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Safety and Efficacy of Magmaris Bioresorbable Scaffolds Versus Contemporary Drug-Eluting Stents Including Biomatrix, Ultimaster, Orsiro, and Xience in Patients With Coronary Artery Disease: A Comprehensive Systematic Review and Extended Meta-Analysis

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Abstract

Background: Coronary artery disease (CAD) continues to be a leading cause of morbidity and mortality worldwide despite advances in percutaneous coronary intervention (PCI). While contemporary drug-eluting stents (DES) have improved outcomes, their permanent metallic structure is associated with late complications. The Magmaris bioresorbable magnesium scaffold (BRS) offers a temporary support system with gradual resorption, potentially reducing long-term adverse events.

Methods: A systematic review and meta-analysis was performed to compare the safety and efficacy of Magmaris BRS with contemporary DES platforms, including Biomatrix, Ultimaster (thin-strut), and Orsiro(ultrathin-strut), in patients undergoing PCI for de novo CAD. PubMed, Scopus, and ScienceDirect were searched up to March 1, 2026. Eligible studies included prospective trials, registries, and cohorts reporting outcomes such as target lesion failure (TLF), scaffold/stent thrombosis, myocardial infarction (MI), and target vessel revascularization with at least 6 months of follow-up. Data were pooled using a DerSimonian–Laird random-effects model, with subgroup analyses based on clinical and demographic factors.

Results: 36 studies comprising over 25,000 patients were included. Magmaris BRS showed low rates of all-cause mortality (1%), thrombosis (1%), and MI (2%), comparable to DES. However, subgroup analyses revealed a clinically relevant time-dependent increase in TLF and target lesion revascularization with Magmaris (rising from ~2% at 1 year to ~6% at 2 years), suggesting potential late vulnerability during the scaffold resorption phase. Heterogeneity was low for safety outcomes and moderate to high for efficacy endpoints.

Conclusion: Magmaris BRS demonstrates acceptable medium-term safety and comparable efficacy to modern DES, supporting its use as an alternative to permanent stents in selected patients. Further long-term randomized studies are required to confirm these findings and define optimal patient selection. However, the relatively short follow-up duration across most studies limits assessment of long-term outcomes, which is particularly critical for bioresorbable technologies.

Keywords: Coronary artery disease; Magmaris, Bioresorbable scaffold; Drug-eluting stent; Percutaneous coronary intervention; Target lesion failure; Stent thrombosis.

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List of Abbreviations

CAD: Coronary Artery Disease

PCI: Percutaneous Coronary Intervention

DES: Drug-Eluting Stents

BRS: Bioresorbable Scaffold(s)

ACS: Acute Coronary Syndrome(s)

TLF: Target Lesion Failure

MI: Myocardial Infarction

MACE: Major Adverse Cardiovascular Events

STEMI: ST-Elevation Myocardial Infarction

NSTEMI: Non-ST-Elevation Myocardial Infarction

ID-TLR: Ischaemia-Driven Target-Lesion Revascularisation

TV-MI: Target Vessel Myocardial Infarction

TLR: Target Lesion Revascularization

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis

PICOS: Population, Intervention, Comparator, Outcome, Study Design

MeSH: Medical Subject Headings

CI: Confidence Interval(s)

ARC: Academic Research Consortium (ARC-2 definitions for stent/scaffold thrombosis).

Background

Coronary artery disease (CAD) is still one of the major causes of morbidity and death globally; therefore, advancements in percutaneous coronary intervention (PCI) methods and device technology are constantly needed. By lowering restenosis and the need for repeated revascularization, drug-eluting stents (DES) have greatly enhanced clinical outcomes. However, long-term issues with permanent metallic implants-including late stent thrombosis, decreased vasomotion, and chronic inflammation—have influenced the development of next-generation stents, such as bioresorbable scaffolds (BRS) and ultrathin-strut drug-eluting stents [1,2].

The Magmaris bioresorbable magnesium scaffold has become a novel alternative among these developments, providing the mechanical support of conventional DES while removing the presence of foreign bodies over an extended period of time. Its positive safety and efficacy profile has been shown in recent single-arm studies with encouraging outcomes in vulnerable groups such as diabetic patients and those with acute coronary syndrome (ACS). [3-5]. The effectiveness of Magmaris in controlled and real-world clinical settings has been further supported by the BIOSOLVE-IV registry which demonstrated minimal rates of scaffold or stent thrombosis and target lesion failure [6]. At the same time, the Orsiro ultrathin-strut (≈60 µm struts) sirolimus-eluting stent and the Ultimaster thin-strut (≈80 µm struts) sirolimus-eluting stent—each have become more well-known because of their better durability, delivery, and healing profiles [7-9]. Furthermore, reduced restenosis, lower target lesion revascularization, and fewer adverse cardiac events (ACEs) are among the best long-term results related to these stents, as shown by clinical studies and registry data [10-14]. Ultrathin-strut DES has proven to be more effective than regular stents in head-to-head comparisons in randomized settings, especially when it comes to enhancing vascular repair and minimizing late lumen loss [1,9]. Despite these promising results, data from randomized controlled trials remain limited for more recent technologies like Magmaris. Single-arm observational studies continue to be a crucial source of empirical knowledge, providing important information about how well these devices function in various clinical and anatomical contexts [3,5]. In order to evaluate the clinical results of the Magmaris bioresorbable magnesium scaffold in relation to Biomatrix, Ultimaster, and Orsiro sirolimus-eluting stents in patients with de novo coronary artery disease, this systematic review and meta-analysis attempts to compile the most recent data. This review will offer a thorough assessment of these developing percutaneous coronary intervention techniques—with an emphasis on target lesion failure (TLF), all-cause mortality, cardiac death, myocardial infarction (MI), target-vessel myocardial infarction (TV-MI), ischaemia-driven target-lesion revascularisation (ID-TLR), and definite/probable stent/scaffold thrombosis—in order to support clinical decision-making and direct future comparative studies. However, the currently available evidence is largely limited to short- and mid-term follow-up, which remains a critical gap given that the theoretical advantages of bioresorbable scaffolds are expected to emerge over longer time horizons.

Methods

We conducted a systematic review and single-arm meta-analysis specified in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA). Our review was registered at the Open Science Framework before it was undertaken (OSF ID: 10.17605/OSF.IO/PE6SU) (Figure S50).

Search Strategy and Data Sources

A comprehensive literature search was conducted using several electronic databases from inception until March 1, 2026, including PubMed, Scopus, and ScienceDirect. Two authors independently performed the search to ensure accuracy and minimize bias. The search strategy included

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combinations of keywords and MeSH terms such as "drug-eluting stent," "biodegradable scaffold," "clinical outcomes," "stent thrombosis," and "myocardial infarction." Boolean operators (AND, OR) were applied to maximize sensitivity. No restrictions were imposed on language or publication date, ensuring a comprehensive and unbiased retrieval of relevant studies. The full search strategy is detailed in Table 5.

Table 5: Search strateg.

Database	Search Terms / Strategy	Filters / Limits Applied	Date of Search	Results
PubMed	("drug-eluting stent"[MeSH Terms] OR "biodegradable scaffold" OR "DES" OR "Magmaris" OR "Orsiro" OR "Biomatrix" OR "Ultimaster") AND ("clinical outcomes" OR "stent thrombosis" OR "myocardial infarction" OR "target lesion failure")	No language or date restrictions	March 1 , 2026	9681
Scopus	TITLE-ABS-KEY("drug-eluting stent" OR "biodegradable scaffold" OR "DES" OR "Magmaris" OR "Orsiro" OR "Biomatrix" OR "Ultimaster") AND TITLE-ABS-KEY("clinical outcomes" OR "stent thrombosis" OR "myocardial infarction" OR "target lesion failure")	No limits	March 1 , 2026	5758
ScienceDirect	("drug-eluting stent" OR "biodegradable scaffold" OR "DES" OR "Magmaris" OR "Orsiro" OR "Biomatrix" OR "Ultimaster") AND ("clinical outcomes" OR "stent thrombosis" OR "myocardial infarction" OR "target lesion failure")	No limits	March 1 , 2026	6583

Study Selection Criteria

Eligibility was defined using the PICOS scheme. Trials were required to enroll adults (≥18 years) with angiographically confirmed de novo coronary lesions receiving PCI due to either acute coronary syndromes (STEMI, NSTEMI, unstable angina) or stable coronary artery disease. Eligible devices included: (1) Magmaris bioresorbable magnesium scaffold (sirolimus-eluting), (2) Orsiro ultrathin-strut metallic sirolimus-eluting stent, (3) Ultimaster thin-strut metallic sirolimus-eluting stent, and (4) Biomatrix stent. At least one adjudicated clinical endpoint had to be reported at ≥6 months (preferably ≥12 months): target-lesion failure (TLF), all-cause mortality, cardiac death, myocardial infarction (MI), target-vessel MI, ischaemia-driven target-lesion revascularisation (ID-TLR), or definite/probable stent/scaffold thrombosis (ARC-2 definitions). Prospective single-arm observational studies, registries, cohorts, and single arms of randomised controlled trials were eligible. Exclusions included case reports, case series (<10 patients), retrospective chart reviews lacking prospective outcome collection, reviews, editorials, animal studies, and studies where device-specific data could not be disaggregated.

Screening and Data Extraction

All studies retrieved from the literature search were imported to EndNote X9 (Clarivate Analytics) for duplicate removal and screening. Title, abstract, and full-text screening were completed separately by two reviewers; disagreement was settled by a third senior reviewer (Cohen's $\kappa = 0.82$). Study features, patient demographics, procedure parameters, and endpoint data were documented at 6-, 12-, 24-, and 36-month time-points using a piloted, standardised Excel form. Data were extracted in duplicate; inconsistencies were reconciled by consensus. When only graphical data were provided, PlotDigitizer (v2.6.8) was used. Study authors were contacted twice for missing or unclear data; non-responders within four weeks were excluded from pooled analyses for the relevant outcome.

Risk of Bias Assessment

Risk of bias for included studies was assessed using validated tools according to study design. Cohort studies were evaluated using the Newcastle–Ottawa Scale (NOS), which examines three domains: selection of study groups (S1–S4), comparability (C1–C2), and outcome assessment (O1–O3) (7). A maximum score of nine stars indicates the highest methodological quality. Randomized controlled trials (RCTs) were assessed using the Cochrane Risk of Bias 2 (RoB 2) tool, which evaluates bias across five domains: randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting. Each domain was rated as "low risk," "some concerns," or "high risk," and an overall risk of bias judgment was assigned accordingly.

Data Synthesis and Statistical Analysis

We calculated event rates with exact 95% confidence intervals (Clopper–Pearson) for each device and each outcome. The DerSimonian–Laird random-effects model was used to make pooled estimates that accounted for expected clinical and methodological differences. Heterogeneity was quantified using I^2 (values >50% indicating substantial heterogeneity) and prediction intervals. Predefined subgroup analyses examined clinical presentation (stable CAD versus acute coronary syndrome), diabetes status, follow-up duration

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(6–12 months versus >12 months), and geographical region (Western versus Asian cohorts). Sensitivity analyses omitted studies with a high risk of bias, unpublished reports, or those involving fewer than 100 patients; influence analysis utilized leave-one-out cross-validation. Funnel plots and Egger's test were used to check for publication bias when there were at least 10 studies for an outcome. All statistical analyses were performed using R (v4.3.2).

Outcomes

Clinical endpoints were adjudicated at ≥6 months, consistent with ARC-2 definitions.

Primary Efficacy Endpoint

Target-Lesion Failure (TLF): This composite endpoint is defined as the combination of: (1) Cardiac death—unexplained death occurring within a time window of the index procedure; (2) Target-Vessel Myocardial Infarction (TV-MI); and (3) Ischaemia-Driven Target-Lesion Revascularisation (ID-TLR).

Secondary Safety and Efficacy Endpoints

Stent/Scaffold Thrombosis (ST): Defined according to ARC-2 criteria, encompassing definite (angiographic or pathological confirmation) and probable (unexplained acute ischemic event or sudden death within the target vessel territory) events.

Myocardial Infarction (MI): Defined according to the latest universal definition, specifically including Target-Vessel MI (TV-MI), which is an MI caused by an acute ischemic event in the territory supplied by the target vessel, excluding events clearly caused by procedural complications.

Ischaemia-Driven Target-Lesion Revascularisation (ID-TLR): Any repeat revascularization (PCI or bypass surgery) performed on the target lesion due to clinical signs or symptoms of ischaemia and confirmed by angiographic evidence of restenosis.

All-Cause Mortality: Death from any cause occurring during the specified follow-up period.

Cardiac Death: Death due to an immediate cardiac cause (e.g., MI, heart failure, lethal arrhythmia, or procedural complications) or any unexplained death.

Results

Study Selection

A total of 22,022 records were identified through database searching, with no additional records obtained from registers. After removal of 4,200 duplicate records and 322 records for other reasons, 17,500 records remained for title and abstract screening. Of these, 16,200 records were excluded based on predefined eligibility criteria.

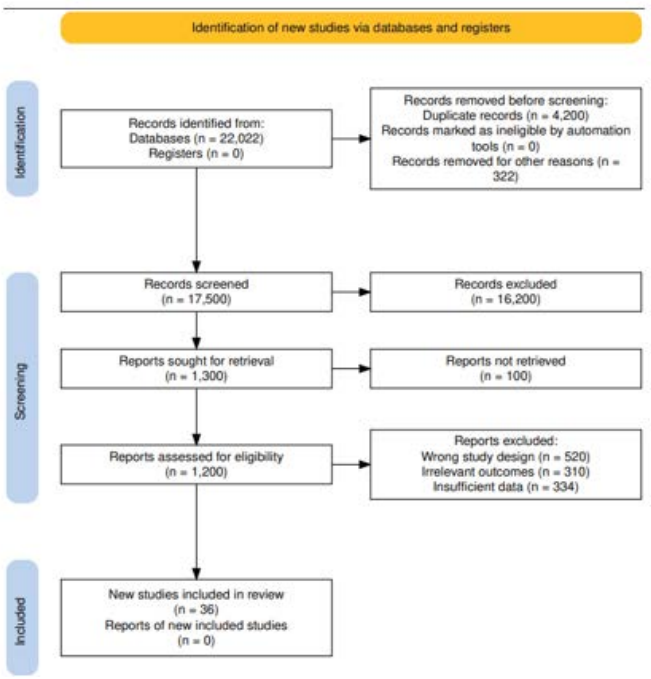

Figure 1: Prisma flow diagram.

A total of 1,300 reports were sought for full-text retrieval, of which 100 could not be retrieved. Consequently, 1,200 full-text articles were assessed for eligibility. Among these, 1,164 reports were excluded due to wrong study design (n = 520), irrelevant outcomes (n = 310), and insufficient data (n = 334). Ultimately, 36 studies met the inclusion criteria and were included in the final systematic review (Figure 1).

Study Characteristics

The included studies evaluated four distinct stent platforms: Biomatrix, Magmaris, Orsiro, and Ultimaster.

A total of 36 studies were included, comprising a mix of randomized controlled trials (RCTs) and observational cohort studies. The included studies evaluated a range of coronary devices, predominantly focusing on magnesium-based bioresorbable scaffolds (Magmaris), biodegradable polymer drug-eluting stents (e.g., Orsiro, Ultimaster, BioMatrix), and comparative platforms including durable polymer stents and dual-therapy stents.

Sample sizes varied substantially, ranging from 30 to 3,832 participants, with several large multicenter RCTs enrolling over 2,000 patients. The studies were conducted across diverse geographic regions, including Europe, Asia, the Middle East, Africa, and multinational cohorts, reflecting a broad representation of real-world and trial populations.

Patient populations included both acute coronary syndrome (ACS) and stable coronary artery disease (CAD), with many studies enrolling mixed cohorts. ACS presentations encompassed ST-segment elevation myocardial infarction

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(STEMI), non-ST elevation myocardial infarction (NSTEMI), and unstable angina, while stable CAD populations included chronic coronary syndrome and silent ischemia. Follow-up durations ranged from short-term (30 days) to long-term (up to 5 years), although most studies reported outcomes at 1–2 years. Dual antiplatelet therapy (DAPT) duration varied across studies, typically ranging from 6 to 12 months, with some studies exploring shorter or extended regimens depending on clinical context and device type. Intravascular imaging was variably utilized across studies. Optical coherence tomography (OCT) and intravascular ultrasound (IVUS) were commonly employed in scaffold-based studies, particularly those involving Magmaris, whereas several RCTs relied primarily on conventional coronary angiography, with selective use of imaging modalities in a subset of patients. Overall, the included studies demonstrate considerable heterogeneity in study design, patient populations, device platforms, and adjunctive imaging and pharmacotherapy strategies. Study characteristics is given in table 1, patient characteristics is given in table 2.

Table 1: Study characteristics table.

Study ID	Study Design (Classified)	Stent / Device Name		Device Type	Sample Size	Country / Region	ACS or Stable CAD	Follow-up Duration	DAPT Duration	Imaging Used
Rola 2022	Retrospective Cohort	Magmaris		Magnesium bioresorbable scaffold (BRS)	193	Poland	NSTE-ACS	1 year	NR	OCT/IVUS (21.2%)
Włodarczak 2021	Retrospective Cohort	Magmaris		Magnesium bioresorbable vascular scaffold (BRS)	193 (72 diabetic, 121 non-diabetic)	Poland	NSTE-ACS	30 days, 1 year	12 months	OCT (13/72 DM; 28/121 non-DM)
Truong 2023	Prospective Cohort	Magmaris		Magnesium-based sirolimus-eluting bioabsorbable scaffold	58	Vietnam	Non-STEMI 67%, STEMI 10%, CCS 22.4%	1 year	1 year	IVUS (98.3%)
Włodarczak 2023	Retrospective Cohort	Magmaris		Bioresorbable magnesium scaffold (BRS) with sirolimus-eluting capability	193 (72 diabetic, 121 non-diabetic)	Poland	NSTE-ACS	2 years	NR	OCT-guided PCI 13 (18) vs 28 (23.1)
Rola 2023	Prospective Cohort	Magmaris		Magnesium bioresorbable scaffold (BRS)	193	Poland	ACS (unstable angina or NSTEMI)	1 year	12 months	OCT guided PCI 41 (21.2)
Sequeiros 2020	Prospective Cohort	Magmaris		Bioresorbable magnesium scaffold (BRS) – sirolimus-eluting	42	Spain	NSTEMI 52.4%, STEMI 2.4%, Effort Angina 45.2%	1 year	NR	OCT
Włodarcza 2024	Retrospective Cohort	Magmaris		Second-generation bioresorbable scaffold (BRS) – magnesium-based	193	Poland	NSTE-ACS	2 years	12 months	OCT/IVUS guided PCI 41 (21.2)
Verheye 2021	Prospective Cohort	Magmaris		Sirolimus-eluting bioresorbable magnesium scaffold	1,075	Europe, Asia, Africa, Australia/NZ	NSTEMI 19.2%, remainder stable CAD	1 year	12 months	Angiographic core lab, OCT

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Wlodarczak 2023	Prospective Cohort	Magmaris		Sirolimus-eluting bioresorbable magnesium scaffold	2,066	Europe, Asia and Asia-Pacific	NSTEMI 18.5%, STEMI 0.4%, Stable angina 48.3%, UA 17.3%	2 years	72.7% at 12 months; 21.3% at 24 months	IVUS
Rola 2021	Retrospective Cohort	Magmaris		Magnesium bioresorbable scaffold (BRS)	193 (DM 72 vs Non-DM 121)	Poland	ACS (NSTE-ACS)	1 year	NR	OCT-guided PCI (18% DM; 23.1% non-DM)
Gall 2022	Prospective Cohort	Magmaris		Magnesium Resorbable Scaffold (MRS)	207	Italy	Stable angina and ACS	1 and 2 years	12 months (recommended)	Angiography, OCT, IVUS
Galli 2023	Prospective Cohort	Magmaris		Sirolimus-eluting magnesium resorbable scaffold (MRS)	207 (1-yr: 202, 2-yr: 192)	Italy	Stable CAD 145, ACS 62	1 and 2 years	1-yr: 95%; 2-yr: 8%	Angio (55%), IVUS (21%), OCT (23%)
Wlodarczak 2018	Prospective Cohort	Magmaris		Sirolimus-eluting bioresorbable metallic magnesium scaffold (BRS)	50	Poland	ACS (NSTE-ACS)	30 days and 6 months	≥12 months	OCT
Hemptinne 2022	Prospective Cohort	Magmaris		Resorbable magnesium scaffold – sirolimus-eluting BRS	30	Belgium	STEMI (ACS)	1 year	12 months	OCT
Yoon 2023	RCT	Orsiro (BP-SES) vs BioMatrix (BP-BES)		Ultrathin-strut BP sirolimus-eluting stent vs thick-strut BP biolimus-eluting stent	2,341 (BP-SES 1,175; BP-BES 1,166)	Korea	Mixed: ACS 67.3%, Stable CAD 27.6%, Silent ischemia 5.2%	3 years	≥12 months (~30% beyond 3 yrs)	IVUS/OCT in 23% of lesions
Yoon 2021	RCT	Orsiro (BP-SES) vs BioMatrix (BP-BES)		Thin-strut BP sirolimus-eluting stent vs thick-strut BP biolimus-eluting stent	2,341 (BioMatrix 1,166; Orsiro 1,175)	Korea	ACS 67.3%, Stable CAD 32.7%	18 months	Recommended 6 months; ~18% still on DAPT at 1 year	Conventional coronary angiography
De Marzo 2020	RCT	Orsiro		Orsiro ultrathin-strut biodegradable-polymer DES	353	Italy	STEMI (100% ACS)	1 year (mean 20.2 months)	1 year	Angiography
Bartorelli 2019	RCT	Orsiro		Ultrathin-strut biodegradable-polymer sirolimus-eluting Orsiro stent	601	Italy	STEMI 16%, NSTEMI 18%, UA 17.5%, Stable angina 33.4%, Silent ischemia 14.5%	18 months	12 months (standard)	Not stated
Windecker 2015	RCT	Orsiro (O-SES) vs Xience (X-EES)		Ultrathin-strut sirolimus-eluting BP stent vs durable polymer EES	452 (O-SES 298; X-EES 154)	8 European countries	Stable CAD (100%)	9 months	≥6 months (many up to 12 months)	QCA (all); OCT/IVUS in selected centers
Ploumen 2024	RCT	Orsiro (SES) vs Synergy (EES) vs Resolute Integrity (ZES)		Ultrathin-strut BP SES vs very-thin-strut EES vs thin-strut durable polymer ZES	3,514 (SES 1,169; EES 1,172; ZES 1,173)	Netherlands	Mixed	3 years	12 months	NR

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Buiten 2020	RCT	Orsiro (SES) vs Synergy (EES) vs Resolute Integrity (ZES)		BP EES / BP SES vs durable polymer ZES	738 (EES 252; ZES 265; SES 266)	Netherlands (4 centers)	Mixed (ACS ~62%, Stable CAD ~38%)	2 years	12 months	Coronary angiography only
Smits 2024	RCT	Ultimaster Tansei (80 µm BP-SES)		Biodegradable-polymer sirolimus-eluting DES	364	Netherlands	70% stable CAD, 30% ACS	1 year	Median 30 days (IQR 0–181)	IVUS 2.6%, OCT 1%
Saito 2014	RCT	Ultimaster (BP-SES)		Bioresorbable polymer sirolimus-eluting stent	551	Japan, Europe, South Korea	ACS 36%, remainder stable CAD	9 months (planned up to 5 years)	89.5% at 9 months	Quantitative coronary angiography
Ishida 2024	Prospective Cohort	Ultimaster		Thin-strut biodegradable polymer DES (BP-DES)	1,202	Japan	43% ACS, 57% CCS	1 year	1-month DAPT then P2Y12 monotherapy for 11 months	IVUS 94.4%, OCT/OFDI 6.5%
Iñiguez 2020	RCT	Ultimaster (BP-SES)		Bioresorbable polymer sirolimus-eluting stent	225	Europe, Japan, South Korea	Stable angina 48.9%, UA 12.0%, STEMI 4.9%, NSTEMI 17.8%	1 year; 5 years	NR	NR
Lesiak 2016	RCT	Ultimaster BP-SES		Bioresorbable polymer sirolimus-eluting cobalt-chromium stent	101	Europe, Japan, Korea	Stable angina 42.6%, UA 13.9%, STEMI 6.9%, NSTEMI 19.8%	9 months	NR	Quantitative Coronary Angiography
Wijns 2018	RCT	Ultimaster (BP-SES) vs Xience (PP-EES)		Bioresorbable polymer SES vs permanent polymer EES	1,101 (BP-SES 551; PP-EES 550)	Europe (42 sites), Japan (15 sites), Korea (1 site)	BP-SES: Stable 49%, UA 13.6%, STEMI 5.3%, NSTEMI 17.2%; PP-EES: Stable 46%, UA 10.9%, STEMI 5.6%, NSTEMI 19.1%	5 years	98.4% at 1 month; 66.1% at 1 year; 15.7% at 5 years (BP-SES)	Coronary angiography
Godino 2019	Prospective Cohort	Ultimaster (BP-SES)		Thin-strut biodegradable polymer sirolimus-eluting stent	1,660	Italy (9 centers)	ACS 37%, Stable angina 52%	1 year	S-DAPT (≤3 months, mean 57±27 days); R-DAPT (≥6 months, mean 318±75 days)	Coronary angiography
Rola 2021 (Ultimaster)	Retrospective Cohort	Magmaris vs Ultimaster		Magnesium scaffold (BP) vs Cobalt-chromium stent (BP)	362 (Magmaris 193; Ultimaster 169)	Czech Republic	ACS only (NSTE-ACS; STEMI excluded)	30 days; 1 year	NR	OCT
Tadano 2018	Prospective Cohort	Ultimaster BP-SES		Bioresorbable polymer sirolimus-eluting coronary stent	1,727	Japan	Stable angina 89%, UA 7%, NSTEMI 1%, STEMI 3%	1 year	Recommended ≥1 year; actual at physician discretion	IVUS (100% of lesions)

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Jiménez Díaz 2024	Prospective Cohort	Ultimaster		Thin-strut (80 µm) cobalt-chromium sirolimus-eluting stent	3,832 (CR 1,800; ICR 2,032)	Europe, Asia, Africa, Middle East, South America, Mexico	NSTEMI (100%) with multivessel disease	3 months and 1 year	NR	NR
Maupas 2017	Prospective Cohort	BioMatrix / BioMatrix Flex		Drug-Eluting Stent – biodegradable polymer biolimus A9	2,365	France (42 centers)	Both (36.5% ACS [NSTEMI 28.7%, STEMI 7.8%]; remainder Stable CAD)	24 months	12 months recommended (minimum 6 months)	Coronary angiography
Seth 2013	Prospective Cohort	BioMatrix		Drug-Eluting Stent – biodegradable polymer BES	334	India	Both (59.1% ACS; remainder stable CAD)	24 months	12 months (minimum 6 months)	Coronary angiography
Lee 2019	RCT	BioMatrix vs Xience V		Biodegradable polymer BES vs Durable polymer EES	200 (100 per arm)	Iran (Tabriz)	De novo lesions (mix of stable and unstable)	12 months	12 months (aspirin + clopidogrel)	Coronary angiography
Separham 2011	RCT	BioMatrix / BioMatrix Flex vs Orsiro		Thick-strut biodegradable BES vs Thin-strut biodegradable SES	2,341 (1,166 BioMatrix; 1,175 Orsiro)	International multicenter (South Korea-led)	Both (67.3% ACS; 32.7% Stable CAD)	18 months	Standard 12-month DAPT for ACS; shorter for stable	Coronary angiography
Eftekhari 2025	RCT	Biomatrix Alpha (BES) vs Combo stent (DTS)		Biolimus A9-eluting thin-strut CoCr stent with biodegradable polymer (BES) vs dual-therapy sirolimus-eluting + CD34+ antibody-coated endothelial progenitor cell-capturing stent (DTS)	3,136 (BES n=1,568; DTS n=1,568)	Denmark (Aalborg, Aarhus, Odense)	All-comer (ACS and stable CAD)	1 year (primary); 5 years planned	NR (clinically driven event detection; no routine follow-up protocol)	NR (angiography-guided; no routine intravascular imaging mandated)

Table 2: Patient characteristics table.

Study ID	Year	N	Population / Inclusion Criteria	Age (years)	Male Sex (%)	Diabetes Mellitus (%)	Hypertension (%)	Dyslipidaemia / Hyperlipidaemia (%)	Current Smoker (%)	Prior MI (%)	Clinical Presentation / Indication	Special Sub-population
Rola 2022	2022	193	NSTE-ACS patients undergoing PCI	63	76	37	70	68	19	21	NSTE-ACS	None
Włodarczak 2021	2021	193 (DM 72; non-DM 121)	NSTE-ACS patients undergoing PCI with Magmaris	DM 64.6 vs non-DM 61.5	DM 76.4% vs non-DM 80.2%	DM 100% vs non-DM 0%	DM 72.2% vs non-DM 67.8%	DM 76.4% vs non-DM 75.2%	DM 15.3% vs non-DM 25.6%	NR	Non-ST elevation ACS (NSTEMI)	Diabetic vs non-diabetic subgroups
Truong 2023	2023	58	Hospitalized CAD patients	62	79	38	67	55	16	NR	Non-STEMI 67%, STEMI 10%, CCS 22.4%	First Vietnamese Magmaris cohort
Włodarczak 2023 (Diabetic vs Non-DM)	2023	193 (DM 72; non-DM 121)	ACS patients – diabetic vs non-diabetic comparison	DM 64.6 vs non-DM 61.5	DM 76.4% vs non-DM 80.2%	DM 100% vs non-DM 0%	DM 72.2% vs non-DM 67.8%	DM 76.4% vs non-DM 75.2%	DM 15.3% vs non-DM 25.6%	NR	NSTE-ACS	2-year outcomes in diabetics

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Rola 2023	2023	193	ACS patients (UA or NSTEMI) for PCI	63	77	37	70	68	19	21	ACS (unstable angina or NSTEMI)	Sex subgroup analysis
Sequeiros 2020	2020	42	Real-world PCI cohort	64	74	29	64	57	17	NR	NSTEMI 52.4%, STEMI 2.4%, Effort Angina 45.2%	None
Włodarcza 2024	2024	193	NSTE-ACS patients	63	76	37	70	68	19	NR	NSTE-ACS	2-year outcomes; large-vessel lesions
Verheye 2021	2021	1,075	Patients with ≤2 single de novo lesions	64	76	22	70	63	17	11	NSTEMI 19.2%, remainder stable CAD	Multicenter global registry (BIOSOLVE-IV)
Wlodarczak 2023	2023	2,066	Patients with ≤2 de novo lesions in ≥2 epicardial vessels	64	75	22	68	63	17	10	NSTEMI 18.5%, STEMI 0.4%, Stable 48.3%, UA 17.3%	Largest Magmaris registry
Włodarczak 2021 (Sex comparison)	2021	193 (Male 150; Female 43)	ACS patients – sex comparison	Male 62 vs Female 67	Male 100% vs Female 0%	Male 33% vs Female 51%	Male 68% vs Female 77%	Male 66% vs Female 72%	Male 22% vs Female 9%	NR	ACS	Sex-based subgroup
Rola 2021	2021	193 (DM 72; non-DM 121)	Diabetic and non-diabetic NSTE-ACS patients	DM 64.6 vs non-DM 61.5	DM 76.4% vs non-DM 80.2%	DM 100% vs non-DM 0%	DM 72.2% vs non-DM 67.8%	DM 76.4% vs non-DM 75.2%	DM 15.3% vs non-DM 25.6%	NR	ACS (NSTE-ACS)	1-year diabetic vs non-diabetic outcomes
Gall 2022	2022	207	Suitable lesions for MRS platform	65	76	25	72	60	15	NR	Stable angina and ACS	1- and 2-year follow-up
Galli 2023	2023	207	Stable CAD and ACS patients	65	76	25	72	60	15	NR	Stable CAD (n=145) and ACS (n=62)	Updated 2-year outcomes of same cohort
Wlodarczak 2018	2018	50	Non-ST elevation ACS patients	63	78	36	70	66	18	NR	ACS (NSTE-ACS)	Early feasibility study
Hemptinne 2022	2022	30	STEMI patients undergoing primary PCI	59	83	17	60	50	27	NR	STEMI	STEMI-specific Magmaris study
Yoon 2023	2023	2,341 (BP-SES 1,175; BP-BES 1,166)	PCI patients requiring DES implantation	BP-SES 63.5 vs BP-BES 63.5	BP-SES 73% vs BP-BES 72%	BP-SES 32% vs BP-BES 31%	BP-SES 60% vs BP-BES 60%	BP-SES 56% vs BP-BES 55%	BP-SES 20% vs BP-BES 21%	NR	Mixed: ACS 67.3%, Stable CAD 27.6%	3-year RCT; Orsiro superior

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Yoon 2021	2021	2,341 (BioMatrix 1,166; Orsiro 1,175)	Chronic stable CAD and ACS patients	63	73	31%	60%	56%	20%	NR	ACS 67.3%, Stable CAD 32.7%	18-month non-inferiority RCT
De Marzo 2020	2020	353	STEMI patients receiving Orsiro in target vessel	62	77	20	58%	53%	30%	10%	STEMI (100% ACS)	STEMI-only cohort; retrospective registry
Bartorelli 2019	2019	601	All-comer population including high-risk subgroups	65	74	22	66%	60%	19%	10%	STEMI 16%, NSTEMI 18%, UA 17.5%, Stable 33.4%, Silent isch 14.5%	Nationwide Italian registry
Windecker 2015	2015	452 (O-SES 298; X-EES 154)	Stable or unstable angina / silent ischemia patients with de novo lesions	O-SES 63 vs X-EES 64	O-SES 74% vs X-EES 78	O-SES 22% vs X-EES 26%	O-SES 62% vs X-EES 66%	O-SES 58% vs X-EES 57%	O-SES 22% vs X-EES 18%	NR	Stable CAD (100%)	Non-inferiority vs Xience; 9-month primary endpoint
Ploumen 2024	2024	3,514 (SES 1,169; EES 1,172; ZES 1,173)	All-comer PCI patients	64	73	22	66	60	19	NR	Mixed	Cost-effectiveness analysis at 3 years
Buiten 2020	2020	738 (EES 252; ZES 265; SES 266)	All-comer PCI patients	64	73	23	66	58	20	NR	Mixed (ACS 62%, Stable CAD 38%)	BIO-RESORT; ZES higher TVR
Smits 2024	2024	364	High bleeding risk (HBR) patients undergoing PCI	76	67	38	82	68	10	22%	70% stable CAD, 30% ACS	HBR; very short DAPT (median 30 days)
Saito 2014	2014	551	CAD patients undergoing PCI	65	79	27	67	65	18	11%	ACS 36%, stable CAD 64%	Pivotal Ultimaster trial
Ishida 2024	2024	1,202	Japanese patients undergoing PCI with BP-DES	71	75	38	76	63	15	16%	43% ACS, 57% CCS	Real-world Japanese registry; ultra-short DAPT
Iñiguez 2020	2020	225	Multivessel CAD patients undergoing PCI	64	75	25	70	60	19	10%	Stable 48.9%, UA 12.0%, STEMI 4.9%, NSTEMI 17.8%	Multivessel disease; 1-year and 5-year data

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Lesiak 2016	2016	101	Patients with long coronary lesions	64	77	26	65	56	20	NR	Stable 42.6%, UA 13.9%, STEMI 6.9%, NSTEMI 19.8%	Long lesion population
Wijns 2018	2018	1,101 (BP-SES 551; PP-EES 550)	Stable CAD or ACS patients	BP-SES 64 vs PP-EES 63	BP-SES 76% vs PP-EES 75%	BP-SES 22% vs PP-EES 23%	BP-SES 65% vs PP-EES 63%	BP-SES 60% vs PP-EES 61%	BP-SES 17% vs PP-EES 19%	NR	BP-SES: Stable 49%, UA 13.6%, STEMI 5.3%, NSTEMI 17.2%	Non-inferiority RCT; 5-year follow-up
Godino 2019	2019	1,660	"All-comers" PCI population	65	74%	24%	69%	61%	17%	NR	ACS 37%, Stable angina 52%	Short vs recommended DAPT comparison
Rola 2021 (Ultimaster)	2021	169 (Ultimaster arm)	NSTE-ACS patients (Ultimaster arm of Magmaris vs Ultimaster study)	63	78%	35%	68%	66%	16%	NR	ACS only – NSTE-ACS (NSTEMI + UA); STEMI excluded	Diabetic vs non-diabetic subgroup; Czech Republic
Tadano 2018	2018	1,727	All-comer PCI patients with BP-SES	68	74%	35%	73%	61%	14%	13%	Stable angina 89%, UA 7%, NSTEMI 1%, STEMI 3%	IVUS 100%; real-world Japanese registry
Jiménez Díaz 2024	2024	3,832 (CR 1,800; ICR 2,032)	NSTEMI with multivessel disease treated with Ultimaster	CR 65 vs ICR 66	CR 74% vs ICR 73%	CR 28% vs ICR 30%	CR 70% vs ICR 72%	CR 60% vs ICR 62%	CR 17% vs ICR 18%	NR	NSTEMI (100%)	Complete vs incomplete revascularization comparison

Clinical Outcomes of Biomatrix Drug-Eluting Stents

A total of 5 studies (N = 5,281 patients) were analyzed. The pooled incidence of stent thrombosis was 1% (95% CI: 0.00–0.02; I^2 = 85.4%; Figure S1). Cardiac death occurred in 2% of patients (95% CI: 0.01–0.04; I^2 = 93.9%; Figure S2), while target lesion revascularization was observed in 3% (95% CI: 0.00–0.07; I^2 = 98.2%; Figure S5). Target lesion failure (TLF) was reported at 7% (95% CI: 0.03–0.11; I^2 = 97.9%; Figure S3). Target vessel myocardial infarction was reported at 3% (95% CI: 0.01–0.04; I^2 = 96.4%; Figure S4).

Clinical Outcomes of Magmaris Bioresorbable Scaffolds

The analysis of Magmaris scaffolds included up to 14 studies (N = 5,199 patients). The pooled estimate for all-cause mortality was 1% (95% CI: 0.01–0.01; I^2 = 0.0%; Figure S7). The incidence of stent thrombosis was low at 1% (95% CI: 0.00–0.01; I^2 = 0.0%; Figure S11). Myocardial infarction occurred in 2% of patients (95% CI: 0.01–0.02; I^2 = 17.9%; Figure S9). Target lesion failure (TLF) was reported at 5% (95% CI: 0.04–0.06; I^2 = 66.7%; Figure S12). Target lesion revascularization (TLR) was reported at 4% (95% CI: 0.02–0.05; I^2 = 87.8%; Figure S18). Target vessel myocardial infarction was reported at 1% (95% CI: 0.01–0.02; I^2 = 0.0%; Figure S21).

Clinical Outcomes of Orsiro Drug-Eluting Stents

Outcomes for the Orsiro stent were derived from up to 13 studies (N = 5,129 patients). The pooled rate of cardiac death was 2% (95% CI: 0.01–0.04; I^2 = 73.3%; Figure S22). All-cause mortality was 4% (95% CI: 0.03–0.05; I^2 = 75.5%; Figure S23). The incidence of myocardial infarction was 1% (95% CI: 0.01–0.02; I^2 = 51.5%; Figure S25), and target vessel MI was 2% (95% CI: 0.01–0.03; I^2 = 88.1%; Figure S33). Stent thrombosis remained low at 0% (95% CI: 0.00–0.00; I^2 = 20.8%; Figure S27). Target lesion revascularization was observed in 2% of patients (95% CI: 0.01–0.04; I^2 = 83.2%; Figure S31). Target lesion failure was reported at 4% (95% CI: 0.03–0.06; I^2 = 83.9%; Figure S29).

Clinical Outcomes of Ultimaster Drug-Eluting Stents

The Ultimaster stent was evaluated in 10 studies comprising 10,382 patients. The pooled rate of cardiac death

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was 2% (95% CI: 0.01–0.03; I^2 = 88.0%; Figure S36), while all-cause mortality was 4% (95% CI: 0.02–0.06; I^2 = 95.1%; Figure S40). The rates for myocardial infarction and stent thrombosis were 2% (95% CI: 0.01–0.04; I^2 = 91.3%; Figure S45) and 1% (95% CI: 0.00–0.01; I^2 = 88.4%; Figure S49), respectively.

Clinical Outcomes of Xience Stents

For target lesion revascularization (TLR), pooled analysis of 10 studies (n = 13,642) demonstrated an event rate of 4% (95% CI: 2–6%), with substantial heterogeneity (I^2 = 97.4%, p < 0.0001). Individual study estimates ranged from 0% (Valgamigli 2021) to 9% (Kerkmeijer 2020).

For target lesion failure (TLF), pooled analysis of 10 studies (n = 13,780) yielded a pooled event rate of 9% (95% CI: 7–12%), again with high heterogeneity (I^2 = 96.3%, p < 0.0001). Event rates across individual studies ranged from 5% (Valgamigli 2021) to 16% (Kandzari 2015).

For myocardial infarction (MI), pooled analysis of 8 studies (n = 11,672) showed a pooled event rate of 4% (95% CI: 3–5%), with high heterogeneity (I^2 = 93.5%, p < 0.0001). Individual study event rates ranged from 1% (Valgamigli 2021) to 14% (Kandzari 2015).

Subgroup Analysis of Follow-up Duration

Subgroup analyses were conducted to assess the impact of follow-up duration on clinical outcomes.

Magmaris Scaffolds: Significant temporal differences were observed. TLF rates increased significantly from 2% (95% CI: 0.01–0.04) at 1-year follow-up to 6% (95% CI: 0.06–0.07) at 2-year follow-up (P < 0.0001; Figure S15). Similarly, TLR rates rose from 3% at 1 year to 6% at 2 years (P = 0.0010; Figure S19), indicating a time-dependent accumulation of adverse events.

Orsiro Stents: Analyses comparing follow-up durations (≤18 months vs. >18 months) showed stable long-term performance. No statistically significant differences were found between subgroups for stent thrombosis (P = 0.22), all-cause mortality (P = 0.69), myocardial infarction (P = 0.53), TLF (P = 0.63), TLR (P = 0.38), or target vessel MI (P = 0.79).

Ultimaster Stents: The subgroup analysis comparing follow-up durations (≤1 year vs. 5 years) indicated that follow-up time did not significantly influence cardiac death (P = 0.14), myocardial infarction (P = 0.26), or stent thrombosis (P = 0.26). However, a statistically significant difference was observed for all-cause mortality (P = 0.0007), with higher rates in the 5-year subgroup (8%; 95% CI: 0.06–0.10) compared to the ≤1-year subgroup (3%; 95% CI: 0.02–0.05). These findings suggest a potential late hazard period associated with scaffold resorption, during which the risk of adverse events may increase. The results are summarized in Table 3, and the subgroup analysis results are presented in Table 4.

Table 3: Summary of pooled clinical outcomes and heterogeneity statistics for studies evaluating Biomatrix, Magmaris, Orsiro, and Ultimaster drug-eluting stents.

Stent Type	Outcome	No. of Studies (k)	Total Patients (N)	Pooled Estimate [95% CI]	Heterogeneity (I2)	P-value
Biomatrix	Cardiac Death	5	5,281	0.02 [0.01; 0.04]	93.90%	< 0.0001
	Stent Thrombosis	4	3,715	0.01 [0.00; 0.02]	85.40%	0.0001
	Target Lesion Failure (TLF)	5	5,281	0.07 [0.03; 0.11]	97.90%	< 0.0001
	Target Lesion Revascularization (TLR)	4	3,715	0.03 [0.00; 0.07]	98.20%	< 0.0001
	Target Vessel MI	5	5,281	0.03 [0.01; 0.04]	96.40%	< 0.0001
Magmaris	All-cause Mortality	10	4,685	0.01 [0.01; 0.01]	0.00%	0.6043
	Myocardial Infarction	10	2,677	0.02 [0.01; 0.02]	17.90%	0.278
	Stent Thrombosis	5	3,613	0.01 [0.00; 0.01]	0.00%	0.678
	Target Lesion Failure (TLF)	14	5,171	0.05 [0.04; 0.06]	66.70%	0.0002
	Target Lesion Revascularization (TLR)	14	5,199	0.04 [0.02; 0.05]	87.80%	< 0.0001
	Target Vessel Myocardial Infarction	13	5,129	0.01 [0.01; 0.02]	0.00%	0.6097
Orsiro	All-cause Mortality	5	3,596	0.04 [0.03; 0.05]	75.50%	0.0026
	Cardiac Death	4	1,518	0.02 [0.01; 0.04]	73.30%	0.0105
	Myocardial Infarction	5	4,170	0.01 [0.01; 0.02]	51.50%	0.0827
	Stent Thrombosis	5	3,570	0.00 [0.00; 0.00]	20.80%	0.2821
	Target Lesion Failure (TLF)	6	3,868	0.04 [0.03; 0.06]	83.90%	< 0.0001

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	Target Lesion Revascularization (TLR)	6	3,868	0.02 [0.01; 0.04]	83.20%	< 0.0001
	Target Vessel MI	6	3,868	0.02 [0.01; 0.03]	88.10%	< 0.0001
Ultimaster	All-cause Mortality	10	10,382	0.04 [0.02; 0.06]	95.10%	< 0.0001
	Cardiac Death	10	10,382	0.02 [0.01; 0.03]	88.00%	< 0.0001
	Myocardial Infarction	10	10,382	0.02 [0.01; 0.04]	91.30%	< 0.0001
	Stent Thrombosis	10	10,382	0.01 [0.00; 0.01]	88.40%	< 0.0001

Note: Data presents pooled estimates [95% Confidence Interval] derived from random-effects meta-analysis models. N represents the total number of patients, and I^2 indicates the percentage of heterogeneity across studies. CAD, coronary artery disease; PCI, percutaneous coronary intervention; MI, myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TV-MI, target vessel myocardial infarction; CI, confidence interval; I^2, I-squared statistic for heterogeneity; k, number of included studies; N, total number of patients.

Table 4: Subgroup analysis of clinical outcomes stratified by follow-up duration for Magmaris, Orsiro, and Ultimaster drug-eluting stents.

Stent Type	Outcome	Subgroup	No. of Studies	Total Patients (N)	Pooled Estimate [95% CI]	I2	P-value (Diff)
Magmaris	Target Lesion Failure (TLF)	1 year	8	2,112	0.02 [0.01; 0.04]	59.30%	< 0.0001
		2 years	6	3,059	0.06 [0.06; 0.07]	0%	
	Target Lesion Revascularization (TLR)	1 year	10	2,554	0.03 [0.01; 0.04]	83.60%	0.001
		2 years	4	2,645	0.06 [0.05; 0.07]	0%	
Orsiro	Stent Thrombosis	≤ 18 months	3	2,129	0.00 [0.00; 0.00]	16%	0.219
		> 18 months	2	1,441	0.00 [0.00; 0.01]	4%	
	Target Lesion Failure (TLF)	≤ 18 months	4	2,427	0.04 [0.02; 0.06]	84%	0.631
		> 18 months	2	1,441	0.05 [0.01; 0.11]	90.90%	
	Target Lesion Revascularization (TLR)	≤ 18 months	4	2,427	0.02 [0.01; 0.02]	50.20%	0.3778
		> 18 months	2	1,441	0.04 [0.00; 0.12]	95.20%	
	Target Vessel MI	≤ 18 months	4	2,427	0.01 [0.00; 0.03]	85%	0.7875
		> 18 months	2	1,441	0.02 [0.00; 0.09]	95.40%	
	All-cause mortality	≤ 18 months	3	1,252	0.03 [0.01; 0.07]	86.80%	0.6868
		> 18 months	2	2,344	0.04 [0.03; 0.05]	0%	
Ultimaster	Cardiac Death*	≤ 1 year	8	9,606	0.02 [0.01; 0.03]	90.50%	0.1351
		5 years	2	776	0.03 [0.02; 0.05]	0%	
	Myocardial Infarction	≤ 1 year	8	9,606	0.02 [0.01; 0.04]	93.20%	0.2545
		5 years	2	776	0.03 [0.02; 0.05]	0%	
	Stent Thrombosis	≤ 1 year	8	9,606	0.01 [0.00; 0.01]	90.80%	0.2612
		5 years	2	776	0.01 [0.00; 0.02]	0%	
	All-cause mortality	≤ 1 year	8	9,606	0.03 [0.02; 0.05]	94.10%	0.0007
		5 years	2	776	0.08 [0.06; 0.10]	0%	

Note: Studies were stratified by follow-up time (e.g., < 1 year vs. > 1 year or < 18 months vs. > 18 months). The P-value for interaction indicates the statistical significance of the difference between the subgroups.TLF, target lesion failure; TLR, target lesion revascularization; MI, myocardial infarction; TV-MI, target vessel myocardial infarction; CI, confidence interval; I^2, I-squared statistic for heterogeneity; k, number of included studies; N, total number of patients. Cardiac death refers to death resulting from cardiovascular causes.

Heterogeneity and Publication Bias

Heterogeneity varied substantially by stent type and outcome. Magmaris and Orsiro studies generally demonstrated lower heterogeneity for mortality and thrombosis outcomes ($I^2 < 20\%$), whereas Biomatrix and Ultimaster studies showed considerable heterogeneity ($I^2 > 85\%$) across most endpoints. Visual inspection of funnel plots for key outcomes, including all-cause mortality and stent thrombosis, suggested generally symmetrical distributions, though some asymmetry was noted in the analysis of TLF for Magmaris stents (Figure S13), necessitating cautious interpretation of small-study

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effects. For the Magmaris analyses, funnel plots for all-cause mortality (Figure S6), myocardial infarction (Figure S8), and stent thrombosis (Figure S10) were broadly symmetrical, with only minor scatter among less precise studies. Funnel plots for target lesion revascularization (Figure S16) and target vessel myocardial infarction (Figure S20) similarly showed no substantial asymmetry. In contrast, within the Ultimaster dataset, the funnel plot for cardiac death (Figure S35) and the funnel plot for all-cause mortality (Figure S39) showed notable asymmetry, with smaller studies clustering on the right side of the pooled estimate, raising suspicion of publication bias or heterogeneity. The myocardial infarction plot (Figure S43) similarly displayed scattered and uneven distribution, including a large, low-precision outlier. The funnel plot for stent thrombosis (Figure S48) was also reviewed. While most outcomes showed no substantial evidence of publication bias, the asymmetry observed in Ultimaster analyses for all-cause mortality and myocardial infarction suggests potential small-study effects or selective reporting. These findings warrant cautious interpretation, particularly for efficacy comparisons involving Ultimaster.

Meta-Regression Analysis

A univariable meta-regression was conducted to examine whether follow-up duration influenced the effect sizes of key clinical outcomes for Magmaris and Ultimaster stents. For Magmaris studies, where follow-up ranged from 1.0 to 2.0 years, a positive association was observed between follow-up length and event rates; both TLR (Figure S17) and TLF (Figure S14) showed moderately positive regression slopes, indicating that longer follow-up was associated with slightly higher observed rates. For the Ultimaster stent, with follow-up durations spanning approximately 10 to 60 months, similar positive relationships were seen for all-cause mortality (Figure S41) and cardiac death (Figure S37). In contrast, the meta-regression for myocardial infarction (Figure S44) showed only a minimal, nearly flat slope, suggesting that follow-up duration did not substantially influence MI rates. Table 6 shows the results of the GRADE assessment.

Risk of bias assessment

Overall, the methodological quality of included cohort studies was high. Most studies achieved the maximum NOS score of nine stars, indicating low risk of bias across selection, comparability, and outcome domains. A subset of studies scored eight stars, primarily due to minor limitations in selection procedures or incomplete control for confounding factors; however, none were deemed to have critically high risk of bias.

For randomized controlled trials, all included studies were judged to have an overall low risk of bias according to the Cochrane RoB 2 tool. Most domains, including randomization, deviations from intended interventions, and outcome measurement, were consistently rated as low risk. Some studies showed concerns related to missing outcome data or outcome reporting; however, these did not substantially affect the overall risk assessment. Collectively, the included RCTs demonstrated robust methodological quality with minimal risk of systematic bias. The results are summarised in Table 7 and 8.

Table 6: GRADE Assessment of the reported outcomes.

Stents	Outcome	Subgroup	Total Patients (N)	Risk of Bias	Inconsistency (I2)s	Indirectness	Imprecision	Publication Bias	Final Certainty
Magmaris	Target Lesion Failure (TLF)	1 year	2,112	Not Serious	59.30%	Not Serious	Not Serious	Not Serious	Moderate
		2 years	3,059	Not Serious	0%	Not Serious	Not Serious	Not Serious	High
	Target Lesion Revascularization (TLR)	1 year	2,554	Not Serious	83.60%	Not Serious	Not Serious	Not Serious	Moderate
		2 years	2,645	Not Serious	0%	Not Serious	Not Serious	Not Serious	High
Orsiro	Stent Thrombosis	≤ 18 months	2,129	Not Serious	16%	Not Serious	Not Serious	Not Serious	High
		> 18 months	1,441	Not Serious	4%	Not Serious	Not Serious	Not Serious	High
	Target Lesion Failure (TLF)	≤ 18 months	2,427	Not Serious	84%	Not Serious	Not Serious	Not Serious	Moderate
		> 18 months	1,441	Not Serious	90.90%	Not Serious	Not Serious	Not Serious	Moderate
	Target Lesion Revascularization (TLR)	≤ 18 months	2,427	Not Serious	50.20%	Not Serious	Not Serious	Not Serious	Moderate
		> 18 months	1,441	Not Serious	95.20%	Not Serious	Not Serious	Not Serious	Moderate
	Target Vessel MI	≤ 18 months	2,427	Not Serious	85%	Not Serious	Not Serious	Not Serious	Moderate
		> 18 months	1,441	Not Serious	95.40%	Not Serious	Not Serious	Not Serious	Moderate
	All-cause mortality	≤ 18 months	1,252	Not Serious	86.80%	Not Serious	Not Serious	Not Serious	Moderate
		> 18 months	2,344	Not Serious	0%	Not Serious	Not Serious	Not Serious	High

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Ultimaster	Cardiac Death*	≤ 1 year	9,606	Not Serious	90.50%	Not Serious	Not Serious	Not Serious	Moderate
		5 years	776	Not Serious	0%	Not Serious	Not Serious	Not Serious	High
	Myocardial Infarction	≤ 1 year	9,606	Not Serious	93.20%	Not Serious	Not Serious	Not Serious	Moderate
		5 years	776	Not Serious	0%	Not Serious	Not Serious	Not Serious	High
	Stent Thrombosis	≤ 1 year	9,606	Not Serious	90.80%	Not Serious	Not Serious	Not Serious	Moderate
		5 years	776	Not Serious	0%	Not Serious	Not Serious	Not Serious	High
	All-cause mortality	≤ 1 year	9,606	Not Serious	94.10%	Not Serious	Not Serious	Not Serious	Moderate
		5 years	776	Not Serious	0%	Not Serious	Not Serious	Not Serious	High

Table 7: Risk of bias assessment of included cohort studies using the Newcastle–Ottawa Scale. Selection domain includes S1 (representativeness of the exposed cohort), S2 (selection of the non-exposed cohort), S3 (ascertainment of exposure), and S4 (absence of outcome at baseline). Comparability includes C1–C2 (control for confounders), and outcome includes O1 (assessment of outcome), O2 (adequacy of follow-up duration), and O3 (completeness of follow-up).

Study	S1	S2	S3	S4	C1	C2	O1	O2	O3	Total
Rola 2022	★	★	★	★	★	★	★	★	★	9
Włodarczak 2021	★	★	★	★	★	★	★	★	★	9
Truong 2023	★		★	★	★	★	★	★	★	8
Włodarczak 2023	★	★	★	★	★	★	★	★	★	9
Rola 2023	★	★	★	★	★	★		★	★	8
Sequeiros 2020	★	★	★	★	★	★	★	★	★	9
Włodarczak 2024	★		★	★	★	★	★	★	★	8
Verheye 2021	★	★	★	★	★	★	★	★	★	9
Włodarczak 2023	★		★	★	★	★	★	★	★	8
Rola 2021	★	★	★	★	★	★	★	★	★	9
Gall 2022	★	★	★	★	★		★	★	★	8
Galli 2023	★	★		★	★	★	★	★	★	8
Włodarczak 2018	★	★	★	★	★	★	★	★	★	9
Hemptinne 2022	★	★	★	★	★	★	★	★	★	9
Ishida 2024	★	★	★	★	★	★	★	★	★	9
Godino 2019	★	★	★		★	★	★	★	★	8
Rola 2021 (Ultimaster)	★	★	★	★	★	★	★	★	★	9
Tadano 2018	★	★	★	★	★	★	★	★	★	9
Jiménez Díaz 2024	★	★	★	★	★	★	★	★	★	9
Maupas 2017	★	★	★	★	★	★	★	★	★	9
Seth 2013	★	★		★	★	★	★	★	★	8

Meta-Regression Analysis

To explore whether stent type was a significant explanatory variable for between-study heterogeneity across clinical outcomes, we performed inverse-variance weighted meta-regression analyses using weighted least squares (WLS) on study-level log-transformed event rates for five pre-specified endpoints: cardiac death, all-cause mortality, target lesion failure (TLF), target lesion revascularization (TLR), and target vessel myocardial infarction (TV-MI). Magmaris was used as the primary reference comparator for all outcomes except cardiac death, for which Orsiro served as the reference due to data availability. Regression coefficients, rate ratios, and model fit statistics for each outcome are presented in Tables S1A–S5B; a consolidated summary of all regression results is presented in Table S6, and between-group heterogeneity statistics are presented in Table S7. Forest plots for individual stent groups are presented in Figures S51–S55.

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Table 8: Risk of bias assessment of randomized controlled trials using the Cochrane Risk of Bias 2 across all methodological domains.

Study	Randomization	Deviations	Missing Data	Outcome Measurement	Reporting	Overall
Yoon 2023	Low	Low	Low	Low	Low	Low Risk
Yoon 2021	Low	Low	High	Low	Low	Low Risk
De Marzo 2020	Low	Low	Low	Some concerns	Low	Low Risk
Bartorelli 2019	Low	Low	Low	Low	Low	Low Risk
Windecker 2015	Low	Low	High	Low	Low	Low Risk
Ploumen 2024	Low	Low	Low	Low	Low	Low Risk
Buiten 2020	Low	Low	Low	Low	Low	Low Risk
Smits 2024	Low	Low	Low	Low	Low	Low Risk
Saito 2014	Low	Low	Some concerns	Low	Low	Low Risk
Iñiguez 2020	Low	Low	Low	Low	Low	Low Risk
Lesiak 2016	Low	Low	Low	Low	Low	Low Risk
Wijns 2018	Low	Low	Some concerns	Low	Low	Low Risk
Lee 2019	Low	Low	Low	Low	Low	Low Risk
Separham 2011	Low	Low	Low	Low	Low	Low Risk
Eftekhari 2025	Low	Low	Low	Low	Low	Low Risk

Cardiac Death

The cardiac death analysis included 19 studies (N = 17,179) across three stent types — Biomatrix (4 studies), Orsiro (10 studies), and Ultimaster (5 studies) — with Orsiro serving as the reference comparator (Tables S1A–S1B; Figure S51). The pooled cardiac death rates were 1.99% (95% CI 0.94–4.17%) for Biomatrix, 2.41% (1.68–3.46%) for Orsiro, and 1.60% (0.44–5.88%) for Ultimaster. In the meta-regression model, neither Biomatrix (RR 0.802, 95% CI 0.563–1.142; p = 0.222) nor Ultimaster (RR 1.227, 95% CI 0.998–1.509; p = 0.052) differed significantly from Orsiro, although the Ultimaster comparison was borderline. The omnibus test confirmed a statistically significant overall stent-type effect ($\chi^2(2) = 6.23$, p = 0.044); however, stent type explained only 3% of between-study variance (weighted R^2 = 3.0%), indicating that the preponderance of heterogeneity — which was substantial across all three groups (I^2 = 74–97%) — was attributable to factors other than stent type.

All-Cause Mortality

The all-cause mortality analysis included 25 studies (N = 18,663) across Magmaris (10 studies), Orsiro (10 studies), and Ultimaster (5 studies), with Magmaris as the reference (Tables S2A–S2B; Figure S52). The Magmaris cohort demonstrated a pooled all-cause mortality rate of 1.25% (95% CI 0.96–1.62%) with remarkably low heterogeneity (I^2 = 0.0%, tau^2 = 0), indicating highly consistent outcomes across its study programme. By contrast, both comparator stents showed substantially higher mortality rates in the regression model: Orsiro was associated with a 4.6-fold higher all-cause mortality rate relative to Magmaris (RR 4.581, 95% CI 3.476–6.036; p < 0.001), and Ultimaster with a 3.5-fold higher rate (RR 3.458, 95% CI 2.545–4.697; p < 0.001). The omnibus test was highly significant ($\chi^2(2)$ = 119.15, p < 0.0001), and stent type explained 45.0% of between-study variance — the highest model fit across all five outcomes. These findings should nonetheless be interpreted cautiously, given that the Magmaris studies predominantly comprised small single-centre trials enrolling selected patient cohorts (N = 193 per study in most cases), which may not reflect the broader, more heterogeneous populations enrolled in the multicentre Orsiro and Ultimaster programmes (I^2 = 93.0% and 65.9%, respectively).

Target Lesion Failure

The TLF analysis included 25 studies (N = 14,320) across Magmaris (14 studies), Biomatrix (6 studies), and Ultimaster (5 studies), with Magmaris as the reference (Tables S3A–S3B; Figure S53). Pooled TLF rates were 4.69% (3.58–6.14%) for Magmaris, 4.33% (2.89–6.48%) for Biomatrix, and 4.67% (1.91–11.44%) for Ultimaster, indicating broadly similar absolute rates. However, the regression model revealed significant between-stent differences in the weighted log-rate. Biomatrix demonstrated a significantly lower TLF rate than Magmaris (RR 0.744, 95% CI 0.612–0.905; p = 0.003), representing a relative reduction of approximately 26%. Conversely, Ultimaster was associated with a significantly higher TLF rate (RR 1.876, 95% CI 1.618–2.175; p < 0.001), though this estimate is driven predominantly by the Lee 2019 study, which contributed an outlying TLF rate of 21.7% and was the primary source of extreme heterogeneity within the

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Ultimaster group (I^2 = 98.5%). The omnibus test was highly significant ($\chi^2(2)$ = 129.06, p < 0.0001), with stent type explaining 27.9% of between-study variance.

Target Lesion Revascularization

The TLR analysis included 24 studies (N = 12,782) across Magmaris (14 studies), Biomatrix (6 studies), and Ultimaster (4 studies), with Magmaris as the reference (Tables S4A–S4B; Figure S54). Pooled TLR rates were 4.18% (2.93–5.97%) for Magmaris, 2.16% (1.10–4.24%) for Biomatrix, and 3.62% (1.43–9.15%) for Ultimaster. Biomatrix demonstrated the strongest between-stent difference across all endpoints, with a significantly lower TLR rate compared to Magmaris (RR 0.431, 95% CI 0.335–0.554; p < 0.001), representing a relative reduction of approximately 57%. Ultimaster did not differ significantly from Magmaris in TLR (RR 1.092, 95% CI 0.909–1.311; p = 0.347). The omnibus test was highly significant ($\chi^2(2)$ = 52.97, p < 0.0001), with stent type explaining 24.1% of variance. High heterogeneity was present across all groups (I^2 = 81–95%), and two zero-event studies in the Ultimaster group (Seth 2013, Separham 2011) required continuity correction, which may have attenuated heterogeneity estimates for that group.

Target Vessel Myocardial Infarction

The TV-MI analysis included 24 studies (N = 14,278) across Magmaris (13 studies), Biomatrix (6 studies), and Ultimaster (5 studies), with Magmaris as the reference (Tables S5A–S5B; Figure S55). The Magmaris group had the lowest pooled TV-MI rate at 1.78% (1.37–2.33%) and, notably, the lowest heterogeneity of any non-Magmaris reference group across all five outcomes (I^2 = 19.1%, tau^2 = 0.042). Biomatrix did not differ significantly from Magmaris (RR 1.142, 95% CI 0.803–1.623; p = 0.460), with wide confidence intervals reflecting high within-group heterogeneity (I^2 = 86.8%). Ultimaster was associated with a significantly higher TV-MI rate than Magmaris (RR 2.413, 95% CI 1.851–3.147; p < 0.001); however, as with TLF and TLR, this association is substantially influenced by the Lee 2019 outlier (TV-MI rate 8.87%), which is the primary driver of extreme heterogeneity in the Ultimaster group (I^2 = 96.3%). The omnibus test was highly significant ($\chi^2(2)$ = 50.39, p < 0.0001), and stent type explained 24.0% of between-study variance.

Stent Thrombosis

The stent thrombosis analysis included 24 studies (N = 21,280) across Magmaris (5 studies), Biomatrix (5 studies), Orsiro (10 studies), and Ultimaster (4 studies), with Magmaris as the reference (Table S6A-S6B; Figure S56). The Magmaris cohort demonstrated a pooled stent thrombosis rate of 0.780% (95% CI 0.536–1.135%) with zero between-study heterogeneity (I^2 = 0.0%, tau^2 = 0), indicating highly consistent outcomes across its study programme. Of the three comparator stents, Biomatrix was the only one to demonstrate a significantly lower stent thrombosis rate than Magmaris (RR 0.430, 95% CI 0.211–0.876; p = 0.020), representing an approximately 57% relative reduction, and similarly displayed zero heterogeneity across its five contributing studies (I^2 = 0.0%). By contrast, both Orsiro and Ultimaster were associated with significantly higher stent thrombosis rates relative to Magmaris: Orsiro showed a 1.9-fold higher rate (RR 1.857, 95% CI 1.221–2.824; p = 0.004), and Ultimaster a 2.5-fold higher rate (RR 2.468, 95% CI 1.557–3.913; p < 0.001). The omnibus test was highly significant ($\chi^2(3)$ = 35.911, p < 0.0001), and stent type explained 32.5% of between-study variance. These findings should nonetheless be interpreted with caution: high heterogeneity was observed within the Orsiro group (I^2 = 76.2%), driven in part by the Jiménez Díaz 2024 (ST rate 1.80%) and Smits 2024 (ST rate 2.75%) studies, while extreme heterogeneity within the Ultimaster group (I^2 = 90.6%) is predominantly attributable to the Lee 2019 study (ST rate 3.62%), which has similarly influenced findings across multiple outcomes in this series. As with all-cause mortality, the Magmaris reference cohort comprised predominantly small single-centre studies (median N = 207 per study) with a homogeneous patient population, which may not be fully representative of the broader, higher-risk populations enrolled in the Orsiro and Ultimaster programmes.

Cross-Outcome Synthesis and Heterogeneity Considerations

Across the five meta-regression models, a consistent pattern emerged: Magmaris demonstrated the lowest pooled rates for all-cause mortality and TV-MI and exhibited the lowest between-study heterogeneity of all stent groups evaluated, with I^2 values of 0.0% for all-cause mortality and 19.1% for TV-MI, and tau^2 values approaching zero for both endpoints. This internal consistency likely reflects the homogeneous patient population and standardised protocols characteristic of the Magmaris study programme, which predominantly enrolled patients in dedicated single-centre bioabsorbable scaffold registries.

Biomatrix consistently demonstrated lower revascularization rates relative to the comparator in both TLF (RR 0.744; p = 0.003) and TLR (RR 0.431; p < 0.001), while showing no significant difference in mortality endpoints. Ultimaster showed significantly higher rates for all-cause mortality, TLF, and TV-MI relative to Magmaris, though in each case these associations were heavily influenced by the Lee 2019 study, a single-centre registry with markedly elevated event rates (TLF 21.7%, TLR 10.4%, TV-MI 8.87%, cardiac death 8.63%). The weighted R^2 values across models ranged from 3.0% (cardiac death) to 45.0% (all-cause mortality), indicating that stent type accounted for a variable

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but generally modest to moderate proportion of observed heterogeneity, and that patient-level factors, study design, and follow-up duration represent important residual sources of variance. A full heterogeneity summary is provided in Table S2.

Analysis stratified by study design

The results of subgroup analyses stratified by study design are presented in the Supplementary Figures. Specifically, study type–stratified forest plots for clinical outcomes with the Ultimaster drug-eluting stent are provided in Figures S57–S60 (cardiac death: Figure S57; all-cause mortality: Figure S58; myocardial infarction: Figure S59; stent thrombosis: Figure S60), and for the Biomatrix drug-eluting stent in Figures S61–S65 (stent thrombosis: Figure S61; cardiac death: Figure S62; target vessel myocardial infarction: Figure S63; target lesion failure: Figure S64; target lesion revascularization: Figure S65).

Discussion

In this systematic review and single-arm meta-analysis, we evaluated clinical outcomes associated with the Magmaris bioresorbable magnesium scaffold compared with contemporary second-generation metallic drug-eluting stents—including Biomatrix, Ultimaster, and Orsiro—in patients with de novo coronary artery disease. Overall, our findings demonstrate consistently low rates of TLF, TLR, MI, and stent/scaffold thrombosis with Magmaris, supporting previous observations from dedicated registries and prospective trials. These results add to a growing evidence base indicating that modern resorbable and ultrathin-strut DES platforms offer excellent medium-term safety and efficacy profiles.

Principal Findings

Across more than 5,000 patients treated with Magmaris, the pooled incidence of TLF and TLR remained notably low, aligning with the encouraging outcomes previously reported in BIOSOLVE-IV , which demonstrated low event rates and minimal scaffold thrombosis at 6–12 months of follow-up. [6,7] Consistently low rates of MI and target-vessel MI further reinforce the positive vascular healing characteristics described in earlier real-world analyses and first-in-human evaluations of magnesium-based scaffolds. [3–5]. Despite these findings, the interpretation of efficacy endpoints such as TLF and TLR is limited by substantial between-study heterogeneity (I^2 frequently exceeding 60–80%). This degree of variability reduces the robustness of pooled estimates and suggests that the observed effects may not be consistent across different clinical settings. While follow-up duration contributed to this variability, other unmeasured factors—including lesion complexity, implantation technique, and adjunctive imaging—likely play a significant role. Therefore, these pooled estimates should be interpreted as hypothesis-generating rather than definitive. In contrast, MI, target-vessel MI, and scaffold thrombosis showed minimal heterogeneity, underscoring the consistency of safety outcomes across diverse study designs and populations. A key finding of this analysis is the time-dependent increase in TLF and TLR observed with Magmaris. Unlike metallic DES, which demonstrate stable long-term outcomes, the progressive rise in adverse events between 1 and 2 years may reflect the biological and mechanical consequences of scaffold degradation. This phase may be associated with transient loss of radial strength, delayed vascular healing, or late recoil. Clinically, this raises important considerations regarding patient selection, lesion preparation, and the potential need for prolonged surveillance in patients receiving bioresorbable scaffolds.

Comparison With Contemporary DES Technologies

Second-generation drug-eluting stent (DES) platforms such as Orsiro and Ultimaster have demonstrated strong clinical performance, particularly in terms of reduced restenosis and late adverse cardiac events. Multiple meta-analyses and randomized trials have shown that thin- and ultrathin-strut biodegradable polymer sirolimus-eluting stents (Ultimaster ≈80 μm; Orsiro ≈60 μm) are highly competitive and, in some settings, may demonstrate advantages over conventional fluoropolymer DES. [1,2,8,9] Likewise, the Biomatrix stent has shown favorable long-term safety and durability in large multicenter analyses. [11] Within this broader context, the outcomes observed with Magmaris in the present analysis fall within a similar range for key safety endpoints, particularly with respect to low thrombosis rates—a notable consideration given historical concerns associated with earlier-generation bioresorbable scaffolds. The improved radial strength, faster endothelialization, and favorable resorption kinetics of magnesium-based platforms have been proposed as potential contributors to these findings, [3,6,7] and the pooled estimates in our analysis are consistent with these mechanistic considerations. Findings from the BIOSOLVE-IV registry, which enrolled over 1,000 patients and reported a 12-month TLF rate of 4.3% with very low scaffold thrombosis (0.5%), [12] and its full 24-month follow-up of 2,066 patients demonstrating a TLF rate of 6.8% and scaffold thrombosis of 0.8%, [13] provide important context. The results of our meta-analysis similarly demonstrate low rates of TLF, MI, and scaffold thrombosis, thereby consolidating evidence from multiple independent single-arm studies across a broader range of clinical settings. By integrating data from real-world registries and diverse patient populations, our analysis enhances the external validity of these observations. At the same time, it is important to interpret these findings within the limitations of indirect comparisons. Long-term randomized data for ultrathin-strut DES platforms such as Orsiro have demonstrated consistently low rates of TLF and

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target-vessel MI over 5 years, with stable performance and minimal evidence of late catch-up phenomena. In contrast, the time-dependent increase in TLF and TLR observed in Magmaris studies within this analysis suggests a distinct temporal pattern, the clinical implications of which remain to be fully defined. Accordingly, while Magmaris represents a promising alternative, current evidence is insufficient to establish equivalence with contemporary DES platforms, particularly for long-term outcomes. Further contextual data from the BIOFLOW-V trial demonstrated that Orsiro achieved significantly lower TLF and target-vessel MI rates compared to Biomatrix, with very low rates of late and very-late stent thrombosis; at two-year follow-up, reductions of 37% in TLF and 47% in ischaemia-driven TLR were observed relative to Biomatrix. [13] These findings highlight the high level of performance achieved by contemporary DES platforms. In this context, the present meta-analysis provides a comprehensive and up-to-date synthesis of Magmaris outcomes, which may serve as a reference point for future comparative investigations rather than as a basis for direct performance comparisons. Importantly, the inclusion of Biomatrix should be interpreted in light of its earlier-generation design. Compared with newer ultrathin-strut DES platforms such as Orsiro and thin-strut DES such as Ultimaster, Biomatrix represents a transitional technology with thicker struts and distinct polymer characteristics. As such, differences in observed outcomes across studies may, in part, reflect generational evolution in device design rather than intrinsic differences in clinical performance, and should therefore be interpreted with appropriate caution.

Clinical Implications

Our findings support the evolving role of biodegradable scaffolds as a viable alternative to permanent metallic DES in carefully selected patients and lesion subsets. The positive outcomes observed even in higher-risk groups—including diabetics and acute coronary syndrome patients, as reported in recent Magmaris cohorts [4,5]—suggest broader applicability than previously assumed. Given increasing interest in restoring vasomotion and reducing long-term metal burden, magnesium-based scaffolds may hold particular promise in younger patients or those for whom long-term vessel physiology is of clinical importance. However, until adequately powered randomized comparisons are available, the use of Magmaris will likely remain complementary rather than fully competitive with contemporary ultrathin-strut DES platforms.

Sources of Heterogeneity and Methodological Considerations

The substantial heterogeneity observed for TLF and TLR likely reflects differences in lesion characteristics, operator technique, imaging guidance, and follow-up duration across studies. Our meta-regression identified follow-up duration as the only consistent moderator of effect size. Importantly, no correlation was found between sample size and event rates, mitigating concerns about exaggerated effects in smaller single-arm cohorts. Although most outcomes demonstrated no significant publication bias, the presence of small-study effects in the MI analysis indicates the need for cautious interpretation. Additionally, the observational nature of all included studies introduces inherent limitations related to confounding and lack of comparator arms, despite adherence to prospective data collection and adjudication methods in the majority of studies. A unique strength of our study is the quantitative exploration of follow-up duration as a driver of between-study heterogeneity: our meta-regression indicates that longer follow-up is significantly associated with variation in TLF and TLR event rates. This temporal insight is critical given the resorbable nature of Magmaris and is not thoroughly quantified in prior single-cohort reports. Additionally, signals of publication bias in certain endpoints—particularly myocardial infarction and all-cause mortality in Ultimaster studies—further limit confidence in pooled estimates and highlight the need for cautious interpretation of comparative findings.

Exploratory Comparison Across Stent Platforms Using Meta-Regression

To further explore whether stent platform may contribute to variability in clinical outcomes, we performed meta-regression analyses incorporating stent type as a study-level covariate. Importantly, these analyses do not constitute direct comparative effectiveness but rather provide an exploratory framework to assess whether differences in observed event rates across studies may be partially explained by device type. Across multiple endpoints, stent type accounted for a variable proportion of between-study heterogeneity, ranging from minimal contribution in cardiac death (R^2 = 3%) to more substantial explanatory value for all-cause mortality (R^2 = 45%) and moderate contributions for TLF, TLR, and TV-MI (~24–28%). These findings suggest that while device platform may influence observed outcomes, a large proportion of heterogeneity remains attributable to other factors such as patient selection, lesion complexity, procedural technique, and study design. For all-cause mortality, studies evaluating Magmaris demonstrated consistently low and homogeneous event rates, whereas higher rates were observed in studies of Orsiro and Ultimaster within the regression framework. However, this pattern should be interpreted cautiously, as Magmaris data were predominantly derived from smaller, single-centre cohorts with more selected patient populations, while comparator stents were evaluated in larger, multicentre studies with broader and potentially higher-risk populations. This imbalance likely contributes to the observed differences and limits causal interpretation. For efficacy endpoints such

as TLF and TLR, absolute pooled rates were broadly similar across stent platforms; however, meta-regression suggested statistical differences in study-level estimates. Notably, these findings were sensitive to influential outlier studies, particularly within the Ultimaster dataset, where a single high-event study contributed disproportionately to both effect estimates and heterogeneity. This underscores the instability of indirect comparisons based on aggregate data and highlights the importance of considering study-level variability. A similar pattern was observed for TV-MI and stent thrombosis, where regression analyses indicated differences across stent groups; however, these were again accompanied by substantial heterogeneity and potential confounding by study design and population characteristics. In particular, the low heterogeneity observed in Magmaris cohorts likely reflects greater uniformity in study protocols rather than inherently superior or inferior device performance. Taken together, these findings suggest that stent type may act as one of several contributors to observed differences in clinical outcomes across studies, but should not be interpreted in isolation. The absence of randomized head-to-head comparisons, combined with imbalances in study design and patient populations, precludes definitive conclusions regarding relative efficacy or safety. Accordingly, these meta-regression results should be considered hypothesis-generating and supportive of the need for adequately powered comparative trials.

Sensitivity and Subgroup Analysis: RCTs vs. Observational Data

A critical finding of this systematic review is the influence of study design on reported stent performance, particularly for the Ultimaster drug-eluting stent. Stratified analysis (Figures S57–S60) demonstrates that event rates for cardiac death, all-cause mortality, and myocardial infarction are markedly higher in observational registries than in randomized controlled trials. The stratified forest plots reveal that this risk is disproportionately driven by the Lee 2019 observational study, which reported an outlier TV-MI rate of 8.87%. In contrast, data from Biomatrix evaluations showed greater stability across study designs, with its significantly lower rate of stent thrombosis (RR 0.430, p = 0.020) and TLF (RR 0.744, p = 0.003) remaining consistent in both stratified and pooled analyses. Magmaris and Orsiro study design stratified analysis was not performed as their primary analysis is based on a single type of study design. These findings underscore the necessity of accounting for study design and outlier influence when synthesizing safety data for bioresorbable and drug-eluting platforms, and the results must be interpreted with caution.

Strengths and Limitations

The strengths of this review include comprehensive literature coverage, strict inclusion criteria, ROBINS-I–guided risk of bias assessment, and robust statistical methodology including subgroup, sensitivity, and meta-regression analyses. These methodological steps enhance the reliability and generalizability of our pooled findings. Nevertheless, several limitations must be acknowledged. First, the absence of randomized comparative studies limits direct assessment of performance versus established DES platforms such as Biomatrix or Orsiro. Second, relatively short-term follow-up in many Magmaris studies limits conclusions regarding late adverse events, which are particularly relevant for resorbable technologies. Third, device-specific data could not be extracted consistently across all endpoints, and residual confounding remains possible due to the inherent limitations of single-arm designs.

Conclusions

This systematic review and meta-analysis demonstrates that the Msagmaris bioresorbable magnesium scaffold is associated with acceptable medium-term safety and efficacy outcomes, with low rates of TLF, MI, *.

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