Evolution of Vascular Stents: Advances in Materials, Structural Design, and Clinical Translation

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Abstract. This study presents a systematic review and meta-analysis on the evolution of vascular stents, with a focus on their clinical applications, material development, and structural innovations. The historical trajectory of stent technology is first outlined, tracing the progression from bare-metal stents (BMS) to drug-eluting stents (DES), and more recently to biodegradable and bioactive regenerative stents. The clinical performance and limitations of these devices are critically assessed, particularly regarding in-stent restenosis, thrombosis risk, biocompatibility, and mechanical durability. Furthermore, key studies published in international journals and major databases since 2010 are analyzed to evaluate the advantages and shortcomings of representative stent materials, including metallic alloys and biodegradable polymers. Based on these findings, the study proposes design strategies balancing clinical performance and biocompatibility. Specific recommendations are provided to guide the optimization of novel materials and structural designs. These design recommendations are expected to translate into improved patient outcomes — for example reduced need for reintervention, faster functional recovery, and lower long-term complication rates. We anticipate this review will guide next-generation stent innovation and accelerate clinical translation toward devices that improve patient outcomes and reduce the need for reintervention.

1 Introduction

In 2022, cardiovascular diseases (CVD) accounted for approximately 19.8 million deaths globally, a significant rise from 12.4 million in 1990. Despite a decline in age-standardized mortality rates, largely due to improved clinical management and demographic shifts, the absolute increase in CVD-related deaths underscores its persistent and substantial public health burden [1]. CVD encompasses a broad spectrum of disorders, including coronary artery disease, cerebrovascular events, and peripheral arterial disease, with ischemic heart disease and stroke alone responsible for nearly 85% of CVD mortality.

Endovascular stenting has become a cornerstone in the interventional treatment of CVD. In percutaneous coronary intervention (PCI), stents maintain vessel patency in stenotic or occluded coronary arteries, with over two million stents implanted globally each year. The application of stents has also expanded to neurovascular interventions; flow diverters, for instance, support embolization and flow modulation in complex intracranial aneurysms. Advances from balloon-expandable and self-expanding platforms to high-density woven flow diverters have improved both occlusion efficacy and safety in wide-neck aneurysm treatment [2]. In peripheral arterial disease (PAD), drug-eluting stents (DES) have become the standard of care, effectively reducing restenosis rates. The global PAD stent market reached USD 1.67 billion in 2022, with a projected annual growth rate of 7.4% [2].

These trends reflect not only the growing global burden of CVD but also substantial regional and disease-specific disparities. Over the past four decades, the evolution of vascular stents has centered on optimizing radial strength, biocompatibility, and endothelial healing. Initial stents in the 1980s and early 1990s were predominantly metallic, constructed from stainless steel or titanium alloys for their mechanical robustness and corrosion resistance. Notable examples include the Cordis Bx Velocity™ (316L stainless steel) and Abbott Multi-Link Vision™(L605 cobalt–chromium), which set benchmarks for procedural reliability.

By the mid-1990s, concerns about chronic inflammation and late restenosis led to the development of fully bioresorbable polymeric stents. Polylactic acid (PLA) devices, such as the Abbott Absorb™ GT1, offered temporary support with gradual resorption over two to three years. The early 21st century saw the advent of DES, combining antiproliferative agents (e.g., rapamycin, paclitaxel) with polymer coatings to inhibit neointimal hyperplasia. Devices like Boston Scientific's TAXUS™ Express² and Abbott's XIENCE™ V significantly reduced restenosis compared to bare-metal stents. More recently, focus has shifted toward bioactive metallic scaffolds that couple high radial strength with controlled biodegradation. Magnesium-based stents,

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such as Biotronik's Magmaris®, degrade within 6–12 months while releasing Mg^{2+} ions that enhance endothelialization. Iron-based absorbable stents also show promise in early studies. These next-generation devices aim to offer transient mechanical support while promoting vascular regeneration through metal-ion release or surface bioactivation.

Given the significance of stent technology in modern cardiovascular care, this review provides a systematic temporal analysis of clinical stent modalities, highlighting their respective strengths and limitations. It further explores how advancements in materials and structural designs shape the interplay between biocompatibility and mechanical performance. Ultimately, this work aims to inform the development of next-generation vascular scaffolds with improved safety, efficacy, and functional integration.

Current technical challenges include: (1) balancing material strength with degradation kinetics-for instance, conventional iron-based bioabsorbable scaffolds exhibit high strength but slow resorption, whereas high-nitrogen iron alloys, engineered via nanoscale twinning, achieve concurrent enhancements in strength and ductility, enabling thinner-strut designs; (2) optimizing surface functionalization-such as antithrombotic coatings and pro-endothelialization modifications-that require long-term safety validation; and (3) surmounting translational barriers, including discrepancies between animal models and the human vascular milieu, limited adaptability to complex lesions, and process-scale stability for mass production.

Future research is likely to emphasize multidisciplinary innovations-such as machine-learning-guided material discovery, organ-on-a-chip platforms for in vitro performance assessment, and bioreactor systems for scaffold maturation-to propel vascular-stent technology toward precision, intelligence, and tunable biodegradation. The present study aims to provide a systematic, temporal review of clinical stent modalities, delineating their respective advantages and constraints, and to elucidate how emerging materials and architectures influence the interplay of biocompatibility and mechanical performance, thereby informing the development of safer, more efficacious, and smarter vascular scaffolds.

2 Stent materials

2.1 Metal stent

The development of metallic stent materials has progressed from 316L stainless-steel bare-metal stents (BMS) and self-expanding memory-alloy devices to magnesium-based bioresorbable drug-eluting stents and, more recently, zinc-based alloys. These advancements reflect continuous efforts to optimize composition, manufacturing, surface modification, and in vivo performance, with each material class presenting distinct trade-offs between mechanical durability, biocompatibility, and long-term safety.

The Cordis Bx Velocity™ stent, fabricated from 316L stainless steel, represents a widely adopted BMS platform. Owing to its favorable mechanical strength and corrosion resistance, it provides reliable vascular scaffolding. Precision laser-cutting of the metallic tube ensures structural accuracy and reproducibility. Although Bx Velocity™ itself lacks a drug component, it served as the foundational platform for the first-generation drug-eluting stent, Cypher™, which incorporated a polymer coating and sirolimus to improve antirestenotic efficacy. The Bx Velocity™ exemplifies the advantages of stainless-steel BMS, including mature design, procedural simplicity, dependable performance, and cost-effectiveness, and has frequently functioned as a benchmark for subsequent stent innovations.

Nevertheless, inherent limitations of 316L stainless steel persist. Its non-degradable nature results in permanent vessel implantation, predisposing patients to long-term complications such as late thrombosis and chronic inflammation. Furthermore, compared with cobalt–chromium alloys, the lower strength of stainless steel necessitates thicker struts, which can exacerbate endothelial disruption and hinder vascular healing. These limitations underscore the impetus for transitioning toward higher-performance alloys and biodegradable alternatives in modern stent design. [3][4]

The Boston Scientific Wallstent™ is a self-expanding bare-metal stent designed for vascular reconstruction and a range of endovascular interventions. It is a non-degradable, non-drug-eluting memory-alloy device typically manufactured from Elgiloy (Phynox) or Nitinol. Elgiloy is an austenitic cobalt-based alloy with high Young's modulus, yield strength and fatigue strength, together with excellent corrosion resistance and biocompatibility, making it suitable for interventional medical devices; Nitinol provides a unique shape-memory effect that enables the stent to recover a preset diameter at body temperature (~37 °C) and offers superior conformability to bending and torsion, which is advantageous for long-term implantation in carotid, venous and peripheral arterial environments. The Wallstent™ is produced by braiding elastic alloy wires into a mesh; it combines high flexibility with a partially constrictable deployment design, and subsequent electrochemical polishing, passivation and the addition of radiopaque marker bands enhance X-ray visibility while balancing scaffolding and vessel conformity. Nevertheless, its lack of drug elution and permanent presence in the vessel raise long-term complication risks, and implantation can increase local vascular complexity and the potential need for secondary interventions. [5]

Magmaris® is a drug-eluting, bioresorbable metal stent manufactured from the WE43 magnesium alloy. It exhibits good biocompatibility and a controllable degradation rate, with inorganic salt products that are harmlessly metabolized; approximately 99.3% degradation is reported within about 12 months after implantation. The stent surface is coated with a poly(lactic-co-glycolic acid) (PLGA) layer loaded with the antiproliferative drug paclitaxel to inhibit neointimal hyperplasia and reduce restenosis. The drug coating releases progressively as the stent degrades, providing

sustained local pharmacotherapy. Magmaris® is fabricated by laser cutting from a single raw tube to preserve mechanical integrity, and its surface receives electrochemical polishing and passivation to form a dense oxide layer that improves corrosion resistance and biocompatibility. Limitations of this design include the lower structural strength of magnesium alloys compared with traditional cobalt-chromium or stainless-steel materials, resulting in reduced radial force that may limit use in complex lesions; additionally, magnesium alloys have relatively poor X-ray visibility, which can affect intraoperative positioning and postoperative assessment. [6]

Recent research has targeted the shortcomings of existing metal stents by developing novel alloy systems. For example, Zn–Ag alloy stents combine biodegradability with improved radiopacity, representing a significant advance in bioresorbable metal stent technology; the addition of silver not only increases material density and mechanical strength but also confers some anti-inflammatory effects. Animal studies in porcine coronary models have been completed and show promising prospects. [7] As shown in Figure 1, to reduce vessel complexity after implantation, investigators have also developed Zn–0.02Mg–0.02Cu alloy stents; by adding Mg and Cu, the degradation rate and structural strength of Zn can be tuned. Animal experiments in the carotid arteries of New Zealand white rabbits demonstrated effective vascular support, very low thrombosis risk, rapid endothelial healing and sustained vessel patency, suggesting this material as a candidate for peripheral or anatomically complex lesions. [8]

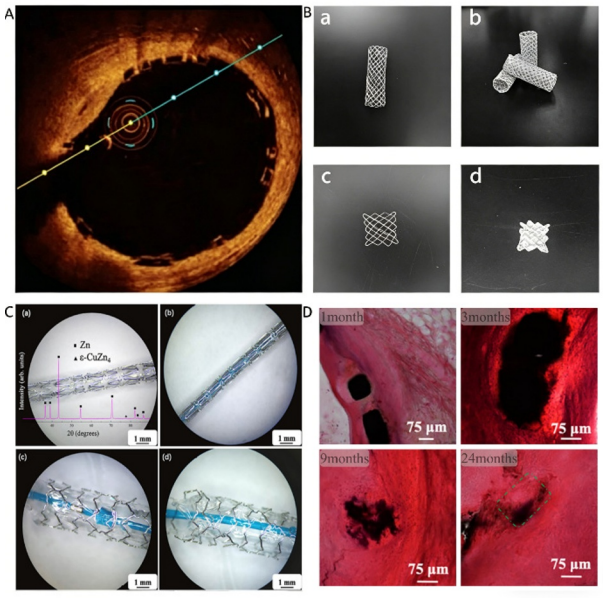

Figure 1. A) Optical coherence tomography (OCT) image of a Cobalt–Chromium stent. B) Microstructural image of a biodegradable magnesium alloy stent. C) Micrograph of a Zn–Cu alloy stent. D) Degradation process of a Zn–Cu alloy stent observed during biological experiments.

In summary, vascular stent materials have evolved from permanent bare-metal platforms to drug-eluting constructs and bioresorbable metal and alloy systems. From the mature, low-cost 316L stainless-steel Bx Velocity™ to braided Elgiloy/Nitinol memory-alloy devices and WE43 magnesium-based drug-eluting bioresorbable stents, and now to novel zinc-based alloys such as Zn–Ag and Zn–0.02Mg–0.02Cu, the field continues to seek an optimal balance among degradability, mechanical support, endothelial healing and radiographic visibility. These material and manufacturing advances provide multiple pathways for tailoring stent design to specific lesion types and clinical needs.

2.2 Polymeric stent

This section turns to polymeric scaffold technologies, which aim to overcome several inherent limitations of metal-based devices. Unlike permanent metallic implants, bioresorbable polymeric scaffolds provide temporary vascular support and are gradually absorbed after fulfilling their short-term mechanical role. This approach theoretically eliminates the long-term foreign-body burden, facilitates restoration of native vascular function, and reduces the complexity of potential secondary interventions. Following the rapid evolution of metal stents, several polymeric scaffold platforms have advanced into clinical and preclinical evaluation.

ART Pure™ (France) is a polymeric scaffold fabricated from a copolymer of approximately 98% L-lactide and 2% D-lactide (PDLLA), manufactured by laser cutting polymer tubes into precise stent geometries. [9] The device does not incorporate a drug coating, making it particularly suitable for patients with contraindications to dual antiplatelet therapy (DAPT). With a strut thickness of ~170 μm and a degradation period of approximately 24 months, ART Pure™ exhibits faster bioresorption and reduced vessel irritation compared with metal stents of similar dimensions, thereby promoting earlier vascular healing. However, its relatively large profile impairs deliverability, and the absence of an antiproliferative drug payload increases the risk of neointimal proliferation and recurrent thrombosis.

Fantom™ utilizes Tyrocore™, a proprietary iodinated tyrosine-derived polycarbonate (PTD-PC) material [10]. The scaffold is produced by injection molding followed by thermal processing and may be combined with a drug-eluting coating. Fantom™ features thinner struts (~125 μm) than many conventional PLA-based scaffolds while achieving tensile strengths of 100–110 MPa and elongations of 120–200%. Its degradation products are relatively mild, eliciting lower levels of inflammation and calcification compared with other polymers. A distinctive advantage is its intrinsic radiopacity, conferred by iodine incorporation, which enables direct X-ray visualization without the need for metallic markers. Nevertheless, its mechanical robustness—particularly under long-term implantation—remains inferior to metallic stents, and current clinical data are insufficient to establish long-term efficacy.

A woven, non-resorbable polyester (polyethylene terephthalate, PET) mesh scaffold developed by Akzo Research Laboratories and Akzo Fibres B.V. represents one of the few durable polymeric scaffold concepts. [11] As shown in Figure 2, constructed from medical-grade PET monofilaments through precision braiding and heat-set at 100 °C to fix a preset geometry and impart stable radial elasticity, this scaffold has filament diameters of roughly 176 μm and combines flexibility with radial support capable of self-expansion or adjunctive balloon dilation to achieve target vessel diameter. Its tensile strength approaches that of stainless-steel stents, while an elongation of 120 ± 15% markedly exceeds that of comparable metallic devices. The non-resorbable PET matrix ensures long-term mechanical support, although mild viscoelastic creep after prolonged loading may require compensation by pre-overdilation or selecting a larger nominal diameter. Histopathological analysis showed neointimal thickness (114 ± 38 μm) comparable to metal stents, but a somewhat higher peristrut inflammatory response and foreign-body fibrotic encapsulation—raising concerns about chronic inflammation and calcification. In animal studies, four-week patency was 84%, providing preliminary evidence of maintained vessel patency, but long-term safety and effectiveness remain to be validated in larger, longer follow-up studies.

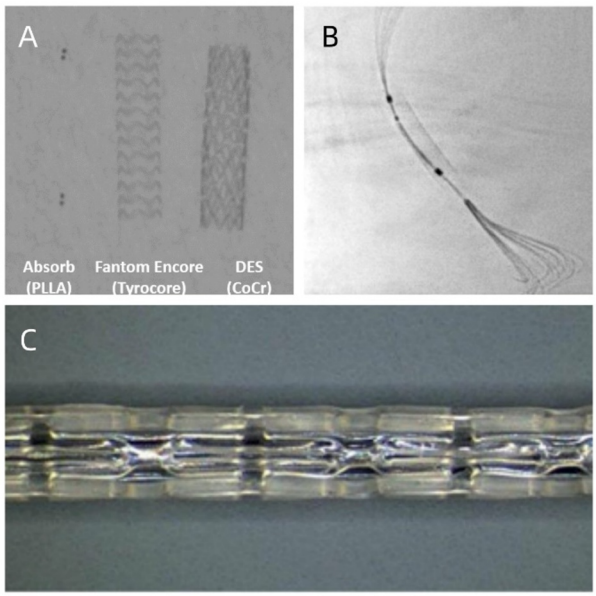

Figure 2. A) Comparative illustration of bioresorbable and metallic stents. B) Optical micrographs of the implantation process of a biodegradable stent. C) Image of a PLA-coated stent product.

Overall, polymeric scaffolds provide distinct advantages over metallic stents, particularly in their tunable degradation kinetics and structural adaptability. Nonetheless, achieving a balance between long-term biocompatibility and sustained mechanical integrity remains a major challenge. Ongoing research has therefore focused on refining polymer chemistry and processing strategies. For instance, a study published in EuroIntervention demonstrated that precise adjustment of the L- to D-lactide monomer ratio can optimize polymer crystallinity and segmental relaxation behavior [12], thereby enabling coordinated control of scaffold performance without reliance on composite fillers. Through thermal processing, local crystalline domain distribution was modulated to enhance initial radial stiffness while limiting acute recoil. Follow-up evaluations indicated that this stereocomposite design maintained stable mechanical support during the critical early healing phase, exhibited predictable and uniform degradation, promoted favorable re-endothelialization, and elicited minimal chronic inflammatory responses. Collectively, these findings highlight stereocomposite engineering as a promising strategy to reconcile the competing demands of mechanical strength and biocompatibility in polymeric scaffold development.

2.3 Polymeric stentage standardized mortality rates

This section turns to composite scaffold strategies, which aim to overcome the intrinsic limitations of single-material implants. By integrating two or more distinct constituents, composite scaffolds can offset the deficiencies of individual materials and deliver a more balanced combination of mechanical performance, degradation kinetics, and biological functionality.

Composite scaffolds are intraluminal support devices fabricated by physically or chemically combining multiple substances, most commonly metallic frameworks with polymeric coatings, polymer matrices with inorganic fillers, or multilayered multiphase architectures. These designs seek to reconcile conflicting requirements that are difficult to achieve with single materials—such as high radial strength, tunable biodegradability, and favorable biocompatibility. For instance, metal–polymer composites can couple robust initial mechanical support with localized drug delivery, while polymer–ceramic or polymer–glass fiber systems can enhance bulk modulus and promote tissue integration. To achieve reliable performance, strong interfacial bonding or mechanical interlocking between phases is essential, with fabrication methods including co-extrusion, solution casting, spray coating, and additive manufacturing employed to ensure homogeneous distribution and precise microstructural control.

In clinical use, composite scaffolds are designed to provide sufficient radial support during the critical early healing period, followed by a gradual transition to biological load bearing through polymer degradation or host tissue ingrowth. This controlled progression is expected to minimize complications such as chronic inflammation, delayed endothelialization, and late-stage calcification. Owing to these advantages, composite scaffolds represent a promising and increasingly important direction for the future development of vascular stent materials.

The most common class comprises metal frameworks with drug-eluting polymer coatings. This design has undergone extensive clinical testing and captures a substantial market share. However, differences in

toughness and degradability between the metal scaffold and the composite coating often lead to imperfect adhesion over the device's working life, and researchers continue to seek engineering solutions to this mismatch. The TAXUS paclitaxel-eluting coronary stent is a notable example. [13] It combines a stainless-steel scaffold with a proprietary triblock copolymer coating (SIBS: styrene–isobutylene–styrene) loaded with paclitaxel and applied by solution spray followed by crosslinking. The SIBS coating is roughly 10 μm thick, chemically inert and mechanically tough; it showed no molecular-weight degradation or fracture after 4 × 10^8 pulsatile fatigue cycles (equivalent to ~10 years of heartbeats) and remained intact without delamination in animal models (rabbit 24 months, porcine 6 months). Its permanent, non-resorbable character provides long-term radial support and predictable drug-release kinetics while avoiding the inflammatory burden associated with polymer degradation products. Preclinical data reported 100% vessel patency at 6 months and favorable histology, establishing durable non-resorbable polymer coatings as a viable approach for controlled drug delivery in stents.

A contrasting composite strategy accelerates metallic corrosion by applying a degradable polymer layer to an iron backbone. A recently developed iron-based metal–polymer composite bioresorbable coronary scaffold uses an iron-alloy frame coated uniformly with a degradable polymer (PLA) to promote homogeneous iron corrosion, addressing the slow degradation and suboptimal biocompatibility of pure-iron scaffolds. The polymer's rapid water-uptake and hydrolytic action accelerate uniform iron corrosion, while serum antioxidants such as albumin were found in vitro to mitigate excessive corrosion and preserve biological safety. In porcine models and a first-in-human implantation, this composite scaffold demonstrated controllable degradation rates, good biocompatibility, sufficient early mechanical support and favorable endothelialization, pointing to a metal–polymer synergistic strategy for translating degradable metal scaffolds into clinical use.

Beyond metal–polymer hybrids, polymer–phosphate-glass-fiber composites represent another emerging class of fully resorbable scaffolds. These devices embed phosphate glass fibers within a polylactic acid (PLA) matrix to overcome PLA's limited strength and uncontrolled degradation. Composites containing 15–30 wt% phosphate glass show markedly increased elastic modulus (up to ~80% improvement) while maintaining comparable extensibility to pure PLA at a 15 wt% loading; in simulated body fluids, protein components such as albumin slow glass dissolution, helping preserve mechanical support and biosafety. Dynamic degradation tests and in vivo models demonstrated a controllable two-stage degradation profile, good biocompatibility, sustained early mechanical support and a progressive shift of load from material to tissue—evidencing the promise of a polymer–glass cooperative degradation strategy for fully bioresorbable scaffolds. [14]

3 Conclusions

Metallic, polymeric, and composite stents each embody distinct advantages and limitations. Metallic stents remain superior in mechanical robustness and radiographic visibility, yet their permanence within the vessel can lead to long-term complications such as late thrombosis and chronic inflammation. Polymeric stents, by contrast, introduce biodegradability and generally favorable biocompatibility, reducing the long-term foreign-body burden; however, their relatively limited mechanical durability and reduced radiopacity remain key challenges. Composite stents seek to reconcile these trade-offs by integrating complementary materials to provide both structural support and biological functionality, though this comes at the cost of increased design and manufacturing complexity.

Looking forward, the trajectory of stent innovation will increasingly depend on advances in materials science. Emerging bioresorbable metal alloys and functionalized polymer systems hold the potential to couple mechanical strength with enhanced biocompatibility, while multiphase and composite constructs may enable predictable degradation kinetics and improved clinical adaptability. In parallel, refinements in microstructural engineering and processing techniques are expected to facilitate more reliable performance and greater personalization of device design. These insights are expected to guide next-generation stent innovation and clinical translation — ultimately improving patient outcomes, reducing reinterventions, and shortening recovery times.

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