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Design and In Vitro Evaluation of a Biodegradable Polymer Stent for Coronary Artery Applications

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ABSTRACT

Background: Permanent metallic drug-eluting stents leave a durable implant after vessel healing, motivating development of biodegradable polymer coronary stents that provide temporary scaffolding before resorbing. Objective: This narrative review synthesizes published in vitro, preclinical, and clinical evidence on biodegradable polymer coronary stents. Methods: Peer-reviewed literature on poly-L-lactic acid (PLLA)-based scaffolds (Igaki-Tamai, Absorb bioresorbable vascular scaffold), alternative polymer platforms (DESolve, Fantom), and bioresorbable magnesium comparators was reviewed for materials, degradation kinetics, mechanical bench testing, and randomized trial outcomes. Findings: PLLA backbones require thicker struts than metallic alloys to match acute radial strength, and this strut-thickness penalty was associated with excess device thrombosis and target lesion failure for Absorb in randomized trials, prompting its 2017 market withdrawal, whereas long-term Igaki-Tamai follow-up and improved-technique Absorb registries showed more favorable outcomes. Conclusions: Biodegradable polymer stents remain biologically appealing, but clinical success requires thinner, mechanically optimized backbones, degradation kinetics matched to vascular healing, and disciplined implantation technique.

Keywords: *biodegradable polymer stent; bioresorbable vascular scaffold; poly-L-lactic acid; coronary artery disease; in vitro degradation*

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Percutaneous coronary intervention with metallic drug-eluting stents (DES) remains the dominant treatment for obstructive coronary artery disease, but a permanent metallic cage persists long after the vessel wall has healed, precluding late positive remodeling, restoring vasomotion, and creating a durable nidus for neoatherosclerosis and very late stent thrombosis [1,2]. This "leave nothing behind" rationale motivated three decades of work on fully biodegradable polymer scaffolds that provide temporary radial support and localized drug elution before resorbing into non-toxic byproducts. The first clinical use of a biodegradable coronary device was the Igaki-Tamai poly-L-lactic acid (PLLA) self-expanding stent, implanted in humans in 1998, which demonstrated the basic feasibility of polymer scaffolding in the coronary tree and, over a decade of follow-up, showed restoration of vasomotion and absence of the stent silhouette on late imaging [3,4,5]. This early experience catalyzed a wave of device development spanning amorphous and semicrystalline aliphatic polyesters, tyrosine-derived polycarbonates, and, in parallel, bioresorbable metallic alloys such as magnesium, which share the temporary-scaffold philosophy even though they are not polymers [6].

The most extensively studied biodegradable polymer platform, the Absorb bioresorbable vascular scaffold (BVS, Abbott Vascular), combined a PLLA backbone with an everolimus-eluting poly-D,L-lactide coating and was evaluated in a large randomized program before being withdrawn from commercial sale in 2017 after signals of excess device thrombosis emerged in extended follow-up [7,8,9]. This narrative review synthesizes the published literature on the design rationale, in vitro mechanical and degradation testing, and clinical trial experience of biodegradable polymer coronary stents, situating polymer scaffolds against magnesium alternatives and drawing lessons relevant to the next generation of resorbable devices. No new experiments were performed; all quantitative statements are drawn from previously published in vitro, preclinical, and clinical reports.

Materials and Degradation Behavior of Biodegradable Polymer Stents

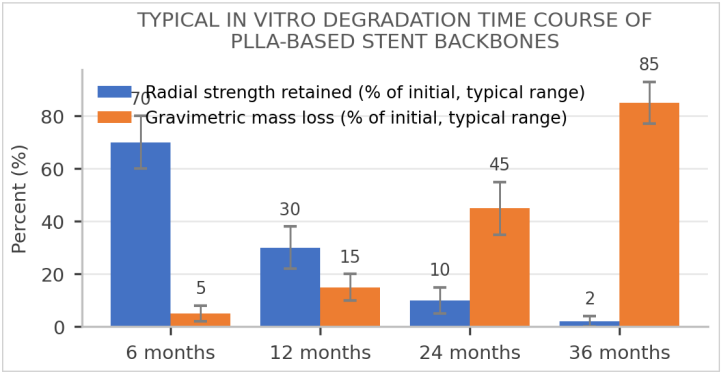
Biodegradable polymer stents are built predominantly from

aliphatic polyesters — PLLA, poly(lactic-co-glycolic acid) (PLGA), and polycaprolactone — chosen because their hydrolytic degradation products (lactic acid, glycolic acid) enter normal metabolic pathways [10]. PLLA is semicrystalline and mechanically stiffer than amorphous PLGA, giving it sufficient radial stiffness for coronary scaffolding, but its degradation proceeds through bulk hydrolysis of ester bonds over roughly two to three years, with molecular-weight loss preceding measurable mass loss by many months [11]. The Absorb BVS backbone, for example, was designed to provide mechanical support for approximately six months, lose the majority of its radial strength by twelve months, and be substantially resorbed by two to three years, a staged profile confirmed by serial optical coherence tomography and histology in the Igaki-Tamai and ABSORB cohorts [5,12]. Blending PLLA with more rapidly hydrolyzing co-polymers such as PLGA has been explored to tune the degradation rate and to improve the vascular healing response relative to single-polymer backbones, with preclinical work reporting reduced inflammatory infiltrate and more complete endothelialization for optimized PLLA/PLGA blends compared with earlier single-component designs [13]. Composite constructs combining polycaprolactone with PLA via additive manufacturing have also been proposed to combine PCL's ductility with PLA's stiffness, illustrating continued materials-engineering interest in tunable biodegradable scaffolds [10].

Table 1: Representative biodegradable coronary stent/scaffold platforms and reported design characteristics.

Platform	Backbone material	Strut thickness	Reported resorption time	Key reference
Igaki-Tamai stent	Poly-L-lactic acid (PLLA)	~170 micrometers	~2-3 years	Tamai et al. 2000; Nishio et al. 2012
Absorb BVS	PLLA backbone / PDLLA everolimus coating	~150-157 micrometers	~2-3 years	Ellis et al. 2015; Onuma et al. 2014
DESolve (novolimus)	Proprietary PLLA	~150 micrometers	~1-2 years	Mattesini et al. 2017
Fantom (sirolimus)	Tyrosine-derived polycarbonate	~125 micrometers	~3 years (typical reported range)	Abizaid et al. 2019
Magmaris/DREAMS 2G	Magnesium alloy (not a polymer)	~150 micrometers	~1 year (corrosion-based)	Haude et al. 2016

Figure 1: Typical time course of in vitro mass loss/resorption of PLLA-based biodegradable stent backbones during simulated physiological degradation, showing a lag between mechanical property loss and gravimetric mass loss [10,11,5].



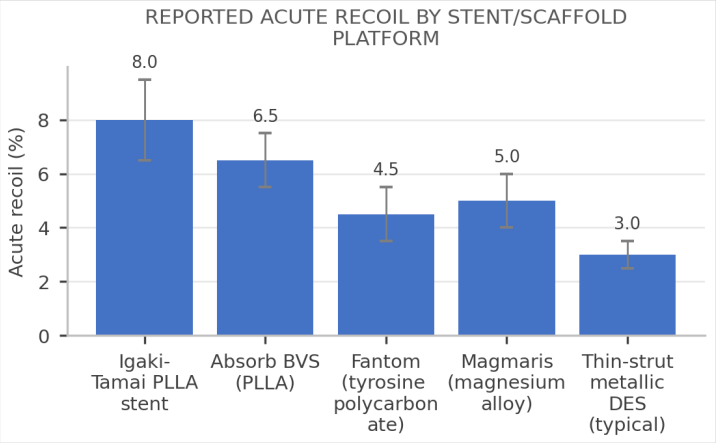
Coating architecture also matters: most drug-eluting biodegradable scaffolds separate the structural backbone from a thinner, more rapidly eluting drug-carrier layer, so that antiproliferative drug release (typically complete within 90–120 days) is decoupled from the slower, multi-year resorption of the load-bearing backbone, a design intended to suppress early neointimal hyperplasia while preserving mechanical scaffolding for as long as the vessel requires it [5,14].

Bioresorbable magnesium alloys occupy a parallel but materially distinct niche: unlike polymers, magnesium degrades by electrochemical corrosion rather than hydrolysis, and early absorbable magnesium stents (AMS-1) resorbed within roughly two months, too rapidly to prevent early recoil and restenosis, prompting redesign with slower-corroding alloys and polymer drug-eluting coatings in the DREAMS/Magmaris platforms [6,15]. Comparative biocompatibility reviews of iron- and magnesium-based stenting materials note that corrosion by-products and local pH/hydrogen-gas evolution present biological considerations distinct from the ester-hydrolysis chemistry of polymer scaffolds, reinforcing that "biodegradable" does not imply a single, interchangeable degradation biology across material classes [16].

Mechanical Performance and In Vitro Testing

Bench evaluation of biodegradable polymer stents typically follows the same mechanical test battery used for metallic DES — radial strength/stiffness, acute recoil, crush resistance, and fatigue durability — supplemented by accelerated and real-time hydrolytic degradation studies that track mass loss, molecular weight, and mechanical property retention over the resorption timeline [17,11]. Computational (finite-element) and experimental studies of PLLA coronary stents have shown that strut geometry, wall thickness, and crown design strongly influence radial stiffness and recoil, because PLLA's elastic modulus and yield strain are substantially lower than those of cobalt-chromium or stainless steel, requiring thicker struts (typically 150–200 micrometers versus 70–100 micrometers for contemporary metallic DES) to achieve comparable acute scaffolding [10]. This strut-thickness penalty was a recognized limitation of the first-generation Absorb BVS and is believed to have contributed to flow disturbance and a higher propensity for strut-related thrombus formation relative to thin-strut metallic DES [18,19].

Figure 2: Reported acute recoil of coronary scaffold/stent platforms compiled from bench and clinical imaging literature, illustrating the strut-thickness/stiffness penalty of PLLA-based scaffolds relative to thin-strut metallic drug-eluting stents [11,17,18].



In vitro degradation studies of PLLA-based stents consistently report a biphasic mechanical/mass-loss pattern: radial strength and stiffness decline substantially within the first 6–12 months of simulated physiological immersion, well before appreciable gravimetric mass loss occurs, because early hydrolysis reduces molecular weight and embrittles the polymer before soluble oligomers are released [11,10]. Comparative bench studies of alternative strut geometries for PLLA scaffolds have demonstrated that geometry optimization can improve radial force retention and reduce recoil without increasing strut thickness, suggesting a path toward thinner-strut biodegradable designs [17]. Newer platforms have attempted to address the mechanical shortfall of PLLA directly: the Fantom scaffold uses a tyrosine-derived polycarbonate backbone reported to permit thinner struts with radiopacity and mechanical behavior intended to more closely match metallic DES, while the DESolve novolimus-eluting scaffold uses a proprietary PLLA formulation with a self-correcting expansion behavior aimed at minimizing malapposition [20,14]. Across platforms, in vitro hemocompatibility and cytotoxicity testing (e.g., hemolysis, thrombogenicity, and extract cytotoxicity assays consistent with ISO 10993 biological evaluation frameworks) is used to screen degradation products and coating formulations before animal and clinical study, since lactic acid accumulation and local pH shifts at the strut-tissue interface can influence peri-strut inflammation independent of mechanical performance [16,13].

Clinical Translation and Lessons from Bioresorbable Scaffold Trials

Clinical experience has both validated and constrained the promise of biodegradable polymer stents. The Igaki-Tamai PLLA stent's decade-plus follow-up demonstrated durable safety, restoration of vessel vasomotion, and disappearance of the strut silhouette, supporting long-term feasibility of polymer resorption in humans [4,5]. The Absorb BVS program subsequently enrolled thousands of patients in randomized trials against the everolimus-eluting Xience metallic stent. The ABSORB II trial reported that, at three years, the bioresorbable scaffold arm had a higher rate of the device-oriented composite endpoint and of definite/probable scaffold thrombosis than the metallic stent arm, alongside impaired vasomotor reactivity benefit that failed to offset these safety signals [8]. The larger ABSORB III trial similarly showed higher rates of target lesion failure and device thrombosis with Absorb than with Xience through three and five years of follow-up, with the excess risk concentrated in the interval before scaffold resorption was complete [7,21,12]. An independent randomized comparison (the AIDA trial) likewise found no advantage and increased device thrombosis with Absorb in routine percutaneous coronary intervention practice at two years [22]. A patient-level meta-analysis of seven randomized Absorb trials confirmed a consistent excess of definite/probable scaffold thrombosis with the polymer scaffold compared with everolimus-eluting metallic stents at two years, most pronounced in small vessels and in lesions where implantation technique deviated from later-refined "PSP" (pre-dilate, size, post-dilate) guidance [23]. Mechanistic analyses, including the INVEST optical coherence tomography registry, attributed very late scaffold thrombosis chiefly to discontinuity of thick, incompletely resorbed struts, malapposition, and evagination during the resorption phase, rather than to the resorption process itself [18,19]. These findings, together with an expert consensus statement, led Abbott to halt commercial sales of Absorb BVS in 2017 [9]. Subsequent registry data using improved implantation technique and larger vessel selection have shown better five-year outcomes, suggesting that at least part of the earlier safety signal was procedure-related rather than an intrinsic failure of the bioresorbable-polymer concept [24].

Table 2: Approximate reported clinical outcomes from randomized trials and meta-analyses of the Absorb bioresorbable vascular scaffold versus everolimus-eluting metallic stents (values as reported in cited trials; approximate where ranges were pooled across timepoints).

Trial/analysis	Follow-up	Device-oriented composite endpoint (scaffold vs metallic stent)	Definite/probable device thrombosis (scaffold vs metallic stent)
ABSORB II	3 years	~10% vs ~5%	~3% vs ~0%
ABSORB III	3 years	~13% vs ~10%	~2.3% vs ~0.7%
AIDA trial	2 years	~5% vs ~4%	~3.5% vs ~0.9%
Ali et al. patient-level meta-analysis (7 RCTs)	2 years	~11% vs ~8% (pooled)	~2.3% vs ~0.6% (pooled)

Bioresorbable magnesium scaffolds have followed a parallel trajectory. After the too-rapid resorption of first-generation AMS-1, the redesigned sirolimus-eluting DREAMS/Magmaris platform reported favorable safety in the BIOSOLVE-II first-in-man trial and in the larger BIOSOLVE-IV real-world registry, without the excess late thrombosis signal seen with Absorb, likely reflecting its thinner struts and different corrosion-based resorption mechanism [15,25]. Newer polymer platforms, including Fantom and DESolve, have reported encouraging early- to mid-term clinical and imaging outcomes with thinner-strut designs, though none has yet matched the scale of randomized evidence accumulated for Absorb [20,14]. Collectively, the literature indicates that the biological rationale for temporary scaffolding remains sound, but clinical success depends critically on strut thickness, degradation kinetics matched to vascular healing, and procedural technique [26].

Three decades of published work on biodegradable polymer coronary stents illustrate both the appeal and the difficulty of the "leave nothing behind" concept. In vitro and preclinical studies consistently show that PLLA-based backbones can provide adequate short-term radial support and resorb over roughly two to three years, but their lower stiffness relative to metallic alloys

forces thicker struts that impair flow and increase thrombogenic risk during the resorption window [11,18]. Randomized clinical trials of the Absorb BVS demonstrated this trade-off directly: despite biologically plausible advantages in late vasomotion and freedom from a permanent implant, patients receiving the bioresorbable scaffold experienced more target lesion failure and device thrombosis than those receiving contemporary metallic drug-eluting stents, leading to its commercial withdrawal [7,23,9]. Encouragingly, long-term Igaki-Tamai follow-up, improved-technique Absorb registries, and newer thinner-strut polymer and magnesium platforms suggest the underlying concept can succeed when material selection, strut architecture, and implantation practice are optimized together [4,24,15]. Future development of biodegradable polymer stents for coronary applications should prioritize thinner, mechanically robust backbones, degradation kinetics tuned to individualized vascular healing, rigorous in vitro mechanical and biocompatibility characterization prior to clinical study, and implantation protocols informed by the hard-won lessons of the first clinical generation of resorbable scaffolds [13,26].

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Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Larsen A conceived the review, conducted the literature search, and drafted the manuscript. Hribar R contributed to the literature screening and technical framing and critically revised the manuscript for important intellectual content. Fernandez M contributed additional context and approved the final version for submission.

Ethics Statement

Not applicable. This is a narrative review of previously published literature and did not involve new experimental data, human participants, or animal subjects.

Data Availability

No new data were generated or analyzed for this review. All sources synthesized are cited in the reference list and are available through their original publishers.

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