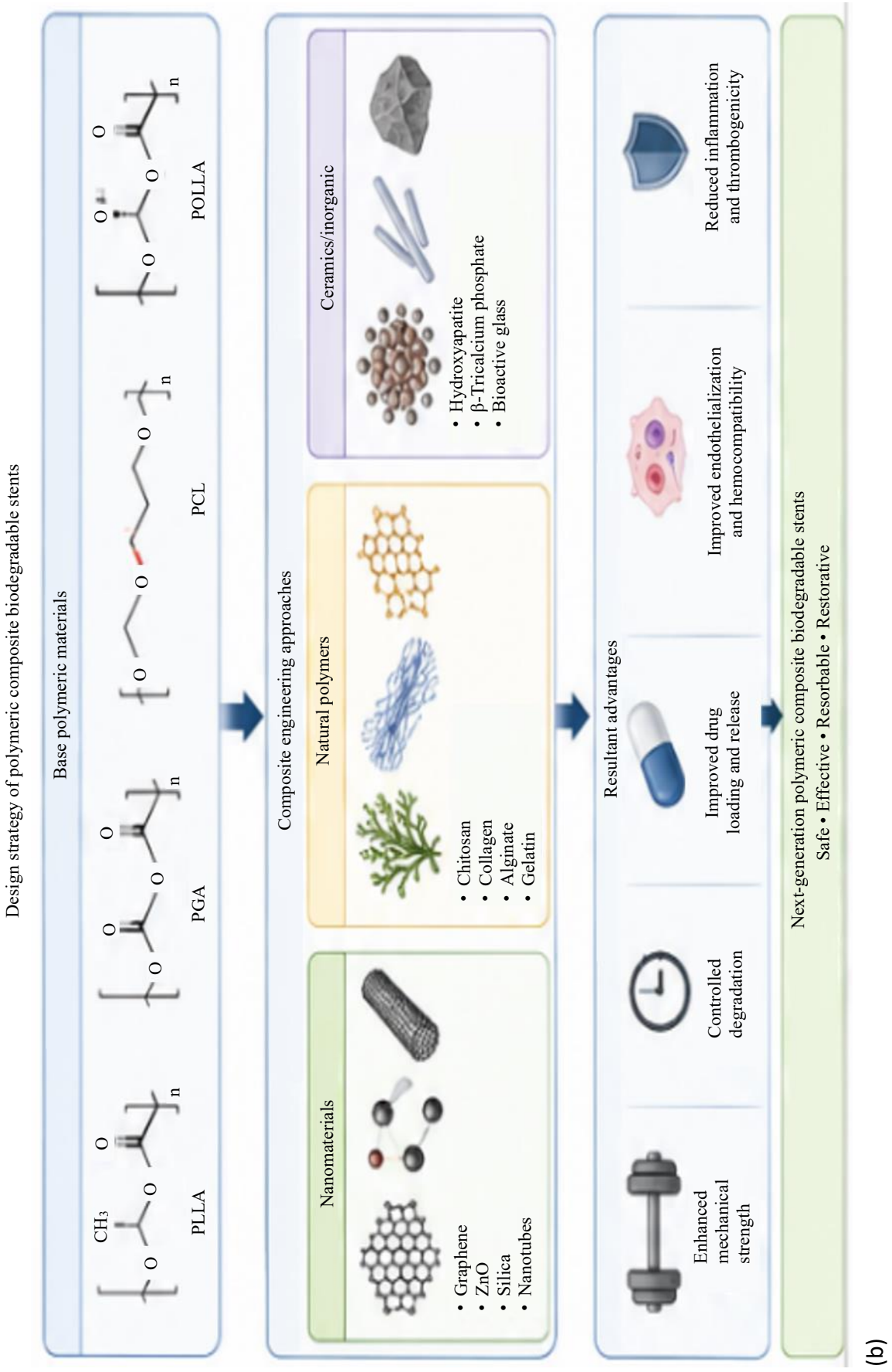

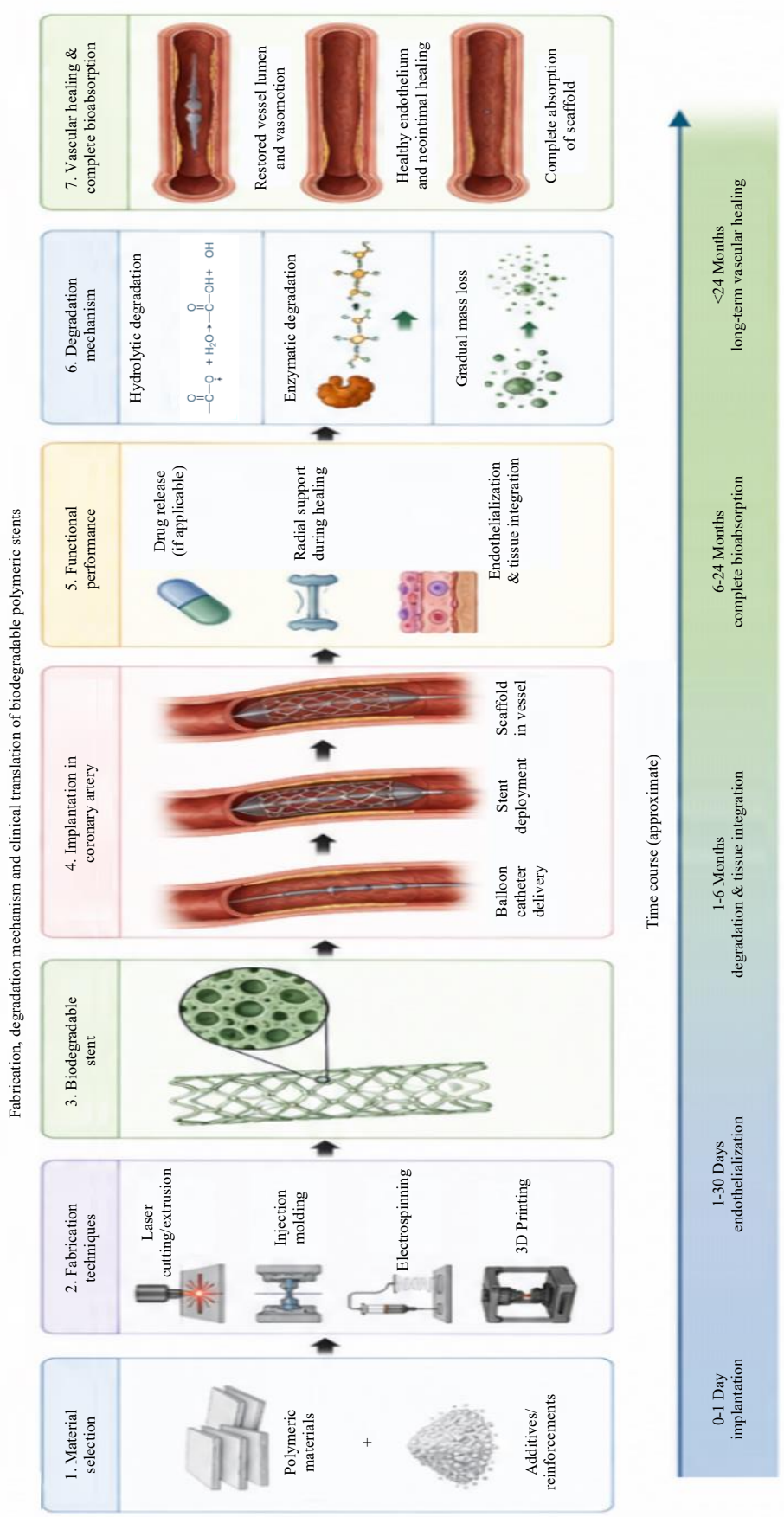

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Figure 1. Graphical overview of evolution, design strategy, fabrication, degradation mechanisms, and clinical translation of biodegradable polymeric composite stents for cardiovascular applications.

DEGRADATION MECHANISMS AND BIOLOGICAL INTERACTIONS OF POLYMERIC COMPOSITE STENTS

Mechanisms of Polymer

Degradation Stents made of polymeric materials biodegrade primarily by hydrolysis and enzymatic action. Hydrolysis of the ester bonds in polymers – such as PLLA, PGA, and PCL – results in polymer chain scission, molecular weight reduction, and a gradual decline in mechanical properties [22]. Factors – such as crystallinity, molecular weight, and hydrophilicity – can all influence the rate of hydrolysis. Hydrolytically unstable, highly crystalline polymers – such as PLLA – degrade at a much slower rate than amorphous copolymers such as PDLLA. Enzymatic degradation of synthetic polymers is not prominent; however, blends of synthetic and natural polymers – such as chitosan or collagen – are composites that facilitate the polymer's natural degradation.

Stages of Degradation

The degradation process of polymer stents is often divided into three phases [23].

- During phase one, Hydration, Water is encompassed in the stent. During which, the stent can maintain structural integrity and resist deformation.
- Loss of mechanical projection with ongoing degradation due to healing of a vessel loss of radial support is likely to occur. While this is collateral to the vascular function restoration.
- Loss of mass and resorption This describes the breakdown polymer steric structure descends hierarchies to oligomers and monomers to be either metabolized or excreted. The degradation products of PLLA polymer enter the Krebs cycle in the form of carbon dioxide and water.

Biology Concerning

Interactions with stents the responses to stent degradation are of great importance for the long-term prognosis. Deformation of the device should not cause local acid. This is also because local inflammatory responses and trombosis are not wanted [19]. Although, it is evident that in some cases the acidification of the local environment resulting in elevated lactate or glycolate level to a local inflammation trigger. To combat this some composites designed with buffering agents – like the phosphates of calcium or bioactive ceramics composites – to counter the acidification [24].

Reendothelialization and Hemocompatibility

The polymeric stents modification and performance is highly defined by hemocompatibility. Substrates featuring polymeric surfaces can capture and absorb thrombus formed plasma proteins with stents. It is, therefore, a requirement to change the surface-topography and particle bronze [25, 26]. Adjustments to the topography to Hydrophilic surfaces by means of plasma treatment or PEG (Poly-Ethylene Glycol) grafting resulted in lower protein adsorption and hence lower levels of platelets to thrombus. The encapsulated lower copolymers heparin or chitosan increases the anticoagulation [25].

Comparative analysis of biodegradable polymeric materials based on mechanical performance, degradation behavior, endothelialization, drug-delivery capability, major limitations, and current stage of clinical development (Table 3).

Table 3. Comparative evaluation of biodegradable polymeric stent materials.

Material	Radial strength	Degradation rate	Endothelialization	Drug delivery	Major limitation	Clinical status
PLLA	High	Slow	Moderate	Moderate	Thick struts, slow degradation	Widely Investigated.
PGA	High	Very Fast	Moderate	Low	Premature loss of support	Experimental.
PCL	Moderate	Very Slow	High	Excellent	Low stiffness	Experimental.
PDLLA	Moderate	Moderate	Moderate	Moderate	Lower mechanical strength	Investigational.
PLGA	Moderate	Tunable	Good	Good	Requires optimization	Investigational.
Polymeric Composites	High	Tunable	Excellent	Excellent	Manufacturing complexity	Emerging.

CURRENT CHALLENGES, RECENT ADVANCES, AND FUTURE PERSPECTIVES

Despite considerable progress in biodegradable polymeric composite stents, several scientific, engineering, and clinical challenges continue to hinder their widespread clinical adoption. Achieving an optimal balance between radial strength, controlled degradation, endothelialization, and long-term vascular remodelling remains a major challenge, as improvements in one property often compromise another. Although PLLA-based scaffolds provide favorable mechanical performance, their prolonged degradation and thick-strut architecture may delay vascular healing, whereas rapidly degrading polymers often fail to maintain sufficient mechanical support during the critical healing phase. Recent advances in composite engineering, nanotechnology, surface functionalization, and additive manufacturing have significantly improved material performance by enhancing mechanical stability, hemocompatibility, drug-loading capacity, and degradation control. Furthermore, emerging technologies – such as artificial intelligence, computational modelling, and patient-specific three-dimensional printing – are opening new opportunities for optimizing scaffold architecture and predicting long-term biological performance. Nevertheless, important knowledge gaps remain regarding long-term safety, standardized degradation assessment, large-scale manufacturing, and multicentre clinical validation. Future research should focus on integrating advanced biomaterials with intelligent design strategies, establishing standardized evaluation protocols, and conducting well-designed clinical studies to accelerate the translation of next-generation biodegradable polymeric stents into routine cardiovascular practice.

CONCLUSION

Expanding on IAVS systems, a rapid absorptive in situ stent deployable through a catheter for interventional procedure, converts to a temporary vascular implant which over time, is absorbed by the body, is slowly overtaking permanent metallic stents. The last 20 years have seen a marked understanding of stent engineering and the attendant biological interactions of the implant materials, through innovative research. Among the many stent fabrication materials, the unique characteristics of bioactive polymeric composite scaffolds, which integrate physical strength, biological responsiveness, and polymeric constituencies, are particularly noteworthy. At the core of nearly all polymeric stent scaffolds are poly (lactic) acid, poly (glycolic) acid, and poly (caprolactone), while adjunctive bioactive polymeric nanofillers, particularly natural polymers, serve to improve the stents hemocompatibility and potential for reendothelialization. Such polymeric composites, by virtue of their unique properties, permit the tailoring of stents to specific patients in terms of mechanical strength, rates of polymer erosion, and patterns of drug elution. Along with controlled macroscale and microscale features, stents manufactured by traditional polymer processing with newer technologies – such as 3D printing and sophisticated polymer surface modification to augment controlled multifunctional stent features – have unlocked the engineering potential of polymeric stents. The vascular healing response coupled with the stent erosion pattern, remains the most significant barriers to the clinical adoption. Polymeric composites are particularly well suited to addressing these barriers, though the clinical paradox of the interminable assimilation of delayed polymer stent reconstructive vasculature biocompatibility, pliability, and stent inflexibility are daunting.

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